080805 01789 U.S. PTO

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	66090-29
First Inventor	Samadpour
Title	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS
Express Mail Label No.	EV734505700US

113261 U.S. PTO 111099 080805

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☑ **Fee Transmittal Form** (e.g., PTO/SB/17)
   (Submit an original and a duplicate for fee processing)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 28]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☐ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* _____]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☑ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 22504 ***OR*** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Fax	

Signature		Date	August 8, 2005
Name (Print/Type)	Barry L. Davison, Ph.D., J.D.	Registration No. (Attorney/Agent)	47,309

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 500

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Samadpour
Examiner Name	
Art Unit	
Attorney Docket No.	67090-29

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 04-0258 Deposit Account Name: Davis Wright Tremaine LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	500
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
20 - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
2 - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round **up** to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: _____	

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 47,309	Telephone 206-628-7621
Name (Print/Type)	Barry L. Davison, Ph.D., J.D.		Date August 8, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

FIELD OF THE INVENTION

Aspects of the present invention relate generally to improving the efficiency of producing food and health related (*e.g.*, pharmaceutical) products, and the safety and quality thereof. Particular embodiments relate to novel methods for microbial pathogen testing that allow for enhanced sensitivity, cost savings and traceability (*e.g.* source tracking) for remedial purposes. The methods are broadly applicable to many product areas including, but not limited to beef, pork, sheep, bison, deer, elk, poultry (*e.g.*, chicken and turkey) and fish and other seafoods, produce, juices, dairy products, dry goods (cereals, nuts, etc), fruits and vegetables, herbs and spices, and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, air samples taken by impingers and filtration, etc), pharmaceuticals, and other types of samples to be analyzed using microorganism enrichment-detection protocols.

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of priority to United States Provisional Patent Application Serial Number 60/599,473, filed 06 August 2004 and entitled MODULAR WET COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, which is incorporated by reference herein in its entirety.

BACKGROUND

Manufacturers and respective regulatory agencies strive to continually improve the safety and the quality of foods, pharmaceuticals, neutraceuticals, water and the environment. Under recent United States Department of Agriculture, Food Safety and Inspection Service (FSIS) directives and guidelines, many food producers in the United States have adopted sampling plans that involve testing, for example, of raw beef trims and/or ground beef for *E. coli* O157:H7, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella*. Similar trends are observed

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in other countries, for products detained for domestic consumption and/or export. For example, the pharmaceutical industry spends considerable resources on sterility testing and environmental monitoring, and the water and wastewater industry and their respective regulatory agencies allocate considerable resources to monitor the quality of water (*e.g.*, drinking, recreational and fisheries resources), wastewater (treated and untreated) and sludge (biosolids). Concern for the quality of air has resulted in monitoring of indoor air for the presence of microbial contaminants and pathogens. These sampling plans associated with such testing determine, for example, the disposition of products and the production lots, or result in decisions regarding the safety of water, receiving waters and recreational waters, and the impact of wastewater discharge, and quality of air.

The operative art with respect to such product "hold and release" monitoring efforts comprises various different sampling plans, typically pursuant to International Commission on Microbial Specifications for Food (ICMSF) guidelines for testing food products, FDA and USDA or EPA guidelines, or intuitive sampling plans. The common feature of these sampling plans is that several samples representing production lots, or a number of environmental samples, are combined into a combined production lot prior to sampling. For example, a typical plan for microbial pathogen detection calls for taking more than one sample, for instance ten (10) to sixty (60) sample pieces from a given sample lot (combined production lot), to form a *composite sample* for testing. The number of pieces taken to form the composite sample depends, under ICMSF or other regulatory guidelines, on the outcome of infection/poisoning (*e.g.*, the severity), the level of hazards, and potential increase in the hazard levels due to storage. The same holds true in detecting microbial constituents and/or spoilage organisms. With respect to *E. coli* O157 testing, for example, a typical plan calls for taking 60 samples (*e.g.*, sample pieces) from a production lot to form a single composite sample. With respect to *Listeria monocytogenes*, thirty (30) samples are typically taken from a production lot to form a composite sample. With respect to sterility testing, a typical plan may call for compositing 10-100 units of the product, and in the

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case of environmental sampling, 2-10 samples are often composited. Generally, the number of samples that are composited reflects: the overall sensitivity of the test method and the limit of detection that applies to the test unit; the ability to concentrate/enrich the composite sample to achieve the desired sensitivity; and the cost of sampling compared with the cost of analysis.

The costs associated with testing food are substantial, and consequently manufacturer's often resort to increasing the size of the "production lot" to be tested. For instance, the standard size production lot for trim testing for *E. coli* O157 in the U.S. beef industry is five (5) 'combos' (each combo weighing approximately 2,000 pounds), and for *Listeria* and *Salmonella* in ready-to-eat (RTE)products, it is one composite sample per production line per shift. A primary problem associated with the use of large size test lots is that a large quantity of products must be downgraded or destroyed when there is a positive finding of a pathogen. Additionally, because of the nature of combination 'lotting' (combining, for purposes of forming the test lot, several independent sub-lots that collectively span a long period of production time), it is very difficult to investigate the cause of the failure and pinpoint the source/cause, and remedial measures cannot be effectively taken. Furthermore, compositing a large number of samples may result in reduced sensitivity for the test unit and adversely effect the limit of detection.

Typically, once a composite sample is constructed (following the art with respect to particular testing) it is then enriched for the presence of a given pathogen/microbe by addition of appropriate amounts of enrichment media and incubation at an appropriate temperature for a given amount of time. If the pathogen/microbe is present, then it grows and multiplies under the favorable conditions of enrichment, thereby providing more material which can be detected by subsequent analysis. The composite sample is then tested by one or more available, art recognized methods including, for example, enrichment followed by immunoassay-based tests or PCR-based methods, or culturing of the organism of interest, or other DNA- or immunochemical-based methods.

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The above-described prior art has several substantial deficiencies. *First*, even though the prior art production lot encompasses several production sublots (for instance 5 combo/pallets of products, or an entire shift of production), if a positive finding is obtained for the production lot (composite test sample), the entire production lot is rejected (all 5 combos/pallets, or one shift of production) and diverted to economically undesirable end uses (*e.g.*, cooking or disposal), even though the pathogen of concern may be confined to only a limited portion of the production sublots (corresponding to one or two combos/pallets or an hour of production) comprising the production lot.

Second, the current art does not allow for retesting of any production sublots, primarily because microbial contaminants are unevenly spread throughout the products, and in many instances the levels of contamination are minute and may be present on very small portions of the products in each sublot. Therefore, once a composite sample is constructed if it tests positive all of the sublots are destroyed. The regulatory agencies do not allow for re-testing of the sublots, premised on the argument that after a production lot tests positive, negative test results obtained for production sublots, or even a new production lot composite sample, are meaningless since the microbial contaminants are not uniformly present throughout the products.

Third, the current protocols for collecting a composite sample representing a production lot often group together production sublots that are unrelated by virtue of product type or hours of production. This makes investigating the nature of the failure a difficult task even when relevant information is available. As an example, information is frequently available on a 'per combo' basis including (but not limited to) hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated combos/pallets are included in a production lot it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option

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since it may not yield the same result). Likewise, for sterility testing, when the composite sample tests positive, the entire production will be disposed.

Therefore, there is a pronounced need in the art to implement novel and effective testing protocols that provide a greater measure of assurance that the food product is safe, that provide economic relief to the producer, and that allow for effective tracking of the contaminated lot(s) for remedial purposes (*e.g.*, pinpointing the time of the contamination and determine the segment of production which was impacted).

SUMMARY OF THE INVENTION

Aspects of the present invention provide novel enrichment, testing and detection methods for detection of pathogens or other microbes in, for example, food, water, wastewater, industrial, pharmaceutical, botanical, environmental samples and other types of samples analyzed by detection methods (*e.g.*, enrichment-detection methods). According to particular aspects, where any microbiological testing program involves compositing a number of samples to form a test lot, independent enrichment of each of the components of the composite sample is performed with subsequent formation of a modular (*e.g.*, wet modula) composite sample by combining portions from each independent enrichment, which allows for determining the outcome of the test for each individual subunit of the composite as opposed to generalizing the results of the test sample to all of it's subunits. This individual outcome determination is achieved by retesting the individual enrichment samples in the event that the composite enrichment tests positive.

In preferred aspects, a reportable lot is defined as a single unit of a modular (e.g., modular wet) composite lot, rather than as an entire composite lot comprised of multiple sublots. For example, a reportable production lot is defined as a single unit of production and corresponds to a single unit of a modular wet composite production lot, rather than (as in the prior art) as an entire composite lot comprised of multiple production units (multiple sublots). With respect to testing each reportable lot (*e.g.*, each single unit of production), a plurality of pieces/portions of

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sample are separately collected from each single reportable lot (*e.g.*, from each single production unit; individual test unit) and composited to form, for example, one '*single-unit production lot sample*' (corresponding, in each case, to a particular single unit of production), which is enriched using appropriate enrichment protocols to allow for the levels of the target organism to reach detection levels and uniformity of presence in the enriched sample. Multiple aliquots of the enrichment media may be removed for analysis, thus circumventing the prior art problem of having to re-sample a test production lot where microbial contaminants are not uniformly present throughout the product.

In the exemplary context of enriched single units of production, equal portions of enrichment buffer are removed (aseptically) from each single-unit production lot sample and combined to form a *Modular Wet Composite Sample* (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target agent (*e.g.*, target organism). If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are released. Significantly, if a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single-unit production lot samples are separately (individually) tested, using the same test protocol, or a test protocol with enhanced sensitivity, or any appropriate test protocol. According to particular preferred aspects, the signal obtained from a MWCS is due to one or more of it's components (*e.g.*, reportable lots (*e.g.*, individually enriched single production units)), and it is, therefore, possible in all cases to trace a positive signal to one or more individual subunits by testing each individual enrichment sample for the same target. When a *positive* finding is obtained for any individual reportable lot sample (*e.g.*, single-unit production lot sample), that particular reportable lot (*e.g.*, single-unit production lot) is deemed to be positive, and appropriate actions are taken based on the result. In the case of pathogen/microbial testing for foods, the individual positive sublots can be diverted to cooking, disposal, or other acceptably safe endpoint. The rest of the individually enriched test units that test negative are deemed to be negative and will be reported as such (are validated).

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DETAILED DESCRIPTION OF THE INVENTION

Particular aspects provide novel enrichment, testing and validation methods for detection of pathogens or other microbes in any type of samples (*e.g.*, food production lots, water, wastewater, industrial, pharmaceutical, botanical, environmental samples, etc.) analyzable by enrichment-detection methods. In preferred aspects, a test lot (single-unit production lot), rather than (as in the prior art) a composite lot comprised of multiple test lots (*e.g.*, single-unit production lot units), is defined and established as the single unit of production. A plurality of portions (*e.g.*, product portions) are separately collected from each test lot (*e.g.*, single-unit production lot) and composited to form a corresponding set of test lot samples (e.g., single-unit production lot samples), which are enriched using suitable enrichment protocols to allow target agents/organisms to reach detectable levels and sample uniformity. In particular embodiments, equal portions of enrichment buffer are removed (preferably aseptically) from the enriched samples, and combined to form a modular composite sample (*e.g.*, modular wet composite sample; MWCS). The MWCS, for example, is tested using a suitable detection assay for the target agent/organism. If a *negative* result is obtained from the MWCS, then all of the individual single-unit production lots are validated and releasable. If a *positive* result is obtained from a MWCS, the enrichment sample corresponding to individual test lots (*e.g.*, individual single-unit production lots) are separately (individually) tested, using the same, or a more sensitive test protocol. If a *positive* finding is obtained for any test lot sample (*e.g.*, individual single-unit production lot sample), that particular respective lot is diverted to cooking, disposal, or other acceptably safe endpoint. If a *negative* finding is obtained for any individual test lot sample (*e.g.*, single-unit production lot sample), then that particular lot is validated and releasable. In this manner, any member lot of the MWCS that tests *negative* using the same method (about 5-fold more sensitive relative to the prior art), or an enhanced method (about fifty times more sensitive), will be validated and releasable for consumption.

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DEFINITIONS

The term "test lot" or "reportable lot" as used herein to refer to an assemblage of one or more specimens of a medium or process (*e.g.*, assemblage of specimens of air, water, solids, or of products of a production process, etc.), where such assemblage can be sampled by taking portions of the one or more specimens thereof, and where the one or more specimens of the assemblage are operationally linked in a manner (*e.g.*, proximity, time, process step, etc.) whereby information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot. In particular instances, portions are synonymous with specimens.

The term "single production unit" or "single-unit production lot" as used herein is a form of test lot, and refers to a single unit of production (*e.g.* for beef trim a "combo," or for almonds a "bin") rather than, as in the prior art, to a composite comprised of multiple, non-operationally linked single production units (production sublots).

The term "product portion" as used herein refers to a product piece (*e.g.*, a piece of solid beef trim, etc.), aliquot of product (*e.g.*, a volume of liquid juice) or weight of product (*e.g.*, a weight of semi-solid pudding). A single unit of production is composed of multiple product portions. In preferred embodiments, the number of product portions which comprise a single unit of production is great enough that removal of some product portions to form a sample does not impose an unacceptable economic loss to the producer. In particular instances, a product portion may be a specimen of a test lot as defined above.

The term "compositing" as used herein refers to combining a number of single product portions to form one larger sample. In preferred embodiments, the number and selection of single product portions to be combined conform to statistical-based sampling plans which seek to form a typical or average sample that is representative of the test lot (*e.g.*, single production unit) being sampled.

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The term "test lot sample" or "single-unit production lot sample" or "single production unit lot sample," as used herein refers to a sample formed by combining multiple product portions from a test lot (*e.g.*, single production unit), such that each test sample (*e.g.*, each single-unit production lot sample) is attributed to a particular corresponding test lot (*e.g.*, production unit). For production lot samples, the number of potions/pieces combined many be essentially any number, but preferably is selected so as to conform to statistical-based sampling plans. Preferably the number of pieces combined is selected from the range group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 product portions. Preferably, the number of independent product portions is selected so as to yield a sample size that is equal to or greater than that required by the subsequent analysis to be applied.

The term "enrichment" as used herein refers to incubating a test lot sample (*e.g.*, single-unit production lot sample) under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform throughout the enriched test lot sample (*e.g.*, single-unit production lot sampl). Preferably, enrichment comprises addition of an amount of an enrichment medium or buffer to a sample, and incubating the sample at a favorable temperature for a period of time sufficient to allow the organism to grow and multiply.

The term "enrichment medium" as used herein refers to a mixture which contains nutrients and which has properties (*e.g.*, pH and/or oxygen content) which favor the growth of the target agent/organism. Preferably, the enrichment medium is formulated to mimic the environment of the target agent/organism or take advantage of a known metabolic property of the target agent/organism. Preferably, the enrichment medium will omit nutrients needed by competing undesired agents/organisms. Preferably, the enrichment medium will include selective agents that will inhibit competing undesired agents/organisms. An example of an enrichment medium is that used for the isolation of nitrogen fixing bacteria (those that can use

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nitrogen gas as their sole nitrogen source) contains no source of fixed nitrogen in the medium. A second example is an enrichment medium for the isolation of bacteria capable of utilizing 2,4-dichlorophenoxyacetic acid (also know as 2,4-D, a common herbicide) as a source of carbon and energy. The enrichment medium is formulated to contain benzoate as the only organic compound.

The term "wet enrichment" as used herein refers to diluting a solid, semisolid or liquid single-unit production lot sample (single production unit lot sample) with enrichment medium in a ratio of approximately 1:10 (wt./v), consistent with conventional methods for expanding and testing a variety of target agents/organisms as set forth in widely recognized published methods. For example, the conventional method for expanding and testing for coliforms, fecal coliforms and *E. Coli* in food, comprises a 1:10 dilution of the samples (*e.g.*, 50 g into 450 ml) (*see, e.g.*, U.S. FDA Bacteriology Analytical Manual Online, Chapter 4 and 4A, describing standard 1:10 dilution procedures for testing of coliforms, fecal coliforms and *E. Coli* in food, shellfish and juices).

The term "dry enrichment" as used herein refers to enriching a solid, semisolid or liquid single unit production lot sample either with no addition of other compounds if the sample's intrinsic properties (water activity, nutrients and pH) are sufficient/proper to promote the growth of the target agent/organism, or by dilution of the sample with minimal amounts of enrichment medium in ratios ranging from about 0.1 (wt/v) to about 1 (wt/v).

The term "modular composite sample" as used herein refers to a sample formed by removing, preferably aseptically, equal portions of each of a plurality of enriched single-unit production lot samples, and combining the removed portions.

The phrase "suitable detection assay" as used herein refers to any assay that is suitable for detecting a particular agent/organism. Preferably, the assay is optimized to detect the particular agent/organism, and may be combined with one or more concentration steps for concentration of the agent/organism being assayed.

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The term "validation" as used herein with respect to production lots refers to determining that a particular sample tests *negative* using the detection assay. Where a modular composite sample tests *negative*, all single-unit production lot samples comprising the composite sample are validated along with the respective single-unit production lots, which are thus cleared for release. Where a modular composite sample tests *positive*, individual single unit production lots may nonetheless yet be validated if particular respective single-unit production lot samples test *negative*.

"Trim" refers to small pieces of meat and fat which are excised during, for example, the beef fabrication process in order to produce primal and subprimal pieces and marketable cuts.

"Trim testing" refers to the process of testing trim, or raw materials which are to be used for ground meat production for microbial/pathogen content.

A "combo" or "combo-bin" refers, in the beef industry, to the single production unit packaging unit. Alternatively raw materials corresponding to a single production unit to be tested can be packaged into boxes, bags or other appropriate containers, which can be placed, for example, on pallets.

A "composite lot-unit" or "five-combo-lot unit" refers to a *composite* unit, comprised of five combos (combo-bins). In prior art sampling plans, the composite lot-unit represents the raw material (composite trim) upon which sampling, testing and acceptance or rejection is based.

Therefore, according to particular aspects, a test lot (or test unit) (*e.g.*, a single-unit production lot or single production unit lot) is defined and taken as one or more operationally-linked specimens of a medium or process. A test lot may be a single unit of production (*e.g.*, a single combo, bin, pallet, or segment of production, etc.), or a single environmental sample (*e.g.*, single air sample, single water and wastewater sample, etc.), rather than, as in the prior art, as a composite of multiple production units or environmental samples.

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In preferred embodiments, a number of pieces or portions of sample are collected from a test lot (*e.g.,* from a single production unit (*e.g.*, from the single combo, bin, pallet, or segment of production, etc.), and composited to form one '*single-unit test sample*' (or '*single-unit production lot sample.*' In particular embodiments (e.g., wet enrichment), enrichment buffer is added to the sample. In alternate embodiments, 'dry enrichment' (as defined herein above) is done.

Significantly, in the inventive modular (*e.g.*, wet modular) compositing method, samples taken from each unit of production are enriched *separately* using appropriate enrichment protocols to allow for the levels of the target organism to reach detection levels and *uniformity of presence* in the enriched sample. In preferred aspects, such enrichment obviates the prior art problem of having microbial contaminants that are not uniformly present throughout the product sample. Specifically, while microbes are not necessarily uniformly distributed in food, water, air, pharmaceuticals, etc, after enriching a sample as described herein, the target microbes are uniformly, or as least substantially uniformly, present in the enrichment medium or extract from dry or semi dried enrichments.

Following incubation for the target organism, equal portions of enrichment buffer or sample are removed (aseptically) from each of several test lot samples (e.g., from several single-unit production lot samples; preferably 5) and pulled together to form a Modular Wet Composite Sample (MWCS). The MWCS is then tested using an appropriate test (detection assay) for the target organism. If a *negative* result is obtained from the MWCS, then all of the individual single unit production Lots are released.

If a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single unit production lot samples are then separately (individually) tested, using the same test protocol, or any other appropriate tests. Alternately, an augmented protocol that uses a concentration step for the target organism, such as immunomagnetic bead separation, affinity

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chromatography, etc., followed by a an appropriate detection method is used to test the enriched individual test lot samples (*e.g.*, the individual single-unit production lot samples).

In preferred aspects, the inventive methods of analysis are modified by introducing a concentration step (*e.g.*, employing antibody-coated paramagnetic beads into the procedure (*e.g.*, DNA-based detection, biosensor based detection, classical microbiological detections, etc)). Antibody-coated paramagnetic beads, for example, afford an approximately 10-fold increase in sensitivity. This concentration step, combined with the fact that the individual test lot samples (*e.g.*, individual single-unit production lot samples) are not 5-fold diluted relative to the MWCS, allows for an overall 50-fold increase in sensitivity relative to prior art sampling and testing protocols. If a lateral flow device is used for detection, such immunomagnetic concentration may or may not be used, in which case the detection sensitivity is increased by about 5-fold.

Where a *positive* finding (test result) is obtained for any individual test lot sample (*e.g.*, single-unit production lot sample), that particular corresponding test lot (*e.g.*, single-unit production lot) is deemed to be positive, and appropriate decisions are then made on the positive results (*e.g.*, in the case of food products, diversion to cooking, disposal, or other acceptably safe endpoint). For each of the rest of the test lot samples (*e.g.*, single-unit production lot samples) belonging to the positive MWCS, where a *negative* finding is obtained, that particular test lot sample (*e.g.*, that single-unit production lots sample) is deemed to be negative. In this manner, any test lot (*e.g.*, any single-unit production lot) that is a member of the group of test lots (*e.g.*, single-unit production lots) that comprise a corresponding MWCS, will be considered to be negative, if it tests *negative* using the same method (about 5-fold more sensitive relative to the prior art), or the enhanced method (about fifty times more sensitive).

In alternate preferred embodiments, a new Modular Wet Composite Sample is reconstructed from the member lots (test lots) that have tested *negative*, and subjected to a third layer of testing to again show (confirm) that they are negative. Specifically if one of the five individual test lots (*e.g.*, individual single-unit production lots) has tested positive (and the other

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four negative), and the protocols call for testing of composites consisting of five test lots, a new single test lot sample can formed from a new test lot, and can be used along with the four negative samples to form a new MWCS.

The methods of the present invention provide substantial economic savings to the food and pharmaceutical industries, because of the precision in detecting in the context of operationally-linked portions of production (e.g., test lots; single production units; single-unit production lots) which are contaminated. The inventive methods prevent unnecessary destruction of *negative* lots that are condemned because of guilt by association (*e.g.*, simply because they were grouped with a contaminated composite prior art multiple production unit lot in a prior art testing protocol). Where a *positive* finding is obtained, a smaller quantity of material is diverted to an economically undesirable end use. The proposed invention has substantial utility (e.g., bringing savings, accuracy and precision in pinpointing problems) in the environmental industry.

Additionally, and significantly, it is easier to trace the source of the contamination and apply remedial measures, because the single-unit test component points, for example, to single point of production or a single sampling site.

Particular Preferred Aspects:

Particular aspect provide a method of sampling, testing and validating test lots, comprising: separately collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more operationally-linked specimens, wherein the assemblage can be sampled by taking portions thereof; combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot; incubating the set of test lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially

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uniform, throughout the respective one or more samples, to provide a set of enriched test lot samples; removing, aseptically, equal portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all test lot samples are validated, and wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

In particular aspects, the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof. In particular aspects, the test lot is a single-unit production lot, comprised of operationally-linked product specimens. In particular aspects, product specimens are synonymous with product portions. In particular aspects, the methods further comprise incubating the modular composite sample prior to testing it. In particular aspects, incubating each test lot sample comprises adding an amount of enrichment medium to the sample, and removing enriched sample portions comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample. In particular aspects, testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

In particular aspects, where testing of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol. Preferably, the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

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In particular aspects, the methods further comprise forming an additional modular composite sample from the enriched test lot samples and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status. In particular aspects, the methods further comprise forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples that test negative, and testing the additional modular composite sample, using the same or a different suitable assay. In particular aspects, the methods further comprise, where testing of the modular composite sample is negative, forming an additional modular composite sample from the enriched test lot samples, and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

In particular aspects, the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a segment of production. Preferably, the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

In particular aspects, the methods further comprise, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive. In particular aspects, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions. Alternativley, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

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Particular aspects provide a method of sampling, testing and validating test lots, comprising: separately collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof; combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot; incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched single-unit production lot samples; removing, aseptically, equal portions of each enriched single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all single-unit production lot samples are validated, and wherein where such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

The following Examples are exemplary are not intended, and should not be construed to limit the scope of the aspects of the present conception that are claimed hereunder.

EXAMPLE I

(The present inventive methods were shown to provide a substantial economic advantage, while providing for enhanced safety, and implementation of remedial measures)

At present, the standard size 'production lot' for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five *combos*, where each *combo* represents a single

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production unit and weighs approximately 2,000 pounds. An inventive modular composite sample method, and in particular a Modular Wet Composite Sample (MWCS) method was implemented at a United States beef producer. TABLE 1 shows, according particular aspects, the result of testing 62,919 MWCS samples, and then retesting the individual single-unit production lot (combo) samples whenever a *positive* result was obtained from the MWCS sample.

TABLE 1 shows that out of 62,919 MWCS samples, a total of 217 yielded a *positive* testing result for *E. coli* O157. Using prior art protocols, all of the single-unit production lots that comprised the 271 positive samples would go to rendering or be downgraded for cooking. As each MWCS represents five single-unit production lots of 2,000 lbs each, this would represent approximately 2,710,000 pounds of product (*i.e.*, 271 x 5 x 2,000 pounds = 2,710,000 pounds).

Specifically, the individual single-unit production lot samples comprising the MWCS were analyzed separately following each *positive* MWCS result. As can be seen in TABLE I, only 391 individual single-unit production lot samples yielded a *positive* result out of the cumulative total of 1,085 individual single-unit production lot samples comprising the MWCS samples which yielded a *positive* result. If only the 391 individual single-unit production lots yielding a *positive* sample result were diverted to rendering or downgraded for cooking this would represent 782,000 lbs of product. The remaining 694 individual single-unit production lots, corresponding to 1,928,000 lbs of product, are, according to preferred aspects of the present invention, validated and releasable into the chain of commerce.

The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 1,9280,000 lbs of beef trim into commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase

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in sensitivity relative to the MWCS testing) provides *substantial* additional assurance of the safety of the food products.

Furthermore, as outlined above under "BACKGROUND," information is frequently available on a 'per combo' basis including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps. However, when five unrelated *combos* are included in a combined 'production lot' (as in the prior art) it is much harder to rationally analyze the available information since there is no way to determine which combo(s) contained the pathogen (as stated above, prior art re-sampling is not a viable option since it may not yield the same result).

By contrast, in this Example I and according to preferred aspects of the present invention, any *combo*-specific information including, but not limited to hour of production, vendor source of raw materials, production employees present, and operational status of microbial intervention process steps can be brought to bear in the context of the 391 individual single-unit production lots yielding a *positive* sample result, thereby providing an effective means not only to trace contamination, but also to affect remedial measures in view thereof.

TABLE 1: Results of modular wet composite sampling of 62,919 multiple lots and number of Individual Production Unit Lot (IPUL) which tested positive when MWCS tested positive

Location	Total # Analyses	# Positives	1 IPUL	2 IPULs	3 IPULs	4 IPULs	5 IPULs
Est. A, B, C.	62,919	271	180	39	18	11	7

EXAMPLE II

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of Ready-to-Eat (RTE) products (*e.g.*, meat and poultry products))

Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may

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adapt an 'end product' sampling program as verification that their product is free of the pathogen *Listeria monocytogenes*. The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (*e.g.*, from 'cleanup to cleanup'), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis.

According to particular aspects of the present invention the producer of RTE meat or poultry products collects samples from individual single-unit production lots. Preferably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), a volume of product such as a pallet of packed boxes produced on a particular production line, or a production area in the plant, etc.

Individual single-unit production lot samples are collected, to which, in wet enrichment embodiments, enrichment medium/buffer is added. Following incubation under conditions suitable to allow levels of a target agent or organism that is present to reach detectable levels and become uniform or substantially uniform throughout the respective sample(s), aliquots of the enrichment medium/buffers from individual single-unit production lot samples are combined to form a MWCS. The MWCS is then analyzed for the presence or absence of, for example, *Listeria* spp. or *L. monocytogenes*. In the event that a *positive* result is obtained for the MWCS, enrichment medium/buffer sample from the individual single-unit production lot samples comprising that MWCS is analyzed using the same, or augmented testing protocols.

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Individual single-unit production lots for which the enrichment medium/buffer from the corresponding sample yields a *positive* result are diverted to cooking, disposal or other safety endpoint. Individual single-unit production lots for which the enrichment medium/buffer from the corresponding sample yields a *negative* result are released into commerce. The latter fraction represents a direct cost savings to the producer relative to a prior art approaches where a 'production lot' is defined to include multiple single-unit production lots (e.g., multiple product lines and an extended period of time ('cleanup to cleanup')).

Furthermore, by defining and establishing the individual single-unit production lots in such a fashion as to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply remediative resources more effectively and efficiently. For example, where a *positive* result(s) is associated with one or more specific production lines, targeted aggressive sanitation is used to resolve the problem. Alternatively, for example, where a *positive* result(s) is associated with one or more specific products, determining whether raw materials are contaminated, or whether process microbial intervention steps were operating properly are effectively and efficiently used.

EXAMPLE III

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility for providing cost-effective and effective monitoring means for pathogen levels in nut products (*e.g.*, almond products) and the like)

A large number of almond products may be produced by using one or more processes including slivering, scalding, blanching, slicing, roasting, and dicing. Anti-microbial treatments may also be applied, such as use of propylene oxide. In practice, these processes may be used in many various combinations, and the output from one process may be the input for another. This makes it very difficult to trace finished product all the way back to raw materials.

As indicated by a recent outbreak, almond products are susceptible to contamination by *Salmonella* spp. According to additional aspects, the present inventive methods provide a cost-

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effective means of implementing an effective monitoring program for pathogen levels in nut products (*e.g.*, almond products). In such embodiments, final almond products of each type are collected at random times over a production shift. The producer defines and establishes individual single-unit production lots as the amount of product produced during a production shift (from 'cleanup to cleanup'), or as some smaller production unit (*e.g.*, a 'truckload'), provided that one sample was collected from each such single-unit production lot. The single-unit production lot samples are combined to form a corresponding composite sample, and, in wet enrichment embodiments, enrichment medium/buffer is added to the composite sample to allow *Salmonella* spp. to grow and multiply under the favorable conditions of enrichment (as described herein above), thereby providing more material that can be detected by subsequent analysis.

Aliquots of the enrichment medium/buffers from individual single-unit production lot samples are combined to form a MWCS. The MWCS are analyzed for the presence or absence, for example, of *Salmonella* spp. Where a *positive* result is obtained for the MWCS, each enrichment buffer from the individual single-unit production lot samples comprising that MWCS is analyzed using the same, or augmented testing protocols.

Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *positive* result are returned for application of additional microbial intervention steps (*e.g.*, roasting), or are diverted to a safe endpoint (*e.g.*, a cooked product). Individual single-unit production lots for which the enrichment buffer from the corresponding sample yields a *negative* result are thereby validated and are releasable into commerce. The latter fraction represents a direct cost savings to the producer relative to prior art approaches where effective testing is not done, and discovery of contamination with a pathogen leads to large scale recalls of product.

Furthermore, by defining and establishing the individual production single-unit production lots in such a fashion as to maximize the information available for investigating the nature of a failure, the producer is able to narrow the scope of investigation and apply

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remediative resources more effectively and efficiently. For example, the processes used to produce the almond product(s) yielding *positive* result(s) are rationally analyzed, and associations between the pathogen contamination and one or more of the processes of slivering, scalding, blanching, slicing, roasting, and dicing are determined, and targeted effective and efficient remedial measures are applied.

EXAMPLE IV

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of contaminants that enter a production line at a given time point, and then clear)

Sterility testing of food and pharmaceuticals, or purity testing of fermentation processes often involves compositing a number of samples to form a composite test lot. Detection of microbial contamination in the composite sample, as discussed in detail herein above, results in rejection of the whole production. Practically speaking, often a pinpoint contaminant enters production at a given time point, and then clears within a few minutes. Aspects of the present invention allow for identifying the time of entry, and informed elimination of products (operationally linked test lots) flanking the contamination event.

EXAMPLE V

(According to particular aspects of the present invention, the inventive sampling methods have substantial utility in the context of environmental monitoring (*e.g.*, with samples of water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids))

In the context of environmental monitoring, when several samples (water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids) are composited and subjected to enrichment, followed by testing to detect environmental contamination, the current invention allows for pinpointing the test lots (*e.g.*, operationally-linked unit(s)) that are positive for the microbe of concern.

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CLAIMS

1. A method of sampling, testing and validating test lots, comprising:

a) separately collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot;

c) incubating the set of test lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched test lot samples;

d) removing, aseptically, equal portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all test lot samples are validated, and wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. The method of claim 1, wherein the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof.

3. The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

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4. The method of claim 3, wherein product specimens are synonymous with product portions.

5. The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. The method of claim 1, wherein incubating each test lot sample in c) comprises adding an amount of enrichment medium to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. The method of claim 1, wherein where testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

9. The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the

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enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a segment of production.

14. The method of claim 1, wherein the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

15. The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive.

16. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions.

17. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions.

18. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions.

19. The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. A method of sampling, testing and validating test lots, comprising:

a) separately collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

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b) combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot;

c) incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched single-unit production lot samples;

d) removing, aseptically, equal portions of each enriched single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all single-unit production lot samples are validated, and wherein where such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

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ABSTRACT OF THE DISCLOSURE

Particular aspects provide a method of sampling, testing and validating test lots (e.g., single-unit production lots), comprising: assembling a plurality of product portions from each of a plurality of test lots and combining the collected product portions to provide a corresponding set of test lot samples (wherein each test lot sample is attributed to a particular corresponding test lot); enriching the set of test lot samples; removing equal portions of each enriched sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample for the target agent/organism, wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a respective enriched test lot sample and obtaining a negative test result. The methods have broad utility for monitoring all sort of test lots (*e.g.*, environmental lots, production lots, pharmaceutical lots, etc.) and for efficiently affecting informed, targeted remedial measures.

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number 11/997,971

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	29 minus 20 =	* 9	X$ 25		OR	X$50	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	X100			X200	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
			TOTAL	509		TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT APPLICATION SERIAL NO _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

08/11/2005 FFANAEIA 00000031 11199871

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 466-267/66033

APPLICATION DATA SHEET

Application Information

Application number::	
Filing Date::	
Application Type::	Regular
Subject Matter::	Utility
Suggested classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	0
Number of copies of CDs::	0
Sequence submission?::	No
Computer Readable Form (CRF)?::	No
Number of copies of CRF::	0
Title ::	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Attorney Docket Number::	66090-29
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	
Small Entity?::	Yes
Petition included?::	No
Petition Type::	
Licensed U.S. Gov't Agency::	No
Contract or Grant No::	

Secrecy Order in Parent Appl.?:: No

First Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Mansour
Middle Name::	
Family Name::	Samadpour
Name Suffix::	
City of Residence::	Seattle
State or Province of Residence::	WA
Country of Residence::	US
Street of mailing address::	6040 50th Ave. NE
City of mailing address::	Seattle
State or Province of mailing address::	WA
Country of mailing address::	US
Postal or Zip Code of mailing address::	98115

Second Applicant Information

Applicant Authority Type::	
Primary Citizenship Country::	
Status::	
Given Name::	
Middle Name::	
Family Name::	
Name Suffix::	
City of Residence::	
State or Province of Residence::	

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Third Applicant Information

Applicant Authority Type::

Primary Citizenship Country::

Status::

Given Name::

Middle Name::

Family Name::

Name Suffix::

City of Residence::

State or Province of Residence::

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Fourth Applicant Information

Applicant Authority Type::

Primary Citizenship Country::

Status::

Given Name::

Middle Name::

Family Name::

Name Suffix::

City of Residence::

State or Province of Residence::

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Correspondence Information

Correspondence Customer Number::	**22504**
Name::	
Street of mailing address::	
City of mailing address::	
State or Province of mailing address::	
Country of mailing address::	
Postal or Zip Code of mailing address::	
Phone number::	206-628-7621
Fax Number:	206-622-3150

E-Mail address:: barrydavison@dwt.com

Representative Information

Representative Customer Number::		**22504**

Domestic Priority Information

Application ::	Continuity Type::	Parent Application::	Parent Filing Date::
This application	Non-provisional of	60/599,473	08/06/04

Foreign Priority Information

Country::	Application number::	Filing Date::	Priority Claimed::

Assignee Information

Assignee name::	
Street of mailing address::	
City of mailing address::	
State or Province of mailing address::	
Country of mailing address::	
Postal or Zip Code of mailing address::	

080805 01789 U.S. PTO

PTO/SB/05 (09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	66090-29
First Inventor	Samadpour
Title	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS
Express Mail Label No.	EV734505700US

113261 U.S. PTO 11/10/05 080805

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☑ **Fee Transmittal Form** (e.g., PTO/SB/17)
   (Submit an original and a duplicate for fee processing)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 28]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☐ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* _____]
5. **Oath or Declaration** [*Total Sheets* _____]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☑ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 22504 ***OR*** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Fax	

Signature		Date	August 8, 2005
Name (Print/Type)	Barry L. Davison, Ph.D., J.D.	Registration No. (Attorney/Agent)	47,309

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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080805 01789 U.S. PTO

PTO/SB/17 (12-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 500

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Samadpour
Examiner Name	
Art Unit	
Attorney Docket No.	67090-29

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 04-0258 Deposit Account Name: Davis Wright Tremaine LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	500
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
20 - 20 or HP =	x	=	

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
2 - 3 or HP =	x	=	

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	**Extra Sheets**	**Number of each additional 50 or fraction thereof**	**Fee ($)**	**Fee Paid ($)**
- 100 =	/ 50 =	(round **up** to a whole number)	x	=

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other:	

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 47,309	Telephone 206-628-7621
Name (Print/Type)	Barry L. Davison, Ph.D., J.D.		Date August 8, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/199,871	08/08/2005	Mansour Samadpour	66090-29

CONFIRMATION NO. 2448

22504
DAVIS WRIGHT TREMAINE, LLP
2600 CENTURY SQUARE
1501 FOURTH AVENUE
SEATTLE, WA 98101-1688

FORMALITIES LETTER

Date Mailed: 09/19/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$65** for a Small Entity

- **$65** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

T. C. H

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 3 - OFFICE COPY

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NOV 23 2005
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PTO/SB/21 (09-04)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	11/199,871
Filing Date	August 8, 2005
First Named Inventor	Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	66090-29

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [x] Reply to Missing Parts/ Incomplete Application
  - [x] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Davis Wright Tremaine LLP		
Signature			
Printed name	Barry L. Davison, Ph.D., J.D.		
Date	11/21/05	Reg. No.	47,309

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Kay Bulen	Date	11/21/05

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

OIPE IAP59 NOV 29 2005 PATENT & TRADEMARK OFFICE

PTO/SB/17 (12-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 65

Complete if Known	
Application Number	11/199,871
Filing Date	August 8, 2005
First Named Inventor	Samadpour
Examiner Name	
Art Unit	
Attorney Docket No.	66090-29

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 04-0258 Deposit Account Name: Davis Wright Tremaine LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____ x	_____ =	_____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____ x	_____ =	_____

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number) x	_____ =	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: Surcharge, late filing of Declaration	65

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 47,309	Telephone 206-628-7621
Name (Print/Type)	Barry L. Davison, Ph.D., J.D.		Date

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

OIPE IAP59
NOV 23 2005
PATENT & TRADEMARK OFFICE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/199,871	08/08/2005	Mansour Samadpour	66090-29

CONFIRMATION NO. 2448

22504
DAVIS WRIGHT TREMAINE, LLP
2600 CENTURY SQUARE
1501 FOURTH AVENUE
SEATTLE, WA 98101-1688

RECEIVED
SEP 21 2005

FORMALITIES LETTER

Date Mailed: 09/19/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

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The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$65** for a Small Entity

- **$65** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts

11/25/2005 MAHMED1 00000022 11199871
01 FC:2051 65.00 OP

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

T.C.V

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 2 - COPY TO BE RETURNED WITH RESPONSE

OIPE IAP59
NOV 23 2005
PATENT & TRADEMARK OFFICE

EXPRESS MAIL NO.: ~~EV734505700US~~

APPLICATION DATA SHEET

Application Information

Application number::	~~——~~11/199,871
Filing Date::	08/08/05
Application Type::	Regular
Subject Matter::	Utility
Suggested classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	0
Number of copies of CDs::	0
Sequence submission?::	No
Computer Readable Form (CRF)?::	No
Number of copies of CRF::	0
Title ::	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Attorney Docket Number::	66090-29
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	
Small Entity?::	Yes
Petition included?::	No
Petition Type::	
Licensed U.S. Gov't Agency::	No
Contract or Grant No::	

Secrecy Order in Parent Appl.?:: No

First Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Mansour
Middle Name::	
Family Name::	Samadpour
Name Suffix::	
City of Residence::	Seattle
State or Province of Residence::	WA
Country of Residence::	US
Street of mailing address::	6040 50th Ave. NE
City of mailing address::	Seattle
State or Province of mailing address::	WA
Country of mailing address::	US
Postal or Zip Code of mailing address::	98115

Second Applicant Information

Applicant Authority Type::	
Primary Citizenship Country::	
Status::	
Given Name::	
Middle Name::	
Family Name::	
Name Suffix::	
City of Residence::	
State or Province of Residence::	

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Third Applicant Information

Applicant Authority Type::

Primary Citizenship Country::

Status::

Given Name::

Middle Name::

Family Name::

Name Suffix::

City of Residence::

State or Province of Residence::

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Fourth Applicant Information

Applicant Authority Type::

Primary Citizenship Country::

Status::

Given Name::

Middle Name::

Family Name::

Name Suffix::

City of Residence::

State or Province of Residence::

Country of Residence::

Street of mailing address::

City of mailing address::

State or Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

Correspondence Information

Correspondence Customer Number::	**22504**
Name::	
Street of mailing address::	
City of mailing address::	
State or Province of mailing address::	
Country of mailing address::	
Postal or Zip Code of mailing address::	
Phone number::	206-628-7621
Fax Number:	206-622-3150

E-Mail address:: barrydavison@dwt.com

Representative Information

Representative Customer Number::		**22504**

Domestic Priority Information

Application ::	Continuity Type::	Parent Application::	Parent Filing Date::
This application	Non-provisional of	60/599,473	08/06/04

Foreign Priority Information

Country::	Application number::	Filing Date::	Priority Claimed::

Assignee Information

Assignee name::	——Institute for Environmental Health, Inc.
Street of mailing address::	——15300 Bothell Way NE
City of mailing address::	——Lake Forest Park
State or Province of mailing address::	——WA
Country of mailing address::	——US
Postal or Zip Code of mailing address::	——98155

OIPE IAP59 NOV 23 2005 PATENT & TRADEMARK OFFICE

PTO/SB/01A (09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

As the below named inventor(s), I/we declare that:

This declaration is directed to:

☐ The attached application, or

☑ Application No. 11/199,871, filed on August 8, 2005

☐ as amended on _____ (if applicable),

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR(S)

Inventor one: Mansour Samadpour

Signature: Samad Citizen of: US

Inventor two:

Signature: Citizen of:

Inventor three:

Signature: Citizen of:

Inventor four:

Signature: Citizen of:

☐ Additional inventors or a legal representative are being named on _____ additional form(s) attached hereto.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

OIPE IAP59 NOV 2 3 2005 PATENT & TRADEMARK OFFICE

PTO/SB/80 (11-04)
Approved for use through 11/30/2005. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

[X] Practitioners associated with the Customer Number: 22504

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

[X] The address associated with Customer Number: 22504

OR

[ ] Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Fax	

Assignee Name and Address:

Institute for Environmental Health, Inc.
15300 Bothell Way NE
Lake Forest Park, WA 98155

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	[signature]	Date	11-17-04
Name	Mansour Samadpour	Telephone	(206) 522-5437
Title	President		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

OIPE IAP59 NOV 23 2005 PATENT & TRADEMARK OFFICE

PTO/SB/96 (09-04)
Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Institute for Environmental Health, Inc.

Application No./Patent No.: 11/199,871 Filed/Issue Date: August 8, 2005

Entitled: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

Institute for Environmental Health, Inc., a Washington corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☑ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest.
The extent (by percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☑ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Mansour Samadpour/ 11/17/05
Signature Date

Mansour Samadpour 206-522-5432
Printed or Typed Name Telephone Number

President
Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Attorney Docket No.: 66090-29

ASSIGNMENT

WHEREAS, I, Mansour Samadpour, residing at 6050 50th Avenue NE, Seattle, Washington 98115, (ASSIGNOR) am the inventor named in an application for a Letters Patent of the United States entitled MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS, said application filed on August 6, 2004 as Provisional Patent Application No. 60/599,473, and on August 8, 2005 as United States Application No. 11/199,871;

AND, WHEREAS, Institute for Environmental Health, Inc., a Washington corporation, having administrative offices at 15300 Bothell Way NE, Lake Forest Park, WA 98155 (hereinafter referred to as **ASSIGNEE**) is desirous of acquiring the entire right, title and interest in the invention described in the said application;

NOW, THEREFORE, for sufficient, good and valuable consideration, the receipt of which is hereby acknowledged, I do hereby sell, assign, and transfer unto said ASSIGNEE, my entire right, title to and interest in said application and said inventions; any patent or reissues of any patent that may be granted thereon; and any applications which are improvements thereon, continuations, continuations-in-part, substitutes, or divisions of said applications, and all foreign applications and patents on said invention(s) to be held and enjoyed by ASSIGNEE as entirely as the same would have been held and enjoyed by me had this sale, assignment, and transfer not been made, and I do hereby further agree and promise to execute all instruments and render all such assistance as ASSIGNEE may request in order to make and prosecute any and all applications on said invention(s), to enforce any and all patents on said invention(s), and to confirm in ASSIGNEE legal title to said invention(s) and all applications and patents on said invention(s), all without charge to ASSIGNEE but at no expense to me.

Executed in Lake Forest Park, Wa, this 17 day of November, 2005.

Mansour Samadpour

HALLEY C. MCQUEEN NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 8-15-09

STATE OF WASHINGTON)
: ss
COUNTY OF King)

On this 17th day of November, 2005, before me, a Notary Public in and for the State and County aforesaid, personally appeared Mansour Samadpour, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be his free act and deed.

NOTARY PUBLIC in and for the State of Washington, residing at Edmonds, Wa
My commission expires 8/15/09

SEA 1694382v1 66090-29
Seattle

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 10/09/2007
DAVIS WRIGHT TREMAINE, LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/199,871	MANSOUR SAMADPOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

General Informal Matters

1. For future reference please note, upon arrival at the United States Patent and Trademark Office (i.e., USPTO, each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning coding and incorporation in to the Electronic File Wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/interview with applicant/applicants' representative, it is suggested that the following information be recited in the header of each page for any filing/response/amendment:

i. Attorney Docket Number;
ii. First Applicant's name (e.g., Smith Jones et al.);
iii. Filing date for said application (e.g., 17 November 2002);
iv. Date of Office Action being responded to (e.g., 27 August 2006);
v. Date of amendment/response (e.g., 27 April 2007); and
vi. Examiner's name (e.g., Dr. Kailash C. Srivastava).

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

Claims Status

2. Claims 1-20 are pending.

Restriction/Election

3. The instant application contains claims directed to the following patentably distinct species of the claimed invention. Accordingly, Restriction to one of the following Species is required under 35 U.S.C.§121:

a. Only one test lot of samples among: environmental lot, pharmaceutical lot or single-unit product lot as detailed in Claim 2;

4. The non-taxonomic species listed above are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these species are not obvious variants of each other based on the current record.

Accordingly, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention.

5. Applicant is required under 35 U.S.C.§121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generics claim is finally held to be allowable. Currently Claims 1 and 20 are generic claims.

There is an examination and search burden for the above-mentioned patentably distinct species due to their mutually exclusive characteristics. The species require a special field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 U.S.C. §101 and or 35 U.S.C. §112, first paragraph.

6. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** among the species listed in categories a-b even though the requirement may be traversed (37 CFR §1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR §1.144. If claims are added after the election, applicant(s) must indicate which of these claims are readable on the elected species.

Should applicant(s) traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled

to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.

In accordance with 37 CFR §1.499, applicants are required that a reply to this requirement must include an identification of the species that are listed in categories (i)-(xii) and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [MPEP §809.02(a)].

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

27 September 2007

CHRISTOPHER R. TATE
PRIMARY EXAMINER

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	MANSOUR SAMADPOUR
	Examiner	Art Unit
	Srivastava, Dr. Kailash C	1657

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/28/2007								
	1	÷								
	2	÷								
	3	÷								
	4	÷								
	5	÷								
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	19	÷								
	20	÷								

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Bib Data Sheet

CONFIRMATION NO. 2448

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/199,871	08/08/2005 RULE	435	1657	66090-29

APPLICANTS
Mansour Samadpour, Seattle, WA; ✓ Citizenship Information in ADS ✓

** CONTINUING DATA **********
This appln claims benefit of 60/599,473 08/06/2004
** FOREIGN APPLICATIONS **********

** SMALL ENTITY **

Foreign Priority claimed	35 USC 119 (a-d) conditions met	Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ yes ☑ no	☐ yes ☐ no ☐ Met after Allowance N/A	Examiner's Signature 9/24/2007 Initials	WA	0	20	2

ADDRESS
22504

TITLE
Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents

FILING FEE RECEIVED	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:
565	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	08 August 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	16 October 2007

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

AND PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Sir:

This is in response to a RESTRICTION REQUIREMENT dated 09 October 2007 for the above-identified patent application.

Kindly amend the above-identified patent application as follows:

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

1. (Currently amended) A method of sampling, testing and validating test lots, comprising:

a) ~~separately~~ collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot;

c) incubating the set of test lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched test lot samples;

d) removing, aseptically, equal portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all test lot samples are validated, and wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. (Original) The method of claim 1, wherein the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof.

3. (Original) The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

5. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. (Original) The method of claim 1, wherein incubating each test lot sample in c) comprises adding an amount of enrichment medium to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. (Original) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. (Original) The method of claim 1, wherein where testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

9. (Original) The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. (Original) The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. (Original) The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a segment of production.

14. (Original) The method of claim 1, wherein the number of test lots is from about 3 to about 10, about 5 to about 8, or about 5.

15. (Original) The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive.

16. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions.

17. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions.

18. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions.

19. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. (Currently amended) A method of sampling, testing and validating test lots, comprising:

a) ~~separately~~ collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot;

c) incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of enriched single-unit production lot samples;

d) removing, aseptically, equal portions of each enriched single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all single-unit production lot samples are validated, and wherein where such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

REMARKS

Claims 1-20 are pending, and have been subjected to a ***species*** election by the Examiner.

Species Election

The Examiner has requested election of a 'species' from among: environmental lot; pharmaceutical lot; or single-unit product lot.

Applicants herein elect the species **single-unit product lot** without traverse.

Voluntary claim amendments

Claim 1 and 20 have been amended to delete the word "separately," because the term is redundant within the claim, which recites "combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples," such that it is already clear that the portions collected from each test lot are combined together (not mixed with portions taken from any other test lot) to provide a set of corresponding test lot samples. Support for the amendment is inherent to the claim. No new matter has been added.

Conclusion

In view of the foregoing amendments and remarks, applicant respectfully requests entry of the present Response and Amendment, and allowance of all claims as presented and amended herein. The Examiner is encouraged to phone applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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Respectfully submitted,
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Attorney for Applicant
Registration No. 47,309

Electronic Acknowledgement Receipt

EFS ID:	2325008
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	16-OCT-2007
Filing Date:	08-AUG-2005
Time Stamp:	12:14:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		66090_29_RSP.pdf	38356 d78bd956f629a011dfdb5332237275f3c1ddc4a4	yes	6

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment - After Non-Final Rejection	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	6
Warnings:			
Information:			
	Total Files Size (in bytes):	38356	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/199,871	08/08/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 10/16/2007

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $25 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
Patsy Zimmerman

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Inventor search history

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=> d his L35

     (FILE 'HCAPLUS' ENTERED AT 14:07:24 ON 31 OCT 2007)
L35          17 S L34 AND HEALTH?/CO,CS,PA,SO

=> d que L35
L34          32 SEA FILE=HCAPLUS ABB=ON  PLU=ON  ("SAMADPOUR M"/AU OR "SAMADPOU
                R MANSOUR"/AU)
L35          17 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L34 AND HEALTH?/CO,CS,PA,SO


=> d his L47

     (FILE 'MEDLINE, BIOSIS, EMBASE, AGRICOLA' ENTERED AT 14:53:24 ON 31 OCT
     2007)
L47          20 S L46 OR L43

=> d que L47
L34          32 SEA FILE=HCAPLUS ABB=ON  PLU=ON  ("SAMADPOUR M"/AU OR "SAMADPOU
                R MANSOUR"/AU)
L35          17 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L34 AND HEALTH?/CO,CS,PA,SO
L39          42 SEA L35
L40          37 SEA L39 AND (BACTERI? OR MICROBIOL? OR SALMONELLA OR COLI)
L41          34 SEA L39 AND (QUALITY OR SAFETY OR FOOD OR PHARMACOL? OR DRUG
                OR ENVIRON?)
L43           6 SEA L39 AND (BROTH OR AGAR OR ENRICH? OR CULTUR? OR MEDIUM OR
                MEDIA)
L44          33 SEA L40 AND L41
L45          35 SEA L43 OR L44
L46          18 SEA L45 AND (SAMPL? OR SCREEN OR CONTROL OR ASSAY OR COUNT)
L47          20 SEA L46 OR L43


=> dup rem L35 L47
FILE 'HCAPLUS' ENTERED AT 15:18:47 ON 31 OCT 2007
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PROCESSING COMPLETED FOR L35
PROCESSING COMPLETED FOR L47
L56          27 DUP REM L35 L47 (10 DUPLICATES REMOVED)
                ANSWERS '1-17' FROM FILE HCAPLUS
                ANSWERS '18-25' FROM FILE MEDLINE
                ANSWERS '26-27' FROM FILE BIOSIS
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Todd, Hooker
@uspto.gov

Inventor search results

=> d L56 1-27 ibib ab

L56 ANSWER 1 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN DUPLICATE 1
ACCESSION NUMBER: 2006:182582 HCAPLUS Full-text
DOCUMENT NUMBER: 145:313435
TITLE: Incidence of enterohemorrhagic Escherichia coli, Escherichia coli O157, Salmonella, and Listeria monocytogenes in retail fresh ground beef, sprouts, and mushrooms
AUTHOR(S): Samadpour, M.; Barbour, M. W.; Nguyen, T.; Cao, T.-M.; Buck, F.; Depavia, G. A.; Mazengia, E.; Yang, P.; Alfi, D.; Lopes, M.; Stopforth, J. D.
CORPORATE SOURCE: Institute for Environmental Health, Inc., Seattle, WA, 98155, USA
SOURCE: Journal of Food Protection (2006), 69(2), 441-443
CODEN: JFPRDR; ISSN: 0362-028X
PUBLISHER: International Association for Food Protection
DOCUMENT TYPE: Journal
LANGUAGE: English
AB The objective of this study was to determine the prevalence of enterohemorrhagic Escherichia coli (EHEC), E. coli O157, Salmonella, and Listeria monocytogenes in retail food samples from Seattle, Wash. A total of 2,050 samples of ground beef (1,750 samples), mushrooms (100 samples), and sprouts (200 samples) were collected over a 12-mo period and analyzed for the presence of these pathogens. PCR assays, followed by culture confirmation were used to determine the presence or absence of each organism. Of the 1,750 ground beef samples analyzed, 61 (3.5%) were pos. for EHEC, and 20 (1.1%) of these were pos. for E. coli O157. Salmonella was present in 67 (3.8%) of the 1,750 ground beef samples. Of 512 ground beef samples analyzed, 18 (3.5%) were pos. for L. monocytogenes. EHEC was found in 12 (6.0%) of the 200 sprout samples, and 3 (1.5%) of these yielded E. coli O157. Of the 200 total sprout samples, 14 (7.0%) were pos. for Salmonella and none were pos. for L. monocytogenes. Among the 100 mushroom samples, 4 (4.0%) were pos. for EHEC but none of these 4 samples were pos. for E. coli O157. Salmonella was detected in 5 (5.0%) of the mushroom samples, and L. monocytogenes was found in 1 (1.0%) of the samples.
REFERENCE COUNT: 12 THERE ARE 12 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 2 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN DUPLICATE 2
ACCESSION NUMBER: 2003:48289 HCAPLUS Full-text
TITLE: Diversity, frequency, and persistence of Escherichia coli O157 strains from range cattle environments
AUTHOR(S): Renter, David G.; Sargeant, Jan M.; Oberst, Richard D.; Samadpour, Mansour
CORPORATE SOURCE: Food Animal Health & Management Center, College of Veterinary Medicine, Kansas State University, Manhattan, KS, 66506-5606, USA
SOURCE: Applied and Environmental Microbiology (2003), 69(1), 542-547
CODEN: AEMIDF; ISSN: 0099-2240
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal; Miscellaneous
LANGUAGE: English
AB Genetic diversity, isolation frequency, and persistence were determined for Escherichia coli O157 strains from range cattle production environments. Over the 11-mo study, anal. of 9,122 cattle fecal samples, 4,083 water source

samples, and 521 wildlife fecal samples resulted in 263 isolates from 107 samples presumptively considered E. coli O157 as determined by culture and latex agglutination. Most isolates (90.1%) were confirmed to be E. coli O157 by PCR detection of intimin and Shiga toxin genes. Pulsed-field gel electrophoresis (PFGE) of XbaI-digested prepns. revealed 79 unique patterns (XbaI-PFGE subtypes) from 235 typeable isolates confirmed to be E. coli O157. By analyzing up to three isolates per pos. sample, we detected an average of 1.80 XbaI-PFGE subtypes per sample. Most XbaI-PFGE subtypes (54 subtypes) were identified only once, yet the seven most frequently isolated subtypes represented over one-half of the E. coli O157 isolates (124 of 235 isolates). Recurring XbaI-PFGE subtypes were recovered from samples on up to 10 sampling occasions and up to 10 mo apart. Seven XbaI-PFGE subtypes were isolated from both cattle feces and water sources, and one of these also was isolated from the feces of a wild opossum (Didelphis sp.). The number of XbaI-PFGE subtypes, the variable frequency and persistence of subtypes, and the presence of identical subtypes in cattle feces, free-flowing water sources, and wildlife feces indicate that the complex mol. epidemiol. of E. coli O157 previously described for confined cattle operations is also evident in extensively managed range cattle environments.

REFERENCE COUNT: 43 THERE ARE 43 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 3 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN DUPLICATE 5
ACCESSION NUMBER: 2002:495533 HCAPLUS Full-text
DOCUMENT NUMBER: 137:221553
TITLE: Laboratory investigation of an Escherichia coli O157:H7 outbreak associated with swimming in Battle Ground Lake, Vancouver, Washington
AUTHOR(S): Samadpour, Mansour; Stewart, Jeff; Steingart, Karen; Addy, Carl; Louderback, John; McGinn, Marty; Ellington, Joe; Newman, Tom
CORPORATE SOURCE: Department of Environmental Health, School of Public Health, University of Washington, Seattle, WA, 98195, USA
SOURCE: Journal of Environmental Health (2002), 64(10), 16-20
CODEN: JEVHAH; ISSN: 0022-0892
PUBLISHER: National Environmental Health Association
DOCUMENT TYPE: Journal
LANGUAGE: English

AB Escherichia coli O157:H7 has been associated with several waterborne outbreaks, but it has never been recovered from an implicated environment. An Aug. 1999 outbreak of E. coli O157:H7 associated with swimming in Battle Ground Lake, Clark Country, Washington, is reported. E. coli O157:H7 were isolated from duck feces and from 2 water samples. The authors used pulsed-field gel electrophoresis to compare these isolates with patent isolates for genetic homol. All isolates yielded the same restriction fragment patterns. Also, using polymerase chain reaction, the authors showed patient isolates and environmental isolates had the same virulence factors (Stx, eaeA, hly).

REFERENCE COUNT: 18 THERE ARE 18 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 4 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2006:516624 HCAPLUS Full-text
TITLE: Food sample collector
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc., USA
SOURCE: PCT Int. Appl., which
CODEN: PIXXD2

DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2006057808	A2	20060601	WO 2005-US40491	20051107
WO 2006057808	A3	20061012		
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW				
RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM				
AU 2005309896	A1	20060601	AU 2005-309896	20051107
CA 2586932	A1	20060601	CA 2005-2586932	20051107
EP 1817405	A2	20070815	EP 2005-851445	20051107
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR				

PRIORITY APPLN. INFO.:
US 2004-625302P P 20041105
US 2005-674912P P 20050426
WO 2005-US40491 W 20051107

AB The present invention provides novel methods and devices for detection of pathogens or other microbes in an analyzed sample (e.g., food, industrial, pharmaceutical, botanical, environmental, etc., sample). The inventive methods and devices provide for increasing the power of detection for pathogens on food surfaces, comprising increasing the number of independent, discrete samples taken during the sampling procedure. The inventive sampling device reduces sampling costs by minimizing time, material and product loss relative to prior art sampling techniques. In particular aspects, a novel surface sampling device for bulk solid foods is provided that operates to remove (e.g., shave) small pieces from contacted product (e.g., product pieces). The device comprises a sampling mechanism having utility to remove samples (e.g., cut slivers from) larger pieces of food or other sample materials. In particular embodiments, the device comprises a primary shaft member (e.g., cylindrical stainless steel), and a shaving means.

L56 ANSWER 5 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2006:147035 HCAPLUS Full-text
TITLE: Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc., USA
SOURCE: PCT Int. Appl.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2006017832	A2	20060216	WO 2005-US28161	20050808
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW				
RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM				
AU 2005271284	A1	20060216	AU 2005-271284	20050808
CA 2576563	A1	20060216	CA 2005-2576563	20050808
US 2006134726	A1	20060622	US 2005-199871	20050808
EP 1786920	A2	20070523	EP 2005-783958	20050808
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR, AL, BA, HR, MK, YU				

PRIORITY APPLN. INFO.:	US 2004-599473P	P	20040806
	WO 2005-US28161	W	20050808

AB Particular aspects provide a method of sampling, testing and validating test lots (e.g., single-unit production lots), comprising: assembling a plurality of product portions from each of a plurality of test lots and combining the collected product portions to provide a corresponding set of test lot samples (wherein each test lot sample is attributed to a particular corresponding test lot); enriching the set of test lot samples; removing equal portions of each enriched sample, and combining the removed portions to provide a modular composite sample; and testing of the modular composite sample for the target agent/organism, wherein where such testing is positive, individual test lots may nonetheless yet be validated by further testing of a respective enriched test lot sample and obtaining a negative test result. The methods have broad utility for monitoring all sort of test lots (e.g., environmental lots, production lots, pharmaceutical lots, etc.) and for efficiently affecting informed, targeted remedial measures.

L56 ANSWER 6 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN

ACCESSION NUMBER:	2006:7146 HCAPLUS Full-text
DOCUMENT NUMBER:	144:92887
TITLE:	System and method for proactive health and environmental management and assessment
INVENTOR(S):	Samadpour, Mansour; Miksch, Robert
PATENT ASSIGNEE(S):	Institute for Environmental Health, USA
SOURCE:	U.S. Pat. Appl. Publ., 23 pp. CODEN: USXXCO
DOCUMENT TYPE:	Patent
LANGUAGE:	English
FAMILY ACC. NUM. COUNT:	1
PATENT INFORMATION:	

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
US 2006000257	A1	20060105	US 2005-153024	20050614

PRIORITY APPLN. INFO.:	US 2004-579446P	P	20040614
	US 2005-683400P	P	20050519

AB Particular aspects of the present invention provide novel systems and methods for method for epidemiol. and environmental monitoring and assessment, and for active management of human health hazards associated with building environments. In particular aspects, the inventive system and methods are used as a human health and environmental health management tool for corporations (e.g., offices, factories), com. buildings, condominiums, hotels, resorts, camps, military installations, schools, daycares, cruise ships, real estate developments, towns and cities, prisons, or any other institutional or community settings. In particular aspects, the inventive system and methods are used in a proactive manner to maintain the health of building occupants. Addnl. aspects provide systems and methods having substantial utility as an investigative tool to substantiate human health claims and correlate underlying environmental factors.

L56 ANSWER 7 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2005:1168917 HCAPLUS Full-text
DOCUMENT NUMBER: 143:417476
TITLE: Trend analysis and statistical process control using multitargeted screening assays for microbial contamination and monitoring
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc., USA
SOURCE: PCT Int. Appl., 70 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005103284	A2	20051103	WO 2005-US13047	20050415
WO 2005103284	A3	20060216		
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW				
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG				
CA 2564145	A1	20051103	CA 2005-2564145	20050415
US 2006115824	A1	20060601	US 2005-107458	20050415
EP 1745139	A2	20070124	EP 2005-737668	20050415
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR				

PRIORITY APPLN. INFO.: US 2004-562302P P 20040415
WO 2005-US13047 W 20050415

AB Aspects of the present invention provide novel multi-targeted microbiol. screening and monitoring methods having substantial utility for monitoring and control of microbial growth and contaminants, microbiol. processes, predictive microbiol., and for exposure and risk assessment. Microbial markers shared by both target and index microbes are used in novel methods for microbial monitoring, monitoring of microbial performance potential, trend anal., and

statistical process control (SPC) in processes or systems that are receptive to a plurality of genetically distinct microbes.

L56 ANSWER 8 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2005:612130 HCAPLUS Full-text
DOCUMENT NUMBER: 143:132238
TITLE: Adherent antimicrobial barrier coating and sanitizing agent for foods and drugs
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc., USA
SOURCE: PCT Int. Appl., 23 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005063308	A1	20050714	WO 2004-US43253	20041222

W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG

PRIORITY APPLN. INFO.: US 2003-531321P P 20031222
AB The present invention provides novel viscous and adherent food-safe antimicrobial compns., and methods for using same in the immediate and residual decontamination of microbial-contaminated substrate surfaces, in reducing or precluding cutting implement-mediated transfer of surface contamination during cutting operations in the food industry, and for reducing or preventing transfer of contamination from contaminated surfaces in the food and pharmaceutical industries. Adherent antimicrobial protective layers are formed on substrate surfaces (e.g., processing equipment and utensils), providing a barrier (e.g., chemical and/or phys.) to the passage or transport of microbial contamination between and among surfaces. The adherent formulations confer residual decontaminating activity, providing for prolonged killing of associated microbial contamination. The inventive solns., are preferably formulated and applied as a gel, syrup or foam, and are preferably prepared using materials which are 'generally-regarded-as-safe' (GRAS) in food products, obviating post-treatment removal prior to consumption. Preferably, the inventive formulations are heated to a temperature equal to or greater than about 80°C prior to application.
REFERENCE COUNT: 2 THERE ARE 2 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 9 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2005:611980 HCAPLUS Full-text
DOCUMENT NUMBER: 143:93546
TITLE: Microbial sampling device
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc.,

USA
SOURCE: PCT Int. Appl., 21 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005062914	A2	20050714	WO 2004-US43254	20041222

W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG

PRIORITY APPLN. INFO.: US 2003-531364P P 20031222

AB Aspects of the present invention provide novel apparatus and methods for sampling microbial organisms present on surfaces. Preferred apparatus comprises: a reservoir suitable for providing microbial collection fluid; a sterilizable sample collection chamber; a sterilizable, integrated collection fluid delivery and collection fluid recovery member, suitable to deliver collection fluid to a target surface, and contemporaneously recover the delivered fluid from the surface; delivery means, in communication with both the reservoir and the integrated member, and operable to aseptically deliver collection fluid from the reservoir to the integrated member; and vacuum means, in communication with both the sample collection chamber and the integrated member, and operable to direct collection fluid, delivered and recovered by the integrated member, to the sample collection chamber. Addnl. aspects provide a method for rapid, high-throughput sampling of microbial organisms present on surfaces, comprising: delivering sample collection fluid to a target surface, and contemporaneously recovering the delivered fluid from the target surface by means of an integrated collection fluid delivery and collection fluid recovery member; and collecting the recovered sample collection fluid into a sample collection chamber in communication with the integrated member, whereby sample collection is, at least in part, achieved. The inventive methods and apparatus can be applied to both surface sampling and to atmospheric sampling.

L56 ANSWER 10 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN

ACCESSION NUMBER: 2006:195202 HCAPLUS Full-text
DOCUMENT NUMBER: 145:288453
TITLE: The use of ribotyping and antibiotic resistance patterns for identification of host sources of Escherichia coli strains
AUTHOR(S): Samadpour, M.; Roberts, M. C.; Kitts, C.; Mulugeta, W.; Alfi, D.
CORPORATE SOURCE: Department of Environmental Health, School of Public Health and Community Medicine, University of Washington, Seattle, WA, USA
SOURCE: Letters in Applied Microbiology (2005), 40(1), 63-68
CODEN: LAMIE7; ISSN: 0266-8254
PUBLISHER: Blackwell Publishing Ltd.

DOCUMENT TYPE: Journal
LANGUAGE: English

AB To compare antibiotic resistance and ribotyping patterns ability to identify triplicate isolates sent from a group of 40 Escherichia coli taken from seven host sources. Of the 120 isolates, 22 isolates were resistant to ampicillin, streptomycin, tetracycline and trimethoprim and 98 isolates were susceptible. Antibiotic patterns identified 33 of the triplicates and three of the six groups had isolates from multiple hosts. Ribotyping divided the isolates into 27 ribotype groups with all triplicates grouped into the same ribotype group with one host per group. Antibiotic susceptibility pattern placed 98 of the isolates in a single group with 50% of the antibiotic susceptibility pattern groups containing multiple host species. Ribotyping groups were host specific with each host having one to seven ribotype groups. Antibiotic susceptibility pattern groups have been used for environmental source identification and fecal pollution tracking, however these groups do not always distinguish between host species. Stability of the markers is a potential concern and this system can only be used if antibiotic resistance levels are high in the isolates studied. All isolates have a ribotype group which was stable and like other mol. methods has advantages over antibiotic susceptibility pattern groups which uses a phenotypic method.

REFERENCE COUNT: 21 THERE ARE 21 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 11 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2004:987954 HCAPLUS Full-text
TITLE: Advanced pathogen testing and carcass-certification methods for slaughter operations
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, USA
SOURCE: PCT Int. Appl.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2004098296	A2	20041118	WO 2004-US14130		20040505
WO 2004098296	A3	20060309			
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW					
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG					
CA 2525460	A1	20041118	CA 2004-2525460		20040505
US 2004241773	A1	20041202	US 2004-839325		20040505
PRIORITY APPLN. INFO.:			US 2003-467301P	P	20030505
			WO 2004-US14130	W	20040505

AB The invention provides methods for certification of carcasses, and for detecting a contaminated carcass and preventing its movement into or across a production area. The inventive methods comprise obtaining, early in the production process (pre-fabrication), a test sample from at least one test location of at least one split-portion of each carcass, wherein the test

samples are obtained prior to or during chilling of the respective split portions, before entry thereof in the production chain. Composite test samples are assayed for pathogens or microbes, whereby certification is afforded, or whereby entry of the chilled split-carcass-Lot into the production area is precluded if the corresponding composite-Lot test sample is contaminated. Methods for remedial reconditioning of contaminated split-carcasses are provided, wherein essentially 100% of the carcasses are targeted to the production line. The inventive methods provide substantial public health benefit, and are efficient and economical to implement.

L56 ANSWER 12 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2004:1036550 HCAPLUS Full-text
DOCUMENT NUMBER: 141:422061
TITLE: Enrichment methods for the detection of pathogens and other microbes
INVENTOR(S): Samadpour, Mansour
PATENT ASSIGNEE(S): Institute for Environmental Health, Inc., USA
SOURCE: U.S. Pat. Appl. Publ., 25 pp.
CODEN: USXXCO
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
US 2004241644	A1	20041202	US 2004-848253	20040517
CA 2567042	A1	20050901	CA 2004-2567042	20040517
WO 2005079181	A2	20050901	WO 2004-US15659	20040517
WO 2005079181	A3	20060406		

W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG

PRIORITY APPLN. INFO.: US 2003-470975P P 20030516
WO 2004-US15659 W 20040517

AB The present invention provides novel enrichment, testing and detection methods for detection of pathogens or other microbes in a food, water, wastewater, industrial, pharmaceutical, botanical, environmental samples and other types of samples analyzed by enrichment-detection methods. In preferred aspects, a sample is obtained at a first location and is diluted (e.g., in the case of a solid or semi-solid sample. or liquid) at the first location at a ratio of about 1:0 (weight/volume) to 1:2 (weight/volume), or greater, preferably at a ratio of about 1:0.1 (weight/volume) or greater, or more preferably, at a ratio of about 1:2 (weight/volume) or greater. The diluted sample is incubated at an optimal temperature in an incubator and either tested locally, or sent in a shipping incubator to a second location that is a remote test location. The incubated sample is received and tested at the second location by assaying the sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe. In alternate embodiments, no dilution at the first location is required, and optionally minimal addns. to adjust intrinsic

deficiencies may be made, but the sample is nonetheless incubated during transit to the test location.

L56 ANSWER 13 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2004:205286 HCAPLUS Full-text
DOCUMENT NUMBER: 140:353543
TITLE: Antibiotic resistance and distribution of tetracycline resistance genes in Escherichia coli O157:H7 isolates from humans and bovines. Comments
AUTHOR(S): Wilkerson, Chris; Samadpour, Mansour; Van Kirk, Nicole; Roberts, Marilyn C.
CORPORATE SOURCE: Departments of Environmental and Occupational Health Sciences, University of Washington, Seattle, WA, 98195, USA
SOURCE: Antimicrobial Agents and Chemotherapy (2004), 48(3), 1066-1067
CODEN: AMACCQ; ISSN: 0066-4804
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English
AB A polemic.
REFERENCE COUNT: 11 THERE ARE 11 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 14 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1997:538908 HCAPLUS Full-text
DOCUMENT NUMBER: 127:180807
TITLE: Comparison of estimated risks of Giardia and Cryptosporidium in drinking water with observations in Pacific Northwest
AUTHOR(S): Kissel, J.; Samadpour, M.; Ongerth, J.
CORPORATE SOURCE: Department of Environmental Health, University of Washington, Seattle, WA, 98195-7234, USA
SOURCE: Proceedings - Annual Conference, American Water Works Association (1996), (Water Research), 751-757
CODEN: PWACDO; ISSN: 0360-814X
PUBLISHER: American Water Works Association
DOCUMENT TYPE: Journal
LANGUAGE: English
AB The Surface Water Treatment Rule includes the following statement: USEPA believes that providing treatment to ensure <1 case of microbiol. caused illness per yr per 10,000 people is a reasonable goal. The level of water treatment necessary to achieve this goal is estimated using models incorporating dose-response information from exptl. trials. Predictions generated by this model are of great significance to cities (common in the Pacific Northwest) which currently use unfiltered surface water supplies for drinking water. To test the predictive capability of the exponential model in non-outbreak conditions for Giardia and Cryptosporidium, simulations were run using data from King County, Washington.
REFERENCE COUNT: 14 THERE ARE 14 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L56 ANSWER 15 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1995:764585 HCAPLUS Full-text
DOCUMENT NUMBER: 123:189529
TITLE: Molecular epidemiology of Escherichia coli O157:H7 by restriction fragment length polymorphism using Shiga-like toxin genes
AUTHOR(S): Samadpour, Mansour

CORPORATE SOURCE: School Public Health and Community Medicine, University Washington, Seattle, WA, 98195, USA
SOURCE: Journal of Clinical Microbiology (1995), 33(8), 2150-4
CODEN: JCMIDW; ISSN: 0095-1137
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English

AB The purpose of this study was to assess a simplified method for interstrain differentiation of Escherichia coli O157:H7 and other Shiga-like toxin-producing E. coli (SLTEC) strains. A method based on the use of nucleic acid probes from Shiga-like toxin (SLT) I and II structural genes was used to generate restriction fragment length polymorphism (RFLP) patterns of SLTEC strains, (SLT-RFLP patterns) resulting from digestion of isolated genomic DNA with 4 different restriction enzymes (BamHI, EcoRI, HindIII, and PvuII) used sep. A total of 165 SLTEC strains from clin., food, and environmental sources, including O157:H7 isolates from 4 food-borne outbreaks in Canada and the United States, were analyzed in the study. SLT-RFLP demonstrated that E. coli O157:H7 strains from each food-borne outbreak had the same unique SLT-RFLP pattern. Fifty-two SLT-RFLP types were found among 96 E. coli O157:H7 isolates from sporadic cases of hemorrhagic colitis and hemolytic uremic syndrome in Washington state. The use of the SLT probes proved to be a very powerful method for interstrain differentiation of SLTEC strains. Although the use of each of the enzymes alone did not give enough differentiative power to be used in epidemiol. studies, the combination of patterns generated by 2 restriction enzymes (EcoRI and PvuII, used sep.) provided the desired sensitivity for such studies. The results clearly demonstrate the usefulness of the method for studying the mol. epidemiol. of E. coli O157:H7. The method is also suitable for establishing an epidemiol. database, in terms of both sensitivity and ease of compilation and interpretation of results.

L56 ANSWER 16 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1995:24607 HCAPLUS Full-text
DOCUMENT NUMBER: 122:124166
TITLE: Development and evaluation of oligonucleotide DNA probes for detection and genotyping of shiga-like toxin producing Escherichia coli
AUTHOR(S): Samadpour, Mansour; Ongerth, Jerry E.; Liston, John
CORPORATE SOURCE: Department Environmental Health, University Washington, Seattle, WA, 98195, USA
SOURCE: Journal of Food Protection (1994), 57(5), 399-402
CODEN: JFPRDR; ISSN: 0362-028X
DOCUMENT TYPE: Journal
LANGUAGE: English

AB Use of antisense oligonucleotide probes (OP) for detection and genotyping of Shiga-like toxin producing Escherichia coli (SLTEC) was evaluated. Based on published DNA sequences of the A subunits of Shiga-like toxin (SLT) I and II genes, three synthetic antisense OP were constructed (OP-1, -2 and -3). Their use for detection and genotyping of SLTEC was evaluated and the results were compared to those obtained using cloned toxin-gene probe fragments. Both the OP-1 and OP-2 hybridized with all 69 SLT-I and II producing strains. Furthermore, the OP-1 hybridized only with all 18 SLT-I-only producing strains, and the OP-2 hybridized only with all 48 SLT-II-only producing strains. OP-3, a pool of four OP, detected all SLTEC strains regardless of toxin genotype. None of the OP hybridized to any of the 91 SLT-neg. strains. These results demonstrate the three OP to be unique reagents for SLTEC epidemiol. studies.

L56 ANSWER 17 OF 27 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1994:24473 HCAPLUS Full-text
DOCUMENT NUMBER: 120:24473
TITLE: Molecular epidemiology of Escherichia coli O157:H7 strains by bacteriophage λ restriction fragment length polymorphism analysis: Application to a multistate foodborne outbreak and a day-care center cluster
AUTHOR(S): Samadpour, Mansour; Grimm, Linda M.; Desai, Bindi; Alfi, Dalia; Ongerth, Jerry E.; Tarr, Phillip I.
CORPORATE SOURCE: Sch. Pub. Health Community Med., Univ. Washington, Seattle, WA, 98185, USA
SOURCE: Journal of Clinical Microbiology (1993), 31(12), 3179-83
CODEN: JCMIDW; ISSN: 0095-1137
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Genomic DNAs prepared from 168 isolates of Escherichia coli O157:H7 were analyzed for restriction fragment length polymorphisms on Southern blots probed with bacteriophage λ DNA. The isolates analyzed included strains from a recent large multistate outbreak of E. coli O157:H7 infection associated with consumption of poorly cooked beef in restaurants, a day-care center cluster, and temporally and geog. unrelated isolates. E. coli O157:H7 isolates recovered from the incriminated meat and from 61 (96.8%) of 63 patients from Washington and Nevada possessed identical λ restriction fragment length patterns. The λ restriction fragment length polymorphisms observed in 11 (91.7%) of 12 day-care center patients were identical, but they differed from that of the strain associated with the multistate outbreak. E. coli O157:H7 from 42 patients temporally or geog. unrelated to either cluster of infection possessed unique and different λ restriction fragment length patterns, except for paired isolates from 3 sep. clusters of infection. These data demonstrate that the hybridization of DNA digests of E. coli O157:H7 with radiolabeled bacteriophage λ DNA can be a useful, stable, and discriminatory epidemiol. tool for analyzing the linkage between strains of E. coli O157:H7.

L56 ANSWER 18 OF 27 MEDLINE on STN DUPLICATE 3
ACCESSION NUMBER: 2004472000 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 15382721
TITLE: Phenotypic library-based microbial source tracking methods: efficacy in the California collaborative study.
AUTHOR: Harwood Valerie J; Wiggins Bruce; Hagedorn Charles; Ellender R D; Gooch Jan; Kern James; Samadpour Mansour; Chapman Annie C H; Robinson Brian J; Thompson Brian C
CORPORATE SOURCE: Department of Biology, SCA 110, University of South Florida, Tampa, FL 33620, USA.
SOURCE: Journal of water and health, (2003 Dec) Vol. 1, No. 4, pp. 153-66.
Journal code: 101185420. ISSN: 1477-8920.
PUB. COUNTRY: England: United Kingdom
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
(RESEARCH SUPPORT, U.S. GOV'T, NON-P.H.S.)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200410
ENTRY DATE: Entered STN: 23 Sep 2004

Last Updated on STN: 29 Oct 2004
Entered Medline: 28 Oct 2004

AB As part of a larger microbial source tracking (MST) study, several laboratories used library-based, phenotypic subtyping techniques to analyse fecal samples from known sources (human, sewage, cattle, dogs and gulls) and blinded water samples that were contaminated with the fecal sources. The methods used included antibiotic resistance analysis (ARA) of fecal streptococci, enterococci, fecal coliforms and E. coli; multiple antibiotic resistance (MAR) and Kirby-Bauer antibiotic susceptibility testing of E. coli; and carbon source utilization for fecal streptococci and E. coli. Libraries comprising phenotypic patterns of indicator bacteria isolated from known fecal sources were used to predict the sources of isolates from water samples that had been seeded with fecal material from the same sources as those used to create the libraries. The accuracy of fecal source identification in the water samples was assessed both with and without a cut-off termed the minimum detectable percentage (MDP). The libraries (approximately 300 isolates) were not large enough to avoid the artefact of source-independent grouping, but some important conclusions could still be drawn. Use of a MDP decreased the percentage of false-positive source identifications, and had little effect on the high percentage of true-positives in the most accurate libraries. In general, the methods were more prone to false-positive than to false-negative errors. The most accurate method, with a true-positive rate of 100% and a false-positive rate of 39% when analysed with a MDP, was ARA of fecal streptococci. The internal accuracy of the libraries did not correlate with the accuracy of source prediction in water samples, showing that one should not rely solely on parameters such as the average rate of correct classification of a library to indicate its predictive capabilities.

L56 ANSWER 19 OF 27 MEDLINE on STN DUPLICATE 4
ACCESSION NUMBER: 2002425745 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 12182487
TITLE: Prevalence of Shiga toxin-producing Escherichia coli in ground beef and cattle feces from King County, Washington.
AUTHOR: Samadpour Mansour; Kubler M; Buck F C; Depavia G A; Mazengia E; Stewart J; Yang P; Alfi D
CORPORATE SOURCE: Department of Environmental Health, School of Public Health, University of Washington, Seattle 98195, USA.. mansour@u.washington.edu
SOURCE: Journal of food protection, (2002 Aug) Vol. 65, No. 8, pp. 1322-5.
Journal code: 7703944. ISSN: 0362-028X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200211
ENTRY DATE: Entered STN: 17 Aug 2002
Last Updated on STN: 12 Dec 2002
Entered Medline: 12 Nov 2002

AB Shiga toxin-producing Escherichia coli (STEC) is increasingly recognized as a common cause of diarrhea. STEC infection is a major public health threat because of its ability to cause serious and potentially life-threatening illnesses. The main reservoirs of STEC are believed to be the intestinal tracts of animals. Several studies have investigated the prevalence of STEC in various food items. The objective of this study was to determine the prevalence of STEC in the Seattle ground beef supply. In addition, the relative amount of STEC contamination between stores was compared, and possible differences between types of ground beef based on fat content (9, 16,

and 23%) were investigated. A survey of Stx-I and/or Stx-II genes in fecal samples from cattle at a local slaughterhouse was also conducted. Of 296 ground beef samples tested from area retail grocery stores, 16.8% were positive for the presence of the toxin genes. Our data showed that there was no statistically significant difference ($P > 0.05$) in the prevalence of STEC between the ground beef samples of different fat contents and between grocery store chains. Of the 103 cattle fecal samples tested, 19 (18.4%) were found positive for the presence of Stx-I and/or Stx-II genes. The presence of a rather high percentage of STEC in the food supply in the absence of large number of cases suggests that not all STEC lineages are pathogenic for humans.

L56 ANSWER 20 OF 27 MEDLINE on STN DUPLICATE 6
ACCESSION NUMBER: 2000416926 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 10927738
TITLE: Where's the beef? The role of cross-contamination in 4 chain restaurant-associated outbreaks of Escherichia coli O157:H7 in the Pacific Northwest.
AUTHOR: Jackson L A; Keene W E; McAnulty J M; Alexander E R; Diermayer M; Davis M A; Hedberg K; Boase J; Barrett T J; Samadpour M; Fleming D W
CORPORATE SOURCE: Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle 98101, USA.
SOURCE: Archives of internal medicine, (Aug 14-28 2000) Vol. 160, No. 15, pp. 2380-5.
Journal code: 0372440. ISSN: 0003-9926.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Abridged Index Medicus Journals; Priority Journals
ENTRY MONTH: 200008
ENTRY DATE: Entered STN: 7 Sep 2000
Last Updated on STN: 7 Sep 2000
Entered Medline: 28 Aug 2000

AB BACKGROUND: From March through August 1993, outbreaks of Escherichia coli O157:H7 occurred at 4 separate Oregon and Washington steak and salad bar restaurants affiliated with a single national chain. OBJECTIVE: To determine the cause of outbreaks of E coli O157:H7 at 4 chain restaurants. METHODS: Independent case-control studies were performed for each outbreak. Available E coli O157:H7 isolates were subtyped by pulse-field gel electrophoresis and by phage typing. RESULTS: Infection was not associated with beef consumption at any of the restaurants. Implicated foods varied by restaurant but all were items served at the salad bar. Among the salad bar items, no single item was implicated in all outbreaks, and no single item seemed to explain most of the cases at any individual restaurant. Molecular subtyping of bacterial isolates indicated that the first 2 outbreaks, which occurred concurrently, were caused by the same strain, the third outbreak was caused by a unique strain, and the fourth was multiclonal. CONCLUSIONS: Independent events of cross-contamination from beef within the restaurant kitchens, where meats and multiple salad bar items were prepared, were the likely cause of these outbreaks. Meat can be a source of E coli O157:H7 infection even if it is later cooked properly, underscoring the need for meticulous food handling at all stages of preparation.

L56 ANSWER 21 OF 27 MEDLINE on STN DUPLICATE 7
ACCESSION NUMBER: 94213452 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 8161171
TITLE: Occurrence of Shiga-like toxin-producing Escherichia

coli in retail fresh seafood, beef, lamb, pork, and poultry from grocery stores in Seattle, Washington.
AUTHOR: Samadpour M; Ongerth J E; Liston J; Tran N; Nguyen D; Whittam T S; Wilson R A; Tarr P I
CORPORATE SOURCE: Department of Environmental Health, School of Medicine, University of Washington, Seattle 98195.
SOURCE: Applied and environmental microbiology, (1994 Mar) Vol. 60, No. 3, pp. 1038-40.
Journal code: 7605801. ISSN: 0099-2240.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199405
ENTRY DATE: Entered STN: 26 May 1994
Last Updated on STN: 26 May 1994
Entered Medline: 13 May 1994

AB Fresh meat, poultry, and seafood purchased from Seattle area grocery stores were investigated for the presence of Shiga-like toxin-producing Escherichia coli by using DNA probes for Shiga-like toxin (SLT) genes I and II. Of the 294 food samples tested, 17% had colonies with sequence homology to SLT I and/or SLT II genes.

L56 ANSWER 22 OF 27 MEDLINE on STN
ACCESSION NUMBER: 2007394746 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 17612069
TITLE: Validation of individual and multiple-sequential interventions for reduction of microbial populations during processing of poultry carcasses and parts.
AUTHOR: Stopforth J D; O'Connor R; Lopes M; Kottapalli B; Hill W E; Samadpour M
CORPORATE SOURCE: Institute for Environmental Health, Inc., 15300 Bothell Way N.E., Seattle, Washington 98155, USA.
SOURCE: Journal of food protection, (2007 Jun) Vol. 70, No. 6, pp. 1393-401.
Journal code: 7703944. ISSN: 0362-028X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE) (VALIDATION STUDIES)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200708
ENTRY DATE: Entered STN: 7 Jul 2007
Last Updated on STN: 15 Aug 2007
Entered Medline: 14 Aug 2007

AB Changes in aerobic plate counts (APC), total coliform counts (TCC), Escherichia coli counts (ECC), and Salmonella incidence on poultry carcasses and parts and in poultry processing water were evaluated. Bacterial counts were estimated before and after individual interventions and after poultry carcasses were exposed to multiple-sequential interventions at various stages during the slaughter process. Individual and multiple-sequential interventions were evaluated at three processing plants: (i) plant A (New York wash, postevisceration wash, inside-outside bird washes 1 and 2, chlorine dioxide wash, chlorine dioxide wash plus chlorine chiller, chiller exit spray, and postchiller wash), (ii) plant B (New York wash, inside-outside bird washes 1 and 2, trisodium phosphate wash, and chlorine chiller), and (iii) plant C (trisodium phosphate wash and chlorine chiller). The majority of individual interventions effectively or significantly ($P < 0.05$) reduced microbial populations on or in carcasses, carcass parts, and processing water.

Reductions in APC, TCC, and ECC due to individual interventions ranged from 0 to 1.2, 0 to 1.2, and 0 to 0.8 log CFU/ml, respectively. Individual interventions reduced Salmonella incidence by 0 to 100% depending on the type of process and product. Multiple-sequential interventions resulted in significant reductions ($P < 0.05$) in APC, TCC, ECC, and Salmonella incidence of 2.4, 2.8, and 2.9 log CFU/ml and 79%, respectively, at plant A; 1.8, 1.7, and 1.6 log CFU/ml and 91%, respectively, at plant B; and 0.8, 1.1, and 0.9 log CFU/ml and 40%, respectively, at plant C. These results enabled validation of in-plant poultry processing interventions and provide a source of information to help the industry in its selection of antimicrobial strategies.

L56 ANSWER 23 OF 27 MEDLINE on STN
ACCESSION NUMBER: 2006371648 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 16786874
TITLE: Microbiological status of fresh beef cuts.
AUTHOR: Stopforth J D; Lopes M; Shultz J E; Miksch R R; Samadpour M
CORPORATE SOURCE: Institute for Environmental Health, Inc., 15300 Bothell Way N.E., Seattle, Washington 98155, USA.
SOURCE: Journal of food protection, (2006 Jun) Vol. 69, No. 6, pp. 1456-9.
Journal code: 7703944. ISSN: 0362-028X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200607
ENTRY DATE: Entered STN: 22 Jun 2006
Last Updated on STN: 25 Jul 2006
Entered Medline: 24 Jul 2006

AB Fresh beef samples (n = 1,022) obtained from two processing plants in the Midwest (July to December 2003) were analyzed for levels of microbial populations (total aerobic plate count, total coliform count, and Escherichia coli count) and for the presence or absence of E. coli O157:H7 and Salmonella. A fresh beef cut sample was a 360-g composite of 6-g portions excised from the surface of 60 individual representative cuts in a production lot. Samples of fresh beef cuts yielded levels of 4.0 to 6.2, 1.1 to 1.8, and 0.8 to 1.0 log CFU/g for total aerobic plate count, total coliform count, and E. coli count, respectively. There did not appear to be substantial differences or obvious trends in bacterial populations on different cuts. These data may be useful in establishing a baseline or a benchmark of microbiological levels of contamination of beef cuts. Mean incidence rates of E. coli O157:H7 and Salmonella on raw beef cuts were 0.3 and 2.2%, respectively. Of the 1,022 samples analyzed, cuts testing positive for E. coli O157:H7 included top sirloin butt (0.9%) and butt, ball tip (2.1%) and for Salmonella included short loins (3.4%), strip loins (9.6%), rib eye roll (0.8%), shoulder clod (3.4%), and clod, top blade (1.8%). These data provide evidence of noticeable incidence of pathogens on whole muscle beef and raise the importance of such contamination on product that may be mechanically tenderized. Levels of total aerobic plate count, total coliform count, and E. coli count did not ($P >$ or $= 0.05$) appear to be associated with the presence of E. coli O157:H7 and Salmonella on fresh beef cuts. E. O157:H7 was exclusively isolated from cuts derived from the sirloin area of the carcass. Salmonella was exclusively isolated from cuts derived from the chuck, rib, and loin areas of the carcass. Results of this study suggest that contamination of beef cuts may be influenced by the region of the carcass from which they are derived.

L56 ANSWER 24 OF 27 MEDLINE on STN
ACCESSION NUMBER: 2006371647 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 16786873
TITLE: Location of bung bagging during beef slaughter influences the potential for spreading pathogen contamination on beef carcasses.
AUTHOR: Stopforth J D; Lopes M; Shultz J E; Miksch R R; Samadpour M
CORPORATE SOURCE: Institute for Environmental Health, Inc., 15300 Bothell Way N.E., Seattle, Washington 98155, USA.
SOURCE: Journal of food protection, (2006 Jun) Vol. 69, No. 6, pp. 1452-5.
Journal code: 7703944. ISSN: 0362-028X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200607
ENTRY DATE: Entered STN: 22 Jun 2006
Last Updated on STN: 25 Jul 2006
Entered Medline: 24 Jul 2006

AB Preevisceration carcass washing prior to bung bagging during beef slaughter may allow pooling of wash water in the rectal area and consequent spread of potential pathogens. The objective of this study was to compare protocols for bung bagging after preevisceration washing with an alternative method for bung bagging before preevisceration washing for the potential to spread enterohemorrhagic Escherichia coli, E. coli O157:H7, and Salmonella on carcass surfaces. The study evaluated incidence rates of pathogens in preevisceration wash water (10 ml) samples (n = 120) and on surface (100 cm2) sponge samples (n = 120) in the immediate bung region when bagging occurred before (prewash bagging) and after (postwash bagging) preevisceration washing. Surface sampling from postwash bagging yielded incidence rates of 58.3, 5, and 8.3%, whereas wash water sampling yielded 28.3, 1.7, and 5% for enterohemorrhagic Escherichia coli, E. coli O157:H7, and Salmonella, respectively. Surface sampling from prewash bagging yielded incidence rates of 35, 1.7, and 0%, whereas wash water sampling yielded 18.3, 0, and 8.3% for enterohemorrhagic Escherichia coli, E. coli O157:H7, and Salmonella, respectively. Results of this research indicate that the rectal area is a significant source of pathogen contamination on carcasses and that wash water is an important mechanism for potential transfer of pathogen contamination from the rectal area. Results from this study suggest that bung bagging, as proposed in this study, before (prewash bagging) rather than after (postwash bagging) preevisceration washing was generally more effective in controlling pathogen contamination and potential spread from the rectal area of carcasses.

L56 ANSWER 25 OF 27 MEDLINE on STN
ACCESSION NUMBER: 2000474079 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 11018165
TITLE: A prospective study of asymptomatic bacteriuria in sexually active young women.
AUTHOR: Hooton T M; Scholes D; Stapleton A E; Roberts P L; Winter C; Gupta K; Samadpour M; Stamm W E
CORPORATE SOURCE: Department of Medicine, University of Washington School of Medicine and School of Public Health and Community Medicine, Seattle, USA.. hooton@u.washington.edu
CONTRACT NUMBER: DK 40045 (NIDDK)
DK 47549 (NIDDK)
SOURCE: The New England journal of medicine, (2000 Oct 5) Vol. 343, No. 14, pp. 992-7.

Journal code: 0255562. ISSN: 0028-4793.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
(RESEARCH SUPPORT, U.S. GOV'T, P.H.S.)
LANGUAGE: English
FILE SEGMENT: Abridged Index Medicus Journals; Priority Journals
ENTRY MONTH: 200010
ENTRY DATE: Entered STN: 12 Oct 2000
Last Updated on STN: 12 Oct 2000
Entered Medline: 5 Oct 2000

AB BACKGROUND: Asymptomatic bacteriuria is common in young women, but little is known about its pathogenesis, natural history, risk factors, and temporal association with symptomatic urinary tract infection. METHODS: We prospectively evaluated 796 sexually active, nonpregnant women from 18 through 40 years of age over a period of six months for the occurrence of asymptomatic bacteriuria (defined as at least 10(5) colony-forming units of urinary tract pathogens per milliliter). The women were patients at either a university student health center or a health maintenance organization. Periodic urine cultures were taken, daily diaries were kept, and regularly scheduled interviews were performed. Escherichia coli strains were tested for hemolysin, the papG genotype, and the ribosomal RNA type. RESULTS: The prevalence of asymptomatic bacteriuria (the proportion of urine cultures with bacteriuria in asymptomatic women) was 5 percent (95 percent confidence interval, 4 percent to 6 percent) among women in the university group and 6 percent (95 percent confidence interval, 5 percent to 8 percent) among women in the health-maintenance-organization group. Persistent asymptomatic bacteriuria with the same E. coli strain was rare. Symptomatic urinary tract infection developed within one week after 8 percent of occasions on which a culture showed asymptomatic bacteriuria, as compared with 1 percent of occasions when asymptomatic bacteriuria was not found (P<0.001). Asymptomatic bacteriuria was associated with the same risk factors as for symptomatic urinary tract infection, particularly the use of a diaphragm plus spermicide and sexual intercourse. CONCLUSIONS: Asymptomatic bacteriuria in young women is common but rarely persists. It is a strong predictor of subsequent symptomatic urinary tract infection.

L56 ANSWER 26 OF 27 BIOSIS COPYRIGHT (c) 2007 The Thomson Corporation on STN

ACCESSION NUMBER: 2000:505780 BIOSIS Full-text
DOCUMENT NUMBER: PREV200000505780
TITLE: Ribotype characterization of E. coli asymptomatic bacteriuria (ASB) strains in young sexually active women.
AUTHOR(S): Hooton, Thomas M. [Reprint author]; Scholes, Delia; Stapleton, Ann; Roberts, Pacita L.; Winter, Carol; Gupta, Kalpana; Samadpour, Mansour; Stamm, Walter E.
CORPORATE SOURCE: Group Health Cooperative, Seattle, WA, USA
SOURCE: Clinical Infectious Diseases, (July, 2000) Vol. 31, No. 1, pp. 214. print.
Meeting Info.: 2000 Annual Meeting of the Infectious Diseases Society of America. New Orleans, Louisiana, USA. September 07-10, 2000.
CODEN: CIDIEL. ISSN: 1058-4838.
DOCUMENT TYPE: Conference; (Meeting)
Conference; Abstract; (Meeting Abstract)
LANGUAGE: English
ENTRY DATE: Entered STN: 22 Nov 2000
Last Updated on STN: 11 Jan 2002

L56 ANSWER 27 OF 27 BIOSIS COPYRIGHT (c) 2007 The Thomson Corporation on

STN

ACCESSION NUMBER:	1998:417616 BIOSIS Full-text
DOCUMENT NUMBER:	PREV199800417616
TITLE:	Occurrence of Escherichia coli O157:H7, other Shiga-like toxin-producing E. coli, and Salmonella in retail fresh ground beef.
AUTHOR(S):	Samadpour, M.; Yang, P.; Buck, F.; Ammerman, S.; Depavia, G.; Mazengia, E.; Alfi, D. [Reprint author]; Barbour, W. M.
CORPORATE SOURCE:	Dep. Environ. Health, Univ. Washington, Seattle, WA, USA
SOURCE:	Abstracts of the General Meeting of the American Society for Microbiology, (1998) Vol. 98, pp. 405. print. Meeting Info.: 98th General Meeting of the American Society for Microbiology. Atlanta, Georgia, USA. May 17-21, 1998. American Society for Microbiology. ISSN: 1060-2011.
DOCUMENT TYPE:	Conference; (Meeting) Conference; Abstract; (Meeting Abstract) Conference; (Meeting Poster)
LANGUAGE:	English
ENTRY DATE:	Entered STN: 2 Oct 1998 Last Updated on STN: 2 Oct 1998

Text search history

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L3        67534 SEA FILE=HCAPLUS ABB=ON  PLU=ON  BACTERIA/CT
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L5         3783 SEA FILE=HCAPLUS ABB=ON  PLU=ON  (COLIFORM/CT OR "COLIFORM
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L8        11734 SEA FILE=HCAPLUS ABB=ON  PLU=ON  SAMPLES/CT
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L20         148 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L16 AND ((COMPOSIT? OR POOL?
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L6           141 SEA FILE=HCAPLUS ABB=ON  PLU=ON  SPORES/CT
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L12              QUE  ABB=ON  PLU=ON  (QUALIT?)(3A)(CONTROL? OR ASSUR? OR
                 SAMPL? OR TEST? OR SEQUEN? OR PROTOCOL?)
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                 H? OR SAMPL? OR PROTOCOL?)
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L18            9 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L16 AND L14
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L20          148 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L16 AND ((COMPOSIT? OR POOL?
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L23           87 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L20 AND (SALMONELLA OR COLI)
L24          126 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L19 OR L23
L25           47 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L24 AND (FOOD OR PHARMACEUT?
                 OR DRUG)
L26           12 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L24 AND (PHARMACOL? OR
                 INGRED? OR AGRIC? OR COMMOD? OR IMPORT OR EXPORT)
L28           52 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L17 OR L18 OR L26
L29           79 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L25 OR L28
L30            2 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L29 AND ((QUALIT?)(3A)(CONTROL
                  OR PROTOCOL OR SAMPL? OR PRODUCT))
L31           11 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L29 AND (QUALIT? OR SAFE?)
L33           16 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L26 OR L30 OR L31
L34           32 SEA FILE=HCAPLUS ABB=ON  PLU=ON  ("SAMADPOUR M"/AU OR "SAMADPOU
                 R MANSOUR"/AU)
L35           17 SEA FILE=HCAPLUS ABB=ON  PLU=ON  L34 AND HEALTH?/CO,CS,PA,SO
L39           42 SEA L35
L40           37 SEA L39 AND (BACTERI? OR MICROBIOL? OR SALMONELLA OR COLI)
L41           34 SEA L39 AND (QUALITY OR SAFETY OR FOOD OR PHARMACOL? OR DRUG
                 OR ENVIRON?)
L43            6 SEA L39 AND (BROTH OR AGAR OR ENRICH? OR CULTUR? OR MEDIUM OR
                 MEDIA)
L44           33 SEA L40 AND L41
L45           35 SEA L43 OR L44
L46           18 SEA L45 AND (SAMPL? OR SCREEN OR CONTROL OR ASSAY OR COUNT)
L47           20 SEA L46 OR L43
L48          116 SEA L33
L49          106 SEA L48 AND (SAMPL? OR SCREEN OR CONTROL OR ASSAY OR COUNT)
L50          106 SEA L49 AND (SALMONELLA OR COLI)
L51          104 SEA L50 AND (FOOD OR PHARMACEUT? OR DRUG OR AGRIC? OR COMMOD?
                 OR INGRED?)
L52           55 SEA L51 AND (BROTH OR AGAR OR ENRICH? OR CULTUR? OR MEDIUM OR
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                MEDIA)
L53           16 SEA L51 AND (HEKTOEN OR SELENITE OR EMB)
L54           16 SEA L52 AND L53
L55           16 SEA L54 NOT L47


=> dup rem L38 L55
FILE 'HCAPLUS' ENTERED AT 15:20:17 ON 31 OCT 2007
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FILE 'AGRICOLA' ENTERED AT 15:20:17 ON 31 OCT 2007
PROCESSING COMPLETED FOR L38
PROCESSING COMPLETED FOR L55
L57           29 DUP REM L38 L55 (3 DUPLICATES REMOVED)
                 ANSWERS '1-16' FROM FILE HCAPLUS
                 ANSWERS '17-27' FROM FILE MEDLINE
                 ANSWER '28' FROM FILE EMBASE
                 ANSWER '29' FROM FILE AGRICOLA
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Text search results

=> d L57 1-16 ibib ed abs hitind

L57 ANSWER 1 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN DUPLICATE 1
ACCESSION NUMBER: 2007:839888 HCAPLUS Full-text
TITLE: Serotyping, PCR, phage-typing and antibiotic sensitivity testing of Salmonella serovars isolated from urban drinking water supply systems of Nepal
AUTHOR(S): Bhatta, D. R.; Bangtrakulnonth, A.; Tishyadhigama, P.; Saroj, S. D.; Bandekar, J. R.; Hendriksen, R. S.; Kapadnis, B. P.
CORPORATE SOURCE: Department of Microbiology, University of Pune, Pune, India
SOURCE: Letters in Applied Microbiology (2007), 44(6), 588-594
CODEN: LAMIE7; ISSN: 0266-8254
PUBLISHER: Blackwell Publishing Ltd.
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 02 Aug 2007
AB Aims: To study the occurrence and diversity of Salmonella serovars in urban water supply systems of Nepal. Methods and Results: Occurrence of Salmonella was detected in 42 out of 300 water samples by enrichment culture technique in selenite F broth followed by plating on Salmonella Shigella agar. A total of 54 isolates identified to genus level by standard tests were subsequently confirmed by serotyping, phage typing and PCR detection of virulence genes (inv A and spv C). The predominant serotype was Salmonella Typhimurium, followed by Salm. Typhi, Salm. Paratyphi A and Salmonella Enteritidis. Most of the Salm. Typhi isolates were E1 phage type followed by UVS4, A and UVS1. All isolates of Salm. Paratyphi A and Salm. Enteritidis were an untypable (UT) phage type. The majority of isolates were multi-drug resistant as revealed by Kirby-Bauer disk diffusion technique. Ceftriaxone resistant isolates of Salm. Enteritidis indicated the presence of one of the ESBL genes, blaSHV, whereas the genes blaTEM and blaCTX were absent. Conclusions: The microbiol. quality of the urban water supply is poor and indicates possibility of fatal outbreaks of enteric fever and related infections in Nepal. Significance and Impact of the Study: The present study will be useful in water borne disease control and prevention strategy formulation in Nepal and in the global context.
CC 10 (Microbial, Algal, and Fungal Biochemistry)
IT INDEXING IN PROGRESS
IT Salmonella
(diverse serotypes of Salmonella detected from urban drinking water systems of Nepal show varied phage type and antimicrobial susceptibility with majority of isolates were multi-drug resistant and possessing inv A and spv C virulence genes)
REFERENCE COUNT: 37 THERE ARE 37 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 2 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2007:249183 HCAPLUS Full-text
DOCUMENT NUMBER: 147:349770
TITLE: Environmental assessment of water-courses of the Turvo Limpo River basin at the Minas Gerais State, Brazil
AUTHOR(S): Jordao, C. P.; Ribeiro, P. R. S.; Matos, A. T.; Bastos, R. K. X.; Fernandes, R. B. A.; Fontes, R. L. F.
CORPORATE SOURCE: Departamento de Solos, Universidade Federal de Vicosa, Vicosa, 36570-000, Brazil
SOURCE: Environmental Monitoring and Assessment (2007),

127(1-3), 315-326
CODEN: EMASDH; ISSN: 0167-6369
PUBLISHER: Springer
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 07 Mar 2007

AB A study was performed to evaluate the environmental contamination in the Turvo Limpo River basin which receives effluent discharges from domestic (residential and com.) activities. The watercourses examined were the Sao Bartolomeu Stream, Turvo Sujo River, and Turvo Limpo River, located in the Minas Gerais State, Brazil. Water samples were collected at the river-side and analyzed for evaluation of pollutant inputs. The pH, temperature, elec. conductivity, redox potential (Eh), dissolved oxygen (DO), total and settleable solids, visual color, hardness, COD, BOD, chloride, total phosphate, total nitrogen, ammonia nitrogen, nitrate, total coliforms and E. coli, as well as the Cd, Pb, Cu, and Zn speciation were determined in the watercourses. The data obtained were compared with those of the Brazilian Environmental Stds. and with data from non-contaminated areas. River water characteristics in some sites were far from the limit values established for superficial waters with satisfactory quality. For instance, the BOD values reached 411 mg L-1 for a maximum limit of 10.0 mg L-1, while the ammonia nitrogen concentration reached 28 mg L-1 for a maximum limit of 13.3 mg L-1. Some sites showed E. coli values above those of non-contaminated regions. Besides the effects of sewage discharges into the water-courses, agriculture activities and the use of the area for cattle husbandry influenced the quality of the river waters, for instance, the pH of a spring-water sample reached the value of 4.3. The Sao Bartolomeu Stream has been contributing to the deterioration of the water quality of the Turvo Sujo River, while the Turvo Limpo River has also been affected by anthropogenic discharges in the Turvo Sujo River. The speciation of Cd, Cu and Pb showed that these metals were mainly found in the particulate fraction (i. e., associated with the suspended material). Fifty five percent of the water samples showed labile Zn concns. greater than that of the nonlabile Zn.

CC 61-2 (Water)
Section cross-reference(s): 10, 19, 53, 60

IT Runoff
(agricultural; environmental assessment of water-courses of Turvo Limpo River basin at Minas Gerais state, Brazil)

IT Biochemical oxygen demand
Chemical oxygen demand
Color
Drinking water pollution
Economics
Electric conductivity
Environmental transport
Escherichia coli
Irrigation waters
Redox potential
River sediments
River water pollution
Temperature
(environmental assessment of water-courses of Turvo Limpo River basin at Minas Gerais state, Brazil)

IT Coliform bacteria
(total; environmental assessment of water-courses of Turvo Limpo River basin at Minas Gerais state, Brazil)

REFERENCE COUNT: 37 THERE ARE 37 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 3 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN

ACCESSION NUMBER: 2007:481263 HCAPLUS Full-text
DOCUMENT NUMBER: 147:412153
TITLE: Pathogens assessment in reclaimed effluent used for industrial crops irrigation
AUTHOR(S): Al-Sa'ed, R.
CORPORATE SOURCE: Water Studies Institute (WSI), Birzeit University, West Bank, Palestinian Territory, Occupied
SOURCE: International Journal of Environmental Research and Public Health (2007), 4(1), 68-75
CODEN: IJERGQ; ISSN: 1660-4601
URL: http://www.mdpi.org/ijerph/papers/ijerph200701001 1.pdf
PUBLISHER: Molecular Diversity Preservation International
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
ED Entered STN: 03 May 2007
AB Reuse of treated effluent is a highly valued water source in Palestine, however with limited success due to public health concerns. This paper assesses the potential pathogens in raw, treated and reclaimed wastewater at Albireh urban wastewater treatment facility, and provides scientific knowledge to update the Palestinian reuse guidelines. Laboratory analyses of collected samples over a period of 4 mo have indicated that the raw wastewater from Albireh city contained high nos. of fecal coliforms and worm eggs while 31% of the samples were Salmonella pos. Treated effluent suitable for restricted irrigation demonstrated that the plant was efficient in removing indicator bacteria, where fecal coliforms and fecal streptococci removal averaged 99.64% and 93.44%, resp. Although not disinfected, treated effluent was free of Salmonella and parasites, hence safe for restricted agricultural purposes. All samples of the reclaimed effluent and three samples of irrigated grass were devoid of microbial pathogens indicating a safe use in unrestricted agricultural utilization. Adequate operation of wastewater treatment facilities, scientific updating of reuse guidelines and launching public awareness campaigns are core factors for successful and sustainable large-scale wastewater reuse schemes in Palestine.
CC 60-2 (Waste Treatment and Disposal)
Section cross-reference(s): 10, 11, 17, 19, 61
IT Ameba
Ascaris
Balantidium coli
Biochemical oxygen demand
Chemical oxygen demand
Coliform bacteria
Cryptosporidium
Entamoeba coli
Entamoeba histolytica
Enterobius vermicularis
Eubacteria
Giardia
Irrigation waters
Nutrients
Pathogen
Protozoa
Public health
Safety
Salmonella
Streptococcus
Strongyloides stercoralis
Trichomonas
Turbidity
(pathogens assessment in reclaimed effluent used for

industrial crops irrigation)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 4 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2006:523904 HCAPLUS Full-text
DOCUMENT NUMBER: 144:484494
TITLE: Antimicrobial susceptibility of Salmonella from organic and conventional dairy farms
AUTHOR(S): Ray, K. A.; Warnick, L. D.; Mitchell, R. M.; Kaneene, J. B.; Ruegg, P. L.; Wells, S. J.; Fossler, C. P.; Halbert, L. W.; May, K.
CORPORATE SOURCE: Department of Population Medicine and Diagnostic Sciences, College of Veterinary Medicine, Cornell University, Ithaca, NY, 14853, USA
SOURCE: Journal of Dairy Science (2006), 89(6), 2038-2050
CODEN: JDSCAE; ISSN: 0022-0302
PUBLISHER: American Dairy Science Association
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 05 Jun 2006
AB The objective of this study was to compare antimicrobial susceptibility of Salmonella isolated from conventional and organic dairy farms in the Midwest and Northeast United States. Environmental and fecal samples were collected from organic (n = 26) and conventional (n = 69) farms in Michigan, Minnesota, New York, and Wisconsin every 2 mo from August 2000 to Oct. 2001. Salmonella isolates (n = 1,243) were tested using a broth microdilution method for susceptibility to amoxicillin-clavulanic acid, ampicillin, ceftiofur, ceftriaxone, cephalothin, chloramphenicol, ciprofloxacin, gentamicin, kanamycin, nalidixic acid, streptomycin, sulfamethoxazole, tetracycline, and trimethoprim-sulfamethoxazole. Herd-level logistic regression and logistic proportional hazards multivariable models were used to examine the association between farm management type and susceptibility to antimicrobial agents. For most antimicrobial agents tested, susceptibility of Salmonella isolates was similar on organic and conventional herds when controlling for herd size and state. Conventional farms were more likely to have at least one Salmonella isolate resistant to streptomycin using logistic regression (odds ratio = 7.5; 95% confidence interval = 1.7-55.4). Conventional farms were more likely to have Salmonella isolates with greater resistance to streptomycin (odds ratio = 5.4; 95% confidence interval = 1.5-19.0) and sulfamethoxazole (odds ratio = 4.2; 95% confidence interval = 1.2-14.1) using logistic proportional hazards models. Although not statistically significant, conventional farms tended to be more likely to have at least one Salmonella isolate resistant to 5 or more antimicrobial agents when compared with organic farms.
CC 10-5 (Microbial, Algal, and Fungal Biochemistry)
IT Agriculture and Agricultural chemistry
Antibiotic resistance
Antibiotics
Bos taurus
Multidrug resistance
Salmonella
(antibiotic susceptibility of Salmonella from organic and conventional dairy farms)
IT 56-75-7, Chloramphenicol 57-92-1, Streptomycin, biological studies 60-54-8, Tetracycline 69-53-4, Ampicillin 153-61-7, Cephalothin 389-08-2, Nalidixic acid 723-46-6, Sulfamethoxazole 1403-66-3, Gentamicin 8063-07-8, Kanamycin 8064-90-2 73384-59-5, Ceftriaxone 79198-29-1, Amoxicillin/clavulanic acid 80370-57-6, Ceftiofur 85721-33-1, Ciprofloxacin
RL: BSU (Biological study, unclassified); THU (Therapeutic use); BIOL

(Biological study); USES (Uses)
(antibiotic susceptibility of Salmonella from organic and conventional dairy farms)
REFERENCE COUNT: 30 THERE ARE 30 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 5 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2006:1001752 HCAPLUS Full-text
DOCUMENT NUMBER: 145:431735
TITLE: Effect of ractopamine HCl supplementation on fecal shedding of Escherichia coli O157:H7 and Salmonella in feedlot cattle
AUTHOR(S): Edrington, T. S.; Callaway, T. R.; Ives, S. E.; Engler, M. J.; Welsh, T. H.; Hallford, D. M.; Genovese, K. J.; Anderson, R. C.; Nisbet, D. J.
CORPORATE SOURCE: Food and Feed Safety Research Unit, ARS-USDA, College Station, TX, 77845, USA
SOURCE: Current Microbiology (2006), 53(4), 340-345
CODEN: CUMIDD; ISSN: 0343-8651
PUBLISHER: Springer
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 27 Sep 2006
AB The effects of the β-agonist ractopamine, recently approved for use in feedlot cattle to improve carcass quality and performance, on fecal shedding Escherichia coli O157:H7 and Salmonella in feedlot cattle was examined In the 1st study, 20 feedlot steers and heifers were randomly assigned to receive ractopamine or no ractopamine (control) by way of oral bolus for 28 days. Fecal samples were collected daily, and shedding of E. coli O157:H7 determined When examined during the entire 28-day exptl. period, ractopamine decreased the percentage of cattle shedding E. coli O157:H7 (58 vs. 42% for control and ractopamine treatments, resp.). A 2nd study was conducted in a com. feedlot facility in the southwestern United States. Eighteen pens of cross-bred beef heifers (approx. 100 head/pen and 9 pens/treatment) were randomly assigned to receive either 0 (control) or 200 mg ractopamine/head·d-1. Fresh fecal samples (30/pen) were collected off the pen floor before ractopamine supplementation and again after approx. 28 days of ractopamine supplementation (within a few days of slaughter); the samples were cultured for E. coli O157:H7 and Salmonella. The percentage of animals shedding E. coli O157:H7 was decreased when data were pooled across replicates in ractopamine-treated cattle compared with controls. The percentage of animals shedding Salmonella tended to be higher with the ractopamine treatment when data were pooled across replicates. Although further research is required to confirm these results, the potential food safety implications of this research are intriguing.
CC 1-5 (Pharmacology)
ST ractopamine feedlot cattle feces Escherichia Salmonella antibiotic
IT Antibiotics
Bos taurus
Escherichia coli
Feces
Salmonella
(ractopamine supplementation on fecal shedding of Escherichia and Salmonella in feedlot cattle)
IT 90274-24-1, Ractopamine hydrochloride
RL: PAC (Pharmacological activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(ractopamine supplementation on fecal shedding of Escherichia and Salmonella in feedlot cattle)

REFERENCE COUNT: 21 THERE ARE 21 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 6 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2007:604903 HCAPLUS Full-text
TITLE: Assessment of salmonella contamination of feed raw materials and their anti-microbial resistance profiles in Imo State, Nigeria
AUTHOR(S): Okoli, Ifeanyi Charles; Ekwueagana, Ifeoma C.; Ogbuewu, I. Prince
CORPORATE SOURCE: Tropical Animal Health and Production Research Laboratory, Department of Animal Science and Technology, Federal University of Technology, Owerri, PMB 1526, Nigeria
SOURCE: Life Science Journal (2006), 3(4), 75-80
CODEN: LSJIAC; ISSN: 1097-8135
PUBLISHER: Zhengzhou University
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 05 Jun 2007
AB This study was conducted to determine the frequency of isolation of salmonella and their microbial resistance profiles, across selected feed raw materials sold in Imo State, Nigeria. Three hundred and sixty (360) bulk samples were collected across different feed raw materials which include animal proteins-foreign fish meal (FFM) and local fish meal (LFM), plant proteins-groundnut cake (GNC) and soybean meal (SBM), fiber sources-palm kernel cake (PKC) and wheat offal (WO), energy grain-maize (MZ) and Minerals-bone meal (BM). The salmonella isolated were tested against 14 anti-microbial agent using disk diffusion method. Bacterial load enumeration of the samples indicated a range of >300 to overgrowth of colony forming unit (CFU) at 4 serial dilution One hundred and twenty (120) samples (33.33%) were pos. for salmonella isolates with fiber sources and animal protein recording 56.00% and 50.91% prevalence, resp. Across the individual raw material types, it recorded LFM (90.0%), WO (60.0%), PKC (50.0%), SBM (40.0%) and GNC (28.67%) prevalence while non were isolated from maize and bone meal. Salmonella isolates showed a high rate of resistance to ampicillin (100%), tetracycline and nitrofurantoin (78.6%) and cotrimoxazole (50%), and moderate rate of 42.6%, 35.7%, and 21.4% against cephalexin, streptomycin and ceftriaxone, and ciprofloxacin resp., while low rates of 7.1% were recorded for amoxycillin clavulanate and pefloxacin and 14.39% for ofloxacin, nalidixic acid and chloramphenicol. The present study showed that feed ingredients sold in Owerri form important vehicles for the introduction of multi-drug resistant salmonella organisms into poultry feeds. It is therefore, recommended that feed raw materials should be hygienically processed before inclusion in livestock feeds.
CC 10-5 (Microbial, Algal, and Fungal Biochemistry)
Section cross-reference(s): 17
ST Salmonella antimicrobial resistance animal feed food contamination
IT Antibiotic resistance
Feed
Food contamination
Salmonella
(assessment of salmonella contamination of feed raw materials and their anti-microbial resistance profiles)
IT 56-75-7, Chloramphenicol 57-92-1, Streptomycin 60-54-8, Tetracycline 67-20-9, Nitrofurantoin 69-53-4, Ampicillin 1403-66-3, Gentamycin 8064-90-2, Cotrimoxazole 15686-71-2, Cephalexin 70458-92-3, Pefloxacin 73384-59-5, Ceftriaxone 79198-29-1 82419-36-1, Ofloxacin 85721-33-1, Ciprofloxacin

RL: BSU (Biological study, unclassified); BIOL (Biological study)
(assessment of salmonella contamination of feed raw materials and their anti-microbial resistance profiles)

REFERENCE COUNT: 36 THERE ARE 36 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 7 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2006:703840 HCAPLUS Full-text
DOCUMENT NUMBER: 145:217048
TITLE: Quality assessment of Nizam Deccan Sugar Factory effluents and water samples collected at different locations along the effluent stream in Bodhan town of Andhra Pradesh
AUTHOR(S): Dasharath, D.; Reddy, E. Narsimha
CORPORATE SOURCE: Department of Chemistry, Girraj Government College, Nizamabad, 503002, India
SOURCE: Oriental Journal of Chemistry (2005), 21(2), 283-286
CODEN: OJCHEG; ISSN: 0970-020X
PUBLISHER: Oriental Scientific Publishing Co.
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 20 Jul 2006
AB The various physico-chemical properties of the Nizam Deccan Sugar Factory wastewater, polluted Pandu lake water, and bore-wells water along the streams of factory effluents flowing with in the heart of the Bodhan town of Nizamabad district in Andhra Pradesh (India) were studied. Non-polluted potable Bellal lake water of Bodhan town was also examined for comparison. Elec. conductivity (salt load) was found in between 1557-13050 μm cm-1. Sugar industry wastewater and Pandu lake water showed the higher BOD above the BIS stds. E. coli and coliform count MPN/100 mL were highest in industrial wastewater and Pandu lake water comparatively it is lower in case of bore wells water in the surroundings of Pandu lake, i.e. ranged 62-1280 and 39-5300 resp. Such water is neither useful for drinking nor for the agricultural fields. Long term application of such water for irrigation may spoil the soil permanently for cultivation.
CC 61-2 (Water)
Section cross-reference(s): 44, 60
IT Wastewater
(industrial; quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))
IT Coliform bacteria
Drinking waters
Electric conductivity
Environmental pollution
Escherichia coli
Irrigation waters
Lake waters
Solids
Turbidity
Water pollution
Well waters
pH
(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))
IT Carbohydrates, preparation
RL: IMF (Industrial manufacture); PREP (Preparation)

(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))

IT Bicarbonates
RL: POL (Pollutant); OCCU (Occurrence)
(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))

IT Chlorides, occurrence
RL: POL (Pollutant); OCCU (Occurrence)
(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))

IT Nitrites
RL: POL (Pollutant); OCCU (Occurrence)
(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))

IT 7439-89-6, Iron, occurrence 7439-95-4, Magnesium, occurrence 7440-09-7, Potassium, occurrence 7440-70-2, Calcium, occurrence
RL: POL (Pollutant); OCCU (Occurrence)
(quality assessment of Nizam Deccan Sugar Factory effluents and its impact on bore wells as well as on lake water used for irrigation and drinking purpose in surrounding areas of sugar factory of Bodhan town (India))

REFERENCE COUNT: 10 THERE ARE 10 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 8 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2005:387649 HCAPLUS Full-text
DOCUMENT NUMBER: 143:404790
TITLE: Salmonella profile in chickens determined by real-time polymerase chain reaction and bacteriology from years 2000 to 2003 in Turkey
AUTHOR(S): Eyigor, Aysegul; Goncagul, Gulsen; Gunaydin, Elcin; Carli, K. Tayfun
CORPORATE SOURCE: Department of Food Hygiene and Technology, Yenisehir Ibrahim Orhan Vocational High School, Uludag University, Gorukle Kampusu, 16059, Turk.
SOURCE: Avian Pathology (2005), 34(2), 101-105
CODEN: AVPADN; ISSN: 0307-9457
PUBLISHER: Taylor & Francis Ltd.
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 05 May 2005
AB From years 2000 to 2003, Salmonella was investigated from a total of 1785 samples comprised of chicken intestinal samples, cloacal swabs, drag swabs, litter samples and chick dust samples collected from 191 poultry breeding flocks belonging to 15 different chicken breeding stock companies in the Marmara region, Turkey by a SYBR green-based real-time polymerase chain reaction (SGBRT-PCR), by a probe-specific real-time polymerase chain reaction (PSRT-PCR) and by standardized bacteriol. as described in the manual of National Poultry Improvement Plan and Auxiliary Provisions, United States Department of Agriculture. Between Jan. 2000 and July 2001, Salmonella was detected at the rates of 5.87% and 4.10% out of a total of 1242 samples by SGBRT-PCR and bacteriol., resp. From July 2001 until Dec. 2003, Salmonella

was found at rates of 11.42% and 5.52% from a total of 543 samples by PSRT-PCR and bacteriol., resp. The dominant Salmonella serovar was determined as Salmonella enterica subsp. enterica Serovar Enteritidis (S.Enteritidis), while serogroup C1 and C2 in 2001 and serogroup E1 in 2002 were isolated as addnl. serovars. As a conclusion, S. Enteritidis seems to be the major problem in poultry breeding flocks in Turkey, and both of the real-time polymerase chain reaction methods were found more sensitive than standard bacteriol. for the detection of Salmonella from poultry samples.

CC 17-5 (Food and Feed Chemistry)
Section cross-reference(s): 3, 10

ST Salmonella chicken meat contamination epidemiol

IT Epidemiology
Food contamination
Gallus domesticus
Poultry
Salmonella
Salmonella enterica enterica
Salmonella enterica enteritidis
(Salmonella in chickens determined by real-time PCR and bacteriol.)

IT Meat
(chicken; Salmonella in chickens determined by real-time PCR and bacteriol.)

IT Meat
(poultry; Salmonella in chickens determined by real-time PCR and bacteriol.)

IT PCR (polymerase chain reaction)
(real-time; Salmonella in chickens determined by real-time PCR and bacteriol.)

REFERENCE COUNT: 31 THERE ARE 31 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 9 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2004:94634 HCAPLUS Full-text
DOCUMENT NUMBER: 140:292034
TITLE: Impact assessment of treated/untreated wastewater toxicants discharged by sewage treatment plants on health, agricultural, and environmental quality in the wastewater disposal area
AUTHOR(S): Singh, Kunwar P.; Mohan, Dinesh; Sinha, Sarita; Dalwani, R.
CORPORATE SOURCE: Environmental Chemistry Division, Industrial Toxicology Research Centre, Lucknow, 226 001, India
SOURCE: Chemosphere (2004), 55(2), 227-255
CODEN: CMSHAF; ISSN: 0045-6535
PUBLISHER: Elsevier Science Ltd.
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 05 Feb 2004

AB Studies were undertaken to assess the impact of wastewater/sludge disposal (metals and pesticides) from sewage treatment plants (STPs) in Jajmau, Kanpur (5 MLD) and Dinapur, Varanasi (80 MLD), on health, agriculture and environmental quality in the receiving/application areas around Kanpur and Varanasi in Uttar Pradesh, India. The raw, treated and mixed treated urban wastewater samples were collected from the inlet and outlet points of the plants during peak (morning and evening) and non-peak (noon) hours. The impact of the treated wastewater toxicants (metals and pesticides) on the environmental quality of the disposal area was assessed in terms of their levels in different media samples viz., water, soil, crops, vegetation, and food grains. The data generated show elevated levels of metals and pesticides

in all the environmental media, suggesting a definite adverse impact on the environmental quality of the disposal area. The critical levels of the heavy metals in the soil for agricultural crops are found to be much higher than those observed in the study areas receiving no effluents. The sludge from the STPs has both pos. and neg. impacts on agriculture as it is loaded with high levels of toxic heavy metals and pesticides, but also enriched with several useful ingredients such as N, P, and K providing fertilizer values. The sludge studied had Cd, Cr and Ni levels above tolerable levels as prescribed for agricultural and lands application. Biomonitoring of the metals and pesticides levels in the human blood and urine of the different population groups under study areas was undertaken. All the different approaches indicated a considerable risk and impact of heavy metals and pesticides on human health in the exposed areas receiving the wastewater from the STPs.

CC 61-2 (Water)
Section cross-reference(s): 5, 17, 19, 60

ST risk wastewater toxicant sewage health agriculture environment

IT Agriculture and Agricultural chemistry
Blood
Coliform bacteria
Crop (plant)
Embryophyta
Pesticides
Plants
Risk assessment
Salmonella
Soil pollution
Streptococcus
Urine
Wastewater
Wastewater treatment sludge
Water pollution
(impact assessment of treated/untreated wastewater toxicants discharged by sewage treatment plants on health and agricultural and environmental quality in wastewater disposal area, India)

IT Heavy metals
RL: POL (Pollutant); OCCU (Occurrence)
(impact assessment of treated/untreated wastewater toxicants discharged by sewage treatment plants on health and agricultural and environmental quality in wastewater disposal area, India)

IT 50-29-3, p,p'-Ddt, occurrence 58-89-9, γ-BHC 72-54-8, p,p'-Ddd 72-55-9, p,p'-Dde, occurrence 319-84-6, α-BHC 319-85-7, β-BHC 7439-89-6, Iron, occurrence 7439-92-1, Lead, occurrence 7439-96-5, Manganese, occurrence 7440-02-0, Nickel, occurrence 7440-09-7, Potassium, occurrence 7440-43-9, Cadmium, occurrence 7440-47-3, Chromium, occurrence 7440-50-8, Copper, occurrence 7440-66-6, Zinc, occurrence 7723-14-0, Phosphorus, occurrence 7727-37-9, Nitrogen, occurrence 14798-03-9, Ammonium, occurrence
RL: POL (Pollutant); OCCU (Occurrence)
(impact assessment of treated/untreated wastewater toxicants discharged by sewage treatment plants on health and agricultural and environmental quality in wastewater disposal area, India)

REFERENCE COUNT: 18 THERE ARE 18 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 10 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2004:374754 HCAPLUS Full-text
DOCUMENT NUMBER: 141:300687
TITLE: Investigation of water quality and

aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama, 2000-01

AUTHOR(S): McPherson, Ann K.; Abrahamsen, Thomas A.; Journey, C. A.

CORPORATE SOURCE: USA

SOURCE: Water-Resources Investigations Report (United States Geological Survey) (2002), 02-4182, I-VIII, 1-120
CODEN: WIREFS

DOCUMENT TYPE: Report

LANGUAGE: English

ED Entered STN: 10 May 2004

AB The US Geol. Survey conducted a 16-mo study of water quality, aquatic-community structure, bed sediment, and fish tissue in Village and Valley Creeks, 2 urban streams that drain areas of highly intensive residential, com., and industrial land use in Birmingham, Alabama. Water- quality data were collected between Feb. 2000 and Mar. 2001 at 4 sites on Village Creek, 3 sites on Valley Creek, and at 2 reference sites near Birmingham, Fivemile Creek and Little Cahaba River, both of which drain less-urbanized areas. Stream samples were analyzed for major ions, nutrients, fecal bacteria, trace and major elements, pesticides, and selected organic constituents. Bed-sediment and fish-tissue samples were analyzed for trace and major elements, pesticides, polychlorinated biphenyls, and addnl. organic compds. Aquatic-community structure was evaluated by conducting one survey of the fish community and instream habitat and 2 surveys of the benthic-invertebrate community. Bed-sediment and fish-tissue samples, benthic-invertebrates, and habitat data were collected between June 2000 and Oct. 2000 at 6 of the 9 water- quality sites; fish communities were evaluated in Apr. and May 2001 at the 6 sites where habitat and benthic-invertebrate data were collected. The occurrence and distribution of chemical constituents in the water column and bed sediment provided an initial assessment of water quality in the streams. The structure of the aquatic communities, the phys. condition of the fish, and the chemical analyses of fish tissue provided an indication of the cumulative effects of water quality on the aquatic biota. Water chemical was similar at all sites, characterized by strong Ca bicarbonate component and Mg components. Median concns. of total N and total P were highest at the headwaters of Valley Creek and lowest at the reference site on Fivemile Creek. In Village Creek, median concns. of nitrite and ammonia increased in a downstream direction. In Valley Creek, median concns. of nitrate, nitrite, ammonia, organic N, suspended P, and orthophosphate decreased in a downstream direction. Median concns. of E. coli and fecal coliform bacteria were highest at the most upstream site of Valley Creek and lowest at the reference site on Fivemile Creek. Concns. of enterococci exceeded the US EPA criterion in 80% of the samples; concns. of E. coli exceeded the criterion in 56% of the samples. Concns. of bacteria at the downstream sites on Village and Valley Creeks were elevated during high flow rather than low flow, indicating the presence of nonpoint sources. Surface water samples were analyzed for chemical compds. that are commonly found in wastewater and urban runoff. The median number of wastewater indicators was highest at the most upstream site on Valley Creek and lowest at the reference site on Fivemile Creek. Concns. of total recoverable Cd, Cu, Pb, and Zn in surface water exceeded acute and chronic aquatic life criteria in ≤24% of the samples that were analyzed for trace and major elements. High concns. of trace and major elements in the water column were detected most frequently during high flow, indicating the presence of nonpoint sources. Of the 24 pesticides detected in surface water, 17 were herbicides and 7 were insecticides. Atrazine, simazine, and prometon were the most commonly detected herbicides; diazinon, chlorpyrifos, and carbaryl were the most commonly detected insecticides. Concns. of atrazine, carbaryl, chlorpyrifos, diazinon, and malathion periodically exceeded criteria for the protection of aquatic life. Trace-element priority pollutants, pesticides, and

other organic compds. were detected in higher concns. in bed sediment at the Village and Valley Creek sites than at the reference site on Fivemile Creek. Bed-sediment concns. of Cr, Cu, Pb, Hg and Ag were highest at the most upstream site on Valley Creek; and concns. of Cd, Ni, Se, and Zn were highest at the second downstream site on Village Creek. Bed-sediment concns. of As, Cd, Cr, Cu, Pb, Hg, Ni, Se, and Zn from the Village and Valley creek sites exceeded median concns. observed nationwide. Concns. of Cd, Se, and Zn were highest in fish-liver tissue samples collected from the second downstream site on Village Creek-concns. of Cu and Hg in fish-liver samples were highest at the most downstream site on Village Creek. The highest total concentration of orgs. detected in bed-sediment samples occurred at the most upstream site on Valley Creek and the lowest total occurred at Fivemile Creek. In Village Creek, concns. of 75% of the detected orgs. increased in a downstream direction; in Valley Creek, concns. of .apprx.70% of the detected orgs. decreased in a downstream direction. Concns. of 10 orgs. in bed-sediment samples, including chlordane and p,p'-DDE, exceeded levels considered harmful to aquatic organisms at sites on Village and Valley Creeks. Concns. of dieldrin, chlordane, and polychlorinated biphenyls in fish-tissue samples exceeded National Academy of Science/ National Academy of Engineering guidelines for the protection of fish-eating wildlife. Fish and benthic-invertebrate community structure differed between Village and Valley Creeks and the reference streams. Multiple lines of evidence, including the richness and d. of benthic invertebrates as well as fish-community structure, indicate that the aquatic community in Village Creek is similar to that of Valley Creek, but that the integrity of the aquatic communities in both creeks is poor in comparison to that observed at the 2 reference sites. The abundance of mayflies and the number of EPT (Ephemeroptera, Plecoptera, Trichoptera) taxa (2 well-known indicators of good water quality) were neg. correlated with industrial land use. The abundance of midges (an indicator of poor water quality) was pos. correlated with industrial land use-and midge d. was pos. correlated with com. land use, providing addnl. evidence that these streams have been neg. affected by urbanization in the basins. The percentage of mosquitofishes (a tolerant species) was pos. correlated with com. land use. In contrast, the number of fish species, fish families, and the percentage of sunfishes (intolerant species) were pos. correlated with forested land use, indicating that the more diverse fish communities were found in basins with a higher percentage of forested land. The concns. of 12 water-quality constituents (including several N species, chloride, Cu, and Mo, and the detection frequency of wastewater indicators) and 18 orgs. detected in bed sediment were pos. correlated with industrial land use. Hg and Mo concns. detected in fish-liver tissue also were pos. correlated with industrial land use. Bed-sediment and water-quality constituents that had significant correlations with land use often were found to be correlated with many biol. indicators, further supporting the link between increased urbanization and changes in aquatic-community structure. The water quality and aquatic-community structure in Village and Valley Creeks are degraded in comparison to streams flowing through less-urbanized areas. Low community richness and increased d. of certain species within the fish and benthic-invertebrate communities indicate that the degradation has occurred during an extended period of time. Decreased diversity in the aquatic communities and elevated concns. of trace elements and organic contaminants in the water column, bed sediment, and fish tissues at Village and Valley Creeks are indicative of the effects of urbanization. The degree of degradation may be related to point and nonpoint sources of contamination originating within the basins. Industrial land use, in particular, was significantly correlated to elevated contaminant levels in the water column, in bed sediment, in fish tissue, and to the declining health of the benthic-invertebrate communities. The results of the 16-mo study have long-range watershed management implications, demonstrating the association of urban development and stream degradation

These data can serve as a baseline from which to determine the effectiveness of stream-restoration programs.

CC 61-2 (Water)
Section cross-reference(s): 5, 60

ST water quality aquatic community Village Valley Creeks Birmingham Alabama

IT Benthic organisms
(invertebrate; water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT Environmental pollution
(sediment; water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT Chironomidae
Coliform bacteria
Detergents
Drugs
Electric conductivity
Enterococcus
Ephemeroptera
Escherichia coli
Fish
Gambusia affinis
Herbicides
Insecticides
Intestinal bacteria
Liver
Pesticides
Plecoptera
River water pollution
Trichoptera
Water pollution
(water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT Chlorides, occurrence
Nitrates, occurrence
Nitrites
Phosphates, occurrence
RL: GOC (Geological or astronomical occurrence); POL (Pollutant); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT Organic compounds, occurrence
RL: POL (Pollutant); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT 3983-19-5, Calcium bicarbonate 7782-44-7, Oxygen, occurrence
RL: GOC (Geological or astronomical occurrence); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT 7439-95-4, Magnesium, occurrence 7723-14-0, Phosphorus, occurrence 7727-37-9, Nitrogen, occurrence 14798-03-9, Ammonium, occurrence
RL: GOC (Geological or astronomical occurrence); POL (Pollutant); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT 50-28-2, 17β-Estradiol, occurrence 50-29-3, occurrence 50-32-8, Benzo[a]pyrene, occurrence 53-19-0 53-70-3, Dibenz[a,h]anthracene 55-38-9, Fenthion 56-38-2, Parathion 56-55-3, Benz[a]anthracene

57-88-5, Cholesterol, occurrence 58-08-2, Caffeine, occurrence 58-89-9, Lindane 59-50-7, 4-Chloro-m-cresol 60-57-1, Dieldrin 63-25-2, Carbaryl 63-98-9 72-20-8, Endrin 72-43-5, p,p'-Methoxychlor 72-54-8 72-55-9, occurrence 76-44-8, Heptachlor 78-48-8, DEF 78-59-1, Isophorone 82-68-8, Pentachloronitrobenzene 83-32-9, Acenaphthene 84-65-1, 9,10-Anthraquinone 84-66-2, Diethyl phthalate 84-74-2, Di-n-butyl phthalate 85-01-8, Phenanthrene, occurrence 85-68-7, Butylbenzyl phthalate 86-30-6, n-Nitrosodiphenylamine 86-50-0, Azinphos-methyl 86-73-7, 9H-Fluorene 86-74-8, Carbazole 88-85-7, Dinoseb 91-20-3, Naphthalene, occurrence 91-22-5, Quinoline, occurrence 91-58-7, 2-Chloronaphthalene 92-52-4D, Biphenyl, chloro derivs. 93-72-1, 2-(2,4,5-Trichlorophenoxy)propionic acid 93-76-5, 2,4,5-T 94-74-6, MCPA 94-75-7, 2,4-D, occurrence 94-81-5, MCPB 94-82-6, 2,4-DB 95-50-1, o-Dichlorobenzene 95-57-8, 2-Chlorophenol 98-86-2, Acetophenone, occurrence 98-95-3, Nitrobenzene, occurrence 101-55-3, 4-Bromophenyl phenyl ether 103-33-3, Azobenzene 104-40-5, p-Nonylphenol 106-44-5, p-CRESol, occurrence 106-46-7, p-Dichlorobenzene 108-95-2, Phenol, occurrence 111-44-4, Bis-2-Chloroethyl ether 111-91-1, Bis(2-Chloroethoxy)methane 114-26-1, Propoxur 115-29-7, Endosulfan 115-86-6, Triphenyl phosphate 115-96-8, Tri (2-chloroethyl) phosphate 116-06-3, Aldicarb 117-81-7, Bis(2-Ethylhexyl) phthalate 117-84-0, Di-n-octylphthalate 118-74-1, Hexachlorobenzene 119-65-3, Isoquinoline 119-91-5, 2,2'-Biquinoline 120-12-7, Anthracene, occurrence 120-36-5, Dichloroprop 120-82-1, 1,2,4-Trichlorobenzene 121-00-6, 3-tert-Butyl-4-hydroxyanisole 121-14-2, 2,4-Dinitrotoluene 121-75-5 122-34-9, Simazine 122-42-9, Propham 129-00-0, Pyrene, occurrence 131-11-3, Dimethyl phthalate 132-65-0, Dibenzothiophene 191-24-2, Benzo[ghi]perylene 193-39-5, Indeno[1,2,3-cd]pyrene 203-64-5, 4H-Cyclopenta[def]phenanthrene 205-99-2, Benzo[b]fluoranthene 206-44-0, Fluoranthene 207-08-9, Benzo[k]fluoranthene 208-96-8, Acenaphthylene 218-01-9, Chrysene 229-87-8, Phenanthridine 230-17-1, Benzo[c]cinnoline 260-94-6, Acridine 298-00-0 298-02-2, Phorate 298-04-4, Disulfoton 309-00-2, Aldrin 314-40-9, Bromacil 319-84-6, α-BHC 319-85-7, β-BHC 319-86-8, δ-BHC 330-54-1, Diuron 330-55-2, Linuron 333-41-5 360-68-9, 3β-Coprostanol 486-56-6, Cotinine 534-52-1, 4,6-Dinitro-2-methylphenol 541-73-1, m-Dichlorobenzene 555-37-3, Neburon 563-12-2, Ethion 573-98-8, 1,2-Dimethylnaphthalene 575-43-9, 1,6-Dimethylnaphthalene 579-66-8, 2,6-Diethylaniline 581-42-0, 2,6-Dimethylnaphthalene 606-20-2, 2,6-Dinitrotoluene 613-12-7, 2-Methylanthracene 621-64-7, N-Nitrosodi-N-propylamine 709-98-8, DCPA 759-94-4, EPTC 786-19-6, Trithion 789-02-6 829-26-5, 2,3,6-Trimethylnaphthalene 832-69-9, 1-Methylphenanthrene 887-54-7, Dacthal monoacid 939-27-5, 2-Ethylnaphthalene 944-22-9, Fonofos 950-37-8, Methidathion 1024-57-3, Heptachlorepoxide 1114-71-2, Pebulate 1194-65-6, Dichlobenil 1300-71-6, Dimethylphenol 1322-97-0 1563-66-2, Carbofuran 1582-09-8, Trifluralin 1610-18-0, Prometon 1646-87-3, Aldicarb sulfoxide 1646-88-4, Aldicarb sulfone 1689-84-5, Bromoxynil 1702-17-6, Clopyralid 1730-37-6, 1-Methyl-9H-fluorene 1825-21-4, Pentachloroanisole 1861-32-1, Dacthal 1861-40-1, Benfluralin 1897-45-6, Chlorothalonil 1912-24-9, Atrazine 1918-00-9, Dicamba 1918-02-1, Picloram 1918-16-7, Propachlor 2008-41-5, Butylate 2032-65-7, Methiocarb 2164-17-2, Fluometuron 2212-67-1, Molinate 2303-17-5, Triallate 2312-35-8, Propargite 2381-21-7, 1-Methylpyrene 2385-85-5, Mirex 2921-88-2, Chlorpyrifos 3380-34-5, Triclosan 3424-82-6 3689-24-5, Sulfotepp 5103-71-9, cis-Chlordane 5103-73-1, cis-Nonachlor 5103-74-2, trans-Chlordane 5902-51-2, Terbacil 5915-41-3, Terbuthylazine 6190-65-4, Deethylatrazine 7005-72-3, 4-Chlorophenyl phenyl ether 7286-84-2, Chloramben, methyl

ester 7429-90-5, Aluminum, occurrence 7439-89-6, Iron, occurrence
7439-91-0, Lanthanum, occurrence 7439-92-1, Lead, occurrence
7439-93-2, Lithium, occurrence 7439-96-5, Manganese, occurrence
7439-97-6, Mercury, occurrence 7439-98-7, Molybdenum, occurrence
7440-00-8, Neodymium, occurrence 7440-02-0, Nickel, occurrence
7440-03-1, Niobium, occurrence 7440-09-7, Potassium, occurrence
7440-20-2, Scandium, occurrence 7440-22-4, Silver, occurrence
7440-24-6, Strontium, occurrence 7440-25-7, Tantalum, occurrence
7440-28-0, Thallium, occurrence 7440-29-1, Thorium, occurrence
7440-31-5, Tin, occurrence 7440-32-6, Titanium, occurrence 7440-36-0,
Antimony, occurrence 7440-38-2, Arsenic, occurrence 7440-39-3, Barium,
occurrence 7440-41-7, Beryllium, occurrence 7440-43-9, Cadmium,
occurrence 7440-44-0, Carbon, occurrence 7440-45-1, Cerium, occurrence
7440-47-3, Chromium, occurrence 7440-48-4, Cobalt, occurrence
7440-50-8, Copper, occurrence 7440-53-1, Europium, occurrence
7440-55-3, Gallium, occurrence 7440-57-5, Gold, occurrence 7440-60-0,
Holmium, occurrence 7440-61-1, Uranium, occurrence 7440-62-2,
Vanadium, occurrence 7440-64-4, Ytterbium, occurrence 7440-65-5,
Yttrium, occurrence 7440-66-6, Zinc, occurrence 7440-69-9, Bismuth,
occurrence 7440-70-2, Calcium, occurrence 7704-34-9, Sulfur,
occurrence 7782-49-2, Selenium, occurrence 8001-35-2, Toxaphene
12789-03-6, Chlordane 13071-79-9, Terbufos 13194-48-4, Ethoprophos
13194-48-4D, Ethoprop, metabolites 15299-99-7, Napropamide 15972-60-8,
Alachlor 16655-82-6, 3-Hydroxycarbofuran 16752-77-5, Methomyl
19044-88-3, Oryzalin 21087-64-9, Metribuzin 21725-46-2, Cyanazine
23135-22-0, Oxamyl 23950-58-5, Pronamide 25057-89-0, Bentazon
27176-92-7 27176-93-8 27304-13-8, Oxychlordane 27314-13-2,
Norflurazon 28249-77-6, Thiobencarb 30667-99-3, o,p'-Methoxychlor
31218-83-4, Propetamphos 34014-18-1, Tebuthiuron 34256-82-1,
Acetochlor 35400-43-2, Sulprofos 39454-62-1, Ethanol,
2-butoxyphosphate 39765-80-5, trans-Nonachlor 40487-42-1,
Pendimethalin 41198-08-7, Profenofos 50594-66-6, Acifluorfen
51218-45-2, Metolachlor 55283-68-6, Ethalfluralin
RL: POL (Pollutant); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and
Valley Creeks, City of Birmingham, Jefferson County, Alabama)

IT 55335-06-3, Triclopyr 61949-76-6, cis-Permethrin 65630-32-2
114282-89-2, Methoxychloro
RL: POL (Pollutant); OCCU (Occurrence)
(water quality and aquatic-community structure in Village and
Valley Creeks, City of Birmingham, Jefferson County, Alabama)

REFERENCE COUNT: 147 THERE ARE 147 CITED REFERENCES AVAILABLE FOR
THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE
FORMAT

L57 ANSWER 11 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2002:145252 HCAPLUS Full-text
DOCUMENT NUMBER: 137:23935
TITLE: Quality of water on the Prairie Band
Potawatomi Reservation, northeastern Kansas, February
1999 through February 2001
AUTHOR(S): Trombley, Thomas J.
CORPORATE SOURCE: USA
SOURCE: Water-Resources Investigations Report (United States
Geological Survey) (2001), 01-4196, i-v, 1-51
CODEN: WIREFS
DOCUMENT TYPE: Report
LANGUAGE: English
ED Entered STN: 26 Feb 2002

AB Water-quality samples were collected from 20 surface-water sites and 7 groundwater sites across the Prairie Band Potawatomi Reservation in northeastern Kansas as part of a water- quality study begun in 1996. Water-quality is a very important consideration for the tribe. Three creeks draining the reservation, Soldier, Little Soldier, and South Cedar Creeks, are important tribal resources used for maintaining subsistence fishing and hunting needs for tribal members. Samples were collected twice during June 1999 and June 2000 at all 20 surface-water sites after herbicide application, and nine quarterly samples were collected at 5 of the 20 sampling sites from Feb. 1999 through Feb. 2001. Samples were collected once at 6 wells and twice at one well from Sept. through Dec. 2000. Surface-water-quality constituents analyzed included nutrients, pesticides, and bacteria. In addition to nutrients, pesticides, and bacteria, groundwater constituents analyzed include major dissolved ions, As, B, and dissolved Fe and Mn. The median nitrite + nitrate concentration was 0.376 mg/L for 81 surface-water samples, and the maximum concentration was 4.18 mg/L as N, which is less than one-half the US EPA's Maximum Contaminant Level(MCL) for drinking water of 10 mg/L as N. Fifty-one of the 81 surface-water-quality samples exceeded the US EPA's recommended goal for total P of 0.10 mg/L for the protection of aquatic life. Triazine concns. in 26 surface-water-quality samples collected during May and June 1999 and 2000 exceeded 3.0 µg/L, the Maximum Contaminant Level established for drinking water by the US EPA. Triazine herbicide concns. tended to be highest during late spring runoff after herbicide application. High concns. of fecal indicator bacteria in surface water are a concern on the reservation with fecal coliform concns. ranging form 4 to greater than 31,000 colonies per 100 mL of water with a median concentration of 570 colonies per 1000 mL. More than one-half of the surface-water-quality samples exceeded the Kansas Department of Health and Environment contact recreation criteria of 200 and 2,000 colonies per 100 mL of water and were collected mostly during the spring and summer. Two wells had sodium concns. of about 10 times the U.S. Environmental Protection Agency health advisory level (HAL) of 20 mg/L; concns. ranged from 241 to 336 mg/L. In water from two wells, sulfate concns. exceeded 800 mg/L, more than three times the U.S. Environmental Protection Agency Secondary Maximum Contaminant Level (SMCL) for drinking water of 250 mg/L. All but two of the eight ground-water-quality samples had dissolved-solids concns. exceeding the SMCL of 500 mg/L. The highest concentration of 2010 mg/L was more than four times the SMCL. Dissolved boron concns. exceeded the US EPA 600-µg/L HAL in water from 2 of the 7 wells sampled. Because the HAL is for a lifetime of exposure, the anticipated health risk due to dissolved B is low. Dissolved Fe concns. in groundwater samples exceeded the 300-µg/L SMCL for treated drinking water in three of the 7 wells sampled. Dissolved Mn concns. in water from the same 3 wells also exceeded the established SMCL of 50 µg/L. Dissolved pesticides were not detected in any of the well samples; however, there were degradation products of the herbicides alachlor and metolachlor in several samples. Insecticides were not detected in any groundwater quality samples. Low concns. of E. coli and fecal coliform bacteria were detected in water from two wells, and E. coli was detected in water from one well. Much higher concns. of E. coli, fecal coliform, and fecal streptococcus were detected in water from one well when samples were collected shortly after the well was drilled. Water quality on the Prairie Band Potawatomi Reservation is generally sufficient to meet the requirements of the tribe. Major concerns for surface water are related to agricultural runoff and include increased triazine herbicide concns. during the spring and summer and high concns. for groundwater are related to high mineral concns. resulting from dissoln. of the surrounding sedimentary rocks.

CC 61-2 (Water)
Section cross-reference(s): 5

IT Coliform bacteria
Escherichia coli

Groundwater pollution
Herbicides
Intestinal streptococcus
Pesticides
(quality of water on Prairie Band Potawatomi Reservation, northeastern Kansas)

IT Nitrates, occurrence
Nitrites
RL: GOC (Geological or astronomical occurrence); POL (Pollutant); OCCU (Occurrence)
(quality of water on Prairie Band Potawatomi Reservation, northeastern Kansas)

IT 7439-89-6, Iron, occurrence 7439-96-5, Manganese, occurrence 7440-38-2, Arsenic, occurrence 7440-42-8, Boron, occurrence 7723-14-0, Phosphorus, occurrence 14798-03-9, Ammonium, occurrence
RL: GOC (Geological or astronomical occurrence); POL (Pollutant); OCCU (Occurrence)
(quality of water on Prairie Band Potawatomi Reservation, northeastern Kansas)

IT 63-25-2, Carbaryl 101-05-3, Triazine 122-34-9, Simazine 139-40-2 333-41-5, Diazinon 579-66-8, 2,6-Diethylaniline 1610-18-0, Prometon 1912-24-9, Atrazine 15972-60-8, Alachlor 21087-64-9, Metribuzine 21725-46-2, Cyanazine 34256-82-1, Acetochlor 36576-42-8, Cyanazine amide 51218-45-2, Metolachlor
RL: POL (Pollutant); OCCU (Occurrence)
(quality of water on Prairie Band Potawatomi Reservation, northeastern Kansas)

REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 12 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 2001:788329 HCAPLUS Full-text
DOCUMENT NUMBER: 135:356973
TITLE: Prevalence of Salmonella serotypes on pig carcasses from high- and low-risk herds slaughtered in three abattoirs
AUTHOR(S): Quirke, A.-M.; Leonard, N.; Kelly, G.; Egan, J.; Lynch, P. B.; Rowe, T.; Quinn, P. J.
CORPORATE SOURCE: Faculty of Veterinary Medicine, UCD, Dublin, Ire.
SOURCE: Berliner und Muenchener Tieraerztliche Wochenschrift (2001), 114(9/10), 360-362
CODEN: BEMTAM; ISSN: 0005-9366
PUBLISHER: Blackwell Wissenschafts-Verlag GmbH
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 31 Oct 2001
AB The aim of this study was to compare the prevalence of Salmonella serotypes at 2 different sites on swine carcasses from herds classified as high-risk or low-risk and to elucidate the relationship between carcass contamination levels and serol. status. Caecal samples and carcass surface swabs were cultured for Salmonella from a total of 210 swine from low risk herds (< 19% of swine in herd Salmonella seropos.) and 209 swine from high risk herds (> 32% of swine in herd Salmonella seropos.) in 3 abattoirs. Meat juice samples were collected for anal. by ELISA. The prevalence of Salmonella in the cecal contents of "low-risk" swine was 10%, which was significantly lower than the 19% prevalence in "high-risk" swine ($p < 0.01$). The corresponding figures for skin samples collected immediately post-evisceration were 2% and 12%. The predominant Salmonella serotype in the cecal contents of both the low-risk and high-risk swine was Salmonella Typhimurium. Salmonella Kentucky and Salmonella Derby were the most frequent isolates from the carcass surface

swabs of low- and high-risk swine resp. There was a pos. association between seropositivity of swine from high-risk herds and cecal carriage ($p < 0.05$). Results showed that herd categorization based on serol. results was useful in predicting Salmonella isolation rates from cecal samples and surface swabs of slaughtered swine.

CC 17-5 (Food and Feed Chemistry)
ST food contamination Salmonella pork carcass slaughterhouse
IT Body, anatomical
(carcass; prevalence of Salmonella serotypes on pig carcasses from high- and low-risk herds)
IT Meat
(pork; prevalence of Salmonella serotypes on pig carcasses from high- and low-risk herds)
IT Food contamination
Quality control
Salmonella
Salmonella derby
Salmonella kentucky
Slaughterhouse
(prevalence of Salmonella serotypes on pig carcasses from high- and low-risk herds)
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 13 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1999:381847 HCAPLUS Full-text
DOCUMENT NUMBER: 131:120389
TITLE: Source and occurrence of pathogens in watersheds
AUTHOR(S): Mager, A. L.; Standridge, J.; Kluender, S. M.; Peterson, L. L.
CORPORATE SOURCE: Wisconsin State Laboratory of Hygiene, Madison, WI, 53706, USA
SOURCE: Proceedings - Water Quality Technology Conference (1998) 1694-1708
CODEN: PWQCD2; ISSN: 0164-0755
PUBLISHER: American Water Works Association
DOCUMENT TYPE: Journal; (computer optical disk)
LANGUAGE: English
ED Entered STN: 22 Jun 1999
AB Recent waterborne disease outbreaks have been attributed to possible failures in the treatment of potable water. While focusing on treatment plant improvements is of utmost importance, there is also recognition that controlling the entry of pathogens and natural organic material through best land use management practices and the stewardship of watersheds will also reduce the risks associated with treatment plant failure. This study was designed to identify the occurrence and sources of pathogens in watersheds. Raw water samples from 109 utilities across North America were tested one time each for the presence or absence of two bacterial pathogens, Salmonella and enteropathogenic Escherichia coli (O157 serotype), from Sept., 1996, through Jan., 1997. Salmonella was found in 10% of the raw water samples, while enteropathogenic E. coli was not detected in any. A subgroup of 20 utilities sent samples of their raw water on four sep. occasions from Mar., 1997, through Oct., 1997. These periodic samples were also tested for the two bacterial pathogens. The largest number of pos. samples occurred during the Mar. and July sampling events, where 20% and 14% of the samples were pos. for Salmonella, resp. E. coli O157 was not found in any of the periodic samples. In another phase of the study, 3 watersheds in Wisconsin with varying land uses (urban, agricultural, and pristine) were characterized and analyzed for potential sources of pathogens. Water samples from the 3 watersheds were

collected biweekly from June to Nov., 1997, and from Apr. to May, 1998, and analyzed for the two bacterial pathogens as well as for Cryptosporidium and Giardia. Salmonella was found in all three watersheds, with a slightly higher occurrence in the urban watershed than in the agricultural and pristine watersheds (53%, 40%, 27%, resp., n = 15). Cryptosporidium occurrence in the pristine watershed (58%, n = 12) was almost twice that in the agricultural watershed and approx. 3 times that in the urban watershed. Giardia occurrence in the pristine watershed (75%, n = 12) was 3 times that in the agricultural watershed and approx. 4 times that in the urban watershed. E. coli O157 was not found in any of the samples collected from the 3 watersheds. Automated samplers were used to collect weather-event samples in the three watersheds in order to more accurately characterize the occurrence of pathogens within the watersheds. Anal. of the data indicated that samples collected later in the weather-event hydrograph and "first flush" samples were most likely to contain pathogens. Finally, fecal samples from wild and domestic animals likely to be found in each of the three watersheds were collected and analyzed for the presence of Salmonella, enteropathogenic E. coli, Cryptosporidium, and Giardia. Salmonella was found primarily in avian species (geese, ducks, and gulls) and in some mammals (deer, raccoons, and groundhogs). E. coli O157 was found in only one beef cattle sample. The highest occurrence of Cryptosporidium was in deer (15%, n = 32), dairy cows <1 yr in age (80%, n = 10), and adult geese (8%, n = 85). The highest occurrence of Giardia was in adult and juvenile geese (22%, n = 85 and 72%, n = 32, resp.). Several rodents were tested during the study, and the occurrence of Cryptosporidium in deer mice was found to be 16% (n = 19). Because of the relatively high occurrence of Cryptosporidium in deer mice and the existence of substantial suitable rodent habitat in the pristine watershed, a mass balance was calculated to determine the approx. contribution of deer mice to Cryptosporidium occurrence in this watershed. Using conservative ests., daily loads of Cryptosporidium due to this rodent could range from 30 oocysts/L to 106 oocysts/L in a worst case scenario. The analyses performed during this study, together with the knowledge of land use practices within watersheds, may enable the identification of pathogen sources and, as a consequence, allow the elimination or regulation of contamination sources.

CC 61-2 (Water)

ST pathogen occurrence source watershed raw water treatment plant; Salmonella occurrence source watershed raw water treatment plant; Escherichia coli occurrence source watershed raw water treatment plant; Giardia occurrence source watershed raw water treatment plant; Cryptosporidium occurrence source watershed raw water treatment plant; deer mouse Cryptosporidium occurrence source watershed

IT Cryptosporidium
Drinking water pollution
Drinking waters
Escherichia coli
Giardia
Salmonella
(source and occurrence of pathogens in watershed water and treatment plant raw water in North America)

L57 ANSWER 14 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN

ACCESSION NUMBER: 1997:626305 HCAPLUS Full-text

DOCUMENT NUMBER: 127:238736

TITLE: Assessment of the exposure of swimmers to microbiological contaminants in fresh waters

AUTHOR(S): Medema, G. J.; van Asperen, I. A.; Havelaar, A. H.

CORPORATE SOURCE: National Inst. Public Health & Environment, Bilthoven, 3720 BA, Neth.

SOURCE: Water Science and Technology (1997), 35(11-12, Health-Related Water Microbiology 1996), 157-163

CODEN: WSTED4; ISSN: 0273-1223
PUBLISHER: Elsevier
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 02 Oct 1997
AB As part of a prospective cohort study among triathletes to determine a relationship between the microbiol. quality of fresh bathing water and the risk of acquiring an intestinal infection, the exposure of the triathletes to microbiol. contaminants was assessed. Waters were collected at seven triathlons (swimming course 1-1.5km) held in the summer of 1993 and 1994 to have a range of water qualities. All were influenced by sewage effluents, most also by agricultural run-off. Samples were collected several weeks before the event to establish a sampling program (1993) and during the actual exposure of the triathletes (1993 and 1994) and examined for thermotolerant coliforms alone (samples preceding the event) and for Escherichia coli, fecal enterococci, Staphylococcus aureus, F-specific RNAphages, enteroviruses (1993 and 1994) and for thermophilic Campylobacter, Salmonella, Aeromonas, Plesiomonas shigelloides and Pseudomonas aeruginosa (1993). The samples taken in the weeks before the exposure showed significant differences in thermotolerant coliform concentration between locations, depths and times. Also during swimmer exposure, significant differences occurred in microorganism levels at the different sampling points over the swimming course. As the triathletes swam as a group, they were exposed to approx. the same water at the same time. The geometric mean concentration was used to characterize each site. In the epidemiol. study, the risk of an intestinal infection correlated with the concentration of thermotolerant coliforms and E. coli but not with the other parameters. The geometric mean concentration of thermotolerant coliforms at the triathlons ranged from 11-330/100mL and 54-1200/100mL E. coli. Ranking of the seven sites by faecal pollution level, based on the geometric mean concentration of a faecal indicator, resulted in a different ranking for each indicator. At the fresh water sites studied, only the ratio between the geometric mean d. of E. coli and thermotolerant coliforms was constant The ratio between the other parameters related to faecal pollution (faecal enterococci, F-specific RNA phages, enteroviruses) varied considerably. Water quality stds. relating to faecal pollution can only be based on parameters that show a significant correlation with risk of intestinal illness.
CC 61-2 (Water)
IT Aeromonas
Bacteriophage
Enterovirus
Escherichia coli
Intestinal streptococcus
Pseudomonas aeruginosa
Public health
Salmonella
Water pollution
(assessment of exposure of swimmers to microbiol. contaminants in fresh waters)
REFERENCE COUNT: 20 THERE ARE 20 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L57 ANSWER 15 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1995:449527 HCAPLUS Full-text
DOCUMENT NUMBER: 122:212388
TITLE: Relative effectiveness of selenite cystine broth, tetrathionate broth, and Rappaport-Vassiliadis medium for the recovery of Salmonella from raw flesh and other highly contaminated foods: precollaborative study

AUTHOR(S): June, Geraldine A.; Sherrod, Patricia S.; Hammack, Thomas S.; Amaguana, R. Miguel; Andrews, Wallace H.
CORPORATE SOURCE: Div. Microbiol. Studies, U.S. Food Drug Administration, Washington, DC, 20204, USA
SOURCE: Journal of AOAC International (1995), 78(2), 375-80
CODEN: JAINEE; ISSN: 1060-3271
PUBLISHER: AOAC International
DOCUMENT TYPE: Journal
LANGUAGE: English
ED Entered STN: 29 Mar 1995
AB The effectiveness of selenite cystine (SC) broth, tetrathionate (TT) broth, and Rappaport-Vassiliadis (RV) medium for recovery of Salmonella spp. from 8 highly contaminated foods was determined RV medium prepared from individual ingredients and incubated at 42° and 43° was compared with 2 com. (Difco and Oxoid) media incubated at 42°. Naturally and artificially contaminated foods were tested under 2 protocols. For Protocol 1, each food was preenriched in the appropriate medium. After incubation, serial 10 fold dilns. of the preenriched foods were inoculated into selective enrichment media and incubated at 35°, 42°, or 43°. Effectiveness of these conditions was evaluated by most probable number determination of Salmonella spp. recovered. Productivity of selective enrichments did not differ significantly with this protocol, except that with Oxoid RV medium the number of Salmonella cells recovered from most of the foods was significantly reduced. For Protocol 2, twenty 25 g test portions from artificially inoculated foods were examined qual. for Salmonella spp. The effectiveness of the broth/temperature combinations was determined by the number of pos. tests under each condition. RV medium prepared from individual ingredients and TT broth incubated at 43° yielded significantly more Salmonella-pos. tests from frog legs and lettuce than did SC and TT broths incubated at 35° or com. RV medium incubated at 42°. With pork sausage and ground beef, fewer Salmonella-pos. tests were found with Oxoid RV medium incubated at 42° and SC incubated at 35° than from other selective enrichments. With chicken, fewer Salmonella -pos. tests were found from SC and TT broths incubated at 35° and Oxoid RV medium incubated at 42° than from other selective enrichments. There were no significant differences among selective enrichments in the recovery of Salmonella spp. from the remaining foods. Overall, RV prepared from individual ingredients and incubated at 42° yielded the highest number of Salmonella-pos. tests.
CC 17-1 (Food and Feed Chemistry)
ST Salmonella food contamination detection culture medium
IT Egg, poultry
Food analysis
Lettuce
Oyster
Salmonella
Shrimp
(culture media for recovery of Salmonella in anal. of contaminated foods)
IT Frog
(legs; culture media for recovery of Salmonella in anal. of contaminated foods)
IT Meat
(beef, culture media for recovery of Salmonella in anal. of contaminated foods)
IT Meat
(chicken, culture media for recovery of Salmonella in anal. of contaminated foods)
IT Meat
(sausage, culture media for recovery of Salmonella in anal. of contaminated foods)

National Beef Ex. 1006
Page 116

L57 ANSWER 16 OF 29 HCAPLUS COPYRIGHT 2007 ACS on STN
ACCESSION NUMBER: 1925:25634 HCAPLUS Full-text
DOCUMENT NUMBER: 19:25634
ORIGINAL REFERENCE NO.: 19:3330c-e
TITLE: A bacteriological study of soda water
AUTHOR(S): Foreman, LeRoy
SOURCE: Public Health News (N. J.) (1925), 10, 228-30
DOCUMENT TYPE: Journal
LANGUAGE: Unavailable
ED Entered STN: 16 Dec 2001
AB Duplicate samples were collected. One bottle was tested at once for bacterial count and B. coli; the second one week later. The first batch showed such good results that some bacterial ingredient was sought. Succeeding samples after planting were seeded with a 24-hr. culture of B. coli. Of inoculated samples 75% failed to show an increase. Blanks with water showed about 500,000 organisms. Acidity as citric acid, solids from immersion reading, dyes used for coloring, and artificial ethers showed no relation to bacterial condition. Total CO2 was determined Conclusions: No single constituent is responsible for the condition shown but the CO2 content is the most potent single factor.
CC 12 (Foods)
IT Bacteria
(in soda water)

=> d L57 17-29 ibib ab hit

L57 ANSWER 17 OF 29 MEDLINE on STN DUPLICATE 2
ACCESSION NUMBER: 1999295457 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 10367381
TITLE: Reveal for Salmonella test system.
AUTHOR: Bird C B; Miller R L; Miller B M
CORPORATE SOURCE: Neogen Corporation, Lansing, MI 48912, USA..
Bird@neogensupport.phonetech.com
SOURCE: Journal of AOAC International, (1999 May-Jun) Vol. 82, No. 3, pp. 625-33.
Journal code: 9215446. ISSN: 1060-3271.
PUB. COUNTRY: United States
DOCUMENT TYPE: (COMPARATIVE STUDY)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199907
ENTRY DATE: Entered STN: 27 Jul 1999
Last Updated on STN: 27 Jul 1999
Entered Medline: 15 Jul 1999
AB The Reveal for Salmonella (RSS) test system is a presumptive qualitative test that detects the presence of Salmonella organisms in foods within 21 h total testing time, allowing the user to release negative products 24 h earlier than when using other rapid test kits. Foods are enriched with a proprietary resuscitation medium called Revive and then selectively enriched with either Selenite Cystine or Rappaport-Vassiliadis selective media . The enriched culture is used to inoculate the RSS detection device, which initiates a lateral flow through a reagent zone containing anti-Salmonella antibodies conjugated to colloidal gold particles that capture antigens present in the culture. The antigen-antibody complex migrates farther and is captured by an additional anti-Salmonella antibody, causing the colloidal gold to precipitate and form a visual line, indicating a positive result. A procedural control line also will form regardless of the presence of Salmonella organisms to

indicate the test is working properly. Existing AOAC Official Methods for Salmonella organisms require a 48 h enrichment before testing. Hence, a food product has to be held before release, adding extra cost to the company and the consumer. The RSS test system was evaluated by quantitative spiking studies. Although AOAC encourages inclusion of naturally contaminated foods, almost all microbiological AOAC validation studies have been performed with artificially contaminated foods for absolute control over the study. The RSS test system is designed to test many food types for Salmonella organisms and has a limit of detection of 5-10 colony-forming units (cfu)/25 g with a false-negative rate of < 1% and a false-positive rate of < 5.0%. It showed an 81% overall agreement with the traditional procedure of the U.S. Department of Agriculture 's Food Safety Inspection Service.

TI Reveal for Salmonella test system.

AB The Reveal for Salmonella (RSS) test system is a presumptive qualitative test that detects the presence of Salmonella organisms in foods within 21 h total testing time, allowing the user to release negative products 24 h earlier than when using other rapid test kits. Foods are enriched with a proprietary resuscitation medium called Revive and then selectively enriched with either Selenite Cystine or Rappaport-Vassiliadis selective media . The enriched culture is used to inoculate the RSS detection device, which initiates a lateral flow through a reagent zone containing anti-Salmonella antibodies conjugated to colloidal gold particles that capture antigens present in the culture. The antigen-antibody complex migrates farther and is captured by an additional anti-Salmonella antibody, causing the colloidal gold to precipitate and form a visual line, indicating a positive result. A procedural control line also will form regardless of the presence of Salmonella organisms to indicate the test is working properly. Existing AOAC Official Methods for Salmonella organisms require a 48 h enrichment before testing. Hence, a food product has to be held before release, adding extra cost to the company and the consumer. The RSS test system was evaluated by quantitative spiking studies. Although AOAC encourages inclusion of naturally contaminated foods, almost all microbiological AOAC validation studies have been performed with artificially contaminated foods for absolute control over the study. The RSS test system is designed to test many food types for Salmonella organisms and has a limit of detection of 5-10 colony-forming units (cfu)/25 g with a false-negative rate of < 1% and a false-positive rate of < 5.0%. It showed an 81% overall agreement with the traditional procedure of the U.S. Department of Agriculture 's Food Safety Inspection Service.

CT Animals
Bacteriological Techniques
Chickens: MI, microbiology
Eggs: MI, microbiology
*Food Microbiology
Immunologic Techniques
Meat: MI, microbiology
Quality Control
*Salmonella: IP, isolation & purification
Sensitivity and Specificity
Shellfish: MI, microbiology

L57 ANSWER 18 OF 29 MEDLINE on STN
ACCESSION NUMBER: 2006110256 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 16496566
TITLE: Validated PCR assay for the routine detection of Salmonella in food.
AUTHOR: Bansal N S; Gray V; McDonell F
CORPORATE SOURCE: Institute of Clinical Pathology and Medical Research, Division of Analytical Laboratories, Western Sydney Area Health Services, Lidcombe, New South Wales, Australia.. nbansal@dal.wsahs.nsw.gov.au

SOURCE: Journal of food protection, (2006 Feb) Vol. 69, No. 2, pp. 282-7.
Journal code: 7703944. ISSN: 0362-028X.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200603
ENTRY DATE: Entered STN: 28 Feb 2006
Last Updated on STN: 11 Mar 2006
Entered Medline: 10 Mar 2006

AB We developed a rapid and reliable PCR assay with genus-specific primers for the detection of Salmonella in food samples. With these primers, no primer-specific amplicons were detected when challenged with cultures of microorganisms other than salmonellae, and positive results, i.e., Salmonella -specific bands, were obtained with pure cultures of all 125 Salmonella isolates tested, which represented 100 serovars. The PCR assay was optimized using both pure cultures and artificially inoculated food samples. The assay results were compared with those of the Australian standard culture methods, using more than 500 "naturally" contaminated food samples, over a period of 9 years. Food samples were subjected to nonselective preenrichment in buffered peptone water followed by selective enrichment in Rappaport Vassiliadis (RV) broth and mannitol selenite cystine (MSC) broth. A simple sample preparation method was developed based on concentrating bacterial cells from 1 ml of RV or MSC broths. The PCR results were in perfect agreement with the results of the standard culture methods; no false-positive or false-negative results were obtained. However, the PCR assay was extremely rapid, and results could be obtained within 4 h of testing of enrichment broths.

TI Validated PCR assay for the routine detection of Salmonella in food.

AB We developed a rapid and reliable PCR assay with genus-specific primers for the detection of Salmonella in food samples. With these primers, no primer-specific amplicons were detected when challenged with cultures of microorganisms other than salmonellae, and positive results, i.e., Salmonella -specific bands, were obtained with pure cultures of all 125 Salmonella isolates tested, which represented 100 serovars. The PCR assay was optimized using both pure cultures and artificially inoculated food samples. The assay results were compared with those of the Australian standard culture methods, using more than 500 "naturally" contaminated food samples, over a period of 9 years. Food samples were subjected to nonselective preenrichment in buffered peptone water followed by selective enrichment in Rappaport Vassiliadis (RV) broth and mannitol selenite cystine (MSC) broth. A simple sample preparation method was developed based on concentrating bacterial cells from 1 ml of RV or MSC broths. The PCR results were in perfect agreement with the results of the standard culture methods; no false-positive or false-negative results were obtained. However, the PCR assay was extremely rapid, and results could be obtained within 4 h of testing of enrichment broths.

CT Australia
Colony Count, Microbial: MT, methods
Consumer Product Safety
DNA Primers
*Food Contamination: AN, analysis
*Food Microbiology
Humans
*Polymerase Chain Reaction: MT, methods
*Polymerase Chain Reaction: ST, standards
Reproducibility of Results
*Salmonella: IP, isolation & purification
Sensitivity and Specificity
Species Specificity

Time Factors

L57 ANSWER 19 OF 29 MEDLINE on STN
ACCESSION NUMBER: 2002662593 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 12409351
TITLE: Alafosfalin as a selective agent for isolation of salmonella from clinical samples.
AUTHOR: Perry J D; Riley G; Gould F K; Perez J M; Boissier E; Ouedraogo R T; Freydiere A M
CORPORATE SOURCE: Department of Microbiology, Freeman Hospital, Newcastle upon Tyne, United Kingdom.
SOURCE: Journal of clinical microbiology, (2002 Nov) Vol. 40, No. 11, pp. 3913-6.
Journal code: 7505564. ISSN: 0095-1137.
PUB. COUNTRY: United States
DOCUMENT TYPE: (COMPARATIVE STUDY)
(EVALUATION STUDIES)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200302
ENTRY DATE: Entered STN: 9 Nov 2002
Last Updated on STN: 7 Feb 2003
Entered Medline: 6 Feb 2003

AB The selectivity of a range of culture media for the detection of Salmonella was assessed using 435 strains of gram-negative bacteria. These media showed limited ability to inhibit non-Salmonella strains found in stool samples . We report the evaluation of alafosfalin as a selective agent for isolation of Salmonella from stool samples. Susceptibility studies with this agent showed that non-typhi Salmonella strains were relatively resistant (mean MIC, 10.2 mg/liter) compared to many coliforms including Escherichia coli (mean MIC, 0.7 mg/liter). A chromogenic medium, ABC medium, was modified to incorporate alafosfalin and was compared with standard ABC medium and Hektoen enteric agar for the isolation of Salmonella from 1,000 stool samples. On direct culture, modified ABC medium showed higher recovery of Salmonella (53.6%) compared with either ABC medium (35.7%) or Hektoen enteric agar (48.2%). We conclude that alafosfalin is a useful selective agent for the isolation of Salmonella from stool samples .

TI Alafosfalin as a selective agent for isolation of salmonella from clinical samples.

AB The selectivity of a range of culture media for the detection of Salmonella was assessed using 435 strains of gram-negative bacteria. These media showed limited ability to inhibit non-Salmonella strains found in stool samples . We report the evaluation of alafosfalin as a selective agent for isolation of Salmonella from stool samples. Susceptibility studies with this agent showed that non-typhi Salmonella strains were relatively resistant (mean MIC, 10.2 mg/liter) compared to many coliforms including Escherichia coli (mean MIC, 0.7 mg/liter). A chromogenic medium, ABC medium, was modified to incorporate alafosfalin and was compared with standard ABC medium and Hektoen enteric agar for the isolation of Salmonella from 1,000 stool samples. On direct culture, modified ABC medium showed higher recovery of Salmonella (53.6%) compared with either ABC medium (35.7%) or Hektoen enteric agar (48.2%). We conclude that alafosfalin is a useful selective agent for the isolation of Salmonella from stool samples .

CT *Alanine: AA, analogs & derivatives
Alanine: ME, metabolism
*Alanine: PD, pharmacology
Bacteriological Techniques
Chromogenic Compounds: ME, metabolism
Culture Media

Drug Resistance, Bacterial
*Feces: MI, microbiology
Gram-Negative Bacteria: GD, growth & development
Gram-Negative Bacteria: IP, isolation & purification
Humans
*Salmonella: DE, drug effects
Salmonella: GD, growth & development
*Salmonella: IP, isolation & purification
Sensitivity and Specificity
CN 0 (Chromogenic Compounds); 0 (Culture Media)

L57 ANSWER 20 OF 29 MEDLINE on STN
ACCESSION NUMBER: 2000387935 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 10813610
TITLE: Retrospective and longitudinal study of salmonellosis in captive wildlife in Trinidad.
AUTHOR: Gopee N V; Adesiyun A A; Caesar K
CORPORATE SOURCE: School of Veterinary Medicine, Faculty of Medical Sciences, University of the West Indies, St. Augustine, Trinidad.
SOURCE: Journal of wildlife diseases, (2000 Apr) Vol. 36, No. 2, pp. 284-93.
Journal code: 0244160. ISSN: 0090-3558.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200008
ENTRY DATE: Entered STN: 18 Aug 2000
Last Updated on STN: 18 Aug 2000
Entered Medline: 10 Aug 2000

AB Morbidity and mortality of captive wildlife at the Emperor Valley Zoo, Trinidad from 1993 to 1996 were analysed to determine involvement of Salmonella spp. A 6 mo longitudinal study was conducted to determine the frequency of isolation of Salmonella spp. from apparently healthy, sick and dead wild mammals, birds, and reptiles. The antibiograms of Salmonella isolates were determined using the disc diffusion method. Fecal samples randomly selected from animal enclosures and cloacal swabs of snakes were cultured for Salmonella spp. following enrichment in tetrathionate and selenite cystine broths. For the 1993-96 period, Salmonella spp. was implicated in 17 (12%) of 141 sick or dead animals and the predominant serotype was S. typhimurium. During the 6 mo prospective study in a mean animal population of 1,186, there were 20 (2%) and 14 (1%) animals that were sick and died respectively; Salmonella spp. was implicated in only one mortality. Overall, of 1,012 samples from apparently healthy wildlife cultured , 66 (7%) yielded 24 serotypes of Salmonella. The predominant serotype were S. seigburg (16 isolates), S. gaminara (6 isolates), and S. thompson (6 isolates). None of the samples yielded S. typhimurium. The frequency of isolation of Salmonella spp. in reptiles (14%) was significantly higher than found in either mammals (7%) or birds (3%). Sixty-five (99%) of 66 Salmonella spp. isolates exhibited resistance to one or more of the nine antimicrobial agents tested. Resistance was high to cephalothin (92%), moderate to streptomycin (35%) and tetracycline (29%), but significantly low to gentamicin (2%), chloramphenicol (0%), and sulphamethoxazole/trimethoprim (0%). The prevalence of asymptomatic infections by Salmonella spp. in zoo animals was high and the very high prevalence of antimicrobial resistance could be a problem when treating salmonellosis.
AB Morbidity and mortality of captive wildlife at the Emperor Valley Zoo, Trinidad from 1993 to 1996 were analysed to determine involvement of Salmonella spp. A 6 mo longitudinal study was conducted to determine the frequency of isolation of Salmonella spp. from apparently healthy, sick and

dead wild mammals, birds, and reptiles. The antibiograms of Salmonella isolates were determined using the disc diffusion method. Fecal samples randomly selected from animal enclosures and cloacal swabs of snakes were cultured for Salmonella spp. following enrichment in tetrathionate and selenite cystine broths. For the 1993-96 period, Salmonella spp. was implicated in 17 (12%) of 141 sick or dead animals and the predominant serotype was S. typhimurium. During the 6 mo prospective study in a mean animal population of 1,186, there were 20 (2%) and 14 (1%) animals that were sick and died respectively; Salmonella spp. was implicated in only one mortality. Overall, of 1,012 samples from apparently healthy wildlife cultured , 66 (7%) yielded 24 serotypes of Salmonella. The predominant serotype were S. seigburg (16 isolates), S. gaminara (6 isolates), and S. thompson (6 isolates). None of the samples yielded S. typhimurium. The frequency of isolation of Salmonella spp. in reptiles (14%) was significantly higher than found in either mammals (7%) or birds (3%). Sixty-five (99%) of 66 Salmonella spp. isolates exhibited resistance to one or more of the nine antimicrobial agents tested. Resistance was high to cephalothin (92%), moderate to streptomycin (35%) and tetracycline (29%), but significantly low to gentamicin (2%), chloramphenicol (0%), and sulphamethoxazole/trimethoprim (0%). The prevalence of asymptomatic infections by Salmonella spp. in zoo animals was high and the very high prevalence of antimicrobial resistance could be a problem when treating salmonellosis.

CT Animals
*Animals, Zoo
Anti-Bacterial Agents: PD, pharmacology
*Birds
Drug Resistance, Microbial
Longitudinal Studies
*Mammals
Morbidity
Prevalence
*Reptiles
Retrospective Studies
Salmonella: CL, classification
Salmonella: DE, drug effects
Salmonella: IP, isolation & purification
*Salmonella Infections, Animal: EP, epidemiology
Salmonella Infections, Animal: MO, mortality
Serotyping: VE, veterinary
Trinidad and Tobago: EP, epidemiology

L57 ANSWER 21 OF 29 MEDLINE on STN
ACCESSION NUMBER: 97425352 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 9279402
TITLE: Fecal shedding of Salmonella in exotic felids.
AUTHOR: Clyde V L; Ramsay E C; Bemis D A
CORPORATE SOURCE: Department of Comparative Medicine, College of Veterinary Medicine, University of Tennessee, Knoxville 37901-1071, USA.
SOURCE: Journal of zoo and wildlife medicine : official publication of the American Association of Zoo Veterinarians, (1997 Jun) Vol. 28, No. 2, pp. 148-52.
Journal code: 8915208. ISSN: 1042-7260.
PUB. COUNTRY: United States
DOCUMENT TYPE: (COMPARATIVE STUDY)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199709
ENTRY DATE: Entered STN: 13 Oct 1997

Last Updated on STN: 13 Oct 1997
Entered Medline: 30 Sep 1997

AB Two collections of exotic felids were screened for the presence of Salmonella by selective fecal culture utilizing selenite broth and Hektoen enteric agar. In > 90% of the samples, Salmonella was isolated from a single culture. A commercial horsemeat-based diet was fed in both collections, and one collection also was fed raw chicken. Salmonella was cultured from the raw chicken and the horsemeat diet for both collections. Multiple Salmonella serotypes were identified, with S. typhimurium and S. typhimurium (copenhagen) isolated most frequently. Approximately half of the Salmonella isolates demonstrated multiple antibiotic resistance. The ability to harbor Salmonella as normal nonpathogenic bacteria of the gastrointestinal tract may be a physiological adaptation to carnivory. The high rate of fecal shedding of Salmonella in healthy individuals clouds the interpretation of a positive fecal culture in an ill felid, or one with diarrhea. All zoo employees having contact with cat feces or raw diets have a high rate of occupational exposure to Salmonella and should exercise appropriate hygienic precautions.

TI Fecal shedding of Salmonella in exotic felids.

AB Two collections of exotic felids were screened for the presence of Salmonella by selective fecal culture utilizing selenite broth and Hektoen enteric agar. In > 90% of the samples, Salmonella was isolated from a single culture. A commercial horsemeat-based diet was fed in both collections, and one collection also was fed raw chicken. Salmonella was cultured from the raw chicken and the horsemeat diet for both collections. Multiple Salmonella serotypes were identified, with S. typhimurium and S. typhimurium (copenhagen) isolated most frequently. Approximately half of the Salmonella isolates demonstrated multiple antibiotic resistance. The ability to harbor Salmonella as normal nonpathogenic bacteria of the gastrointestinal tract may be a physiological adaptation to carnivory. The high rate of fecal shedding of Salmonella in healthy individuals clouds the interpretation of a positive fecal culture in an ill felid, or one with diarrhea. All zoo employees having contact with cat feces or raw diets have a high rate of occupational exposure to Salmonella and should exercise appropriate hygienic precautions.

CT Check Tags: Female; Male
Acinonyx: MI, microbiology
Animal Feed: MI, microbiology
Animals
*Animals, Zoo: MI, microbiology
Anti-Bacterial Agents: PD, pharmacology
*Carnivora: MI, microbiology
Carrier State: EP, epidemiology
Carrier State: MI, microbiology
*Carrier State: VE, veterinary
Drug Resistance, Microbial
*Feces: MI, microbiology
Food Microbiology
Incidence
Lions: MI, microbiology
Meat: MI, microbiology
Microbial Sensitivity Tests
Prevalence
Salmonella: CL, classification
Salmonella: DE, drug effects
*Salmonella: IP, isolation & purification
*Salmonella Infections, Animal: EP, epidemiology
Salmonella Infections, Animal: MI, microbiology
Serotyping: VE, veterinary
Tennessee: EP, epidemiology

L57 ANSWER 22 OF 29 MEDLINE on STN

ACCESSION NUMBER: 97102200 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 8946709
TITLE: Relative effectiveness of selenite cystine broth, tetrathionate broth, and rappaport-vassiliadis medium for recovery of Salmonella spp. from raw flesh, highly contaminated foods, and poultry feed: collaborative study.
AUTHOR: June G A; Sherrod P S; Hammack T S; Amaguana R M; Andrews W H
CORPORATE SOURCE: U.S. Food and Drug Administration, Division of Microbiological Studies, Washington, DC 20204, USA.
SOURCE: Journal of AOAC International, (1996 Nov-Dec) Vol. 79, No. 6, pp. 1307-23.
Journal code: 9215446. ISSN: 1060-3271.
PUB. COUNTRY: United States
DOCUMENT TYPE: (COMPARATIVE STUDY)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199701
ENTRY DATE: Entered STN: 28 Jan 1997
Last Updated on STN: 28 Jan 1997
Entered Medline: 16 Jan 1997

AB A collaborative study was performed in 18 laboratories to validate use of Rappaport-Vassiliadis (RV) medium in the standard culture method for recovery of Salmonella spp. from raw, highly contaminated foods and poultry feed. RV medium made from its individual ingredients and incubated at 42 degrees C was compared with selenite cystine (SC) broth incubated at 35 degrees C and tetrathionate (TT) broth incubated at 35 degrees and 43 degrees C for effectiveness in recovery of Salmonella spp. Four artificially contaminated foods (oysters, frog legs, mushrooms, and shrimp) and poultry feed and one naturally contaminated food (chicken) were analyzed. The artificially contaminated foods were inoculated with single serovars of Salmonella at target levels of 0.04 colony-forming units (CFU)/g for the low level and 0.4 CFU/g for the high level. For analysis of 1125 test portions, RV medium (42 degrees C) recovered Salmonella from 409 test portions; TT (43 degrees C), from 368 test portions; TT (35 degrees C), from 310 test portions; and SC (35 degrees C), from 334 test portions. Overall, RV medium was comparable with or better than other selective enrichments for recovery of Salmonella from the foods in this study, except mushrooms. From mushrooms, SC broth (35 degrees C) recovered more positive test portions than did RV medium (42 degrees C) and TT broth (43 degrees C). The method for detection of Salmonella in raw, highly contaminated foods and poultry feed using RV medium has been adopted by AOAC INTERNATIONAL. AOAC Official Method 967.25, Salmonella in Foods, Preparation of Culture Media and Reagents, has been revised to include RV medium , and the applicability of AOAC Official Method 967.26, Salmonella in Foods, Detection, has been restricted to processed foods.

TI Relative effectiveness of selenite cystine broth, tetrathionate broth, and rappaport-vassiliadis medium for recovery of Salmonella spp. from raw flesh, highly contaminated foods, and poultry feed: collaborative study.
AB A collaborative study was performed in 18 laboratories to validate use of Rappaport-Vassiliadis (RV) medium in the standard culture method for recovery of Salmonella spp. from raw, highly contaminated foods and poultry feed. RV medium made from its individual ingredients and incubated at 42 degrees C was compared with selenite cystine (SC) broth incubated at 35 degrees C and tetrathionate (TT) broth incubated at 35 degrees and 43 degrees C for effectiveness in recovery of Salmonella spp. Four artificially contaminated foods (oysters, frog legs, mushrooms, and shrimp) and poultry feed and one naturally contaminated food (chicken) were analyzed. The artificially

contaminated foods were inoculated with single serovars of Salmonella at target levels of 0.04 colony-forming units (CFU)/g for the low level and 0.4 CFU/g for the high level. For analysis of 1125 test portions, RV medium (42 degrees C) recovered Salmonella from 409 test portions; TT (43 degrees C), from 368 test portions; TT (35 degrees C), from 310 test portions; and SC (35 degrees C), from 334 test portions. Overall, RV medium was comparable with or better than other selective enrichments for recovery of Salmonella from the foods in this study, except mushrooms. From mushrooms, SC broth (35 degrees C) recovered more positive test portions than did RV medium (42 degrees C) and TT broth (43 degrees C). The method for detection of Salmonella in raw, highly contaminated foods and poultry feed using RV medium has been adopted by AOAC INTERNATIONAL. AOAC Official Method 967.25, Salmonella in Foods, Preparation of Culture Media and Reagents, has been revised to include RV medium , and the applicability of AOAC Official Method 967.26, Salmonella in Foods, Detection, has been restricted to processed foods.

CT *Animal Feed: ST, standards
Animals
Colony-Forming Units Assay
Culture Media
Food Analysis
Food Contamination
*Food Microbiology
Poultry
*Salmonella: ME, metabolism
Selenocysteine: CH, chemistry
Temperature
Tetrathionic Acid: CH, chemistry

CN 0 (Culture Media)

L57 ANSWER 23 OF 29 MEDLINE on STN
ACCESSION NUMBER: 94355174 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 8074974
TITLE: Modes of inhibition of foodborne non-Salmonella bacteria by selenite cystine selective broth.
AUTHOR: Chen H; Fraser A D; Yamazaki H
CORPORATE SOURCE: Department of Biology, Carleton University, Ottawa, Ontario, Canada.
SOURCE: International journal of food microbiology, (1994 May) Vol. 22, No. 2-3, pp. 217-22.
Journal code: 8412849. ISSN: 0168-1605.
PUB. COUNTRY: Netherlands
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199410
ENTRY DATE: Entered STN: 13 Oct 1994
Last Updated on STN: 3 Mar 2000
Entered Medline: 5 Oct 1994

AB Various cell densities of six common foodborne non-Salmonella bacteria were exposed to selenite cystine (SC) Salmonella selective medium. The insensitivity of Pseudomonas aeruginosa and Proteus vulgaris to SC was confirmed. Selenite cystine selective medium was effective against the sensitive bacteria up to certain cell densities, beyond which the bacteria survived. As judged from the minimum cell number required for survival in SC, Staphylococcus aureus was the most sensitive to SC, followed by Bacillus cereus, Escherichia coli and Citrobacter freundii. When sensitive bacteria were grown in SC, they enriched resistant variants which exhibited no or reduced sensitivity to SC. The change in density of sensitive cells after

exposure to SC suggested that bacterial sensitivity to SC depended on the efficiency of killing and growth inhibition by SC as well as the fraction of resistant variants in the bacterial population. Since Salmonella samples generally contain unknown numbers and types of sensitive bacteria, it is difficult to predict the effectiveness of their selective inhibition by SC.

TI Modes of inhibition of foodborne non-Salmonella bacteria by selenite cystine selective broth.

AB Various cell densities of six common foodborne non-Salmonella bacteria were exposed to selenite cystine (SC) Salmonella selective medium. The insensitivity of Pseudomonas aeruginosa and Proteus vulgaris to SC was confirmed. Selenite cystine selective medium was effective against the sensitive bacteria up to certain cell densities, beyond which the bacteria survived. As judged from the minimum cell number required for survival in SC, Staphylococcus aureus was the most sensitive to SC, followed by Bacillus cereus, Escherichia coli and Citrobacter freundii. When sensitive bacteria were grown in SC, they enriched resistant variants which exhibited no or reduced sensitivity to SC. The change in density of sensitive cells after exposure to SC suggested that bacterial sensitivity to SC depended on the efficiency of killing and growth inhibition by SC as well as the fraction of resistant variants in the bacterial population. Since Salmonella samples generally contain unknown numbers and types of sensitive bacteria, it is difficult to predict the effectiveness of their selective inhibition by SC.

CT Animals
*Bacteria: DE, drug effects
Bacteria: GD, growth & development
Culture Media
*Cystine: PD, pharmacology
*Food Microbiology
*Salmonella: IP, isolation & purification
*Sodium Selenite: PD, pharmacology

RN 10102-18-8 (Sodium Selenite); 56-89-3 (Cystine)

CN 0 (Culture Media)

L57 ANSWER 24 OF 29 MEDLINE on STN

ACCESSION NUMBER: 93374667 MEDLINE Full-text

DOCUMENT NUMBER: PubMed ID: 8365957

TITLE: Comparison of classical isolation protocols with a 24 h screen to detect viable salmonellas in faeces.

AUTHOR: Cherrington C A; Huis in't Veld J H

CORPORATE SOURCE: Department of the Science of Food of Animal Origin, Faculty of Veterinary Medicine, University of Utrecht, The Netherlands.

SOURCE: The Journal of applied bacteriology, (1993 Jul) Vol. 75, No. 1, pp. 65-8.
Journal code: 7503050. ISSN: 0021-8847.

PUB. COUNTRY: ENGLAND: United Kingdom

DOCUMENT TYPE: (COMPARATIVE STUDY)
Journal; Article; (JOURNAL ARTICLE)
(RESEARCH SUPPORT, NON-U.S. GOV'T)

LANGUAGE: English

FILE SEGMENT: Priority Journals

ENTRY MONTH: 199310

ENTRY DATE: Entered STN: 22 Oct 1993
Last Updated on STN: 22 Oct 1993
Entered Medline: 6 Oct 1993

AB A 24 h screen which detects three viable salmonella cells per g of faeces was compared with classical isolation procedures for their ability to identify salmonella-positive samples from a pig rearing unit. The screen involved an overnight enrichment in Muller-Kauffmann tetrathionate (MK) broth, subculture

for 4 h in M broth containing 10 micrograms ml-1 novobiocin, followed by detection of the presence of salmonellas by BacTrace and Salmonella-tek ELISAs. The classical protocols were: (1) an overnight and 48 h incubation in MK or selenite cysteine broth; or (2) overnight incubation in buffered peptone water and 24 h subculture in Rappaport-Vassiliadis broth (BPW-RV). Salmonellas were isolated from the broth cultures on xylose lysine deoxycholate and brilliant green agars. Thirty four of 100 samples were positive for salmonellas but no single isolation protocol identified all of them. The best of the classical isolation protocols, 48 h incubation in MK broth, identified 27 (79%) of the 34 positive samples whilst the screen identified 26 (76%) of the 34 positive samples. False-positive results were obtained from all isolation protocols except BPW-RV.

TI Comparison of classical isolation protocols with a 24 h screen to detect viable salmonellas in faeces.

AB A 24 h screen which detects three viable salmonella cells per g of faeces was compared with classical isolation procedures for their ability to identify salmonella-positive samples from a pig rearing unit. The screen involved an overnight enrichment in Muller-Kauffmann tetrathionate (MK) broth, subculture for 4 h in M broth containing 10 micrograms ml-1 novobiocin, followed by detection of the presence of salmonellas by BacTrace and Salmonella-tek ELISAs. The classical protocols were: (1) an overnight and 48 h incubation in MK or selenite cysteine broth; or (2) overnight incubation in buffered peptone water and 24 h subculture in Rappaport-Vassiliadis broth (BPW-RV). Salmonellas were isolated from the broth cultures on xylose lysine deoxycholate and brilliant green agars. Thirty four of 100 samples were positive for salmonellas but no single isolation protocol identified all of them. The best of the classical isolation protocols, 48 h incubation in MK broth, identified 27 (79%) of the 34 positive samples whilst the screen identified 26 (76%) of the 34 positive samples. False-positive results were obtained from all isolation protocols except BPW-RV.

CT Animals
Cell Division: DE, drug effects
Culture Media
Dose-Response Relationship, Drug
Drug Resistance, Microbial
False Positive Reactions
*Feces: MI, microbiology
Novobiocin: PD, pharmacology
Salmonella: DE, drug effects
*Salmonella: IP, isolation & purification
Salmonella: PH, physiology
*Swine: MI, microbiology

CN 0 (Culture Media)

L57 ANSWER 25 OF 29 MEDLINE on STN
ACCESSION NUMBER: 85235508 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 3891846
TITLE: Rapid and automated detection of salmonella by electrical measurements.
AUTHOR: Easter M C; Gibson D M
SOURCE: The Journal of hygiene, (1985 Jun) Vol. 94, No. 3, pp. 245-62.
Journal code: 0375374. ISSN: 0022-1724.
PUB. COUNTRY: ENGLAND: United Kingdom
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 198508
ENTRY DATE: Entered STN: 20 Mar 1990
Last Updated on STN: 3 Mar 2000

Entered Medline: 15 Aug 1985

AB A rapid method for determining the presence of salmonella in food is described. It consists of pre-enrichment in buffered peptone water modified by the addition of dulcitol and trimethylamine oxide, followed by selective enrichment in a selenite-cystine broth with similar modifications. Changes in the conductance of the selective enrichment broth are monitored continuously using a suitable impediometric instrument. Most of the Salmonella spp. tested gave a fast (approximately 100 microS/h) and large (greater than 600 microS) change in conductance, other enteric bacteria much less or no change. The assay is usually complete within 24 h. Samples of foodstuffs, naturally and artificially contaminated with Salmonella spp., were all correctly classified. Some strains of Citrobacter freundii produced a false positive conductance response, and they could not be selectively eliminated using antibiotics or cyanide. The conductance method is simple and easy to use, gives rapid results and involves less media and subculturing than is required for traditional methods.

TI Rapid and automated detection of salmonella by electrical measurements.

AB A rapid method for determining the presence of salmonella in food is described. It consists of pre-enrichment in buffered peptone water modified by the addition of dulcitol and trimethylamine oxide, followed by selective enrichment in a selenite-cystine broth with similar modifications. Changes in the conductance of the selective enrichment broth are monitored continuously using a suitable impediometric instrument. Most of the Salmonella spp. tested gave a fast (approximately 100 microS/h) and large (greater than 600 microS) change in conductance, other enteric bacteria much less or no change. The assay is usually complete within 24 h. Samples of foodstuffs, naturally and artificially contaminated with Salmonella spp., were all correctly classified. Some strains of Citrobacter freundii produced a false positive conductance response, and they could not be selectively eliminated using antibiotics or cyanide. The conductance method is simple and easy to use, gives rapid results and involves less media and subculturing than is required for traditional methods.

CT *Bacteriological Techniques
Citrobacter: ME, metabolism
Culture Media
Electric Conductivity
*Food Microbiology
Galactitol: PD, pharmacology
Lactose: PD, pharmacology
*Methylamines: ME, metabolism
Oxidation-Reduction
Phosphates: PD, pharmacology
*Salmonella: IP, isolation & purification
Salmonella: ME, metabolism
Selenious Acid
Selenium: PD, pharmacology
Temperature
Time Factors

CN 0 (Culture Media); 0 (Methylamines); 0 (Phosphates)

L57 ANSWER 26 OF 29 MEDLINE on STN
ACCESSION NUMBER: 76086637 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 1200629
TITLE: Treatment of Salmonella-Arizona-infected turtle eggs with terramycin and chloromycetin by the temperature-differential egg dip method.
AUTHOR: Siebeling R J; Neal P M; Granberry W D
SOURCE: Applied microbiology, (1975 Nov) Vol. 30, No. 5, pp. 791-9. Journal code: 7605802. ISSN: 0003-6919.

PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
(RESEARCH SUPPORT, U.S. GOV'T, NON-P.H.S.)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 197602
ENTRY DATE: Entered STN: 13 Mar 1990
Last Updated on STN: 13 Mar 1990
Entered Medline: 13 Feb 1976

AB Attempts to eliminate Salmonella and Arizona infection from newly hatched turtles were made by dipping fresh eggs in cold solutions of Terramycin and Chloromycetin at 1,000, 1,200, 1,500 and 2,000 mug per ml for either 10, 20, or 30 min. Control groups consisted of hatchings produced from nondipped eggs or eggs dipped in chilled water. In two of the four experiments 5 to 10 eggs were blended on days 15, 30, and 45 post antibiotic dip treatment. Twenty-five to 60 hatchlings from each control or experimental dip groups were held in containers and the water was tested (excretion method) for Salmonella and Arizona every 15 or 30 days for 180 to 210 days after hatching. Representative turtles were homogenized (blending method) to determine if systemic infections were present. All specimens tested were enriched in tetrathionate and selenite cystine broth. Nondipped eggs and water-dipped eggs routinely showed Salmonella and Arizona present in egg homogenate and hatchlings emerging from these eggs excreted these pathogens. Terramycin- and Chloromycetin-dipped eggs were uniformly negative for these pathogens, only if fresh eggs were dipped. Bacteriological assay of container water and whole turtle homogenate from hatchlings were negative for Salmonella and Arizona if eggs were dipped in 1,000 mug of Terramycin early in the egg laying season or if eggs were dipped in 1,500 or 2,000 mug of Terramycin per ml late in the egg laying season. The results of temperature-differential egg dip studies suggest that this is a feasible and promising method by which to eradicate Salmonella and Arizona from the turtle.

TI Treatment of Salmonella-Arizona-infected turtle eggs with terramycin and chloromycetin by the temperature-differential egg dip method.

AB Attempts to eliminate Salmonella and Arizona infection from newly hatched turtles were made by dipping fresh eggs in cold solutions of Terramycin and Chloromycetin at 1,000, 1,200, 1,500 and 2,000 mug per ml for either 10, 20, or 30 min. Control groups consisted of hatchings produced from nondipped eggs or eggs dipped in chilled water. In two of the four experiments 5 to 10 eggs were blended on days 15, 30, and 45 post antibiotic dip treatment. Twenty-five to 60 hatchlings from each control or experimental dip groups were held in containers and the water was tested (excretion method) for Salmonella and Arizona every 15 or 30 days for 180 to 210 days after hatching. Representative turtles were homogenized (blending method) to determine if systemic infections were present. All specimens tested were enriched in tetrathionate and selenite cystine broth. Nondipped eggs and water-dipped eggs routinely showed Salmonella and Arizona present in egg homogenate and hatchlings emerging from these eggs excreted these pathogens. Terramycin- and Chloromycetin-dipped eggs were uniformly negative for these pathogens, only if fresh eggs were dipped. Bacteriological assay of container water and whole turtle homogenate from hatchlings were negative for Salmonella and Arizona if eggs were dipped in 1,000 mug of Terramycin early in the egg laying season or if eggs were dipped in 1,500 or 2,000 mug of Terramycin per ml late in the egg laying season. The results of temperature-differential egg dip studies suggest that this is a feasible and promising method by which to eradicate Salmonella and Arizona from the turtle.

CT Check Tags: Female
Animals
*Chloramphenicol: PD, pharmacology
*Eggs

*Oxytetracycline: PD, pharmacology
*Salmonella: DE, drug effects
Salmonella: IP, isolation & purification
*Salmonella Infections, Animal: PC, prevention & control
Seasons
*Sterilization: MT, methods
Temperature
*Turtles
Turtles: MI, microbiology

L57 ANSWER 27 OF 29 MEDLINE on STN
ACCESSION NUMBER: 70132183 . MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 4906997
TITLE: Increased sensitivity of immunofluorescent assay for Salmonella in nonfat dry milk.
AUTHOR: Reamer R H; Hargrove R E; McDonough F E
SOURCE: Applied microbiology, (1969 Sep) Vol. 18, No. 3, pp. 328-31.
Journal code: 7605802. ISSN: 0003-6919.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 197004
ENTRY DATE: Entered STN: 1 Jan 1990
Last Updated on STN: 1 Jan 1990
Entered Medline: 20 Apr 1970

AB The necessity of developing a quick, sensitive, and reliable test for Salmonella in nonfat dry milk (NDM) is evident from the recent tracing of Salmonella outbreaks to this product. Normally, coagulation of casein occurs when assaying NDM under regular cultural conditions, raising the possibility of trapped bacteria. After 20 hr of incubation of NDM in preenrichment lactose broth, enrichment was achieved by using Selenite-Cystine Broth. Smears from the enrichment broth were examined by the fluorescent-antibody technique (FAT) with a commercially available polyvalent O globulin conjugated with fluorescein. Standard cultural methods (SCM) were performed for comparison with FAT. Sensitivity of FAT was definitely improved by the use of trypsin. Casein coagulation of NDM can be avoided by addition of trypsin to samples during initial preenrichment in lactose broth. Samples containing approximately one Salmonella per 10 g were easily detected by FAT with the use of trypsin-treated samples. The method required only 42 hr to complete. Additionally, the use of trypsin enhanced recovery of Salmonella by use of SCM, as evidenced by alteration in the observed coliform to Salmonella ratios.

TI Increased sensitivity of immunofluorescent assay for Salmonella in nonfat dry milk.

AB The necessity of developing a quick, sensitive, and reliable test for Salmonella in nonfat dry milk (NDM) is evident from the recent tracing of Salmonella outbreaks to this product. Normally, coagulation of casein occurs when assaying NDM under regular cultural conditions, raising the possibility of trapped bacteria. After 20 hr of incubation of NDM in preenrichment lactose broth, enrichment was achieved by using Selenite-Cystine Broth. Smears from the enrichment broth were examined by the fluorescent-antibody technique (FAT) with a commercially available polyvalent O globulin conjugated with fluorescein. Standard cultural methods (SCM) were performed for comparison with FAT. Sensitivity of FAT was definitely improved by the use of trypsin. Casein coagulation of NDM can be avoided by addition of trypsin to samples during initial preenrichment in lactose broth. Samples containing approximately one Salmonella per 10 g were easily detected by FAT with the use of trypsin-treated samples. The method required only 42 hr to complete.

Additionally, the use of trypsin enhanced recovery of Salmonella by use of SCM, as evidenced by alteration in the observed coliform to Salmonella ratios.

CT Animals
Caseins: ME, metabolism
Culture Media
Cystine: ME, metabolism
*Fluorescent Antibody Technique
*Food Microbiology
Immune Sera
Lactose: ME, metabolism
Methods
*Milk
*Salmonella: IM, immunology
Salmonella: IP, isolation & purification
Serotyping
Trypsin: PD, pharmacology

CN 0 (Caseins); 0 (Culture Media); 0 (Immune Sera); EC 3.4.21.4 (Trypsin)

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ACCESSION NUMBER: 2007506983 EMBASE Full-text
TITLE: [Identification of Salmonella spp in water, cantaloupe melons and iguanas' feces in a melon orchard]. IDENTIFICACION DE SALMONELLA SPP EN AGUA, MELONES CANTALOUPE Y HECES FECALES DE IGUANAS EN UNA HUERTA MELONERA.
AUTHOR: Aguilar G.A.F.; Ramirez M.G.; Garcia A.M.; Gonzalez R.Y.; Navarrete J.E.; Escutia Ma.C.S.; Madrigal J.C.
CORPORATE SOURCE: Dr. J.C. Madrigal, Padre Lloreda 434-1, Centro, CP 58000, Morelia, Michoacan, Mexico. jcmavocat@yahoo.com.mx
SOURCE: Medicina Interna de Mexico, (Jul 2005) Vol. 21, No. 4, pp. 255-258.
Refs: 6
ISSN: 0186-4866 CODEN: MIMXFI
COUNTRY: Mexico
DOCUMENT TYPE: Journal; Article
FILE SEGMENT: 004 Microbiology: Bacteriology, Mycology, Parasitology and Virology
LANGUAGE: Spanish; Castilian
SUMMARY LANGUAGE: English; Spanish; Castilian
ENTRY DATE: Entered STN: 30 Oct 2007
Last Updated on STN: 30 Oct 2007

AB Background: Recent outbreaks of foodborne Salmonella infections have been reported in the United States and Canada, associated with melon consumption, primarily cantaloupe imported from Mexico. Salmonella serotype poona is isolated from nonhuman sources such as reptiles, in particular from turtles and iguanas. Objective: To identify Salmonella spp in water samples, cantaloupe melons and iguanas in a melon orchard. Material and methods: Four visits to a melon orchard were made, 38 samples of melons were evaluated, lees and related agricultural implements were studied, in which Escherichia coli and fecal coliforms counts were made by the most-probable-number method; the detection of Salmonella spp was made by means of pre-enrichment in lactose broth, enrichment in Rappaport- Vassiliadis and tetrathionate broth, poured in plates of XLD agar, Hektoen enteric agar, SS and bismuth sulfite agar, and biochemical identification in TSI, LIA, MIO agar and urea was carried out, by agglutinating particles in the polyvalent antiserum. Serum typification was made in the National Laboratory of Public Health. Results: Salmonella spp was identified in 12 samples, it was not isolated from any other melon; isolated serotypes were: S. poona, S infantis and S. anatum. Conclusions: Since there

were various sources of contamination, it is necessary to apply good sanitary and agricultural practices in order to obtain non-contaminated fruits suitable for exportation.

TI [Identification of Salmonella spp in water, cantaloupe melons and iguanas' feces in a melon orchard].
IDENTIFICACION DE SALMONELLA SPP EN AGUA, MELONES CANTALOUPE Y HECES FECALES DE IGUANAS EN UNA HUERTA MELONERA.

AB Background: Recent outbreaks of foodborne Salmonella infections have been reported in the United States and Canada, associated with melon consumption, primarily cantaloupe imported from Mexico. Salmonella serotype poona is isolated from nonhuman sources such as reptiles, in particular from turtles and iguanas. Objective: To identify Salmonella spp in water samples, cantaloupe melons and iguanas in a melon orchard. Material and methods: Four visits to a melon orchard were made, 38 samples of melons were evaluated, lees and related agricultural implements were studied, in which Escherichia coli and fecal coliforms counts were made by the most-probable-number method; the detection of Salmonella spp was made by means of pre-enrichment in lactose broth, enrichment in Rappaport- Vassiliadis and tetrathionate broth, poured in plates of XLD agar, Hektoen enteric agar, SS and bismuth sulfite agar, and biochemical identification in TSI, LIA, MIO agar and urea was carried out, by agglutinating particles in the polyvalent antiserum. Serum typification was made in the National Laboratory of Public Health. Results: Salmonella spp was identified in 12 samples, it was not isolated from any other melon; isolated serotypes were: S. poona, S infantis and S. anatum. Conclusions: Since there were various sources of contamination, it is necessary to apply good sanitary and agricultural practices in order to obtain non-contaminated fruits suitable for exportation.

CT Medical Descriptors:
article
*bacterium contamination
bacterium detection
bacterium isolation
Canada
cantaloupe
  Escherichia coli
fecal coliform
lizard
melon
Mexico
  Salmonella
*salmonellosis
sanitation
serotype
United States

L57 ANSWER 29 OF 29 AGRICOLA Compiled and distributed by the National Agricultural Library of the Department of Agriculture of the United States of America. It contains copyrighted materials. All rights reserved. (2007) on STN

ACCESSION NUMBER: 2000:13813 AGRICOLA Full-text
DOCUMENT NUMBER: IND22020442
TITLE: Prevalence of Salmonella in chorizo and its survival under different storage temperatures.
AUTHOR(S): Escartin, E.F.; Castillo, A.; Hinojosa-Puga, A.; Saldana-Lozano, J.
CORPORATE SOURCE: Universidad Autonoma de Queretaro, Mexico.
SOURCE: Food microbiology, Oct 1999. Vol. 16, No. 5. p. 479-486
Publisher: London ; Orlando : Academic Press, c1984-
ISSN: 0740-0020

NOTE: Includes references
PUB. COUNTRY: England; United Kingdom
DOCUMENT TYPE: Article
FILE SEGMENT: Non-U.S. Imprint other than FAO
LANGUAGE: English

AB The prevalence of Salmonella in chorizo, a raw pork sausage, was studied in two locations in Mexico. Sixty samples were collected from butcher shops and retail markets in Guadalajara city, and another 80 samples were collected from butcher shops (40 samples) and grocery stores (40 samples) in Queretaro city. Samples obtained from butcher shops had been produced at the same butchery, whereas those obtained from grocery stores in Queretaro had been processed at national meat processing plants. In Guadalajara, 88% of the samples tested positive to Salmonella. In Queretaro, 78% of the samples collected from butcher shops and 5% of the samples collected from grocery stores tested positive to Salmonella. The ability to isolate Salmonella from chorizo was affected by the method of analysis and was best achieved by preenrichment of 20 g of sample in buffered peptone water for 24 h, followed by enrichment in tetrathionate brilliant green and selenite cystine broths. The five most frequent serovars isolated were S. derby (26%), S. anatum (14%), S. infantis (14%), S. typhimurium (12%) and S. brandenburg (6%). Five selected samples that tested positive for Salmonella were selected for enumeration by most probable number (MPN) and subsequent survival studies during storage of chorizo at refrigeration (4-6 degrees C) and at room temperature (18-22 degrees C). Initial numbers of Salmonella varied from 900 to 0(.)04 MPN g(-1), and with the exception of the sample containing 900 Salmonella MPN g(-1), all other samples were cleared from this pathogen after 21 days of refrigeration or 5-10 days at room temperature. Salmonella contamination in chorizo can be prevented by improving the bacteriological quality and safety of the raw materials and by controlling the natural aging process of this product.

TI Prevalence of Salmonella in chorizo and its survival under different storage temperatures.

AB The prevalence of Salmonella in chorizo, a raw pork sausage, was studied in two locations in Mexico. Sixty samples were collected from butcher shops and retail markets in Guadalajara city, and another 80 samples were collected from butcher shops (40 samples) and grocery stores (40 samples) in Queretaro city. Samples obtained from butcher shops had been produced at the same butchery, whereas those obtained from grocery stores in Queretaro had been processed at national meat processing plants. In Guadalajara, 88% of the samples tested positive to Salmonella. In Queretaro, 78% of the samples collected from butcher shops and 5% of the samples collected from grocery stores tested positive to Salmonella. The ability to isolate Salmonella from chorizo was affected by the method of analysis and was best achieved by preenrichment of 20 g of sample in buffered peptone water for 24 h, followed by enrichment in tetrathionate brilliant green and selenite cystine broths. The five most frequent serovars isolated were S. derby (26%), S. anatum (14%), S. infantis (14%), S. typhimurium (12%) and S. brandenburg (6%). Five selected samples that tested positive for Salmonella were selected for enumeration by most probable number (MPN) and subsequent survival studies during storage of chorizo at refrigeration (4-6 degrees C) and at room temperature (18-22 degrees C). Initial numbers of Salmonella varied from 900 to 0(.)04 MPN g(-1), and with the exception of the sample containing 900 Salmonella MPN g(-1), all other samples were cleared from this pathogen after 21 days of refrigeration or 5-10 days at room temperature. Salmonella contamination in chorizo can be prevented by improving the bacteriological quality and safety of the raw materials and by controlling the natural aging process of this product.

CT cell culture; cold storage; culture media; food contamination; food storage; isolation techniques; microbial contamination; pork; refrigeration; salmonella; sausages; serovars; supermarkets; survival; temperature

Full search history

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=> d his nofile

     (FILE 'HOME' ENTERED AT 14:07:14 ON 31 OCT 2007)

     FILE 'HCAPLUS' ENTERED AT 14:07:24 ON 31 OCT 2007
                E US20060134726 /PN
L1              1 SEA ABB=ON  PLU=ON  US20060134726 /PN
                D L1
                D SCAN
                E MICROORGANISMS/CT
L2           8671 SEA ABB=ON  PLU=ON  MICROORGANISMS/CT
                E BACTERIA/CT
L3          67534 SEA ABB=ON  PLU=ON  BACTERIA/CT
L4           8220 SEA ABB=ON  PLU=ON  SALMONELLA/CT
                E COLIFORM/CT
L5           3783 SEA ABB=ON  PLU=ON  (COLIFORM/CT OR "COLIFORM BACTERIA"/CT)
                E SPORES/CT
L6            141 SEA ABB=ON  PLU=ON  SPORES/CT
                E AGAR/CT
                E SELENITE/CT
L7            557 SEA ABB=ON  PLU=ON  SELENITES/CT
L8          11734 SEA ABB=ON  PLU=ON  SAMPLES/CT
                E QUALITY CONTROL/CT
L9          17112 SEA ABB=ON  PLU=ON  "QUALITY CONTROL"/CT
                E QUALITY ASSURANCE/CT
L10         17112 SEA ABB=ON  PLU=ON  "QUALITY CONTROL"/CT
L11               QUE ABB=ON  PLU=ON  (SEQUENT?)(3A)(SAMPL? OR SUBSAMPL? OR
                  TEST? OR QUALIT? OR CONTROL? OR ASSUR?)
L12               QUE ABB=ON  PLU=ON  (QUALIT?)(3A)(CONTROL? OR ASSUR? OR SAMPL?
                  OR TEST? OR SEQUEN? OR PROTOCOL?)
L13               QUE ABB=ON  PLU=ON  (SELENIT?)(3A)(MEDIUM OR MEDIA OR BROTH?
                  OR AGAR? OR ENRICH? OR SCREEN? OR AGAR? OR ENTERIC?)
L14               QUE ABB=ON  PLU=ON  (HEKTOEN?)(3A)(MEDIUM OR MEDIA OR BROTH?
                  OR AGAR? OR ENRICH? OR SCREEN? OR AGAR? OR ENTERIC?)
L15               QUE ABB=ON  PLU=ON  (COLI? OR SALMONELL?)(3A)(SCREEN? OR TEST?
                  OR CHECK? OR ASSAY? OR ASSESS? OR CULTUR? OR ENRICH? OR SAMPL?
                  OR PROTOCOL?)
L16          2465 SEA ABB=ON  PLU=ON  (L2 OR L3 OR L4 OR L5 OR L6) AND (L8 OR L9
                  OR L11 OR L12 OR L15)
L17            33 SEA ABB=ON  PLU=ON  L16 AND L13
L18             9 SEA ABB=ON  PLU=ON  L16 AND L14
L19            41 SEA ABB=ON  PLU=ON  L17 OR L18
L20           148 SEA ABB=ON  PLU=ON  L16 AND ((COMPOSIT? OR POOL? OR COMBIN? OR
                  COLLECT?)(3A)(SAMPL? OR SUBSAMPL? OR PORTION? OR LOT OR TEST))
L21             0 SEA ABB=ON  PLU=ON  L20 AND EMB
L22             0 SEA ABB=ON  PLU=ON  L21 AND (SALMONELLA OR COLI)
L23            87 SEA ABB=ON  PLU=ON  L20 AND (SALMONELLA OR COLI)
L24           126 SEA ABB=ON  PLU=ON  L19 OR L23
L25            47 SEA ABB=ON  PLU=ON  L24 AND (FOOD OR PHARMACEUT? OR DRUG)
L26            12 SEA ABB=ON  PLU=ON  L24 AND (PHARMACOL? OR INGRED? OR AGRIC?
                  OR COMMOD? OR IMPORT OR EXPORT)
L27            67 SEA ABB=ON  PLU=ON  L20 AND (COUNT? OR TITER OR TITRE OR
                  CONCENT? OR POPUL? OR INFEST? OR INFECT?)
L28            52 SEA ABB=ON  PLU=ON  L17 OR L18 OR L26
L29            79 SEA ABB=ON  PLU=ON  L25 OR L28
L30             2 SEA ABB=ON  PLU=ON  L29 AND ((QUALIT?)(3A)(CONTROL OR PROTOCOL
                  OR SAMPL? OR PRODUCT))
```

```
L31          11 SEA ABB=ON  PLU=ON  L29 AND (QUALIT? OR SAFE?)
L32          58 SEA ABB=ON  PLU=ON  L29 AND (SAMPL? OR PROTOCOL OR PROCED?)
L33          16 SEA ABB=ON  PLU=ON  L26 OR L30 OR L31
                E SAMADPOUR M?/AU
L34          32 SEA ABB=ON  PLU=ON  ("SAMADPOUR M"/AU OR "SAMADPOUR MANSOUR"/AU
                )
L35          17 SEA ABB=ON  PLU=ON  L34 AND HEALTH?/CO,CS,PA,SO
L36           0 SEA ABB=ON  PLU=ON  L34 AND ENVIROMENTAL?/CO,CS,PA,SO
L37          16 SEA ABB=ON  PLU=ON  L33 NOT L35
L38          16 SEA ABB=ON  PLU=ON  L33 AND L37
                SAVE TEMP L35 SRI871HCIN/A
                SAVE TEMP L38 SRI871HCTX/A

     FILE 'MEDLINE, BIOSIS, EMBASE, AGRICOLA' ENTERED AT 14:53:24 ON 31 OCT
     2007
L39          42 SEA ABB=ON  PLU=ON  L35
L40          37 SEA ABB=ON  PLU=ON  L39 AND (BACTERI? OR MICROBIOL? OR
                SALMONELLA OR COLI)
L41          34 SEA ABB=ON  PLU=ON  L39 AND (QUALITY OR SAFETY OR FOOD OR
                PHARMACOL? OR DRUG OR ENVIRON?)
L42           0 SEA ABB=ON  PLU=ON  L39 AND (HEKTOEN OR SELENITE)
L43           6 SEA ABB=ON  PLU=ON  L39 AND (BROTH OR AGAR OR ENRICH? OR
                CULTUR? OR MEDIUM OR MEDIA)
L44          33 SEA ABB=ON  PLU=ON  L40 AND L41
L45          35 SEA ABB=ON  PLU=ON  L43 OR L44
L46          18 SEA ABB=ON  PLU=ON  L45 AND (SAMPL? OR SCREEN OR CONTROL OR
                ASSAY OR COUNT)
L47          20 SEA ABB=ON  PLU=ON  L46 OR L43
                SAVE TEMP L47 SRI871MLIN/A
L48         116 SEA ABB=ON  PLU=ON  L33
L49         106 SEA ABB=ON  PLU=ON  L48 AND (SAMPL? OR SCREEN OR CONTROL OR
                ASSAY OR COUNT)
L50         106 SEA ABB=ON  PLU=ON  L49 AND (SALMONELLA OR COLI)
L51         104 SEA ABB=ON  PLU=ON  L50 AND (FOOD OR PHARMACEUT? OR DRUG OR
                AGRIC? OR COMMOD? OR INGRED?)
L52          55 SEA ABB=ON  PLU=ON  L51 AND (BROTH OR AGAR OR ENRICH? OR
                CULTUR? OR MEDIUM OR MEDIA)
L53          16 SEA ABB=ON  PLU=ON  L51 AND (HEKTOEN OR SELENITE OR EMB)
L54          16 SEA ABB=ON  PLU=ON  L52 AND L53
L55          16 SEA ABB=ON  PLU=ON  L54 NOT L47
                SAVE TEMP L55 SRI871MLTX/A
                D QUE L35
                D QUE L47

     FILE 'HCAPLUS, MEDLINE, BIOSIS, EMBASE' ENTERED AT 15:18:47 ON 31 OCT 2007
L56          27 DUP REM L35 L47 (10 DUPLICATES REMOVED)
                     ANSWERS '1-17' FROM FILE HCAPLUS
                     ANSWERS '18-25' FROM FILE MEDLINE
                     ANSWERS '26-27' FROM FILE BIOSIS
                D L56 1-27 IBIB AB
                D QUE L38
                D QUE L55

     FILE 'HCAPLUS, MEDLINE, EMBASE, AGRICOLA' ENTERED AT 15:20:17 ON 31 OCT
     2007
L57          29 DUP REM L38 L55 (3 DUPLICATES REMOVED)
                     ANSWERS '1-16' FROM FILE HCAPLUS
                     ANSWERS '17-27' FROM FILE MEDLINE
                     ANSWER '28' FROM FILE EMBASE
                     ANSWER '29' FROM FILE AGRICOLA
```

D L57 1-16 IBIB ED ABS HITIND
D L57 17-29 IBIB AB HIT

Q15	Q10 same Q12	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q16	Q10 same Q13	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q17	Q10 same Q11	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q18	Q1 same Q4	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q19	(animal or cattle) same (feces or feccal)	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q20	Q1 same Q19	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q21	Q3 same Q20	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q22	Q4 same Q20	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q23	Q4 same Q12	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q24	Q4 and Q12	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q25	Q4 and Q1	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q26	Q3 and Q1	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q27	Q2 and Q26	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q28	Q27 and Q7	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q29	Q27 and Q8	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q30	Q29 and Q19	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q31	Q25 and Q5	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q32	(435/34).ccls.	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q33	Q24 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q34	Q25 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q35	Q30 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q36	Q1 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q37	Q2 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q38	Q3 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q39	Q4 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q40	Q5 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q41	Q6 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q42	Q7 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q43	Q8 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES

Q44	Q19 and Q32	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q45	Q37 and Q44	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q46	Q38 and Q45	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q47	Q40 and Q46	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q48	Q41 and Q47	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q49	5985593.pn.	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q50	Q49 and Q1	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q51	Q7 and Q50	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q52	Q8 and Q50	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q53	sample or ssamp$5	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q54	Validat$5	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q55	(Quality Assurance) and method	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q56	sample or specimen or portion or aliquot	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q57	Q53 and Q56	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q58	Q54 and Q57	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q59	Q55 and Q58	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q60	Samadpour	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q61	Q55 and Q60	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q62	Q54 and Q60	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES
Q63	Q56 and Q62	PGPB,USPT,USOC,EPAB,JPAB,DWPI	None	ADJ	YES

Overwrite Cancel

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 01/10/2008
DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed 16 October 2007 to Office Action mailed 09 October 2007 is acknowledged and entered.

2. Preliminary Amendment filed under 37 C.F.R. §1.115 on 16 October 2007 is acknowledged and entered.

Claims Status

3. Claims 1 and 20 have currently been amended.

4. Claims 1-20 are pending.

Restriction/Election

5. Election without traverse of "single-unit product lot" as the species for further prosecution in the instant application filed 16 October 2007 in response to Election Requirement in Office Action mailed 09 October 2007 is acknowledged and entered.

Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, All Claims drawn to specimens that are not from "single-unit product lot" are withdrawn from further consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and M.P.E.P. §821.03.

6. Claims 1-20 are examined on merits.

Priority

7. Applicants' claim for domestic priority under 35 U.S.C. §119 (e) to U.S. Provisional Applications 60/ 599, 473 filed 06 August 2004 is acknowledged.

Objection To Specification

8. The specification is objected to because Line one of first page of specification, in its present form does not cite the application priority data. Please update Application Priority Data at Line 1 of the First Page of the Specification.

Objection To Claims

9. Claims 1-19 are objected to for following reasons:

- Recitations, "enriched" in Claims 1c) and 11, and "enrichment medium" in Claim 6 are objected because it is not clear how one will "enrich" a chemical for example, by simply incubating said sample. Accordingly, it is not clear what is being enriched.

- Phrase "removing aseptically" in claim 1 d) is objected to for redundancy, because claims 1a to 1c are not drawn to a process/method that is encompassing any microorganisms or germs, or any microbial culture.

- Phrase, "wherein, where" at Claim 1e), Lines 2-3 and at Claim 8, Line 1 is objected to since said phrase renders said claim unclear.

- Phrase, "more sensitive protocol" at Claim 1e), Lines 4-5 and Claim 8, Line 3 is objected to since it is unclear how a more sensitive protocol will help in obtaining a negative result.

- Claim 2 is objected to because in addition to being drawn to "single-unit product lot", it is drawn to non-elected species.

- Phrase, "segment of production" at Claim 13, Line 2 is objected because said phrase renders said claim unclear.

All other claims depend directly from the rejected claim 1, and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. §112

10. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

11. Claims 1-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In each of sub-claims 1c, 1d, 1e, 20c, 20d and 20e the limitation, "sample" lacks sufficient antecedent basis because in Claims 1a-1b and 20a-20b that precede Claims 1c-1e and 20c-20e, the limitation used is "portions".

- At Claim 4, line 2, the limitation, "portions" lacks sufficient antecedent basis because in Claim 3 from which Claim 3 depends, the limitation, "specimen" rather than "portions" has been used and "portions" is absent in Claim 3.

- At Claim 7, Line 3, the limitation, "microbial agent or organism" lacks sufficient antecedent basis because in Claim 1 from which Claim 7 depends, the stated limitation is "agent or organism".

- At Claim 9, Line 2, the limitation, "microbial agent or organism" lacks sufficient antecedent basis because in Claim 8 from which Claim 9 depends said limitation is absent and in Claim 1 from which Claim 8 depends, the stated limitation is "agent or organism".

- Claims 14 and 16 are rejected because of the range within range, i.e. broad limitation followed by a narrow limitation.

  A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation, e.g., "about 3 to about 10" and the claim also recites " about 5 to about 8" which is the narrower statement of the range/limitation. Similarly, in Claim 16, the recited broad range is "about 5 to about 100" and in the same claim the narrow ranges arre: "about 10 to about 90", "about 20 to about 80", "about 30 to about 70", "about 30 to about 60" and "about 40 to about 50".

- At Claim 15, the limitation, "application of remedial measures that are specific to one or more individual test lots that test positive" bridging lines 2-3 lacks sufficient antecedent basis because Claim 1 from which Claim 15 depends is limited only to a "method to sample, test and validate test lots".

- Recitation, "in the range of about number (e.g., 118.1) to number (e.g., 3.5) renders Claims 14 and 16-18, incomprehensible, unclear and vague. The word "about" in and by itself means "in vicinity of" whereas the phrase "number (e.g., 118.1) to number (e.g., 3.5) gives the range along with the variation in those numbers or the vicinity of which those numbers or parameter should be present. Thus, this is a range in range situation, one range given according to the recitation, "about" and the other, according to the phrase, "number (e.g., 118.1) to number (e.g., 3.5)". As explained above, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range and range situation is identified because of the recitation" about" followed by a range of numbers. The about giving the connotation of broader range. Appropriate correction is required.

All other claims depend directly from the rejected claims (e.g., Claim 14) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claims Rejection - 35 U.S.C. §102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

13. Claims 1, 11-12 and 16-19 are rejected under 35 U.S.C. §102(b), as anticipated by Renter et al (Diversity, Frequency and Persistence of *Escherichia coli* O157:H7 Strains from Range Cattle Environment. Applied and Environmental Microbiology, Volume 69, Pages 542-547, 2003).

Claims recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. In said method the plurality of samples collected from each test lot ranges between 5 to 100.

Regarding Claims 1, 11-12 and 16-19, Renter et al. teach a method to evaluate diversity and persistence of *Escherichia coli* O157:H7 in 9,122 cattle fecal samples, 40, 883 water samples and 521 wildlife samples obtained from Range cattle environment (Page 542, Abstract, Lines 12-14). Samples were analyzed through enrichment, subsequent incubation and confirmation via latex agglutination, Polymerase Chain Reaction (i.e., PCR) and microbiological culture techniques on composite samples from additional enriched test lot samples (Abstract, Lines 14-22). Seven most frequently isolated isolates represented over 124 of 235 frequently isolated *Escherichia coli* O157:H7 isolates. Thus, presence of *Escherichia coli* O157:H7 was evaluated and confirmed from multiple contiguous cattle, water and wildlife environmental source sample lots (Page 546, Column 2, Lines 28 –33) and more than one sample from different parallel sample lots were evaluated. Note also that Renter et al. tested an enormous number of sample lots and isolates from within the sample lots wherein parallel un-evaluated samples were also evaluated. Additionally, regarding Claims 16-19, the number of samples analyzed and *Escherichia coli* O157:H7 isolates obtained from sample lots and composite sampling of samples encompasses the entire range of 5 to 100 separately collected samples. Thus, representing a plurality of samples from a plurality of test lots. Note that in the prior art reference, the cattle lot or water sample represents a "single unit product. Therefore, the cited prior art both expressly and inherently teaches the instantly claimed method because the prior art method is employing the same strategy, components and steps as has been claimed instantly (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

14. Claims 1-10, 13-16 and 20 are rejected under 35 U.S.C. §102(b), as anticipated by Samadpour et al. (Laboratory Investigation of an E. coli O157:H7 Outbreak Associated with Swimming in Battle Ground Lake, Vancouver, Washington. Journal of Environmental Health, Volume 64, Pages 16-20, 2002).

Claims recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. In said method the plurality of samples collected from each test lot ranges between 5 to 100.

Regarding Claims 1-10, 13-16 and 20, Samadpour et al. teach a method to establish *Escherichia coli* O157:H7 outbreak in the samples collected from the recreational waters as well as landscape surrounding a lake. Said method comprised collecting a total of 80 water and lake sediment samples and 28 additional animal feces samples from cow, coyote, deer, duck and rabbit (Page 17, Column 1, Lines 16-26). Said samples were enriched via incubation in tryp-soy broth at 37 °C, concentrated through filtration, the filters re-incubated in same broth and subsequently aliquots plated on McConkey sorbitol comprising effixime and tellurite plates as well as probed for the *Escherichia coli* O157:H7 virulence factor. Thus, presence of *Escherichia coli* O157:H7 was evaluated and confirmed by two different methods through assaying pools of enriched samples from a plurality of environmental sources (Page 17, Column 1, Line 47 to Column 3, Line 35). Note, that of the total of 108 samples, negative samples were also evaluated for the target virulence factor (Table 1, Column 8, Lines 12-14 and Figure 1). The lake was closed for recreational water activity and sampling continued at consecutive weekly intervals post-closure of the lake for recreational activities until the lake water and sediment samples showed negative results (Page 19, Column 2, Line 53 to Column 3, Line 5). Thus, regarding the limitations in each of the Claims 1-10, 13-16 and 20, Samadpour et al. teach sampling of at least 108 samples of which at least 80 were from lake, said samples were analyzed for the *Escherichia coli* O157:H7 virulence factor and presence of coliforms through primary enrichment, in a culture broth, subsequent incubation of said culture broth at 37 °C, followed by organism concentration, re-incubating said filters in the same broth and evaluating the broth for *Escherichia coli* O157:H7 through PCR and direct plating on specific microbiological media. Samples showing negative results re-evaluated. Furthermore, Samadpour et al. also teach preventive

measures for the positive environmental sample lot because the water recreational activity was closed on the environmental sample lot, i.e., lake until three consecutive lake water and sediment samples assayed negative for the test organism(s). Note that in the prior art reference, the water sample for example represents a "single unit product". Therefore, the cited prior art both expressly and inherently teaches the claimed method because the prior art method is employing the same strategy, components and steps as has been claimed instantly (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. §103

15. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §102(f) or (g) prior art under 35 U.S.C. §103(a).

17. Claims 1-20 are rejected under 35 U.S.C. §103 (a) as obvious over combined teachings from Samadpour et al. (Journal of Environmental Health, Volume 64, Pages 16-20, 2002) in view of Renter et al (Applied and Environmental Microbiology, Volume 69, Pages 542-547, 2003).

Claims recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. In said method the plurality of samples collected from each test lot ranges between 5 to 100.

Teachings from each of Samadpour et al., and Renter et al. references have already been discussed *supra* under the rejection of Claims 1-10, 13-16 and 20 and Claims 1, 11-12 and 16-19 under 35 U.S.C. §102 (b). Samadpour et al., however, do not exhaustively elaborate on each and every element for the steps of sample collection, sample analysis including details of each step during validation of analyzed samples. Renter et al. reference, not only teaches the methods of sample collection, validation and analysis of a plurality of samples, but elaborates on each of the component steps for the validation of test samples.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Samadpour et al., with those from Renter et al., obtain a method to sample, test and validate samples in a single point product lot; because both Samadpour et al., and Renter et al. teach a method to sample, test and validate a plurality of samples obtained from a plurality of single point test lots, and Renter et al. additionally elaborate on the validation steps of the process and test a larger population of single point product lot than Samapour et al..

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Samadpour et al., with those from Renter et al., to obtain a method to sample, test and validate a plurality of samples in a single point product lot because; Renter et al. remedy the deficiency of elaborated validated steps lacking in Samadpour et al's reference.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

18. For aforementioned reasons, no Claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

05 January 2008

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1281/1657

Notice of References Cited	Application/Control No. 11/199,871	Applicant(s)/Patent Under Reexamination SAMADPOUR, MANSOUR	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Samadpour et al. 2002. Laboratory Investigation of an E. coli O157:H7 Outbreak Associated with Swimming in Battle Ground Lake, Vancouver, Washington.Journal of Environmental Health, Volume 64, Issue 10, Pages 16-20.
	V	Renter et al 2003.Diversity, Frequency and Persistence of Escherichia coli O157:H7 Strains from Range Cattle Environment. Applied and Environmental Microbiology, Volume 69, Pages 542-547.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	MANSOUR SAMADPOUR
	Examiner	**Art Unit**
	Srivastava, Dr. Kailash C	1657

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/28/2007	01/05/2008							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	✓							
	8	÷	✓							
	9	÷	✓							
	10	÷	✓							
	11	÷	✓							
	12	÷	✓							
	13	÷	✓							
	14	÷	✓							
	15	÷	✓							
	16	÷	✓							
	17	÷	✓							
	18	÷	✓							
	19	÷	✓							
	20	÷	✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	SAMADPOUR, MANSOUR
	Examiner	Art Unit
	Srivastava, Dr. Kailash C	1657

SEARCHED

Class	Subclass	Date	Examiner
Performed Partial Search in WEST	Performed Partial Search in WEST	01/02/2008	KCS
NONE	NONE	01/02/2008	KCS

SEARCH NOTES

Search Notes	Date	Examiner
WEST SEARCH: DWPI, EPAB, JPAB, PGPB. USOC, USPT	01/02/2008	KCS
STN SEARCH: AGRICOLA, BIOSIS, EMBASE, HCAPLUS, MEDLINE,	10/31/2007	KCS
Search Strategy:E.coli, Samadpour, test sample, validat, test lot, quality assurance method, sampl, scrren, portion, Salmonella, Screen, coliform, count, control, protocol, safety, food	01/02/2008	kcs
Perform Inventor Search	01/02/2008	KCS
Verified priority data and information (e.g., 60/599,473 filed 08/06/2004).	01/02/2008	KCS
Google Search: EPA method for water analysis, Method 1622, Giardia, Cryptosporidium	01/03/3008	KCS

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/199,871	08/08/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/19/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 33	Minus	** 34	= 0	X $25 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MARY PEOPLES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	08 August 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	25 April 2008

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

This is a RESPONSE AND AMENDMENT in reply to an Office Action dated 10 January 2008 in the above identified application. Please extend the time for response one months, up to and including, 10 May 2008. A Request for a One-Month Extension of time and the requisite fee are enclosed.

Kindly amend the above-identified patent application as follows:

Application No.: 11/199,871
Attorney Docket No.: 66090-29
First Applicants' Name: Mansour Samadpour
Application Filing Date: 08 August 2005
Office Action Dated: January 10, 2008
Date of Response: 25 April 2008
Examiner: Kailash C. Srivastava

IN THE SPECIFICATION:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the specification:

Kindly ***insert*** the following paragraph immediately after the Title on page 1, and ***delete*** identical paragraph from its current position at lines 16-20 of page 1:

--CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of priority to United States Provisional Patent Application Serial Number 60/599,473, filed 06 August 2004 and entitled MODULAR WET COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, which is incorporated by reference herein in its entirety.--

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

1. (Currently amended) A method of sampling, testing and validating test lots, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot;

c) incubating the set of test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of ~~enriched~~ test lot samples enriched for the target microbial agent or organism;

d) removing~~, aseptically, equal~~ portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when~~where~~ such testing is negative all test lot samples are validated, and wherein when~~where~~ such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. (Withdrawn) The method of claim 1, wherein the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental

specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof.

3. (Original) The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

5. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. (Currently amended) The method of claim 1, wherein incubating each test lot sample in c) comprises incubating with~~adding an amount of~~ enrichment medium suitable to enrich for the target microbial agent or organism, to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. (Original) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. (Currently amended) The method of claim 1, wherein ~~where~~ testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

9. (Original) The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. (Original) The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. (Currently amended) The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a ~~segment of~~ production assemblage.

14. (Currently amended) The method of claim 1, wherein the number of test lots is from ~~about~~ 3 to ~~about~~ 10~~, about 5 to about 8, or about 5~~.

15. (Currently amended) The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, ~~and~~

application of remedial measures to said positive test lots, and validating by further testing of a portion of the respective remediated test lots and obtaining a negative test result ~~that are specific to one or more individual test lots that test positive~~.

16. (Currently amended) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions ~~selected from the group consisting of~~ from ~~about~~ 5 to ~~about~~ 100~~, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions~~.

17. (Currently amended) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot ~~about~~ 30 to ~~about~~ 60 portions.

18. (Currently amended) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting 30 portions from each test lot ~~about 30 portions~~.

19. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. (Currently amended) A method of sampling, testing and validating test lots, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot;

c) incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of ~~enriched~~ single-unit production lot samples enriched for the target microbial agent or organism;

d) removing~~, aseptically, equal~~ portions of each enriched single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when~~where~~ such testing is negative all single-unit production lot samples are validated, and wherein when~~where~~ such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

21. (New) The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched test lot samples.

22. (New) The method of claim 20, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched single-unit production lot samples.

23. (New) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria*, *Salmonella* and *Escherichia coli*.

24. (New) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

25. (New) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

26. (New) The method of claim 1, wherein removing portions of each enriched test lot sample comprises removing equal volume portions of each enriched test lot sample.

27. (New) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.

28. (New) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (New) The method of claim 1, wherein the test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. (New) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (New) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (New) The method of claim 1, wherein the test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

33. (New) The method of claim 1, wherein the test lots are production lots of a ready-to-eat product.

34. (New) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing undesired microbial agent or organisms.

REMARKS

Claims 1-20 are pending, and stand objected to and/or rejected.

Applicant acknowledges the Examiner's objection to the specification and has made responsive amendments as described herein to obviate the objection.

Applicant acknowledges the Examiner's objections to the claims and has made responsive amendments as described herein to obviate the objections.

Applicant acknowledges the Examiner's rejection of claims 1-20, under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicant has made responsive amendments and/or rebuttal arguments, as described herein, to obviate the objections.

Applicant acknowledges the Examiner's rejection of claims 1, 11-12 and 16-19, under 35 U.S.C. § 102, as allegedly being anticipated by Renter et al (*Applied and Environmental Microbiology*, 69:542-547, 2003). Applicant respectfully traverses this rejection, and has provided appropriate rebuttal arguments to obviate the rejection.

Applicant acknowledges the Examiner's rejection of claims 1-10, 13-16 and 20, under 35 U.S.C. § 102, as allegedly being anticipated by Samadpour (*J. Enviro. Health*. 2002, 64:10, 16-20). Applicant respectfully traverses this rejection, and has provided appropriate rebuttal arguments to obviate the rejection.

Applicant acknowledges the Examiner's rejection of claims 1-20, under 35 U.S.C. § 103, as allegedly being obvious in view of Samadpour et al., (*supra*) in view of Renter (*supra*). Applicant respectfully traverses this rejection, and has provided appropriate rebuttal arguments to obviate the rejection.

New *dependent* claims 21-31 have been added, as discussed herein, and are fully supported by the originally filed specification.

No new matter has been added.

Objection to Specification

The Examiner has objected to the specification in view of failure to recite application priority data on line one of the first page of the application. Applicants have, as described herein, undated the application priority date at line one of the first page of the specification to obviate this objection.

Objection to Claims

First, the Examiner has objected to the claims in view of recitation of "enriched" (claims 1c and 11) and "enrichment medium" (claim 6) in view of the fact that it is not clear what is being enriched. Applicant has amended claim 1 to recite "to provide a set of ~~enriched~~ test lot samples enriched for the target agent or organism;..." Applicant has amended claim 6 to recite "wherein incubating each test lot sample in c) comprises adding an amount of enrichment medium, suitable to enrich for the target agent or organism, to the sample, and wherein removing in d) comprises removing a portion of the ~~enrichment~~ medium from each enriched sample and combining the removed portions to provide a modular composite sample." Applicant contends that the amendments to claims 1 and 6 clarify that the target agent or organism is being enriched, and further that these amendments clarify claim 11 without amendment of claim 11.

Although not requested by the Examiner, conforming amendments have been made to claim 20 to facilitate prosecution.

Second, the Examiner has objected to recitation of "removing aseptically" in claim 1d) based on alleged redundancy. Applicant points out that the subject matter of claim 1 is in fact

drawn to a process encompassing microorganisms and/or microbial agents, and that "aseptically," as is appreciated in the art, refers to using good sterile technique so as not to contaminate the enriched test lost samples with foreign organisms. Applicant, therefore, traverses this objection. Applicant has, however, amended claim 1 to delete the reference to aseptically, and has rather added new claim 21, drawn to the method of claim 1, wherein removing in step d) is removing equal portions aseptically so as to preclude contamination of the enriched test lot samples.

Although not requested by the Examiner, conforming amendments have been made to claim 20 to facilitate prosecution, and new claim 22 has been added, drawn to the method of claim 20, wherein removing in step d) is removing equal portion aseptically so as to preclude contamination of the enriched single-unit production lot samples.

Support for the amendments if found in the original specification at page 6, ll. 5-11, where removing aliquots of enrichment medium to for a composite sample is generally discussed, and in exemplary preferred embodiments, removal of equal portions, aseptically, of enrichment medium is explicitly discussed. No new matter has been added.

Third, the Examiner has objected to the phrase "wherein, where" in claim 1e) and claim 8, in view of alleged lack of clarity. Applicant has amended claims 1e) to recite "wherein when" in place of "wherein where", and has further amended claim 8 by deleting the word "where" to obviate these objections.

Fourth, the Examiner has objected to the phrase "more sensitive protocol" in claim 1e) and claim 8 in view of alleged lack of clarity. Applicant respectfully traverses these objections because it is clear from the claim language and specification that the recited "more sensitive protocol" is not intended, as urged by the Examiner, to "help in obtaining a negative result", but

rather is intended, as appreciated in the art, to provide a greater degree of confidence that an obtained negative result is truly negative, and not simply an apparent negative based on an insufficiently sensitive assay being employed. Obviously, one would not need a more sensitive test where a sample already tested positive with a less sensitive lest. The more sensitive can thus be used to provide greater confidence that a sample testing negative is truly negative.

Fifth, the Examiner has objected to claim 2, in view of recitation of non-elected species. Applicant respectfully traverses this objection, based on the fact that claim 2 recites a proper Markush group of species, and Applicant is therefore entitled to examination of the other species upon a determination of allowable subject matter with respect the "single-unit product lot" species (as recited in claim 3) is found allowable. Applicant has nonetheless withdrawn claim 2, until such time as "single-unit product lot" is determined to be allowable in the context of claim 1.

Sixth, the Examiner has objected to the phrase "segment of production" in claim 13, in view of alleged lack of clarity. Applicant has amended claim 13 to recite "and a ~~segment of~~ production assemblage" to obviate this objection.

Support for the amendments is found in the originally filed specification (e.g., under definitions), including the original claims (e.g., original claims 1 and 20). No new matter has been added.

Applicant, therefore, respectfully requests withdrawal of the Examiner's objections to the claims, based on Applicant's responsive claim amendments and supportive arguments.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-20, under 35 U.S.C. § 112, second paragraph, for

alleged indefiniteness.

First, the Examiner alleges that there is no antecedent basis for recitation of "sample" in claims 1c, 1d, 1e, 20c, 20d, and 20e. Applicant respectfully traverses this rejection, because there is proper and explicit antecedent basis for such recitation of "sample", in view of the recitation of "combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot ***samples***" in claims 1b and 20b (emphasis added).

Second, the Examiner alleges that there is no antecedent basis in claim 3 for recitation of "portions" in claim 4. Applicant respectfully traverses this rejection, because there is clear and explicit antecedent basis in claim 1, from which claim 3 depends, for recitation of "portions" in claim 4. It is clear from the specification and claim language that a lot comprises a plurality of specimens, and that "collecting a plurality of portions" in 1a) may be collecting a plurality of portions from a single specimen, or a plurality of specimens, where, as recited in claim 4, the portions are synonymous with specimens.

Third, the Examiner alleges that there is no antecedent basis in claim 1 for recitation of "microbial agent or organism" in claim 7. Applicant has responsively amended claims 1, 6 and 20 to recite "microbial agent or organism" in place of "agent or organism" to obviate this rejection.

Fourth, the Examiner alleges that there is no antecedent basis in claim 1 for recitation of "microbial agent or organism" in claims 8 or 9. As stated above, Applicant has responsively amended claims 1 and 6 (and 20) to recite "microbial agent or organism" in place of "agent or organism" to obviate this rejection.

Fifth, the Examiner alleges that claims 14 and 16 are indefinite in view of recitation of a broad limitation, followed by a narrow limitation falling within the broad range. Applicant has

responsively amended claims 14 and 15 by deleting the respective narrow limitation(s) falling within the respective broad range.

Sixth, the Examiner alleges that there is no antecedent basis in claim 1 for recitation of "Application of remedial measures that are specific to one or more individual test lots that test positive" because claim 1 is limited to "a method to sample, test and validate." Applicant respectfully traverses this rejection because the phrase "a method to sample, test and validate" is in the preamble and does not, therefore, limit the claim as urged by the Examiner. Furthermore, the limitations of claim 15 are actually within the scope of claim 1, even where, for the sake of argument the claim were to be construed to be limited to "a method to sample, test and validate" as urged by the Examiner, because remediation as recited in claim 15 is an optional part of the validation process of claim 1. Applicant, in response to the Examiner's comments, has nonetheless amended claim 15 to further recite "application of remedial measures to said positive test lots, and validating by further testing of a portion of the respective remediated test lots and obtaining a negative test result ~~that are specific to one or more individual test lots that test positive~~." That is, remediation is an optional step of the validation process of claim 1.

Seventh, the Examiner alleges that claims 14 and 16-18 are indefinite in view of recitation of "about." Applicant has deleted the word "about" from these claims to obviate the rejection.

Rejections under 35 U.S.C. § 102

Renter et al:

The Examiner has rejected claims 1, 11-12 and 16-19, under 35 U.S.C. § 102, as allegedly being anticipated by Renter et al (*Applied and Environmental Microbiology*, 69:542-547, 2003).

Specifically, the Examiner construes the presently claimed subject matter as follows: Claims recite method of sampling, testing and validating test lots, wherein single-unit production lots are sampled, the sampled samples pooled, and then enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents, wherein if upon completion of analysis the target microorganisms are not recovered or found in the test lots, the test lots are considered validated, wherein if, however, test lots reveal the presence of microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. a plurality of samples, and wherein a plurality of samples are collected and pooled and analyzed, and wherein, in certain aspects, between 5 to 100 samples are collected from each test lot.

As an initial matter, Applicant respectfully points out that, based on the Examiner's summary of the presently claimed subject matter, the Examiner has not appreciated or recognized several fundamental aspects of the presently claimed subject matter, because in Applicant's method, not only are enriched "*test lot samples*" and "*modular composite samples*" used (and these are not used in Renter as will be discussed below), but if a modular composite sample reveals the presence of microorganism(s), the test is NOT, as construed by the Examiner, "repeated," on the modular composite sample, but rather on the respective individual enriched test lot samples.

The Examiner additionally states, with respect to claims 1, 11-12 and 16-19, that Renter et al., teach a method to evaluate diversity and persistence of *Escherichia coli* O157:H7 in 9,122 cattle fecal samples, 40,883 water samples and 521 wildlife samples obtained from range cattle environment (citing page 542, Abstract, ll. 12-14). The Examiner states that the samples were

enriched, incubated and confirmed using latex agglutination, PCR, and culture techniques "on *composite* samples" (citing Abstract, ll. 14-22). The Examiner (citing page 546, col. 2, ll. 28-33) additionally states that the presence of *Escherichia coli* O157:H7 was evaluated and confirmed form multiple contiguous cattle, water and wildlife source sample lots, and more than one sample from different parallel sample lots were evaluated. With respect to claims 16-19, the Examiner states "that the number of samples analyzed and *Escherichia coli* O157:H7 isolates obtained from sample lots and *composite sampling* of samples encompass the range of 5 to 100 separately collected samples, thus representing a plurality of samples from a plurality of test lots." Finally, the Examiner states the cattle lot or water sample represents a "single unit product" and thereby concludes that Renter teaches the instant claimed subject matter, because it teaches the same strategy, components and steps as instantly claimed.

Applicant has italicized the word "*composite*" in the above recital of the Examiner's comments, because, as discussed in detail below, there is no teaching or suggestion of *composite* sampling in Renter et al).

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the fact that the Examiner has fundamentally misconstrued the limited teachings of Renter et al. In fact, Renter does not teach or suggest all the elements of the presently claimed subject matter, because Renter does teach or suggest, either combining samples to provide a "test lot sample" (as recited in present claim 1b) prior to enrichment, or the use of a "modular composite sample" (as recited in present claim 1d).

Significantly, the present Applicant (Dr. Mansour Samadpour) is the senior author of the

asserted Renter reference, and Applicant attests that Renter does not in fact teach or suggest, either combining samples to provide a "test lot sample" (as recited in present claim 1b) prior to enrichment, or the use of a "modular composite sample" (as recited in presentclaim 1d).

Specifically, Applicant respectfully contends that the Examiner's conclusions regarding the teachings of Renter et al., are unsupportable, because Renter's teachings do not provide for the distinguishing aspects of the present invention. Specifically, in assessing the diversity, frequency and persistence of *E. coli* O157 in range cattle environment, Renter took a large number of samples, and tested them individually (see page 543 under Material and Methods where all fecal and water samples were collected individually, and individually processed and analyzed). Contrary to the Examiner's urging, there was in fact no combining of individual samples to form either a "test lot sample" as presently recited in claim 1(b), and no combining of enriched test lot samples to provide for a "modular composite sample" as recited in claim 1(d)) for the presence of *E. coli* O157. That is, in Renters work, individual fecal or environmental samples were *individually* collected, each was *individually* enriched and each sample was tested *individually* for the presence of the target organism. If the individual samples were positive, Renter *individually* worked up a maximum of three *individually* isolated (not pooled) *E. coli* O157 colonies from the positive samples, and *individually* characterized the isolates by PFGE (see page 543, col. 1, last full paragraph and carry-over paragraph to col. 3). At no point is there any sample pooling.

Applicants respectfully further point out that there is no support whatsoever for the Examiner's conclusion that Renter teaches *composite* samples in the Examiner's own respective citations (citing page 542, Abstract, ll. 12-14; citing Abstract, ll. 14-22; citing page 546, col. 2, ll.28-33). The Examiner has misconstrued the limited teachings of Renter, which do not

encompass pooling of samples to form a test lot sample, followed by enrichment and combining of enriched test sample aliquots to form a modular composite sample. Additionally, as discussed above, the Examiner has not appreciated or recognized several fundamental aspects of the presently claimed subject matter, because in Applicant's method, not only are enriched "*test lot samples*" and "*modular composite samples*" used, but if a modular composite sample reveals the presence of microorganism(s), the test is NOT "repeated," on the modular composite sample (as erroneously construed by the Examiner), but rather on the respective individual enriched test lot samples.

Applicant's claimed subject matter:

Applicant respectfully directs the Examiner's attention to EXHIBIT A, prepared by Applicant and attached hereto, which diagrammatically depicts and compares an exemplary embodiment of Applicant's inventive method (upper portion of EXHIBIT A), with the methods of Renter (and of Samadpour et al., discussed below) (lower portion of EXHIBIT A). In going from left to right, the upper portion of EXHIBIT A illustrates an exemplary preferred embodiment of Applicant's invention as applied to lot testing of food products such as beef trim, in which a plurality of portions (e.g.. 60 independent portions; or a higher or a lower number of portions can be used to increase or decrease the confidence in the results) are collected from each test lot, and are placed into a single bag (or other suitable test containers) to provide a respective set of test lot samples (see the vertical dashed line, labeled "a), b)" between the test lots and the test lot samples, which corresponds to steps a) and b) of claim 1). Each test lot sample is then enriched individually (see the vertical dashed line, labeled "c)" between the test lot samples and the enriched test lot samples, which corresponds to step d) of claim 1). A portion (e.g., equal volume

portions) of medium is removed from each of the five (the numbers can be lower or higher) enriched test lot samples and placed together into a single wet modular composite sample (e.g., test tube) (see the vertical dashed line, labeled "d)" between the enriched test lot samples and the Modular composite sample, which corresponds to step d) of claim 1). The wet composite is then tested (see the vertical dashed line, labeled "e)" between the Modular composite sample and the final testing step, which corresponds to step e) of claim 1). The diagram further depicts an optional incubation/enrichment step between the Modular Composite Sample and the Enriched Modular Composite Sample. If a negative test result form microbial agents or organisms is obtained, all of the test lot members of the composite are deemed to be negative for the pathogen of interest. On the other hand, if a positive result is obtained on the Modular Composite Sample, samples from each of the individual enriched test lot samples that were used to prepare to the wet Modular Composite Sample are individually tested, e.g., using the same test protocol or an alternate protocol with at least the same level of sensitivity.

By contrast, and referring to the lower portion of EXHIBIT A, the methods of Renter (and of Samadpour et al., discussed below) simply involve incubation of individual collected samples (not combined samples corresponding to Applicant's test lot samples) to obtain an Enriched Individual Sample, and then removing portions from each of the Enriched Individual Samples for direct individual testing (no preparation, or testing of a Modular Composite Sample as in Applicants method).

Again, the presently claimed subject matter does not recite analysis of a number of individual samples as *individual* test units as does Renter and Samadpour et al. Rather, in Applicant's method, each test lot sample is itself composed of a plurality of portions (e.g., 60

portions in a preferred embodiment) from each of a plurality of test lots, the resulting test lot sample is then enriched, and aliquots or portions from each of a plurality of enriched test lot samples are then pooled (e.g., by removing an equal volume portion of each enriched test lot sample) to provide a modular composite sample, such that a modular composite sample comprise a plurality of enriched test lot sample aliquots, each of which comprises of a plurality of test lot portions. Applicant's invention is, therefore, not taught or suggested by Renter (nor be Samadpour, alone or in combination with Renter).

In summary, Renter neither teaches pooling of samples to provide a combined test sample, nor combining portions of enriched combined test sample to provide a wet modular composite sample. Therefore, Renter does not, and in fact could not, teach that if a modular composite sample reveals the presence of microorganism(s), the test is repeated on the respective individual enriched test lot samples.

Applicant, therefore, respectfully requests withdrawal of the Examiner's anticipation rejection, based on assertion of Renter et al.

Samadpour et al:

The Examiner has additionally rejected claims 1-10, 13-16 and 20, under 35 U.S.C. § 102, as allegedly being anticipated by Samadpour (*J. Enviro. Health.* 2002, 64:10, 16-20).

The Examiner states that Samadpour et al. teach a method to establish an *Escherichia coli* O157:H7 outbreak in recreational water samples and landscape samples surrounding a lake, comprising collecting 80 water and lake sediment samples, and 28 additional animal feces samples (citing page 17, col. 1, ll.16-26). The Examiner states (citing page 17, col. 1, line 47 to col. 2, line

35) that the samples were enriched, concentrated by filtration, re-incubated, and subsequently plated and probed for virulence factor, thus evaluating and confirming the presence of *Escherichia coli* O157:H7 by two different methods through assaying pools (not true) of enriched samples from a plurality of environmental sources. The Examiner states that negative samples ere evaluated for target virulence factor (citing Table 1, col. 8, ll. 12-14 and Figure 1), and that after the lake was closed sampling continued at weekly intervals (citing page 19, col. 2, line 53 to col. 3, line 35). The Examiner concludes that Samadpour teaches sampling of 108 samples, subsequent incubation followed by organism concentration, re-incubation and evaluation for *Escherichia coli* O157:H7 through PCR and direct plating, where *negative* samples were re-evaluated. The Examiner additionally states that Samadour additionally teaches preventative measures for positive environmental samples, because the lake was closed until consecutive samples tested positive, and further states that water samples represent "single unit product." Based on this, the Examiner concludes that Samadpour et al., anticipate the presently claimed subject matter.

Applicant's traversal:

As an initial matter, Applicant respectfully points out that it is irrelevant that Samadpour et al., collected a plurality of samples from a plurality of environmental locations. What is relevant is how Samadpour (and Renter as discussed above) handled, enriched and tested this plurality of samples—and the teachings of Samadpour and Renter are distinguished from the instantly claimed subject matter precisely because Samadpour and Renter collected and handled each sample individually, incubated and enriched each sample individually, and tested each of their plurality of

samples individually. Moreover, as discussed below in relation to the Examiner's alleged obviousness rejection, the purposes and goals of Samadpour et al., and Renter et al., were fundamentally different that those of the present subject matter, and thus it is not surprising that the methods are fundamentally distinguishable.

Applicant, therefore, respectfully traverses the rejection, based on the fact that the Examiner has fundamentally misconstrued the limited teachings of Samadpour et al,. Samadpour does not teach or even suggest all the elements of the presently claimed subject matter, because Samadpour does teach or suggest, either combining samples to provide a "test lot sample" (as recited in claim 1b) prior to enrichment, or the use of a "modular composite sample" (as recited in claim 1d).

Significantly, the present Applicant (Dr. Mansour Samadpour) is the primary author of the asserted Samadpour reference, and Applicant attests that Samadpour et al., do not in fact teach or suggest, either combining samples to provide a "test lot sample" (as recited in claim 1b) prior to enrichment, or the use of a "modular composite sample" (as recited in claim 1d).

Applicant respectfully contends that the Examiner's conclusions regarding the teachings of Samadpour et al., are unsupportable, because Samadpour's teachings do not provide for the distinguishing aspects of the present invention. Specifically, the samples were in fact not pooled in Samadpour et al., and the Examiner's cited text (citing page 17, col. 1, ll.16-26; citing page 17, col. 1, line 47 to col. 2, line 35; citing Table 1, col. 8, ll. 12-14 and Figure 1; and citing page 19, col. 2, line 53 to col. 3, line 35) does not support such a conclusion.

In Samadpour et al., like Renter et al., discussed above, a number of environmental and animal samples were *individually* collected (see page 17, under materials and methods), each

sample was *individually* enriched, and was *individually* tested for the presence of the target organism.

In summary, Applicant contends that Samadpour neither teaches pooling of samples to provide a combined test lot sample, nor combining portions of enriched combined test lot samples to provide a modular composite sample. Therefore, Samadpour does not, and in fact could not, teach that if a modular composite sample reveals the presence of microorganism(s), the test is repeated on the respective individual enriched test lot samples. By contrast, and as discussed above in detail with reference to Applicant's EXHIBIT A, the current invention, for example in preferred embodiments, is applied to lot testing of food products such as beef trim, in which a plurality (e.g.. 60 independent portions; or a higher or a lower number of portions can be used to increase or decrease the confidence in the results) are collected from each test lot, and are placed into a single bag (or other suitable test containers) to provide a test lot sample, each test lot sample is enriched individually, and then a wet modular composite sample comprising a portion of five (e.g., in the preferred embodiment, the numbers can be lower or higher) enriched test lot samples is produced by removing an equal volume of each enriched test lot and placing them together into a single wet composite test tube (the modular composite sample). The wet composite is then tested, and if a negative result is obtained all of the test lot members of the composite are deemed to be negative for the pathogen of interest. If a positive result is obtained on the composite sample, each of the individual members of the wet composite is tested, by testing individual broth samples from each enriched test lot samples, e.g., using the same test protocol or an alternate protocol with at least the same level of sensitivity. Again, the presently claimed subject matter does not recite analysis of a number of individual samples as *individual* test units. Rather, each

test lot sample is itself composed of a plurality of portions (60 portions in the preferred embodiment) from each of a plurality of test lots, the resulting test lot sample is then enriched, and aliquots from each of a plurality of enriched test lot samples are then pooled (by removing an equal portion of each enriched test lot sample) to provide a modular composite sample, such that a modular composite sample comprise a plurality of enriched test lot sample aliquots, each of which comprises of a plurality of test lot portions. Applicant's invention is, therefore not taught or suggested by Samadpour et al.

Applicant, therefore, respectfully requests withdrawal of the Examiner's anticipation rejection, based on assertion of Samadpour et al.

Rejections under 35 U.S.C. § 103

Samadpour et al., in view of Renter et al:

The Examiner has rejected claims 1-20, under 35 U.S.C. § 103, as allegedly being obvious in view of Samadpour et al., (*supra*) in view of Renter (*supra*).

Specifically, the Examiner states that while Samadpour, as construed by the Examiner, does not exhaustively elaborate on each and every element of the steps of sample collection, sample analysis (including details of each step during validation of analyzed samples), Renter nonetheless not only teaches sample collection, validation and analysis of a plurality of samples, but elaborates on each of the component steps for the validation of test samples. The Examiner further states that there would have been motivation to combine the two asserted references to obtain a method to sample, test and validate samples in a single point product lot, because both Samadpour and Renter teach a method to sample, test and validate a plurality of samples obtained

from a plurality of single point test lots, and Renter additionally elaborates on the validation steps of the process and tests a larger population of single point product lots than Samadpour et al. The Examiner concludes, based on this, that it would have been *prima facie* obvious to combine the teachings of Samadpour and Renter to arrive at Applicant's claimed subject matter, because Renter remedies the deficiency of elaborated validated steps lacking in the teachings of Samadpour et al.

Applicant respectfully traverses the Examiner's obviousness rejection, because no *prima facie* case of obviousness is supportable, based on the teachings of Samadpour, alone or in combination with Renter.

APPLICABLE LAW. Under KSR v. Teleflex, application of the TSM test is valid provided that such application does not require an overly rigid or explicit application of the asserted prior art. Accordingly, as already stated in the record, and in keeping with KSR, to establish a *prima facie* case of obviousness there must be: (i) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art (POSITA), to modify the reference or to combine reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and knowledge generally available to POSITA, and not based on Applicant's disclosure (*In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); and see MPEP §§ 2143-2143.03). Therefore, to support a conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of

reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Moreover, there can be no reasonable expectation of success where the art, alone or in combination, *teaches away* from the invention.

Analysis:

The limitations of Renter et al., and Samadpour et al., have been discussed in detail herein above, and have been distinguished from the presently claimed subject matter with reference to the exemplary EXHIBIT A. The present Applicant (Mansour Samadpour) is the senior and primary author of the asserted Renter and Samadpour references, respectively, and points out that neither Samadpour nor Renter, alone or in combination, teach or suggest, either combining samples to provide a "test lot sample" (as recited in claim 1b) prior to enrichment, or the use of a "modular composite sample" (as recited in claim 1d).

The limited teachings of Renter have been misconstrued, and do not encompass pooling of samples to form a test lot sample, followed by enrichment and combining of enriched test lot sample aliquots to form a Modular Composite Sample. Moreover, the Examiner has not recognized or appreciated several fundamental aspects of the presently claimed subject matter, because in Applicant's method, not only are enriched "*test lot samples*" and "*modular composite samples*" used, but if a modular composite sample reveals the presence of microorganism(s), the test is not "repeated," on the modular composite sample (as construed in the Examiner's summay of Applicant's claimed subject matter), but rather on the respective individual enriched test lot samples.

Neither Renter nor Samadpour, alone or in combination, teach or suggest, directly or indirectly, pooling of samples to provide a combined *test lot sample*, nor combining portions of

enriched combined test lot samples to provide a *modular composite sample*. Therefore, Renter and Samadpour, alone or in combination, do not, and in fact could not, teach that if a modular composite sample reveals the presence of microorganism(s), the test is repeated on the respective individual enriched test lot samples.

By contrast, the current invention is as discussed above in detail in relation to the Examiner's alleged anticipation by Renter and Samadpour (see also the exemplary embodiment of EXHIBIT A).

Moreover, both Renter and Samadpour actually ***teach away*** from the present invention because they teach, exclusively, procurement, enrichment and analysis of individual samples because they were concerned with gaining information on the diversity, frequency and persistence of *Escherichia coli* O157:H7 strains in individual isolates within an environmental range, and much of this information would have been lost if the samples were combined into test lot samples (as in the instant sense), and further into modular composite samples (as in the instant sense). By contrast, the goal of the present invention is not to track diversity and/or frequency of one strain relative to another in a geographical range, but rather to provide rapid, cost effective methods for validating the absence of *Escherichia coli* O157:H7 strains, and thereby avoiding waste by teaching identification of positive, contaminated sub lots, so as avoid having to throw out an entire combined lot that may comprise, for example, only a single contaminated sub lot. Applicant's modular compositing method, as claimed herein, addresses these needs for the first time, and not only speeds up analysis, but eliminates waste thereby increasing overall efficiency, particularly in those validation embodiments comprises remediation of positive testing test lot samples.

Applicant respectfully contends, therefore, that no *prima facie* case of obviousness is

supportable in view of any asserted references of record, alone or in combination, because **(a)** there is no suggestion or motivation embodied in the asserted art alone or in combination, even in view of knowledge generally available to one of ordinary skill in the art, to arrive at Applicant's invention, and **(b)** even if there were, there is no reasonable expectation of success based thereon where the references fundamentally *teach away* from the present invention, and **(c)** the references do not, in fact, teach all the claim limitations, and further teach elements (such as individual sample enrichment and testing) that would preclude provision of the presently claimed subject matter.

Applicant, therefore, respectfully requests withdrawal of the Examiner's rejection of claims 1-20, under 35 U.S.C. § 103(a), as being obvious over Samadpour et al., in view of Renter et al.

New Claims

Applicant has added new *dependent* claims 21-34, which are entirely supported by the originally filed Specification as follows:

Dependent claims 21 and 22 are discussed herein above, and are drawn to preferred embodiments of claims 1 and 20, respectively, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched test lot samples, or the enriched single-unit production lot samples, respectively. Support for the amendments is as discussed herein above.

Dependent claims 23 and 24 are drawn to embodiments wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria*, *Salmonella* and *Escherichia coli* or from the group consisting of *Listeria* spp., *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms. Support for the claims is found in the originally filed specification, e.g., at page 1, line 26, page 10, line 10, page 20, line 6 and page 21, line27 among others.

Dependent claim 25 is drawn to embodiments wherein the target microbial agent or organism comprises a spoilage organism. Support for the claim is found in the originally filed specification at page 2, line 22.

Dependent claim 26 is drawn to embodiments wherein removing portions of each enriched test lot sample comprises removing equal volume portions of each enriched test lot sample. Support for the claim is found in the originally filed specification at page 6.lines 9-10, for example.

Dependent claim 27 is drawn to embodiments wherein testing of the modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method. Support for the claim is found in the originally filed specification at page 12, line 24 through page 13, line 11, for example.

Dependent claim 28 is drawn to embodiments wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography. Support for the claim is found in the originally filed specification at page 12, line 24 through page 13, line 11, for example.

Dependent claim 29 is drawn to embodiments wherein the test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively. Support for the claim is found in the originally filed specification at page 1 under Field of invention, and Example II beginning on page 19.

Dependent claim 30 is drawn to embodiments wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively. Support for the claim is found in the originally filed specification at page 8, line 21, page 11, line 10, page 17, line 26, page 18, line 23, for example.

Dependent claim 31 is drawn to embodiments wherein the meat is that of beef, pork, sheep or bison. Support for the claim is found in the originally filed specification at page 1 under Field of invention, for example.

Dependent claim 32 is drawn to embodiments wherein the test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively. Support for the claim is found in the originally filed specification at page 1 under Field of invention, for example.

Dependent claim 33 is drawn to embodiments wherein the test lots are production lots of a ready-to-eat product. Support for the claim is found in the originally filed specification at page 19, line 27, for example.

Dependent claim 34 is drawn to embodiments wherein the medium comprises a selective agent that will inhibit a competing undesired microbial agent or organisms. Support for the claim is found in the originally filed specification at page 9, ll. 24-25.

No new matter has been added. All the claims are dependent claims fully supported by the originally filed specification, and should all be allowable, upon allowance of the respective independent claims as amended herein.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Response and Amendment, and allowance of all claims as presented and amended herein. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

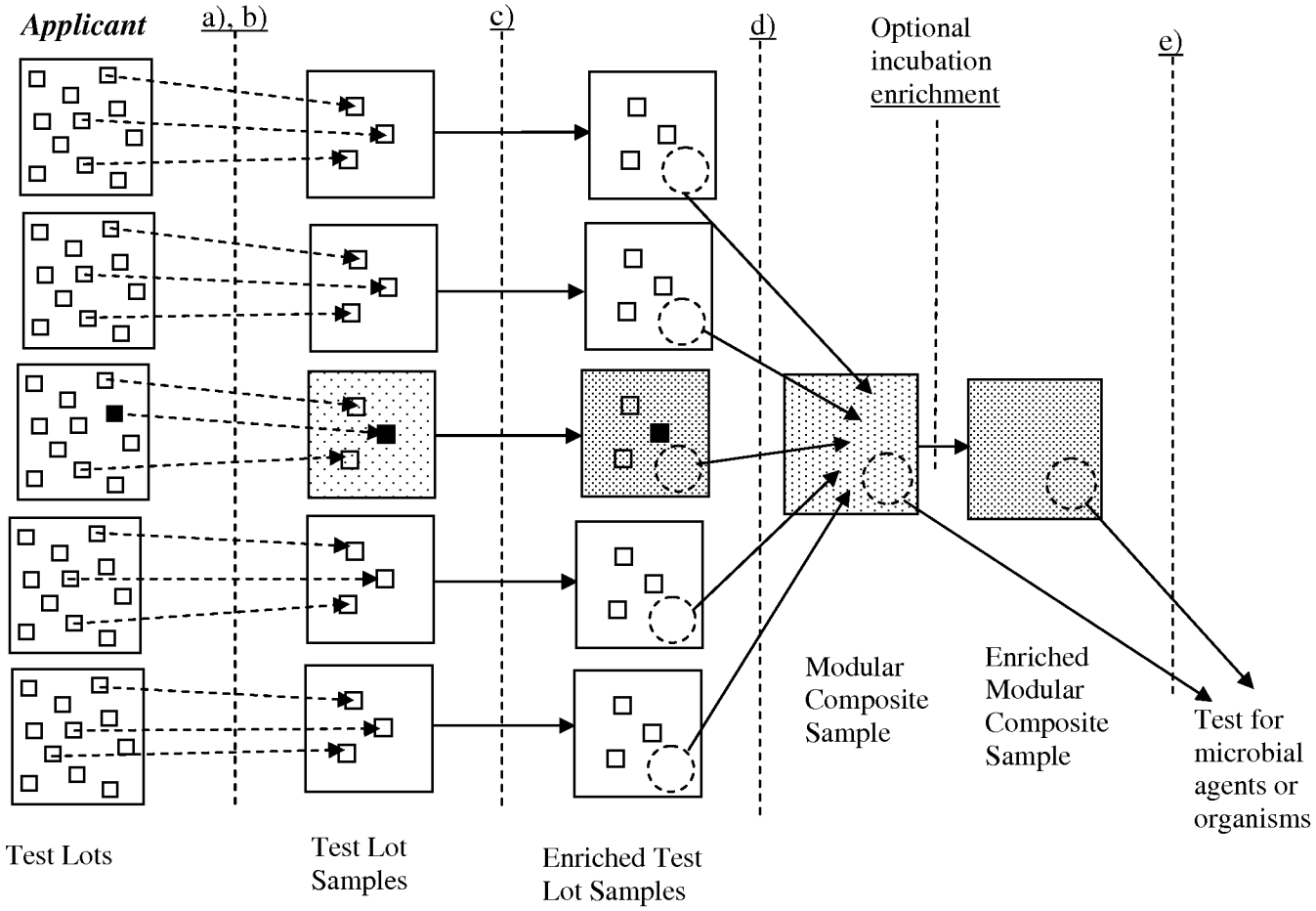
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

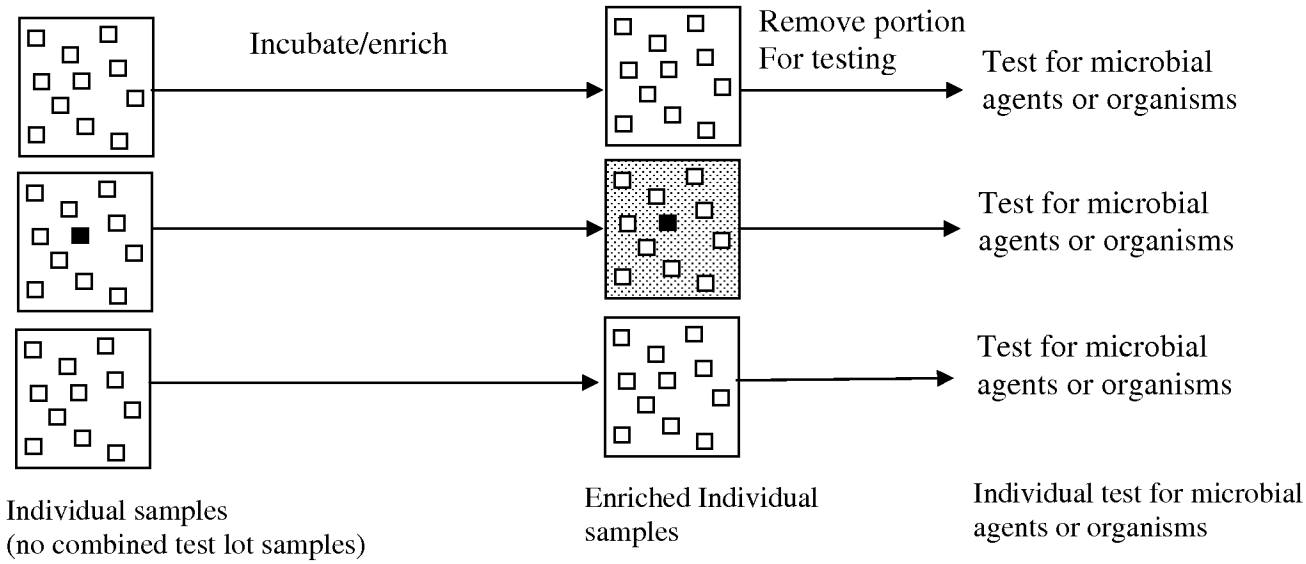
/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Applicant
Registration No. 47,309

EXHIBIT A

Current Applicant



Renter et al., Samadpour et al.



Electronic Patent Application Fee Transmittal

Application Number:	11199871
Filing Date:	08-Aug-2005
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Filer:	Barry Davison/Shelley Salisbury
Attorney Docket Number:	66090-29

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	60	60

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**60**

Electronic Acknowledgement Receipt

EFS ID:	3213756
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Shelley Salisbury
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	25-APR-2008
Filing Date:	08-AUG-2005
Time Stamp:	19:32:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$60
RAM confirmation Number	3578
Deposit Account	040258
Authorized User	

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Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		66090_29_RESPONSE_TO_FINAL_OFFICE_ACTION.pdf	304281 eec543ced0f6de1b8a60dc9e1fc2d26dfbf278c6	yes	33

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment After Final	1	1
Specification	2	9
Applicant Arguments/Remarks Made in an Amendment	10	33

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8215 e7ae113894a6ca4775517cca683b43858ae5380c	no	2

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/199,871	08/08/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 04/25/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 34	Minus	** 20	= 14	X $25 =	350	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	350	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KATRINA S. TURNER/

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11199871
Filing Date	2005-08-08
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

	1	"Enumeration of Escherichia coli and the Coliform Bacteria," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4.html on June 17, 2008	☐
	2	"Diarrheagenic Escherichia coli," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4A, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4a.html on June 17, 2008	☐

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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2008-06-19
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Electronic Patent Application Fee Transmittal

Application Number:	11199871
Filing Date:	08-Aug-2005
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Filer:	Barry Davison/Judy Redmayne
Attorney Docket Number:	66090-29

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
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Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	3483463
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	19-JUN-2008
Filing Date:	08-AUG-2005
Time Stamp:	12:07:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
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1	Information Disclosure Statement (IDS) Filed	66090_29_IDS.pdf	574010 ae6af2c78bc0e1c89275c482c3c2259091a94009	no	4
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Information:					
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2	NPL Documents	66090_29_ref4.PDF	4577551 2ddcc19ff41bea250b5dc8c9708f444f96d473ca	no	15
Warnings:					
Information:					
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Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	8236 61c31cd4385d6db31023483030bd2b162533f6d8	no	2
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PTO/SB/08a (03-08)
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Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

	1	ROHLF et al., "Optimizing Composite Sampling Protocols," Environmental Science and Technology, 1996, pp. 2899-2905, Volume 30	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2008-07-16
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11199871
Filing Date:	08-Aug-2005
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Filer:	Barry Davison/Judy Redmayne
Attorney Docket Number:	66090-29

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	3624308
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	16-JUL-2008
Filing Date:	08-AUG-2005
Time Stamp:	12:24:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	7304
Deposit Account	040258
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)

1	Information Disclosure Statement (IDS) Filed	66090_29_IDS.pdf	573915 e6527d278ea098daa6e56a3cd3e90a967317670b	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	NPL Documents	66090_29_REF.PDF	624620 6ed688c0aa7bf780e96406de647327f5fc9ec90a	no	7
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	8236 426d9a6fac66ef02235cf915c0c019cea542434a	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1206771	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 07/29/2008

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Dr. Kailash C. Srivastava, Examiner*. (3)_____.

(2) *Dr. Barry L. Davison, Applicant's Representative*. (4)_____.

Date of Interview: *16 July 2008*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: *NONe*.

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *That of Record*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657
Examiner's signature, if required

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's Representative informed the Examiner that a response to pending Office Action was filed04/25/2008 and enquired if the Examiner had a chance to review said response. Examiner advised the Representative that Examiner had a chance to review the subject response, discussed with Examiner's Supervisor and Examiner was preparing another rejection in the instant application in view of additional prior art found in the latest search. The representative's then asked the Examiner, why did the Examiner not find said prior art before writing the first rejection? Examiner responded because (I) the claims have been amended in response to the first Office Action, and (ii) Office procedure requires that a case be searched for prior art before issuing every Office Action. The representative did not seem to be satisfied with Examiner's response and commented, "this is because you did not understand the invention".

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	August 8, 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	August 6, 2008

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF THE INTERVIEW

This is a REPLY to an Office Communication (Interview Summary) dated July 29, 2008, in the above identified application.

REMARKS

Subsequent to a telephonic interview with Examiner Srivastava on July 16, 2008, Applicant's Representative received an Office Communication, dated July 29, 2008, summarizing the interview, and requesting a Reply in the form of a "STATEMENT OF SUBSTANCE OF THE INTERVIEW." Since a reply to the last Office Action in the case has already been filed, Applicant's Representative hereby files the following Statement of Substance of The Interview.

STATEMENT OF SUBSTANCE OF THE INTERVIEW

The Examiner stated in the Office Communication (Interview Summary) that:

"Applicant's Representative informed the Examiner that a response to pending Office Action was filed 04/25/2008 and enquired if the Examiner had a chance to review said response. Examiner advised the Representative that Examiner had a chance to review the subject response, discussed with Examiner's Supervisor and Examiner was preparing another rejection in the instant application in view of additional prior art found in latest search. The representative's then asked the Examiner, why did the Examiner not find said prior art before writing the first rejection? Examiner responded because (1) the claims have been amended in response to the first Office Action, and (ii) Office procedure requires that a case be searched for prior art before issuing every Office Action. The representative did not seem to be satisfied with Examiner's response and commented, "this is because you did not understand the invention."

Applicant's Representative does not disagree with the Examiner's Summary, other than to point out that the Examiner's Summary is incomplete with respect to the nature of the dissatisfaction expressed by Applicant's Representative. Specifically, as explained by Applicant's Representative during the interview, based on the insufficient nature of the alleged prior art that

was asserted in the first Office Action, Applicant's Representative felt that at the time of conducting the initial search and issuing of the first Office Action the Examiner had not adequately understood the invention as claimed, but should have been able to, based on the original specification. Moreover, during the telephonic interview the Examiner stated that he was grateful for Applicant's last Response to the first Office Action, because it "helped him understand the invention" and that a further search had been done. Applicant's Representative then stated and requested that if there was to be another rejection in the next Office Action, it should not be a *final* action because the Patent Office should have been able to perform an adequate initial search based on the specification prior to issuing the first Office Action and, thus, Applicant would be effectively prejudiced if the next action was a final action. While Applicant's Representative understands that the Office may perform additional searches, for example when claims are amended, Applicant's Representative believes that the additional search in question was not necessitated by Applicant's minor amendments in responding to the first Office Action, but rather by the fact that the invention as originally claimed was not properly searched in the first place. Applicant's Representative, therefore, is actually grateful that the Office has performed an additional search, but would hope that the next Office Action not be a final rejection.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests entry of the present Statement of Substance of The Interview. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this

application.

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Applicant
Registration No. 47,309

Electronic Acknowledgement Receipt

EFS ID:	3737868
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	06-AUG-2008
Filing Date:	08-AUG-2005
Time Stamp:	14:46:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	66090_29_STM.pdf	24368 fe7899888dc9c9466e6a74696f61250c4bf32e68	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	24368

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 08/20/2008

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/19 & 07/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Response and amendment filed 25 April 2008 to Office Action mailed 10 January 2008 are acknowledged and entered. The text of those sections of Title 35 U.S. Code (i.e., U.S.C.) not included in this action can be found in a prior Office action.

Withdrawals of Objection/Rejection based on Applicant's Amendments

2. In view of remarks and amendments filed 29 April 2008 the following objection/ rejections in the Office Action mailed 29 January 2008 are hereby withdrawn.

- Objection to specification regarding application priority data;
- Objection to Claims 1c and 11 regarding the recitation, "enriched";
- Objection to Claim 1d) because of redundant phrase "removing aseptically";
- Objection to phrase, "wherein, where" at Claim 1e), Lines 2-3 and at Claim 8, Line 1;
- Objection to phrase, "more sensitive protocol" at Claim 1e), Lines 4-5 and Claim 8, Line 3 for non-clarity;
- Objection to phrase, "segment of production" at Claim 13, Line 2;

- Indefiniteness rejection to Claims 1-20 under 35 U.S.C. §112, 2nd paragraph;

- Anticipatory rejection to Claims 11-12 and 16-19 under 35 U.S.C. §102(b) by Renter et al (Diversity, Frequency and Persistence of *Escherichia coli* O157:H7 Strains from Range Cattle Environment. Applied and Environmental Microbiology, Volume 69, Pages 542-547, 2003);

- Anticipatory rejection to Claims 1-10, 13-16 and 20 are rejected under 35 U.S.C. §102(b) by Samadpour et al. (Laboratory Investigation of an E. coli O157:H7 Outbreak Associated with Swimming in Battle Ground Lake, Vancouver, Washington. Journal of Environmental Health, Volume 64, Pages 16-20, 2002)); and

- Obviousness rejection to Claims 1-20 under 35 U.S.C. §103 (a) over combined teachings from Samadpour et al. (Journal of Environmental Health, Volume 64, Pages 16-20, 2002) in view of Renter et al (Applied and Environmental Microbiology, Volume 69, Pages 542-547, 2003).

Claims Status

3. According to the list of Claims presented with response and amendment filed 25 April 2008 cited *supra,* following is the current status of Claims:

- Claim 2 has currently been withdrawn.
- Claims 21-34 have been added.
- Claims 1, 6, 8, 13-18 have been amended.
- Claims 1-34 are pending. .
- Claims 1 and 3-34 are examined on merits.

Information Disclosure Statement

4. Applicant's Information Disclosure Statements (i.e., IDSs) filed 19 June and 16 July 2008 are acknowledged, have been made of record, considered and duly initialed and signed copies of appropriate USPTO form are enclosed with the instant Office Action.

Information Request under 37 C.F.R. §1.105

5. **Applicant and the assignee of this application are required under 37 C.F.R. §1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. This requirement is subject to the provisions of 37 C.F.R. §§1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 C.F.R. §1.136(a).**

Claims 21-25 and 28-34 as currently presented list microorganisms, quality assurance/control practices applied in food, meat processing and pharmaceutical industries and types of food products that have been known both to the pertinent industries and the consumers. Furthermore, said materials have been made of record within either the background information to the instantly claimed invention (See, e.g., Page 1, Line 26), or in the context of USDA or other Inspection services requirements and practices (See, e.g., Page 1, Line 26; Page 17, Line 26 to Page 18, Line 1; Page 19, Line 26 to Page 20, Line 2; Page 20, Line 6 or Page 20, Lines 10-16).

The information as currently presented in the specification for the instant application does not transparently clarify, whether applicant performed those inspection methods for above-cited microorganisms and food items/ lines of products; or is only referring to the microorganisms, methods and protocols applied/required by the regulatory authorities (e.g., Food sanitation inspection Services) that food services/sanitation inspectors perform at the site of food production/processing sites. For

determining the patentability of Claims (i.e., Claims 21-25 and 28-34) listed *supra,* distinguishing information between the claimed subject matter and subject matter presented as background information is solicited.

Objection to Specification

6. The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. §112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: e.g., "a an" at Page 13, line 1; "validated 1, 9280,000 lbs" at Page 18, Line 23. The examiner suggests that the applicant should carefully revise the specification including the abstract to make the specification clearly comprehensible. The applicant is warned to be careful to not add any new matter while revising the application for corrections to eliminate inexact or verbose terms.

Examiner has not checked the entire specification to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Said errors, if any detected should be corrected in response to this Office Action.

Claim Rejections – 35 U.S.C. §112

7. Following are new rejections to Claims 1-20 and newly presented Claims 21-34 based on amendment filed 25 April 2008.

8. Claims 1, 3-34 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- At each of Claims 1c), 1e) and 20 c) and 20 e), line 2, the limitation, "microbial agent or organism" lacks sufficient antecedent basis because the preamble in each of Claims 1 and 20 does not specify that said methods are to test for microbial contamination of said "test lots"; or said sampling testing and validating test lots is related to microbial contamination. Please also note that in each of Claims 1 and 20, the preamble breathes life and meaning in to said claims.

- At Claims 1c), line 4 and 20 c), line 5, the limitation, "enriched for the target microbial agent or organism" lacks sufficient antecedent basis because the preamble in each of Claims 1 and 20 does not specify that said methods are to test for microbial contamination of said "test lots"; or said sampling testing and validating test lots is related to microbial contamination. Please also note that in each of Claims 1 and 20, the preamble breathes life and meaning in to said claims.

- The recitation, "undesired" in Claim 34 is similar to the word "preferably" and therefore, renders Claims confusing, unclear, vague and therefore indefinite. It is not clear whose desire is being referred to, and further, how can one determine with clarity and accuracy when the "desire" is to be exercised and what are the metes and bounds of the term, "desired". Metes and bounds for the recitation, "desired' should be defined.

All other claims depend directly from the rejected claims (e.g., Claim 14) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

9. Following are new rejections to Claims 1, 3-20 and newly presented Claims 21-27, 29-31 and 33-34 based on amendment filed 25 April 2008.

10. The following is a quotation of 35 U.S.C. §102 which forms the basis for all obviousness rejections set forth in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

11. Claims 1, 3-9, 13-26, 29, 31 and 34 are rejected under 35 U.S.C. § 102(a) as anticipated by Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology, Volume 95, Pages1016–1025).

Claims 1, 3-9, 13-26, 29-31 and 34 recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test

microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis, the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. The test lots comprise one or more meat specimens from among beef, pork, sheep or bison.

Regarding Claims 1, 3-9, 13-26, 29-31 and 34 Davies et al., teach, twenty pig herds were chosen at random from the regular suppliers of two abattoirs. From the 20 herds a total of 430 serum, 421 juice, 421 carcass swab, 418 caecal and 369 pooled pen fecal samples were collected for testing. The aim was to attempt to test and compare samples from at least 20 pigs from each farm and 20 (or maximum available number if <20) pooled feces samples from finishing pens (Page 1017, Lines 46-53). Davies et al teach, samples of meat juice, serum, caecal contents, carcase swabs and pooled feces from pig pens were taken from 20 commercial pig finishing farms and comparisons were made between the results of *Salmonella* culture, individual ELISA tests on serum and meat juice and pooled samples of serum and meat juice. *Salmonella* was isolated from samples from 19 of 20 farms. Serum mean optical density (O.D.) from pools of five, 10 or 20 sera showed a significant correlation with the *Salmonella* status of farm pen faeces. Results of the study teach, Pooled serum or meat juice samples could be used as a cheaper substitute for serological screening of farms for *Salmonella* than individual samples (Abstract, Lines 5-16). Davies et al., additionally teach, Culturing for *Salmonella* as follows. The pooled pen feces samples, the carcass swabs and the individual pig caecum contents were added to buffered peptone water (i.e., BPW) and incubated at 37 °C for 16–20 h. After incubation 0.2 ml of the BPW was dispensed into the depth of a semisolid Diassalm plate and all inoculated plates were incubated at 41.5 °C for 24 h. On day 3 the Diassalm culture plates were examined for suspect *Salmonella* growth and where the growth was seen a sample of the agar was inoculated onto a Rambach agar plate, which was incubated at 37 °C for 18–24 h. After incubation, the Rambach plates were examined for suspicious *Salmonella* colonies, which were confirmed serologically and biochemically. A subculture of each confirmed *Salmonella* isolate was subsequently serotyped and if applicable phage typed. (Page 1018, Lines 7-24). Thus, Davies et al., expressly and intrinsically teach analysis for *Salmonella* from meat samples, wherein meat is pork and further clearly detail that said analysis was carried out on pooled and the individual sample analyses and further the suspicious sample were further analyzed and finally all *Salmonella* isolates were confirmed through sero- and if applicable through phage typing. Despite the fact that Davies et al., are silent about

poultry, said Claims are also inherently anticipated, because poultry is also a type of meat. Thus, Davies et al., teach each and every element claimed in Claims 1, 3-9, 13-26, 29-31 and 34.

Therefore Claims 1, 3-9, 13-26, 29-31 and 34 are deemed to be anticipated by Davies et al.

12. Claims 1, 3-9, 13-26, 29-30 and 34 are rejected under 35 U.S.C. § 102(b) as anticipated by Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

Claims 1, 3-9, 13-26, 29-30 and 34 recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis, the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. The test lots comprise one or more poultry specimens.

Regarding Claims 1, 3-9, 13-26, 29-30 and 34 Skov et al., compared four sampling methods for determining *Salmonella* in broiler flocks. At least one method comprised hand-picked 300 fecal samples consisting of samples of pools of 5 samples (i.e., 60 pools), The collected pooled and individual samples were analyzed for *Salmonella* according to art-known standard bacteriological procedures for *Salmonella* isolation Abstract, Lines -20; Page 696, Column 1, Lines 2-10; Column 2, Lines 27-50; Page 697, Column 1, Lines 2-5). Thus, Skov et al. teach methods to determine *Salmonella* from broiler flocks (i.e., chicken) through pooled sampling and analysis of individual samples. Also note the number of pools is 60 which is within the range of pooled samples claimed instantly.

Therefore Claims 1, 3-9, 13-26, 29-31 and 34 are deemed to be anticipated by Davies et al.

13. Following are new rejections to Claims 1, 3-20 and newly presented Claims 21-27, 29-31 and 33-34 based on amendment filed 25 April 2008.

Claim Rejections - 35 U.S.C. § 103

14. Claims 1, 3-27, 29-31 and 33-34 are rejected under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., (1998. Sample pooling to expedite bioanalysis and pharmacokinetic research,

Journal of Pharmaceutical and Biomedical Analysis 16 (1998) 837–846) in view of Budiman et al. (2004. Localization of jointless-2 gene in the centromeric region of tomato chromosome 12 based on high resolution genetic and physical mapping, Theoretical and Applied Genetics, Volume 108, Pages: 190–196) and further in view of Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology 2003, Volume 95, Pages1016–1025) and Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

Claims recite a method of sampling, testing and validating test lots, wherein single-unit product lots are sampled. The sampled samples are pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis, the target microorganisms are not recovered or found in the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganism(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. In said method the plurality of samples collected from each test lot ranges between 5 to 100. The test lots comprise one or more meat or poultry specimens from among beef, pork, sheep or bison or sea food product specimen or a ready-to-eat product.

Regarding Claims 1, 3-31 and 34, Kuo et al., teach the concept of a method of individual sampling and pooled sampling to obtain pharmacokinetic data on the effect of drugs. Kuo et al., also detail the entire method and provide experimental evidence of the proposed concept. Briefly, post dosing with a given dose of each of the compounds in separate animals, serial blood samples were collected from the jugular vein into heparinized tubes from each rat at 0.5, 1, 2, 4, and 8 h postdose to characterize plasma profiles of the prelead compounds. Plasma was separated from the red blood cells by centrifugation and stored at −20°C until analysis. Sample pooling at each point is illustrated S follows: 100 µl of one of the three 30 min samples for each prelead (C1–C6) drug were randomly mixed with 100 µl of one of the three 30 min samples for each of the other five compounds. Each pool had a total of 600 µl. Similarly, other pooled samples were formed so that there were 15 pooled plasma samples—three pooled samples (n=3) for each of the five sampling time points. In preparing standards and quality control samples, 100 µl of standard or quality control sample was mixed with 500 µl of blank plasma so as to keep the same overall plasma volume between standards, quality control samples, and unknowns. Post-extraction of said samples, the samples were analyzed through high performance liquid chromatography (i.e., HPLC, Page 839, Column 1, Line 32 to Column 2, Line 45). From the data obtained (Page 844,

Column 2, Line 33 to 40; Page 845, Column 1, Line 2-35), Kuo et al., drew the conclusion that several drugs could be identified as the highest to lowest effective, nevertheless for establishing a protocol for pharmacokinetics, a pooled sample analysis followed by one on one sample analysis will best serve the purpose (Page 845, Column 1, Line 35 to Column 2, Line 8). Kuo et al., however, are silent about a DNA-based method, analysis of test lots comprising meat or poultry product, wherein said samples are from beef, bison, pork or sheep and enrichment for a bacterial organism, wherein said bacterial organism is one among: *Escherichia coli*, *Listeria* or *Salmonella*.

Budiman et al. also teach a general concept of individual as well as pooled sampling and further teach a DNA-based analysis because Budiman et al., teach gene mapping in he centromeric region of tomato chromosome 12 Page 190, Title, Lines 1-3). Budiman et al., teach extracting tomato genomic DNA from pooled and individual samples for restriction fragment length polymorphism analysis (Page 191, Column 1, Lines 42-50). Please note that Budiman et al. teach analysis of Pooled as well as individual samples for a DNA-based method for tomato gene mapping.

Davies et al., teach, twenty pig herds were chosen at random from the regular suppliers of two abattoirs. From the 20 herds a total of 430 serum, 421 juice, 421 carcass swab, 418 caecal and 369 pooled pen fecal samples were collected for testing. The aim was to attempt to test and compare samples from at least 20 pigs from each farm and 20 (or maximum available number if <20) pooled feces samples from finishing pens (Page 1017, Lines 46-53). Davies et al teach, samples of meat juice, serum, caecal contents, carcass swabs and pooled feces from pig pens were taken from 20 commercial pig finishing farms and comparisons were made between the results of *Salmonella* culture, individual ELISA tests on serum and meat juice and pooled samples of serum and meat juice. *Salmonella* was isolated from samples from 19 of 20 farms. Serum mean optical density (O.D.) from pools of five, 10 or 20 sera showed a significant correlation with the *Salmonella* status of farm pen feces. Results of the study teach, Pooled serum or meat juice samples could be used as a cheaper substitute for serological screening of farms for *Salmonella* than individual samples (Abstract, Lines 5-16). Davies et al., additionally teach, Culturing for *Salmonella* as follows. The pooled pen feces samples, the carcass swabs and the individual pig caecum contents were added to buffered peptone water (i.e., BPW) and incubated at 37 °C for 16–20 h. After incubation 0.2 ml of the BPW was dispensed into the depth of a semisolid Diassalm plate and all inoculated plates were incubated at 41.5 °C for 24 h. On day 3 the Diassalm culture plates were examined for suspect *Salmonella* growth and where the growth was seen a sample of the agar was inoculated onto a Rambach agar plate, which was incubated at 37 °C for 18–24 h. After incubation, the Rambach plates

were examined for suspicious *Salmonella* colonies, which were confirmed serologically and biochemically. A subculture of each confirmed *Salmonella* isolate was subsequently serotyped and if applicable phage typed. (Page 1018, Lines 7-24). Thus, Davies et al., expressly and intrinsically teach analysis for *Salmonella* from meat samples, wherein meat is pork and further clearly detail that said analysis was carried out on pooled and the individual sample analyses and further the suspicious sample were further analyzed and finally all *Salmonella* isolates were confirmed through sero- and if applicable through phage typing.

Skov et al., compared four sampling methods for determining *Salmonella* in broiler flocks. At least one method comprised hand-picked 300 fecal samples consisting of samples of pools of 5 samples (i.e., 60 pools), The collected pooled and individual samples were analyzed for *Salmonella* according to art-known standard bacteriological procedures for *Salmonella* isolation Abstract, Lines -20; Page 696, Column 1, Lines 2-10; Column 2, Lines 27-50; Page 697, Column 1, Lines 2-5). Thus, Skov et al. teach methods to determine *Salmonella* from broiler flocks (i.e., chicken) through pooled sampling and analysis of individual samples. Also note the number of pools is 60 which is within the range of pooled samples claimed instantly.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Kuo et al. with those from Budiman et al., Davies et al., and from Skov et al., to obtain a method to sample, test and validate samples in a single point product lot a plurality of samples are collected and pooled and analyzed. In said method the plurality of samples collected from each test lot ranges between 5 to 100. The test lots comprise one or more meat or poultry specimens from among beef, pork, sheep or bison or sea food product specimen or a ready-to-eat product ; because Budiman et al. aside from teaching and reiterating the basic concept of multiple samples and pooled samples teach a DNA-based method for the claimed method of analysis, Davies et al., and Skov et al., teach analysis of pooled samples followed by individual samples to isolate and detect *Salmonella* in pork and broiler (i.e., poultry) samples. Additionally, each one of Budiman et al. Davies et al., and Skov et al., elaborate analysis of individual samples and Davies et al., further elaborate on the further analysis of positive samples.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Kuo et al., with those from Budiman et al., Davies et al., and from Skov et al., to obtain a method to sample, test and validate a plurality of samples in a single point product lot and pooled sample lots, wherein said methods teach detection of *Salmonella* in meat and

poultry samples. because; Budiman et al. remedy the deficiency of DNA- based methods, Davies e al., remedy the deficiency of *Salmonella* detecting methods and Skov remedies the deficiency of *Salmonella* detection in samples from poultry. Certain components, or concentration thereof or culture media for *Salmonella* isolation of the above discussed prior art references are not the same as claimed instantly. However, the adjustment of particular conventional working conditions (e.g., the quantities of each one of components in a particulate composition, types of equifunctional components (e.g., culture media or components thereof) and equifunctional conditions with certain guidance) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter which is well within the purview of the skilled artisan. E.g., the range of pooled samples in Skov et al., within the range of that instantly claimed.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

15. No Claims are allowed for the aforementioned reasons. However, Claims 28 and 32 should be rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Upon resolution of the above-stated issues under 35 U.S.C. §112, further searching and/or consideration may be required.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for

unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

16 August 2008
/David M. Naff/
Primary Examiner, Art Unit 1657

Notice of References Cited	Application/Control No. 11/199,871	Applicant(s)/Patent Under Reexamination SAMADPOUR, MANSOUR	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Kuo et al., 1998. Sample pooling to expedite bioanalysis and pharmacokinetic research, Journal of Pharmaceutical and Biomedical Analysis Volume 16, Pages 837–846.
	V	Budiman et al. 2004. Localization of jointless-2 gene in the centromeric region of tomato chromosome 12 based on high resolution genetic and physical mapping, Theoretical and Applied Genetics, Volume 108, Pages 190-196. Published on Line 20 Septgember 2003.
	W	Davies et al., 2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for Salmonella, Journal of Applied Microbiology, Volume 95, Pages1016–1025.
	X	Skov et al., 1999. Evaluation of Sampling Methods for the detection of Salmonella in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700.

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	MANSOUR SAMADPOUR
	Examiner	Art Unit
	Srivastava, Dr. Kailash C	1657

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/28/2007	01/05/2008	08/18/2008						
	1	÷	✓	✓						
	2	÷	✓	N						
	3	÷	✓	✓						
	4	÷	✓	✓						
	5	÷	✓	✓						
	6	÷	✓	✓						
	7	÷	✓	✓						
	8	÷	✓	✓						
	9	÷	✓	✓						
	10	÷	✓	✓						
	11	÷	✓	✓						
	12	÷	✓	✓						
	13	÷	✓	✓						
	14	÷	✓	✓						
	15	÷	✓	✓						
	16	÷	✓	✓						
	17	÷	✓	✓						
	18	÷	✓	✓						
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	26			✓						
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	28			✓						
	29			✓						
	30			✓						
	31			✓						
	32			✓						
	33			✓						
	34			✓						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	SAMADPOUR, MANSOUR
	Examiner	Art Unit
	Srivastava, Dr. Kailash C	1657

SEARCHED

Class	Subclass	Date	Examiner
Performed Partial Search in WEST	Performed Partial Search in WEST	01/02/2008	KCS
NONE	NONE	01/02/2008	KCS
Updated Partial Search in WEST	Updated Partial Search in WEST	08/17/2008	KCS
NONE	NONE	KCS	KCS

SEARCH NOTES

Search Notes	Date	Examiner
WEST SEARCH: DWPI, EPAB, JPAB, PGPB. USOC, USPT	01/02/2008	KCS
STN SEARCH: AGRICOLA, BIOSIS, EMBASE, HCAPLUS, MEDLINE,	10/31/2007	KCS
Search Strategy:E.coli, Samadpour, test sample, validat, test lot, quality assurance method, sampl, scrren, portion, Salmonella, Screen, coliform, count, control, protocol, safety, food	01/02/2008	kcs
Perform Inventor Search	01/02/2008	KCS
Verified priority data and information (e.g., 60/599,473 filed 08/06/2004).	01/02/2008	KCS
Google Search: EPA method for water analysis, Method 1622, Giardia, Cryptosporidium	01/03/3008	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.	08/17/2008	KCS
Updated Google Search	08/17/2008	KCS
Updated Inventor Search	8/17/2008	KCS
Consulted strategy to upgrade search and strategy for Office Action with Dr. Weber	7/8/2008	KCS

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

WEST Search History for Application 11199871

Creation Date: 2008081719:00

Query	DB	Op.	Plur.	Thes.	Date
quality control	USPT	ADJ			08-17-2008
composite sample	USPT	ADJ			08-17-2008
(mixed lot) (sample)	USPT	ADJ			08-17-2008
Intermediate sample	USPT	ADJ			08-17-2008
ladder sampl$5	USPT	ADJ			08-17-2008
(mixed lot) same (sample)	USPT	ADJ			08-17-2008
(quality control) same ((mixed lot) same (sample))	USPT	ADJ			08-17-2008
(composite sample) same (Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) same (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
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(Intermediate sample) same (quality control same composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(quality control) same (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control) same (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (ladder sampl$5)	USPT	ADJ			08-17-2008
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(quality control and Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(stepwise)same (sample analysis)	USPT	ADJ			08-17-2008
	USPT	ADJ			08-17-2008

(quality control) and ((stepwise)same (sample analysis))					
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(composite sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
discriminat$8 same sampl$5	USPT	ADJ			08-17-2008
((stepwise)same (sample analysis)) same (discriminat$8 same sampl$5)	USPT	ADJ			08-17-2008
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(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			08-17-2008
(quality control) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
((mixed lot) same (sample)) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Pharmaceutical sample)	USPT	ADJ			08-17-2008
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(ladder sampl$5) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008

(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample and (Pharmaceutical sample)) and @pd > 20080817	USPT	ADJ			08-17-2008
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((stepwise) same (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
quality control	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
composite sample	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) (sample)	EPAB,	ADJ	YES		08-17-2008

	JPAB, DWPI				
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((Pharmaceutical sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((stepwise)and (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008

PTO/SB/08a (03-08)
Approved for use through 06/30/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11199871
Filing Date	2005-08-08
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

/K.S./	[1]	"Enumeration of Escherichia coli and the Coliform Bacteria," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4.html on June 17, 2008	☐
/K.S./	[2]	"Diarrheagenic Escherichia coli," U.S. Food and Drug Administration, Bacteriological Analytical Manual Online, Chapter 4A, retrieved from http://www.cfsan.fda.gov/~ebam/bam-4a.html on June 17, 2008	☐

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EXAMINER SIGNATURE

Examiner Signature	/Kailash Srivastava/	Date Considered	06/30/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (03-08)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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(Not for submission under 37 CFR 1.99)

Application Number	11199871
Filing Date	2005-08-08
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

/K.S./	1	ROHLF et al., "Optimizing Composite Sampling Protocols," Environmental Science and Technology, 1996, pp. 2899-2905, Volume 30	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Kailash Srivastava/	Date Considered	08/01/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	08 August 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	24 October 2008

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 C.F.R. § 1.111

Sir:

This is a RESPONSE AND AMENDMENT in reply to a non-final Office Action dated 20 August 2008 in the above identified application.

Kindly amend the above-identified patent application as follows:

Application No.:	11/199,871
Attorney Docket No.:	66090-29
First Applicant's Name:	Mansour Samadpour
Application Filing Date:	08 August 2005
Office Action Dated:	20 August 2008
Date of Response:	24 October 2008
Examiner:	Kailash C. Srivastava

IN THE SPECIFICATION:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the specification:

Kindly ***substitute*** the following paragraph for the corresponding paragraph at page 9, lines 12 to 18:

--The term "enrichment" as used herein refers to incubating a test lot sample (*e.g.*, single-unit production lot sample) under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform throughout the enriched test lot sample (*e.g.*, single-unit production lot sample~~sampl~~). Preferably, enrichment comprises addition of an amount of an enrichment medium or buffer to a sample, and incubating the sample at a favorable temperature for a period of time sufficient to allow the organism to grow and multiply.--

Kindly ***substitute*** the following paragraph for the corresponding paragraph beginning at page 12, line 22 and extending to page 13, line 2:

--If a *positive* result is obtained from a MWCS, the enrichment buffers from each of the individual single unit production lot samples are then separately (individually) tested, using the same test protocol, or any other appropriate tests. Alternately, an augmented protocol that uses a concentration step for the target organism, such as immunomagnetic bead separation, affinity chromatography, etc., followed by [[a]] an appropriate detection method is used to test the enriched individual test lot samples (*e.g.*, the individual single-unit production lot samples).--

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Kindly ***substitute*** the following paragraph for the corresponding paragraph at page 16, lines 14-26:

--In particular aspects, the methods further comprise, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive. In particular aspects, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions. Alternatively~~Alternativley~~, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.--

Kindly ***substitute*** the following paragraph for the corresponding paragraph at page 16, lines 14-26:

--The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 19,280,000~~1,9280,000~~ lbs of beef trim into commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in

sensitivity relative to the MWCS testing) provides *substantial* additional assurance of the safety of the food products.--

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IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected portions corresponding to each of the test lots to provide a corresponding set of test lot samples, wherein each test lot sample is attributed to a particular corresponding test lot;

c) incubating the set of test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all test lot samples are validated, and wherein when such testing is positive, individual test lots may nonetheless yet be validated by further testing of a portion of the respective enriched test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. (Withdrawn) The method of claim 1, wherein the test lot is selected from the group consisting of an environmental lot comprising one or more operationally-linked environmental specimens, pharmaceutical lot comprising one or more operationally-linked pharmaceutical

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specimens, single-unit product lot comprising one or more operationally-linked product specimens, and combinations thereof.

3. (Original) The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

5. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. (Previously presented) The method of claim 1, wherein incubating each test lot sample in c) comprises incubating with enrichment medium suitable to enrich for the target microbial agent or organism, to the sample, and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched sample and combining the removed portions to provide a modular composite sample.

7. (Original) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. (Previously presented) The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual test lots are further tested, such further testing comprises use of the more sensitive protocol.

9. (Original) The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from the enriched test lot samples of c) and testing the additional

modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. (Original) The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched test lot sample along with any enriched test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. (Original) The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the enriched test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. (Previously presented) The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.

14. (Previously presented) The method of claim 1, wherein the number of test lots is from 3 to 10.

15. (Previously presented) The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual test lots are positive, application of remedial measures to said positive test lots, and validating by further testing of a portion of the respective remediated test lots and obtaining a negative test result.

16. (Previously presented) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions from 5 to 100.

17. (Previously presented) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot 30 to 60 portions.

18. (Previously presented) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting 30 portions from each test lot.

19. (Original) The method of claim 1, wherein, in a) separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.

20. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein the assemblage can be sampled by taking portions thereof;

b) combining the collected product portions corresponding to each of the single-unit production lots to provide a corresponding set of single-unit production lot samples, wherein each single-unit production lot sample is attributed to a particular corresponding single-unit production lot;

c) incubating the set of single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more samples, to provide a set of single-unit production lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all single-unit production lot

samples are validated, and wherein when such testing is positive, individual single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

21. (Previously presented) The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched test lot samples.

22. (Previously presented) The method of claim 20, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched single-unit production lot samples.

23. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria*, *Salmonella* and *Escherichia coli*.

24. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

25. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

26. (Previously presented) The method of claim 1, wherein removing portions of each enriched test lot sample comprises removing equal volume portions of each enriched test lot sample.

27. (Previously presented) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.

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28. (Previously presented) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Previously presented) The method of claim 1, wherein the test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. (Previously presented) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Previously presented) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (Previously presented) The method of claim 1, wherein the test lots are production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

33. (Previously presented) The method of claim 1, wherein the test lots are production lots of a ready-to-eat product.

34. (Currently amended) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target~~undesired~~ microbial agent or organisms.

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REMARKS

Claims 1-34 are pending, and stand rejected.

Applicant thanks the Examiner for withdrawal of the prior claim objections and of the prior rejections under 35 U.S.C. § 112, second paragraph, under 35 U.S.C. § 102 and under 35 U.S.C. § 103 in response to Applicant's arguments and prior claim amendments.

Applicant thanks the Examiner for entering and considering Applicant's Information Disclosure Statements filed on 19 June 2008 and 16 July 2008.

Information Request under 37 C.F.R. § 1.105

The Examiner has made an Information Request under 35 U.S.C. § 1.105 to facilitate determining the patentability of claims 21-25 and 28-34. Specifically, the Examiner states that these claims as currently presented list microorganisms, quality assurance/control practices applied in food, meat processing and pharmaceutical industries and types of food products that have been known both to pertinent industries and the consumers, and that said materials have been made of record within either the background information (citing page 1, line 26) or in the context of USDA or other Inspection services requirements and practices (citing page 1, line 26; page 17, line 26, to page 18, line 1; page 19, line 26, to page 20, line 2; page 20, line 6, or page 20, lines 10-16). The Examiner further alleges that the information as presented does not transparently clarify, whether applicant performed those inspection method for above-cited microorganisms and food items/lines of products; or is only referring to the microorganisms, methods and protocols applied/required by the regulatory authorities (e.g., Food sanitation inspection Services) that food services/sanitation inspectors perform at the site of food production/processing sites.

Applicant responsively further clarifies the record as follows:

The statement at the bottom of page 1 referring to "United States Department of

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Agriculture, Food Safety and Inspection Service (FSIS) directives and guidelines, many food producers in the United States have adopted sampling plans that involve testing, for example, of raw beef trims and/or ground beef for *E. coli* O157:H7, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella*" is background information about prior art directives and guidelines that have been adopted in certain industry sectors. These directive and guidelines are distinct from the presently claimed subject matter, which is distinguished from the prior art in the current prosecution record and in this Response and Amendment.

The statement at page 17, line 26, to page 18, line 1, referring to "At present, the standard size 'production lot' for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five *combos*, where each *combo* represents a single production unit and weighs approximately 2,000 pounds" is background information and refers to the fact, as well recognized in the art, that production lot for purposes of trim testing consists of five separate "combos," each combo lot being a single production unit weighing about 2,000 lbs. That is, the prior art teaches that a production lot consists of five separate combo lots, and Applicant is merely restating that aspect of the prior art. This is presented as background information, a point of departure and reference, from which the present invention can be explained and distinguished as already in the prosecution record.

The statement at page 19, line 26, to page 20, line 2, referring to "Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may adapt an 'end product' sampling program as verification that their product is free of the pathogen *Listeria monocytogenes*" is background information and refers to the fact, as well recognized in the art, that an "end product" sampling program may be adopted under the regulations as verification. Again, this is presented as background information, a point of departure and reference, from which the present invention

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can be explained and distinguished as already in the prosecution record.

Likewise, the statement at page 20, line 2, to line 8 "The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (*e.g.*, from 'cleanup to cleanup'), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis" is background information and refers to the fact, as well recognized in the art, that composite samples are formed and enriched to provide more material for testing. Again, this is presented as background information, a point of departure and reference, from which the present invention can be explained and distinguished as already in the prosecution record. Applicant recognizes, as broadly recognized in the art, that certain composite samples are known in the art, but this is not the distinguishing basis of the presently claimed invention, as is clear from Applicant's originally filed and claimed subject matter, as already discussed in the present prosecution record.

The statement at page 20, lines 10 to 16, "Preferably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), a volume of product such as a pallet of packed boxes produced on a particular production line, or a production area in the plant, etc" is background information and refers to the fact, as well recognized in the art, that single unit production lots can take different forms such as all of the product produced on a particular production run, or alternatively a portion of the production run corresponding to a

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certain time period of production during the run, or a corresponding to a volume amount of the production run (e.g., a 2,000 lb combo lot as referred to above). Again, this is presented as background information, a point of departure and reference, from which the present invention can be explained and distinguished as already in the prosecution record.

As explained and taught in Applicant's originally filed specification, Applicant's invention can be applied to essentially any type of prior art production lot, and with respect to essentially any target agent or organism (including all the known prior art target agents and organisms), and represents a fundamental improvement over the above referenced prior art federal regulations for the way production lots are sampled and validated.

Finally, Applicant's Examples II-V were, as of the time of filing of the present application, prophetic examples that extend the teachings of the originally filed specification in the context of ready-to-eat meat an poultry products, nut products (*e.g.*, almond products) and the like, contaminants that enter a production line at a given time point, and then clear, and in the context of environmental monitoring (*e.g.*, with samples of water, wastewater, sludge, soil, surface sponges, surface swabs, condensates, air or liquids). The examples are clearly written in the present tense consistent with their prophetic but supported nature.

Objections to Specification

The Examiner objected the specification. Specifically the Examiner alleges that certain terms are unclear, inexact or verbose, such as: "a an" at page 13, line 1; "validated 1, 9280,000 lbs at page 18, line 32.

Applicant has responsively amended the specification to correct these and other inadvertent typographical errors, as described above to obviate this objection. No new matter has been added.

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Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1 and 3-34, under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicant has made responsive amendments and/or rebuttal arguments, as described herein, to obviate the objections.

The preambles of claims 1 and 20 have been amended to recite "microbial" as suggested by the Examiner.

Claim 34 has been amended by recitation of "non-target" in place of "undesired."

Applicant, therefore, respectfully requests withdrawal of these indefiniteness rejections.

Rejections under 35 U.S.C. § 102

Davies et al.: The Examiner rejected claims 1, 3-9, 13-26, 29-31, and 34, under 35 U.S.C. § 102, as being allegedly anticipated by Davies et al. (Journal of Applied Microbiology 95:1016-1025, 2003).

The Examiner states that "claims 1, 3-9, 13-26, 29-31 and 34 recite a method of sampling, testing and validating test lots, wherein single-unit production lots are sampled. The samples pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis, the target microorganisms are not recovered or founding the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganisms(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. The test lots comprise one or more meat specimens from among beef, pork sheep or bison."

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the fact that the Examiner has fundamentally misconstrued the limited teachings of Davies et al. In fact, Davies does not teach

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or suggest all the elements of the presently claimed subject matter, because Davies does teach or suggest, enrichment of a "test lot sample" (as recited in present claim 1 steps b) and c)) for use in preparing a "modular composite sample" (as recited in present claim 1d). Rather, Davies only teaches simple sample pooling to make a classical composite sample for enrichment and then assaying the enriched sample directly (see Applicant's Exhibit A attached hereto), which, in terms of Applicant's novel scheme, only amounts to preparation and enrichment of a "test lot sample," but in Davies, there is a complete absence of preparing and assaying a modular composite sample as presently claimed (see Applicant's Exhibit B attached hereto) and which allows, in the case of a positive testing modular composite sample, for returning to assay the retained individual enriched test lot samples determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted.

Davies et al:

The teachings of Davies are limited to the use of pooled samples to provide a cheaper Salmonella monitoring program to identify infected finishing pig herds (e.g., see Abstract of Davies; page 1017, col. 1, second full paragraph; Table 4; Figure 2, etc.). Specifically, Davies sampled meat juice, serum, caecal contents, carcass swabs and pooled faeces from pig pens from 20 commercial finishing farms. The aim was to determine whether pooled serum and meat juice could be used to identify finishing pig herds with a high prevalence of infection by *Salmonella*. Specifically, comparisons were made between assay results of: *Salmonella* culture, individual ELISA tests on serum and meat juice; and pooled samples of serum and meat juice. While *Salmonella* was isolated from the samples of 19 of the 20 commercial farms, the ELISA tests failed to show significant correlation with caecal carriage of *Salmonella* or contamination of carcasses. However, mean optical density (O.D.) from pools of sera (from 5, 10 or 20 sera), showed a significant correlation with the *Salmonella* status of farm pen faeces. The conclusion of

Davies is that while there is a generally poor correlation between serological and bacteriological results, pooled serum or meat juice samples can be used as a cheaper substitute for serological screening of farms for Salmonella than individual samples. Davies, therefore, teaches pooling of samples to provide cheaper monitoring, but nothing more.

As stated above, Davies teaches only simple sample pooling to make a classical composite sample for enrichment and then assaying the enriched sample directly. For example, as explained on page 1017 and 1018 (under Laboratory tests), pooled pen faeces samples are added to media and incubated (enriched) prior to assay. Applicants have attached EXHIBITS A and B to facilitate the Examiner's review. Specifically, Davies teaches only classical sample pooling to make a composite sample for enrichment and testing as shown in the diagram of EXHIBIT A. Significantly however, none of the pooled samples of Davies were used, after enrichment to prepare the equivalent of a 'modular composite sample' as presently claimed by Applicants. Applicant directs the Examiner to review EXHIBIT B, which diagrammatically reproduces the method of Applicant's claims.

Specifically, the upper portion of EXHIBIT B illustrates an exemplary preferred embodiment of Applicant's invention as applied to lot testing of food products such as beef trim, in which a plurality of portions (e.g.. 60 independent portions; or a higher or a lower number of portions can be used to increase or decrease the confidence in the results) are collected from each test lot, and are placed into a single bag (or other suitable test containers) to provide a respective set of test lot samples (corresponds to steps a) and b) of claim 1). Each test lot sample is then enriched individually (corresponds to step c) of claim 1). A portion (e.g., equal volume portions) of medium is removed from each of the enriched test lot samples and placed together into a single wet modular composite sample (e.g., test tube) (_corresponds to step d) of claim 1). The wet composite is then tested (corresponds to step e) of claim 1). Not shown in thhe diagram is an

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optional incubation/enrichment step between the Modular Composite Sample and the Enriched Modular Composite Sample. If a negative test result form microbial agents or organisms is obtained with respect to the modular composite sample, all of the test lot members of the composite are deemed to be negative for the pathogen of interest. On the other hand, if a positive result is obtained on the modular composite sample, samples from each of the individual enriched test lot samples (retained) that were used to prepare to the wet modular composite sample are individually tested (e.g., using the same test protocol or an alternate protocol with at least the same level of sensitivity).

Davies **does not** teach suggest or perform, for example steps 3 and 4 of the diagram, which correspond to preparation and testing of a modular composite sample as in Applicant's claim 1, steps d) and e). Likewise in Davies, pooled serum and meat juice samples were tested individually and as pools, but these were not enriched but rather assayed directly by ELISA.

Therefore, while the method of Davies provides, as intended, merely a cheaper way of assaying by making classical pooled samples (composite samples), Davies does not make modular composite samples from enriched pooled samples. Thus, for example in Davies, for the pens of each of 20 commercial pig finishing farms, one pooled sample was made for each specific farm pen, and the samples were separately submitted for analysis (see Davies page 1017, col. 2, first full paragraph). There was, however, no formation of a overall modular composite sample comprising aliquots of the 20 farm-specific pooled pen samples (or enriched farm-specific pooled pen samples). Thus, while Davies practices assay of classic pooled pen samples for efficiency, Davies did not practice or teach the presently claimed methods.

By way of further illustration of the distinctions of the presently claimed methods, application of the present methods to the problem of Davies, for example, would involve enrichment of each of the 20 farm-specific pooled pen samples (and retention of the enrichments),

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followed by formation of an overall modular composite sample comprising aliquots of the 20 enriched farm-specific pooled pen samples, and assay of the modular composite sample (or assay of an enriched modular composite sample)—resulting in a much greater efficiency than provided for by classical methods of Davies, because using Applicant's method one would not have had to initially assay each of the 20 enriched farm-specific pooled pen samples, and would rather have needed to assay them only in the case where the single modular composite sample was determined to be positive for a particular target microorganism.

Applicant respectfully contends, therefore, that the teachings of Davies have been inadvertently but fundamentally misconstrued by the Examiner and respectfully request withdrawal of the Examiner's rejection of claims 1, 3-9, 13-26, 29-31, and 34, under 35 U.S.C. § 102.

Skov et al.: The Examiner rejected claims 1, 3-9, 13-26, 29-31, and 34, under 35 U.S.C. § 102, as being allegedly anticipated by Skov et al. (Journal of Applied Microbiology 95:1016-1025, 2003).

The Examiner states that Skov et al. teach comparing four sampling methods for determining *Salmonella* in boiler flocks. At least one method comprised hand-picked 300 fecal samples consisting of 60 pooled samples, each pooled sample comprising 5 individual samples. The collected pooled and individual samples were analyzed for *Salmonella* according to art-recognized standard bacteriological procedures for *Salmonella* (citing Abstract, lines -20, page 696, column 1, lines 2-10; column 2, lines 27-50; page 697, column 1, lines 2-5). Based on this, the Examiner concludes that Skov teaches methods to determine Salmonella in broiler flocks through pooled sampling and analysis of individual samples, and that the number of pools is 60, which is within that range of pooled samples claimed by Applicant.

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the fact that the Examiner has fundamentally misconstrued the limited teachings of Skov et al. In fact, Skov does not teach or suggest all the elements of the presently claimed subject matter, because Skov does not teach or suggest, enrichment of a "test lot sample" (as recited in present claim 1 steps b) and c)) for use in preparing a "modular composite sample" (as recited in present claim 1d). Rather, Skov only teaches simple sample pooling to make a classical composite sample for enrichment and then assaying the enriched sample directly (see Applicant's Exhibit A attached hereto), which, in terms of Applicant's novel scheme, only amounts to preparation and enrichment of a "test lot sample," but in Skov, there is a complete absence of preparing and assaying a modular composite sample as presently claimed (see Applicant's Exhibit B attached hereto) and which allows, in the case of a positive testing modular composite sample, for returning to assay the retained individual enriched test lot samples determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted.

By way of further illustration of the distinctions of the presently claimed methods, application of the present methods to the problem of Skov, for example, would involve enrichment of each of the 60 individual pooled pen samples (and retention of the enrichments), followed by formation of an overall modular composite sample comprising aliquots of the 60 enriched pooled samples, and assay of the modular composite sample (or assay of an enriched modular composite sample)—resulting in a much greater efficiency than provided for by classical methods of Skov, because using Applicant's method one would not have had to initially assay each of the 60 enriched pooled samples, and would rather have needed to assay them only in the case where the single modular composite sample was determined to be positive for a particular target microorganism.

Again, Applicant invites the Examiner to compare the methods of attached Exhibits A and B, which serve to graphically illustrate prior art methods using mere composite samples, compared to Applicant's claimed modular compositing methods, respectively.

Applicant respectfully contends, therefore, that the teachings of Skov have been inadvertently but fundamentally misconstrued by the Examiner and respectfully request withdrawal of the Examiner's rejection of claims 1, 3-9, 13-26, 29-31 and 34, under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

Kuo et al., in view of Budiman et al., Davies et. al., and Skov et al.:

The Examiner has rejected claims 1-20, under 35 U.S.C. § 103, as allegedly being obvious in view of Kuo et al. (*Journal of Pharmaceutical and Biomedical Analysis* 16:837-846, 1998) in view of Budiman et al. (Theoretical and Applied Genetics, 108:190-196, 2004) and further in view of Davies (*supra*) and Skov (*supra*).

Specifically, the Examiner states that Kuo teaches the concept of a method of individual sampling and pooled sampling to obtain pharmacokinetic data of the effect of drugs. To preclude the possibility of cross reactions occurring between multiple drugs (C1-C6) given to a given animal, a given dose of each drug compound is given to individual animals (three individual animals are used for each drug compound C1-C6), serial blood samples were collected at 0.5, 1, 2, 4, and 8 h postdose from each animal and placed into separate tubes. Plasma was separated from the red cells and stored until analysis. Pooled samples were then made by combining 100 microliter aliquots taken from one of the three 0.5 h samples corresponding to each drug to provide pooled samples of 600 microliters. For each time point, three such pooled samples were prepared. Kuo drew the conclusion that several drugs would be identified as the highest to lowest effective, and that a pooled sample analysis followed by one on one sample analysis will best

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serve the purpose of establishing pharmacokinetics. The Examiner states that while Kuo is silent about a DNA-based method, analysis of test lots comprising meat or poultry product (e.g., beef, bison, pork, sheep) and enrichment for a bacterial organism (e.g., *Escherichia coli*, *Listeria* or *Salmonella*), Budiman et al. nonetheless teach DNA-based analysis of pooled and individual samples, Davies nonetheless teaches pig herds (as discussed herein above in this Response and Amendment), and Skov nonetheless teaches collected individual and pooled samples (as discussed herein above in this Response and Amendment).

The Examiner, based on this, concludes that one of ordinary skill in the art would have been motivated to combine the teachings from Kuo with those from Budiman, Davies, and Skov to obtain a method to sample, test and validate a plurality of samples in a single point product lot an pooled sample lots with respect to *Salmonella* in meat and poultry samples.

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the fact that the Examiner has fundamentally misconstrued the limited teachings of Kuo et al. In fact, Kuo, alone or in combination with the other asserted art, does not teach or suggest all the elements of the presently claimed subject matter, because Kuo does not teach or suggest, enrichment of a "test lot sample" (as recited in present claim 1 steps b) and c)) for use in preparing a "modular composite sample" (as recited in present claim 1d). Budiman, Davies and Skov do not make up for the deficiencies of Kuo, and therefore do not support a *prima facie* case of obviousness in combination with Kuo.

Analysis:

Despite reliance by the Examiner on other references for "enrichment," Kuo still only teaches classical sample pooling (600 microliter pooled sample, comprising one 100 micro liter aliquot from each of six individual serum samples) to make a classical composite sample (and in this case with no enrichment) and then assaying the classical composite sample directly (see

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Applicant's Exhibit A attached hereto), which, in terms of Applicant's novel scheme, actually falls short of preparation of even a "test lot sample" as presently claimed, because a plurality of portions has not been taken from each test lot (in Kuo case, from each animal) to make a pooled sample, and rather the pooled sample of Kuo is a pooled sample of single sample portions taken from individual test lots (animals). However, even if, *arguendo*, the pooled sample of Kuo is construed, as urged by the Examiner to be equivalent to one of Applicant's "test lot samples," Kuo's pooled samples are not "modular composite samples" as presently claimed, and there is a complete absence of preparing and assaying a modular composite sample as presently claimed (see Applicant's Exhibit B attached hereto) and which allows, in the case of a positive testing modular composite sample, for returning to assay the retained enriched test lot samples (retained pool samples) to determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted. While Kuo might be practiced to retain the original individual rat-specific serum samples, thereby providing the ability to assay individual rat samples if desired in addition to assaying of the pooled sample, the pooled samples of Kuo are not "modular composite samples," and the individual samples of rat serum are not "test lot sample" as disclosed and claimed by the present Applicant. Modular composite samples, as disclosed and claimed herein, are pools of pools, and the pools of Kuo are but pools of individual samples, each sample from an individual rat—and even here they are not even true test lot samples as disclosed and claimed by the present Applicant.

By way of further illustration of the distinctions of the presently claimed methods, although the facts and subject matter of Kuo do not provide for enrichment, application of the present methods in the context of the problem of Kuo, for example, might involve forming, for each different administered drug candidate compound, a respective test lot sample, in each case comprising a plurality of samples (e.g., 0.5 h time points) taken from a plurality of animals all

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receiving the same drug (a drug group of animals) to provide a respective set of "test lot samples" (a test lot pool) for each different drug, followed by making a modular composite sample comprising an aliquot from each of the respective drug test lot samples (that is, making a pool of pools) and analyzing of the modular composite sample for a particular characteristic. Where the target characteristic is identified in the modular composite sample, it would be possible to go back and assay each of the respective test lot samples, to determine which drug group or groups was responsible for the desired characteristic. In cases where it is desirable to correlate a target characteristic with action of a particular drug, application of Applicant's method would enable the use of larger animal cohorts while reducing the number of assays required, yet retaining to ability identify the particular drug group(s) giving rise to the characteristic being assayed. However, this is not what Kuo teaches, and rather as stated above Kuo teaches that serial blood samples were collected at 0.5, 1, 2, 4, and 8 h postdose from each animal and placed into separate tubes. Pooled samples were then made by combining 100 microliter aliquots taken from one of the three 0.5 h samples corresponding to each drug to provide pooled samples of 600 microliters. Thus, Kuo teaches classical pooling (composite sample), and does not teach or suggest the instantly claimed subject matter. In fact, not only does Kuo not teach or suggest a true "test lot sample" in the present sense (rather only a pool of single samples each from a different individual), Kuo also does not teach or suggest "modular composite samples" as disclosed and claimed by the present Applicant. Modular composite samples, as disclosed and claimed herein, are pools of pools, and the pools of Kuo are but pools of individual samples, each sample from an individual rat.

Moreover, While Budiman, Davies, and Skov provide teaching in the area of DNA methods, *Salmonella* assays, they do not remedy the above described deficiencies of Kuo with respect to the absence of teachings for modular composite samples. Both Davies and Skov have been discussed and rebutted in detail above with respect to the absence of teachings of modular

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composite samples, and Budiman is relied on by the Examiner only for DNA-based analysis.

Finally, there would have been no motivation to combine Budiman, Davies, and Skov with Kuo because the subject matter of Kuo is not amenable to enrichment.

Applicant, therefore, respectfully requests withdrawal of the Examiner's rejection based on the rebuttal arguments described herein above with respect to Kuo, Davies, Skov, and Budiman.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Response and Amendment, and allowance of all claims as presented and amended herein. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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Respectfully submitted,
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EXHIBIT A

TRADITIONAL COMPOSITING

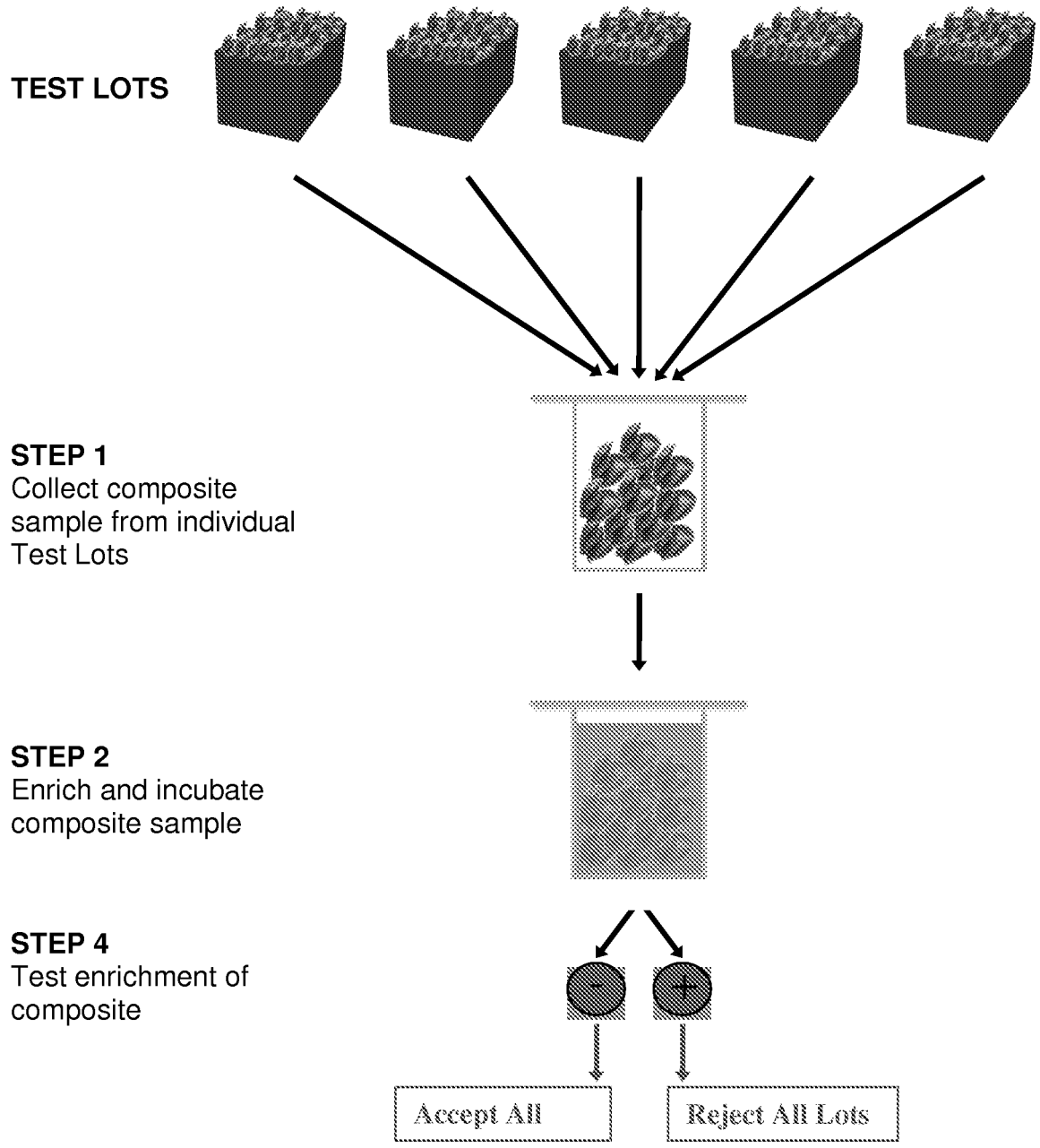


EXHIBIT B

IEH MODULAR WET COMPOSITING

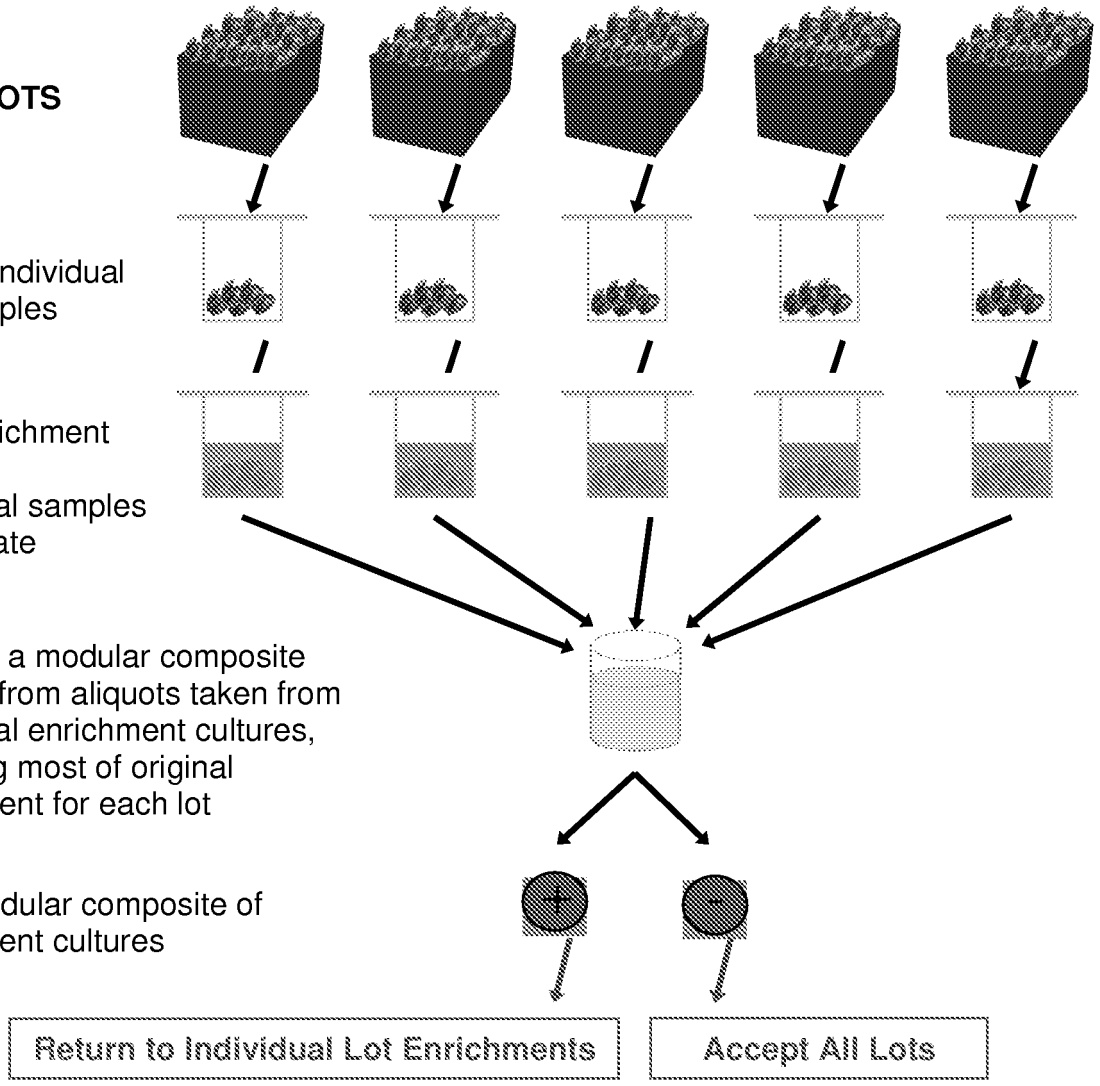
TEST LOTS

STEP 1
Collect individual Lot samples

STEP 2
Add enrichment broth to individual samples & incubate

STEP 3
Prepare a modular composite sample from aliquots taken from individual enrichment cultures, retaining most of original enrichment for each lot

STEP 4
Test modular composite of enrichment cultures



STEP 5
A positive signal in composite is the result of a positive in one or more original individual enrichments. Because individual enrichments have been retained, they can be tested to see which enrichments contributed to the positive result. Those that contributed are rejected while those that did not are accepted.

Electronic Acknowledgement Receipt

EFS ID:	4176504
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	24-OCT-2008
Filing Date:	08-AUG-2005
Time Stamp:	19:25:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		66090_29_AMD.pdf	1563786 315f40d6542f66d50bc7e68bbc3338e4577401d3	yes	27

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	4
	Claims	5	10
	Applicant Arguments/Remarks Made in an Amendment	11	27
Warnings:			
Information:			
	Total Files Size (in bytes):	1563786	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/199,871	08/08/2005	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **10/24/2008**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 34	Minus	** 32	= 2	X $26 =	52	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	52	OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIMBERLY PANNELL/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 12/03/2008

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Dr. Kailash C. Srivastava, Examiner*. (3)_____.

(2) *Mr. Barry L. Davison, Applicant's Representative*. (4)_____.

Date of Interview: *13 November 2008*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: *NONE*.

Claim(s) discussed: *NONE*.

Identification of prior art discussed: *NONE*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Applicant's Representative called around 5 P.M. to inform the Examiner that the Inventor, Dr. Samadpour was visiting Washington D.C. on 11/14/2008 and sought an in-person interview on 11/14/2008 with the Examiner. Examiner informed the Representative that the Examiner would have accommodated Dr. Samadpour's request even at such a short notice, despite Fridays being Examiner's non-working day. However, on 11/14/2008, (i) Examiner has a prior commitment and (ii) Examiner's supervisor whom Examiner would like to be present at this interview is going to be on vacation abroad. Examiner offered the Representative any date after 11/24/2008 and before 12/11/2008 for said interview*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Lisa J. Hobbs/ Primary Examiner, Art Unit 1657	/Dr. Kailash C. Srivastava/ Examiner, Art Unit 1657

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

.

PTO/SB/08a (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11199871
Filing Date	2005-08-08
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

	1	PRICE et al., "Salmonella Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples," Applied Microbiology, 1972, pp. 679-682, Volume 23	☐
	2	SILLIKER et al., "ICMSF methods studies. I. Comparison of analytical schemes for detection of Salmonella in dried foods," Canadian Journal of Microbiology, 1973, pp. 475-479, Volume 19	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Barry L. Davison, Ph.D., J.D./	Date (YYYY-MM-DD)	2008-12-04
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47309

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	4399181
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	04-DEC-2008
Filing Date:	08-AUG-2005
Time Stamp:	17:06:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	66090_29_IDS.pdf	608190 122ddac06601cf4d758c1150dde2dd7587371555	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	NPL Documents	66090_29_REF1.PDF	1000464 59446ca1f48a9b53cd4a222d2ac97b80eca03f13	no	4
Warnings:					
Information:					
3	NPL Documents	66090_29_REF2.PDF	1404574 a90d341a7cc09b29df12bd336a27e945c7214f5f	no	5
Warnings:					
Information:					
			Total Files Size (in bytes):	3013228	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 01/05/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
01/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response and amendment filed 24 October 2008 to the Office Action mailed 20 August 2008 is acknowledged and entered.

Informal Matters

2. Applicant's response filed 24 October 2008 to the Information Request under 37 C.F.R. §1.105 in the Office Action mailed 20 August 2008 is acknowledged and is made of record. In view of said Information, the patentability of the Claims currently under examination will be discussed in the instant Office Action that follows.

3. Applicant's response filed 24 October 2008 is incomplete because applicant has not responded to item 15, "Claims 28 and 32 should be rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims" in the Office Action mailed 20 August 2008. In the interest of expediting the prosecution of instant application, however, the Examiner is writing the Office Action that follows. Applicant must respond to the above stated rejection in response to the instant Office Action.

4. Contrary to Applicant's assertion at Page 11, Line 9, in the Office Action cited *supra*, Claims 1 and 3-34 stand rejected, Claim 2 has been withdrawn from consideration (See Office Action Summary accompanying the Office Action mailed 20 August 2008 items 4a and 6). Please update the record accordingly.

5. Contrary to Applicant's assertion at Page 21, Line 17, in the Office Action cited *supra*, not Claims 1-20; rather Claims 1, 3-27, 29-31 and 33-34 are rejected under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., in view of Budiman et al., and further in view of Davies et al., and Skov et al (See Office Action mailed 20 August 2008, Page 7, item 14). Please update the record accordingly.

6. Applicant's response filed 24 October 2008 is incomplete because applicant has not responded to item 15, "Claims 28 and 32 should be rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims" in the Office Action mailed 20 August 2008.

7. This application contains claim 2 drawn to an invention nonelected without traverse in the reply filed on 16 October 2007. A complete reply to the instant final rejection must include cancellation of nonelected claim, or other appropriate action (See, 37 C.F.R. §1.144 and M.P.E.P. §821.01).

Amendments and Response based Withdrawals

8. In view of remarks and amendments filed 24 October 2008 the following objection and rejection in the Office Action mailed 20 August 2008 are hereby withdrawn:

- Objection to specification;
- Indefiniteness rejection to Claims 1 and 3-34 under 35 U.S.C. §112, second paragraph; and
- Anticipation rejection to Claims 1, 3-9, 13-26, 29-30 and 34 under 35 U.S.C. § 102(b) as anticipated by Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

Claims Status

9. According to the list of Claims presented with response and amendment filed 24 October 2008 cited *supra,* following is the current status of Claims:

- Claims 1-34 are pending.
- Claim 2 remains withdrawn.
- Claims 1 and 3-34 are examined on merits.

Information Disclosure Statement

10. The Information Disclosure Statement (i.e., IDS) filed 04 December 2008 is acknowledged, has been made of record, considered, and duly signed USPTO form 1449 or equivalent is enclosed with the instant Office Action.

Information Request under 37 C.F.R. §1.105

11. Applicant and the assignee of this application are required under 37 C.F.R. §1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. This requirement is subject to the provisions of 37 C.F.R. §§1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 C.F.R. §1.136(a).

In response applicant has submitted the requested information only in part because regarding some of the information applicant comments, e.g., "Again, this is presented as background information, a point of departure and reference, from which the present invention can be explained and distinguished as already in the prosecution record (See, Remarks filed 24 October 2008, Page 12, Lines 30-31and Page 13, Line 8). Applicant, however, has not described said point of departure as well as where in the prosecution record said "departure point" has been presented or discussed. Appropriate information is required and should be made of clear record.

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.***

13. Claims 1, 3-9, 13-26, 29, 31 and 34 are rejected under 35 U.S.C. § 102(a) as anticipated by Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology, Volume 95, Pages1016–1025).

In response filed 24 October 2008 to the above-cited rejection under 35 U.S.C. §102(a) in the Office Action mailed 20 August 2008, Applicant presents Exhibits A and B in an attempt to distinguish the instantly claimed method with the method that Davies et al., teach, comments that "teachings of Davies have been inadvertently but fundamentally misconstrued" (See, Remarks filed 24 October 2008, Page 15, Lines 30-31) and presents the arguments:

i. "Davies does not teach or suggest all the elements of the presently claimed subject matter because according to applicant enrichment of a test lot sample as recited in the claim steps b) and c) to enrich a "test lot sample: to prepare "modular composite sample as recited in present claim 1d)" (See, Remarks filed 24 October 2008, Page 16, Lines 8-10);

ii. Davies et al., teach a step to prepare and enrich a "test lot sample, but in Davies preparing and assaying a modular composite sample as presently claimed" is completely absent (See, Remarks filed 24 October 2008, Page 16, Lines 10-18);

iii. "Davies teaches only sample pooling to make a classical composite sample for enrichment and then assaying the enriched sample directly" (See, Remarks filed 24 October 2008, Page 17, Lines 12-13).

First of all, Applicant has to be clear and consistent that the prior art reference being discussed for the recited rejection under 35 U.S.C. §102(a) has multiple authorship. Consequently, both technically as one proficient in the pertinent art would know, and legally; the reference should be recited as Davies et al., not Davies; because Davies gives the connotation of only one author or inventor.

Secondly, the Applicant can not have it both ways (See items i and ii above). Either Davies et al., do not teach to prepare and enrich a "test lot sample, as applicant argues at (See, Remarks filed 24 October 2008, Page 16, Lines 8-10; item i above); or Davies et al., teach a step to prepare and enrich a "test lot sample (See, Remarks filed 24 October 2008, Page 16, Lines 10-18; item ii above). As stated above, Applicant needs to clear and succinct regarding which of the two arguments is correct representation of Davies et al's teachings according to the Applicant.

Note, Davies et al., teach the steps as are instantly claimed because Davies et al., have enriched and analyzed what applicant calls "test lot sample" because Davies et al. have enriched samples from each herd wherein each herd is constituted of a given number of pigs and then different samples of different herds from each of 20 different farms. Thus, what applicant calls "test lot sample" is the sample that Davies et al., have collected from a given farm. Since Davies et al., have also enriched samples collected and pooled from different farms as different samples; Davies et al., have also prepared and assayed samples according to steps d) and e) of applicant's Claim 1); i.e., what Applicant calls "preparing and assaying a modular composite sample" (See Davies et al., Page 1017, Column 1, Line 44 to Page 1017, Column 2, Line 21, especially Column 2, Lines 2-5 where lots are described and Column 2, Lines 7-21 where the other part of pooling is described). Thus, contrary to Applicant's arguments presented at Remarks filed 24 October 2008, Page15, Line 30 to Page 19, Line 18; Davies et al., expressly and intrinsically teach analysis for *Salmonella* from pork and further clearly detail that said enrichment for *Salmonella* and analysis/assay for *Salmonella* was carried out on pooled sample from herds of animals at each farm (i.e., equivalent of what Applicant calls test lot sample) and then pooled samples from herd samples at each of 20 Farms (i. e., equivalent of Applicant's "Modular composite sample"). Additionally, Davies et al., further assayed the suspicious sample and

finally all *Salmonella* isolates were confirmed through sero- and if applicable through phage typing (i.e., an alternative method of assay/analysis).

Applicants' arguments filed 24 October 2008 regarding the anticipatory rejection of Claims 1, 3-9, 13-26, 29, 31 and 34 under 35 U.S.C. §102(a) as anticipated by Davies et al., in the Office Action mailed 20 August 2008 have been fully and carefully considered but are not persuasive for the reasons of record at pages 5-7, items 9-11 in the Office Action mailed 20 August 2008 and those discussed *supra*. Thus, the rejection of Claims 1, 3-9, 13-26, 29, 31 and 34 under 35 U.S.C. §102(a) as anticipated by Davies et al., in the Office Action mailed 20 August 2008 is maintained and is adhered to.

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention of***

15. Claims 1, 3-27, 29-31 and 33-34 are rejected under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., (1998. Sample pooling to expedite bioanalysis and pharmacokinetic research, Journal of Pharmaceutical and Biomedical Analysis 16 (1998) 837–846) in view of Budiman et al. (2004. Localization of jointless-2 gene in the centromeric region of tomato chromosome 12 based on high resolution genetic and physical mapping, Theoretical and Applied Genetics, Volume 108, Pages: 190–196) and further in view of Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology 2003, Volume 95, Pages1016–1025) and Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

In response filed 24 October 2008 to the above-cited rejection under 35 U.S.C. §103(a) in the Office Action mailed 20 August 2008, Applicant comments that "Examiner has fundamentally misconstrued the limited teachings of Kuo et al", and further presents following arguments:

iv. "In fact, Kuo, alone or in combination with the other asserted art, does not teach or suggest all the elements of the presently claimed subject matter, because Kuo does not teach or suggest, enrichment of a "test lot sample (as recited in present Claim 1steps b)

and c)) for use in preparing a "modular composite sample" (as recited in present claim 1d). Budiman, Davies and Skov do not make up for the deficiencies of Kuo and therefore do not support a *prima facie* case of obviousness in combination with Kuo" (See, Remarks filed 24 October 2008, Page 22, Lines 20-26);

v. presents Exhibit A to illustrate what Kuo et al. do not even teach preparation of "test lot sample" (See, Remarks filed 24 October 2008, Page 22, Lines 28-31 and Page 23, Line 8) and further presents a detailed discussion of Kuo et al's teaching (Page 23, Line 9 to Page 24, Line 27); and

vi. "there would have been no motivation to combine Budiman, Davies and Skov with Kuo because the subject matter of Kuo is not amenable to enrichment" (Page 25, Lines 9-10).

Thus, Applicant argues, Claims 1 and 3-34 are unobvious over either the individual teachings of Kuo et al., or the combined teachings from Kuo et al., with those in view of Budiman et al., and further in view of Davies et al., and Skov et al., because there is no teaching or suggestion of all the elements of the presently claimed subject matter and there is no motivation to combine teachings from Kuo et al., with those of Budiman et al., Davies et al., and Skov et al.

First of all, Applicant has to be clear and consistent that each of the prior art references being discussed for the recited rejection under 35 U.S.C. §103(a) cited *supra* have multiple authorship. Consequently, both technically as one proficient in the pertinent art would know, and legally; each of the references should be recited as Kuo et al., Budiman et al., Davies et al., and Skov et al., not Kuo, Budiman, Davies, and Skov; because e.g., Davies gives the connotation of only one author or inventor which is not the case with the references recited/cited *supra*.

Please note, although each of the Examiner-cited references by themselves do not teach every component as claimed in the claims under prosecution in the instant application, those references are not relied upon exclusively but in combination. Note further, the concept of the instantly claimed method as stated in the preamble of instantly presented Claim 1 is, "sampling, testing and validating test lots for microbial contamination. " Said preamble breathes life and meaning into the instantly Claimed method. Both Kuo et al., and Budiman et al., teach concepts of collecting samples, pooling said samples and subsequently analyzing said pooled samples. Kuo et al., additionally teach evaluating the microbial contamination in each of said pooled samples. Additionally, in view of Applicant's response filed 24 October 2008 to information furnished under 37 C.F.R. §1.105, Applicant admits on record that "samples

collected at random times over a production shift (i.e., 'cleanup to cleanup') are combined to form a composite sample and enrichment buffer is added to the composite sample to enrich , e.g., for *Listeria* spp. or *L. monocytogenes*" and applicant has submitted said information as background information (See e.g., Remark filed 24 October 2008, Page 13, Lines 11-13), Consequently, the claimed subject matter at least in the concept form was well known and recognized in the pertinent art before Applicant filed the instant application for patent protection. Kuo et al., are silent about specific details in instantly claimed dependent claims (e.g., enrichment, which applicant discusses at length as stated in items iv-v above), however, Kuo et al., clearly teach the basic concept presented in instantly presented Claim 1. Thus, applicant's argument regarding "subject matter of Kuo is not amenable to enrichment" (Page 25, Lines 9-10) is not pertinent; because the enrichment steps for both types of samples , i.e., applicant-designated "test lot samples" that are prepared by "taking assemblages of one or more specimens" and "modular composite sample " prepared by pooling together the "test lot samples") is claimed in the dependent claims; said dependent claims are is clear from the teachings from Davies et al.

Davies et al., as discussed above, expressly and intrinsically teach analysis for *Salmonella* from samples taken from pigs in a herd, pooled samples from pigs within a herd (i.e., equivalent of what Applicant calls "test lot sample") and further pooled samples from pigs from 20 different farms (i. e., equivalent of Applicant's "Modular composite sample"); and further clearly detail that said enrichment for *Salmonella* and analysis/assay for *Salmonella* was carried out on said samples from herds of animals at each farm (i.e., equivalent of what Applicant calls test lot sample) and then pooled samples from herd samples at each of 20 Farms (i. e., equivalent of Applicant's "Modular composite sample"). Thus, deficiencies in the teachings from Kuo et al., have been remedied in the teachings from secondary references, especially Davies et al. As discussed *supra* at item 10, paragraph 8. Davies et al., teach analysis for *Salmonella* from pork and further clearly detail that said enrichment for *Salmonella* and analysis/assay for *Salmonella* was carried out on pooled sample from herds of animals at each farm (i.e., equivalent of what Applicant calls "test lot sample") and then pooled samples from herd samples at each of 20 Farms (i. e., equivalent of Applicant's "Modular composite sample"). Additionally, Davies et al., further assayed the suspicious sample and finally all *Salmonella* isolates were confirmed through sero- and if applicable through phage typing (i.e., an alternative method of assay/analysis). Thus, since the rejection under 35 U.S.C. §103(a) to Claims 1, 3-27, 29-31 and 33-34 in Office Action mailed 20 August 2008 is on the teachings of Kuo et al., with those of secondary references and Kuo et al., also teach collecting samples, pooling them and assaying individual and pooled samples for *Salmonella*, the

motivation to combine Kuo et al's teachings with those of Budiman et al., Davies et al., and Skov et al., is present in Kuo et al.

Additionally, even if the conditions claimed instantly are not same as those taught in the cited prior art as applicant argues at page Please see item vi above); the adjustment of particular conventional working conditions (e.g., choice of an enrichment schedule, or duration of incubation, application of materials having same functional effect, i.e., doctrine of equivalents) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan, especially if certain guidance is given in the relevant prior art. Since the prior art teaches methods to enrich and further identify *Salmonella* by additional or alternate methods in samples obtained from said enrichments of samples that are equivalent of what Applicant calls "Modular composite sample"/, one of ordinary skill will be able to obtain the instantly claimed method for "sampling, testing and validating test lots for microbial contamination".

Thus, the instant invention claimed in Claims 1, 3-27, 29-31 and 33-34 is rendered obvious and unpatentable over combined teachings from the examiner-cited prior art references.

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Additionally, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made.

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary

skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons have been discussed above and also cited at pages 7-11, item 14 in the Office Action mailed 20 August 2008. Furthermore, a rejection under 35 U.S.C. §103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

Applicant's arguments filed 24 October 2008 regarding the obviousness rejection of Claims 1, 3-27, 29-31 and 33-34 under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., in view of Budiman et al., and further in view of Davies et al., and Skov et al., in the Office Action mailed 20 August 2008 have been fully and carefully considered. Said arguments, however, are not persuasive for the reasons of record at pages 7-11, item 14 in the Office Action mailed 20 August 2008 and those discussed *supra*. Thus, the rejection of Claims 1, 3-27, 29-31 and 33-34 under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., in view of Budiman et al., and further in view of Davies et al., and Skov et al., in the Office Action mailed 20 August 2008 is maintained and is adhered to.

Conclusion

16. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. No Claims are allowed for the aforementioned reasons. However, as stated in item 3 *supra*, Claims 28 and 32 should be rewritten to overcome the rejection(s) under 35 U.S.C. §112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Upon resolution of the above-stated issues under 35 U.S.C. §112, further searching and/or consideration may be required.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

28 December 2008
/David M. Naff/
Primary Examiner, Art Unit 1657

WEST Search History for Application 11199871

Creation Date: 2008122621:30

Query	DB	Op.	Plur.	Thes.	Date
quality control	USPT	ADJ			08-17-2008
composite sample	USPT	ADJ			08-17-2008
(mixed lot) (sample)	USPT	ADJ			08-17-2008
Intermediate sample	USPT	ADJ			08-17-2008
ladder sampl$5	USPT	ADJ			08-17-2008
(mixed lot) same (sample)	USPT	ADJ			08-17-2008
(quality control) same ((mixed lot) same (sample))	USPT	ADJ			08-17-2008
(composite sample) same (Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) same (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) same (composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) same (quality control same composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(quality control) same (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control) same (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (composite sample)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(stepwise)same (sample analysis)	USPT	ADJ			08-17-2008
(quality control) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008

(ladder sampl$5) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(composite sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
discriminat$8 same sampl$5	USPT	ADJ			08-17-2008
((stepwise)same (sample analysis)) same (discriminat$8 same sampl$5)	USPT	ADJ			08-17-2008
(stepwise) same (sample analysis)	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) same ((stepwise) same (sample analysis))	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			08-17-2008
(quality control) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
((mixed lot) same (sample)) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Pharmaceutical sample)	USPT	ADJ			08-17-2008
(quality control) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(Intermediate sample) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(ladder sampl$5) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(ladder sampl$5) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008

(composite sample and (Pharmaceutical sample)) and @pd > 20080817	USPT	ADJ			08-17-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ	YES		08-17-2008
((stepwise) same (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
quality control	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
composite sample	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot)and (sample)		ADJ	YES		08-17-2008

	EPAB, JPAB, DWPI				
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((Pharmaceutical sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((stepwise)and (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
quality control	USPT	ADJ			12-26-2008
composite sample	USPT	ADJ			12-26-2008
Intermediate sample	USPT	ADJ			12-26-2008
ladder sampl$5	USPT	ADJ			12-26-2008

(mixed lot) same (sample)	USPT	ADJ			12-26-2008
(composite sample) same (Intermediate sample)	USPT	ADJ			12-26-2008
(quality control) same (composite sample)	USPT	ADJ			12-26-2008
(quality control) and (Intermediate sample)	USPT	ADJ			12-26-2008
(stepwise)same (sample analysis)	USPT	ADJ			12-26-2008
discriminat$8 same sampl$5	USPT	ADJ			12-26-2008
(stepwise) same (sample analysis)	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			12-26-2008
(Pharmaceutical sample)	USPT	ADJ			12-26-2008
(quality control) and ((Pharmaceutical sample))	USPT	ADJ			12-26-2008
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			12-26-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ			12-26-2008
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ			12-26-2008
quality control	EPAB, JPAB, DWPI	ADJ			12-26-2008
composite sample	EPAB, JPAB, DWPI	ADJ			12-26-2008
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ			12-26-2008

(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ			12-26-2008
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ			12-26-2008
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ			12-26-2008
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ			12-26-2008
sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))	PGPB, USPT	ADJ	YES		12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)))	PGPB, USPT	ADJ	YES		12-26-2008
(pooled same (lot sample))	PGPB, USPT	ADJ	YES		12-26-2008
(pooled same sample)	PGPB, USPT	ADJ	YES		12-26-2008
sample Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		12-26-2008
((pooled same sample)) same (sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella same sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		12-26-2008
		ADJ	YES		12-26-2008

(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT				
sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
(pooled and sample)	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
sample and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
((pooled and sample)) and (sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
(sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))) and ((pooled and sample) and sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	SAMADPOUR, MANSOUR
	Examiner	Art Unit
	Srivastava, Dr. Kailash C	1657

SEARCHED

Class	Subclass	Date	Examiner
Performed Partial Search in WEST	Performed Partial Search in WEST	01/02/2008	KCS
NONE	NONE	01/02/2008	KCS
Updated Partial Search in WEST	Updated Partial Search in WEST	08/17/2008	KCS
NONE	NONE	08/17/2008	KCS
		12/26/2008	

SEARCH NOTES

Search Notes	Date	Examiner
WEST SEARCH: DWPI, EPAB, JPAB, PGPB. USOC, USPT	01/02/2008	KCS
STN SEARCH: AGRICOLA, BIOSIS, EMBASE, HCAPLUS, MEDLINE,	10/31/2007	KCS
Search Strategy:E.coli, Samadpour, test sample, validat, test lot, quality assurance method, sampl, scrren, portion, Salmonella, Screen, coliform, count, control, protocol, safety, food	01/02/2008	kcs
Perform Inventor Search	01/02/2008	KCS
Verified priority data and information (e.g., 60/599,473 filed 08/06/2004).	01/02/2008	KCS
Google Search: EPA method for water analysis, Method 1622, Giardia, Cryptosporidium	01/03/3008	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.	08/17/2008	KCS
Updated Google Search	08/17/2008	KCS
Updated Inventor Search	8/17/2008	KCS
Consulted strategy to upgrade search and strategy for Office Action with Dr. Weber	7/8/2008	KCS
Consulted strategy to upgrade search and strategy for Office Action with Dr. Weber	12/09/2008	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.Additional terms searched- mixed lot composxite sample	12/26/2008	KCS
Updated Inventor Search	12/26/2008	KCS

/Dr. Kailash C Srivastava/ Examiner.Art Unit 1657	

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

/Dr. Kailash C Srivastava/ Examiner.Art Unit 1657	

PTO/SB/08a (11-08)
Approved for use through 12/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11199871
Filing Date	2005-08-08
First Named Inventor	Mansour Samadpour
Art Unit	1657
Examiner Name	Kailash C. Srivastava
Attorney Docket Number	66090-29

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11199871
	Filing Date	2005-08-08
	First Named Inventor	Mansour Samadpour
	Art Unit	1657
	Examiner Name	Kailash C. Srivastava
	Attorney Docket Number	66090-29

/K.S./	1	PRICE et al., "Salmonella Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples," Applied Microbiology, 1972, pp. 679-682, Volume 23	☐
/K.S./	2	SILLIKER et al., "ICMSF methods studies. I. Comparison of analytical schemes for detection of Salmonella in dried foods," Canadian Journal of Microbiology, 1973, pp. 475-479, Volume 19	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Kailash C. Srivastava/	Date Considered	12/24/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	August 8, 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	January 5, 2009

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF THE INTERVIEW

This is a REPLY to an Office Communication (Interview Summary) dated December 3, 2008, in the above identified application.

REMARKS

Subsequent to a telephonic interview with Examiner Srivastava on November 13, 2008, Applicant's Representative received an Office Communication dated Decmber 3, 2008, summarizing the interview, and requesting a Reply in the form of a "STATEMENT OF SUBSTANCE OF THE INTERVIEW." Since a reply to the last Office Action in the case has already been filed, Applicant's Representative hereby files the following Statement of Substance of the Interview.

STATEMENT OF SUBSTANCE OF THE INTERVIEW

In response to a request by Applicant's Representative for an interview between the Examiner and Dr. Samadpour, the Examiner stated in the Office Communication (Interview Summary) that:

"Examiner offered the Representative any date after 11/24/2008 and before 12/11/2008 for said interview."

Applicant's Representative agrees with the Examiner's Summary. Unfortunately, Dr. Samadpour was unable to schedule the interview during this period and will likely try to schedule another interview date.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests entry of the present Statement of Substance of the Interview. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

Application No.:	11/199,871
Attorney Docket No.:	66090-29
First Applicants' Name:	Mansour Samadpour
Application Filing Date:	08 August 2005
Interview Summary Dated:	December 3, 2008
Date of Response:	January 5, 2009
Examiner:	Kailash C. Srivastava

Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101-3045
Telephone: 206-757-8023
Facsimile: 206-757-7023

Respectfully submitted,
Mansour Samadpour
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./
Barry L. Davison, Ph.D., J.D.
Attorney for Applicant
Registration No. 47,309

Electronic Acknowledgement Receipt

EFS ID:	4557495
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	05-JAN-2009
Filing Date:	08-AUG-2005
Time Stamp:	18:15:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	66090_29_SOS.pdf	11666 30084d501ff5317dbdae27a3f30bbe1f24370a60	no	3

Warnings:	
Information:	

Total Files Size (in bytes):	11666

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 02/11/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
02/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Kailash C. Srivastava, Examiner*. (3)_____.

(2) *Mr. Barry L. Davison. Applicant's Representative*. (4)_____.

Date of Interview: *02/04-051200*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Suggested claim 1 attached hereto*.

Claim(s) discussed: *Those of record*.

Identification of prior art discussed: *NONE*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Kailash C Srivastava/ Examiner, Art Unit 1657	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to, if an agreement was reached, or any other comments: Applicant's Representative telephoned the Examiner on 02/04/2009 to follow-up regarding the interview of 01/29/2009 among the Applicant, Applicant's Representative, the Examiner and Examiner's Supervisor. The Examiner suggested that the Examiner will consult Examiner's Supervisor to draft a suggested amendment to claim(s). On 02/05/2009, Examiner following the telephone interview of 02/04/2009 suggested to the Applicant's Representative the enclosed Examiner's suggested amendment and conversed with the Applicant's Representative to incorporate the suggested Claim language presented for Claim 1 into other currently pending independent or dependent Claims that are currently under Examination.

The Applicant's Representative suggested that the Applicant will file a response to the currently outstanding Final Office Action mailed on 01/05/2009.

.

Examiner's Suggested Amendment to Claim

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 02/17/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Kailash C. Srivastava, Examiner*.

(2) *Jon Weber, SPE*.

(3)*Dr, M, Samadpour, Inventor*.

(4)*Mr. Barry L. Davison. Applicant's Representative*.

Date of Interview: *29 January 2009*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☒ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Please see attached drawings*.

Claim(s) discussed: *Those of record*.

Identification of prior art discussed: *That of Record*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

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/Kailash C Srivastava/ Examiner, Art Unit 1657	

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A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

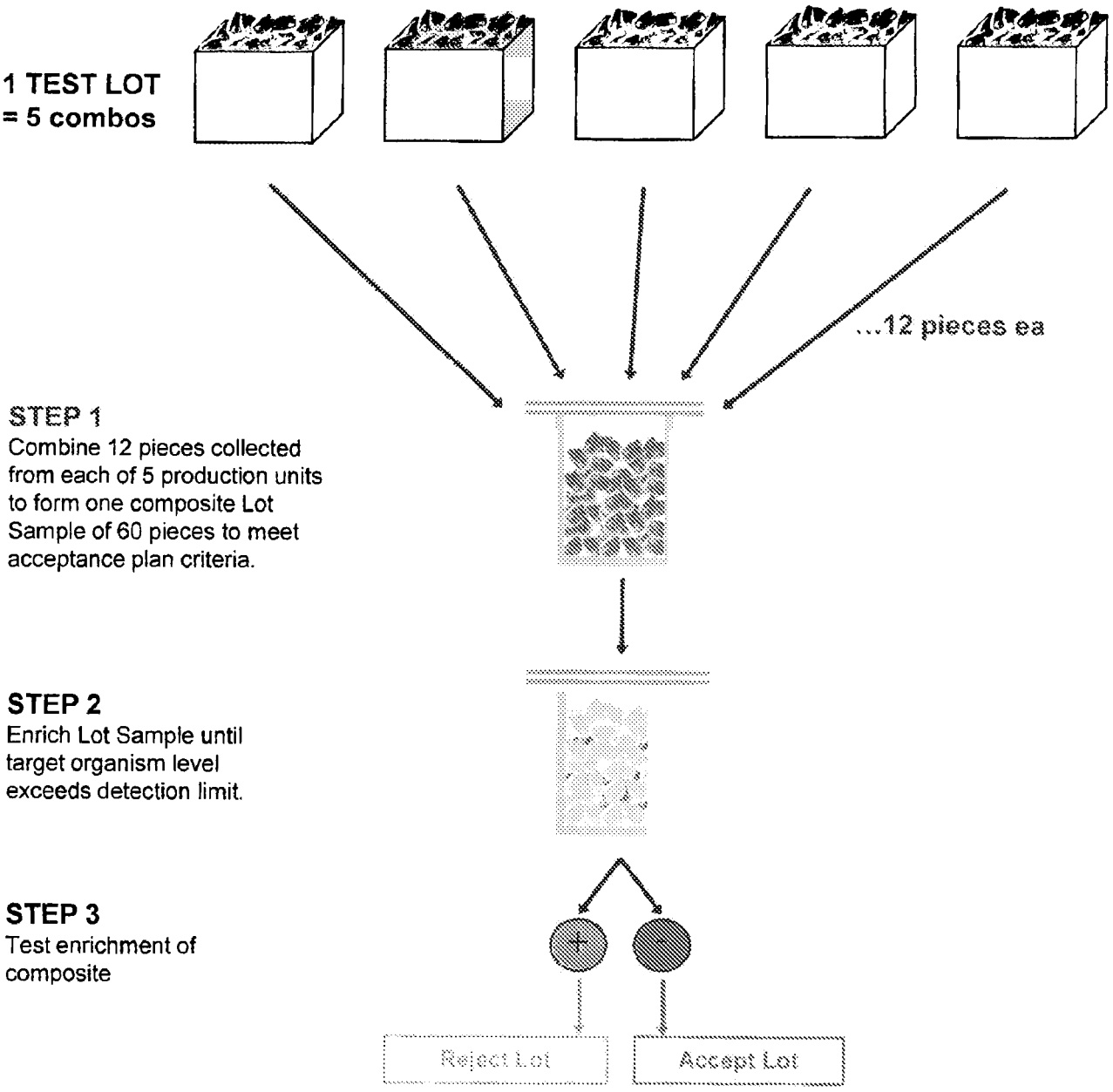
Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to, if an agreement was reached, or any other comments: Applicant's Representative and the Applicant presented the Applicant's invention as supported in the enclosed drawings. The inventive step over the prior art of record is the enrichment of individual pooled sampling lots comprised of plurality of samples, subsequently pooling enriched samples together and then testing the pooled, enriched sample for the presence/absence of a pathogenic microorganism. In the event of a positive test for the presence of a pathogen, the invention allows to test each of the individual enrichments to identify the pooled lot that gave the positive test for the pathogenic microorganism. The Examiners and the Applicant's Representative will work together to write claim language to clarify Applicant's claimed invention.

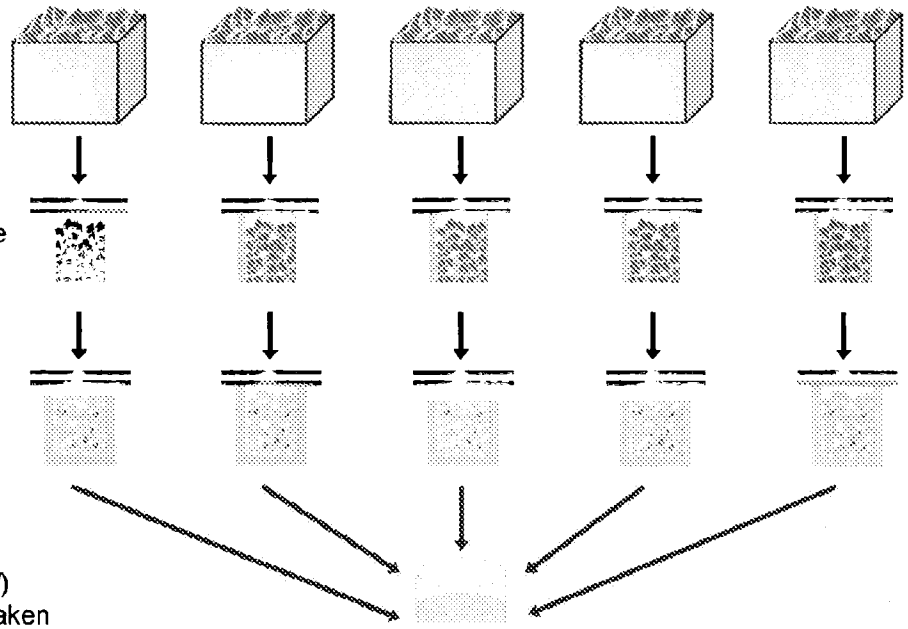
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PRESENT INDUSTRY ART



CURRENT INVENTION

1 TEST LOT = 1 combo, 5 Lots tested simultaneously

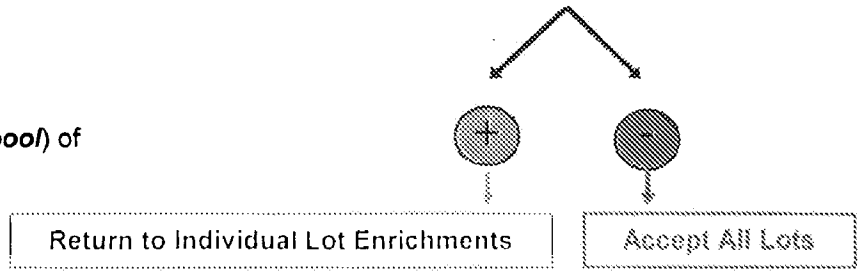


STEP 1
Collect 60 portions from each Lot to form individual composite Lot Samples and meet acceptance sampling plan criteria.

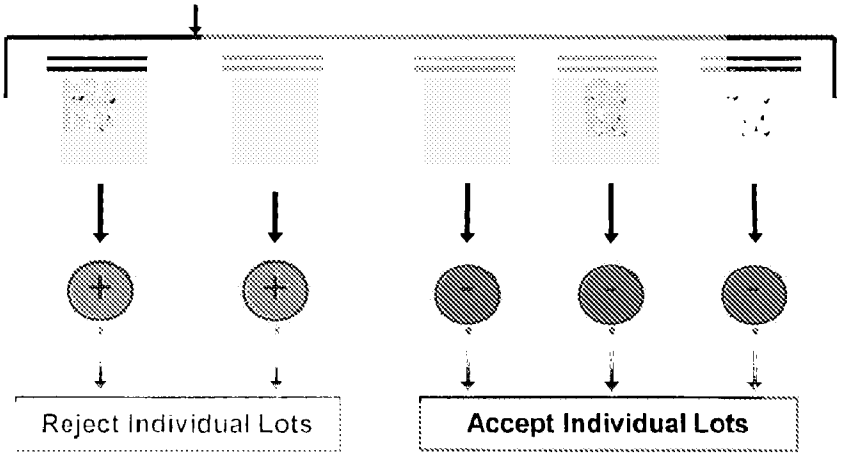
STEP 2
Enrich and incubate each Lot Sample to ***N x the limit of detection*** for target organism.

STEP 3
Prepare a wet composite (***pool***) from ***N - 1*** equal size aliquots taken from individual Lot sample enrichments. Retain Lot Sample enrichments.

STEP 4
Test wet composite (***pool***) of enrichment cultures



STEP 5
A positive signal in wet composite (***pool***) is the result of a positive in one or more original individual enrichments. Even one positive can be detected in the ***pool*** when diluted because N/(N-1) > 1 x det limit. Because individual Lot sample enrichments are retained, they can be immediately tested to see which ones contributed to the positive result. Those that contributed are rejected while those that did not are accepted.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 02/17/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Kailash C. Srivastava, Examiner*. (3)_____.

(2) *Mr. Barry L. Davison, Applicant's Representative*. (4)_____.

Date of Interview: *02/04-05/2009*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: *NONE*.

Claim(s) discussed: *Those of record*.

Identification of prior art discussed: *NONE*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Kailash C Srivastava/ Examiner, Art Unit 1657	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
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- Date of interview
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- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

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A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to, if an agreement was reached, or any other comments: Applicant's Representative telephoned the Examiner on 02/04/2009 to follow-up regarding the interview of 01/29/2009 among the Applicant, Applicant's Representative, the Examiner and Examiner's Supervisor. The Examiner suggested that the Examiner will consult Examiner's Supervisor to draft a suggested amendment to claim(s). On 02/05/2009, Examiner following the telephone interview of 02/04/2009 suggested to the Applicant's Representative the enclosed Examiner's suggested amendment and conversed with the Applicant's Representative to incorporate the suggested Claim language presented for Claim 1 into other currently pending independent or dependent Claims that are currently under Examination.

Examiner's Suggested Amendment to Claim

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising: a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately the assemblage can be sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

The Applicant's Representative suggested that the Applicant will file a response to the currently outstanding Final Office Action mailed on 01/05/2009.

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Examiner's Suggested Amendment to Claim

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour
Serial No.:	11/199,871
Filed:	08 August 2005
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
Examiner:	Kailash C. Srivastava
Art Unit:	1657
Docket No.:	66090-29
Date:	19 February 2009

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 C.F.R. § 1.116

Sir:

This is a RESPONSE AND AMENDMENT in reply to a final Office Action dated 05 January 2009 in the above identified application. No fees are deemed necessary.

Kindly amend the above-identified patent application as follows:

Application No.:	11/199,871
Attorney Docket No.:	66090-29
First Applicant's Name:	Mansour Samadpour
Application Filing Date:	08 August 2005
Office Action Dated:	05 January 2009
Date of Response:	19 February 2009
Examiner:	Kailash C. Srivastava

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. (Cancelled)

3. (Original) The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

5. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. (Currently amended) The method of claim 1, wherein incubating each separate test lot sample in c) comprises incubating each separate test lot sample with enrichment medium suitable to enrich for the target microbial agent or organism, ~~to the sample,~~ and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate test lot sample and combining the removed portions to provide a modular composite sample.

7. (Original) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. (Currently amended) The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples~~lots~~ are further tested, such further testing comprises use of the more sensitive protocol.

9. (Original) The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Currently amended) The method of claim 1, further comprising, forming an additional modular composite sample from the set of enriched separate test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. (Currently amended) The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched separate test lot sample along with any enriched separate test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. (Currently amended) The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the set of enriched separate test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. (Previously presented) The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.

14. (Currently amended) The method of claim 1, wherein the number of separate test lots is from 3 to 10.

15. (Currently amended) The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual separate test lots are positive, application of remedial measures to said separate positive test lots, and validating by further testing of a portion of the respective remediated separate test lots and obtaining a negative test result.

16. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot a number of portions from 5 to 100.

17. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot 30 to 60 portions.

18. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting 30 portions from each separate test lot.

19. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot about 60 portions.

20. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein each single-unit production lot is separately~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of product portions corresponding to each of the separate single-unit production lots to provide a corresponding set of separate single-unit production lot samples, wherein each separate single-unit production lot sample is attributed to a particular corresponding separate single-unit production lot;

c) incubating the set of separate single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate single-unit production lot samples, to provide a set of separate single-unit production lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate single-unit production lot samples are validated, and wherein when such testing is positive, individual separate single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

21. (Currently amended) The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate test lot samples.

22. (Currently amended) The method of claim 20, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate single-unit production lot samples.

23. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria*, *Salmonella* and *Escherichia coli*.

24. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

25. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

26. (Currently amended) The method of claim 1, wherein removing portions of each enriched separate test lot sample comprises removing equal volume portions of each enriched separate test lot sample.

27. (Previously presented) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.

28. (Previously presented) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Currently amended) The method of claim 1, wherein the separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. (Previously presented) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Previously presented) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (Currently amended) The method of claim 1, wherein the separate test lots are separate production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

33. (Currently amended) The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.

34. (Currently amended) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism[[s]].

REMARKS

Claims 1 and 3-34 are pending and stand rejected.

Claim 2, previously withdrawn as being drawn to non-elected subject matter, has been cancelled herein without prejudice.

Applicant thanks the Examiner for withdrawal of the prior specification objections and of the prior rejections under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 102 in view of Skov.

Applicant acknowledges the Examiner's remaining rejections under 35 U.S.C. § 102 in view of Davies et al. and under 35 U.S.C. § 103(a) in view of Kuo et al., Budiman et al., Davies et al., and Skov et al. Applicant has responsively amended the claims and provided appropriate rebuttal argument to overcome these rejections.

Applicant has, in the context of this Response and Amendment and as agreed to with the Examiner (see statement of Substance of Interview below), provided the specific claim amendments suggested by the Examiner and the Examiner's supervisor, and respectfully contends that the claims as amended and presented herein are now in allowable form.

STATEMENT OF SUBSTANCE OF THE INTERVIEWS

In an Office Communication, dated 11 February 2009 the Examiner summarized the telephonic interview of 29 January 2009 and the follow-up telephone call of the 04 February 2009, in which the Examiner, Applicant, and Applicant's representative discussed possible claim amendments. Specifically, the Examiner confirmed that the Examiner had consulted with the Examiner's supervisor to draft a suggested amendment to the claims as was suggested during the 29 January 2009 interview and that Agreement with respect to the claims was reached. The Examiner provided, via facsimile on 05 February 2009, a specific suggested amendment of claim

1 (see currently amended claim 1), which was also attached, in mark-up form, to the Office Communication of 11 February 2009. Additionally, in a follow-up telephone call of the 04 February 2009, the Examiner suggested that the rest of the claims be amended to conform with the suggested amendments to claim 1 (see currently amended claim set, which has been amended to conform with amended claim 1). In a subsequent Office Communication, dated 17 February 2009, the Examiner again summarized the telephonic interview of 29 January 2009, again attaching the facsimile of 05 February 2009, and again attaching the mark-up form of claim with the suggested amendments.

Finally, the Examiner and Applicant's representative agreed that the claim amendments should be included in the present Response to the outstanding Office Action, dated 05 January 2009.

Informal Matters

The further "Information Request" requested by the examiner is provided herein.

Applicant contends that *dependent* claims 28 and 32 are allowable as presented. There is no rejection of record of these claims under 35 U.S.C. 112, second paragraph, that has not already been obviated by Applicant's prior amendments of the respective independent claims. These claims depend from claims that Applicant contends are allowable as presently amended.

Further Information Request under 37 C.F.R. § 1.105

The Examiner has made a further Information Request under 35 U.S.C. § 1.105. Specifically, the Examiner states that in Applicant's reply to the Examiner's prior Information Request, the Applicant indicated that certain information was provided as "background information, a point of departure and reference, from which the present invention can be explained

and distinguished as already in the prosecution record," but that Applicant had not described said point of departure and a reference to said point in the prosecution record.

Applicant responsively further clarifies the record as follows:

The statement at the bottom of page 1 referring to "United States Department of Agriculture, Food Safety and Inspection Service (FSIS) directives and guidelines, many food producers in the United States have adopted sampling plans that involve testing, for example, of raw beef trims and/or ground beef for *E. coli* O157:H7, and ready-to-eat products for *Listeria monocytogenes* and/or *Salmonella,*" is background information about prior art directives and guidelines that have been adopted in certain industry sectors. These are prior art directives and guidelines that were, at the time of filing of the instant specification, art-recognized guidelines that are distinct from the presently claimed subject matter. Applicant's claimed methods represent a departure point from these prior art methods, in that they don't teach or suggest the present methods that involve the steps a)-e) of Applicant's independent claims 1 and 20 and dependent claims thereof. This is precisely why these prior art guidelines are in the Background section. These prior art methods and the limitation thereof are presented in pages 1-4, under Background, and Applicant's Summary Section, Detailed Description and claims, all of which disclose the departure from such prior art methods and limitations.

The statement at page 17, line 26, to page 18, line 1, referring to "At present, the standard size 'production lot' for trim testing for *E. coli* O157 in the beef industry in the USA is a combination of five *combos*, where each *combo* represents a single production unit and weighs approximately 2,000 pounds," is background information and refers to the fact, as well recognized in the art, that production lot for purposes of trim testing consists of five separate "combos," each combo lot being a single production unit weighing about 2,000 lbs. That is, the prior art teaches that a production lot consists of five separate combo lots, and Applicant is merely restating that

aspect of the prior art. This is presented as background information, that relates only to the description of representative individual "test lots" as found in the beef processing industry. The departure point in that while the presently claimed methods can be practiced starting with such test lots, Applicant's Summary Section, Detailed Description, and claims disclose the methods that can be used to sample and validate such test lots; that is, the inventive methods are the departure from such art-recognized test lots.

The statement at page 19, line 26, to page 20, line 2, referring to "Under United States Department of Agriculture, Food Safety and Inspection Service (USDA FSIS) guidelines, producers of Ready-to-Eat (RTE) meat and poultry products may adapt an 'end product' sampling program as verification that their product is free of the pathogen *Listeria monocytogenes,*" is background information and refers to the fact, as well recognized in the art, that an "end product" sampling program may be adopted under the regulations as verification. Again, however, Applicant's claimed methods are distinguished from any such prior art "end product" sampling programs, which don't teach or suggest the present methods that involve the steps a)-e) of Applicant's independent claims 1 and 20 and dependent claims thereof, as presented in pages 1-4, under Background, and Applicant's Summary Section, Detailed Description, and claims, all of which disclose the departure from such prior art methods and limitations.

Likewise, the statement at page 20, line 2, to line 8, "The frequency of end product sampling is selected by the producer/establishment, based on valid sampling statistics. Typically, samples are collected at random times over a production shift (*e.g.*, from 'cleanup to cleanup'), and from several product lines. The samples are combined to form a composite sample, and enrichment buffer is added to the composite sample to allow *Listeria* spp. or *L. monocytogenes* to grow and multiply under the favorable conditions of enrichment, thereby providing more material that can be detected by subsequent analysis," is background information and refers to the fact, as

well recognized in the art, that composite (pooled) samples can be formed and enriched to provide more material for testing. Again, however, Applicant's claimed methods are distinguished from any such prior art, classic pooling methods, which don't teach or suggest the present methods that involve the steps a)-e) of Applicant's independent claims 1 and 20 and dependent claims thereof, as presented in pages 1-4, under Background, and Applicant's Summary Section, Detailed Description, and claims, all of which disclose the departure from such prior art methods and limitations.

The statement at page 20, lines 10 to 16, "Preferably, the producer defines and produces these single-unit lots in such a fashion as to maximize the information available for investigating the nature of a failure. For example, possible definitions of an individual single-unit production lot include, but are limited to all of the product produced by a particular production line (or produced by a particular production line in a particular period of time), a volume of product such as a pallet of packed boxes produced on a particular production line, or a production area in the plant, etc.," is background information and refers to the fact, as well recognized in the art, that single unit production lots can take different forms such as all of the product produced on a particular production run, or alternatively a portion of the production run corresponding to a certain time period of production during the run, or a corresponding to a volume amount of the production run (e.g., a 2,000 lb combo lot as referred to above). Again, however, Applicant's claimed methods are distinguished from any such prior art knowledge about the particular forms of single unit production lots, which are simple representative "test lots," which don't teach or suggest the present methods, used on such test lots, which involve the steps a)-e) of Applicant's independent claims 1 and 20 and dependent claims thereof, as presented in pages 1-4, under Background, and Applicant's Summary Section, Detailed Description, and claims, all of which disclose the departure from such prior art methods and limitations.

As explained and taught in Applicant's originally filed specification, Applicant's invention can be applied to essentially any type of prior art production lot, and with respect to essentially any target agent or organism (including all the known prior art target agents and organisms), and represents a fundamental improvement over the above-referenced prior art federal regulations for the way production lots (test lots) are sampled and validated.

Rejections under 35 U.S.C. § 102

Davies et al.: The Examiner has rejected claims 1, 3-9, 13-26, 29-31, and 34 under 35 U.S.C. § 102, as being allegedly anticipated by Davies et al. (Journal of Applied Microbiology 95:1016-1025, 2003).

The Examiner states that "claims 1, 3-9, 13-26, 29-31 and 34 recite a method of sampling, testing and validating test lots, wherein single-unit production lots are sampled. The samples pooled, enriched for test microorganisms and subsequently evaluated for the presence or absence of potential microbial agents. If upon completion of analysis, the target microorganisms are not recovered or founding the test lots, the test lots are considered validated. If, however, test lots reveal presence of target microorganisms(s), the test is repeated, possibly with an alternate method to test the absence, or presence of target microorganisms. In said method a plurality of samples are collected and pooled and analyzed. The test lots comprise one or more meat specimens from among beef, pork sheep or bison."

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the current claim amendments and the fact that the limited teachings of Davies et al. have been misconstrued in relation to Applicant's claimed invention. Davies et al. does not teach or suggest all the elements of the presently claimed subject matter, because while Davies et al. may teach classic sample pooling

and enriching thereof, Davies et al. does teach or suggest enrichment of a "test lot sample", as recited in present claim 1 steps (b) and (c), **for use in** preparing a "modular composite sample," as recited in present claim 1 (d). Rather, Davies et al. only teaches simple sample pooling (**in the absence of modular composite sample as presently claimed**) to make a classical composite sample for enrichment and then assaying the enriched sample directly (see Applicant's Exhibit A attached hereto, presented at the Examiner's interview of 29 January 2009), which, in terms of Applicant's novel scheme, only amounts to preparation and enrichment of a "test lot sample," but in Davies et al, there is a complete absence of preparing and assaying a modular composite sample as presently claimed (see Applicant's Exhibit B attached hereto, presented at the Examiner's interview of 29 January 2009) and which allows, in the case of a positive testing modular composite sample, for returning to assay the retained individual enriched test lot samples determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted.

Davies et al.:

The teachings of Davies et al. are limited to the use of pooled samples to provide a cheaper *Salmonella* monitoring program to identify infected finishing pig herds (e.g., see Abstract of Davies et al.; page 1017, column 1, second full paragraph; Table 4; Figure 2, etc.). Specifically, Davies et al. sampled meat juice, serum, caecal contents, carcass swabs, and pooled faeces from pig pens from 20 commercial finishing farms. The aim was to determine whether pooled serum and meat juice could be used to identify finishing pig herds with a high prevalence of infection by *Salmonella*. Specifically, comparisons were made between assay results of: *Salmonella* culture, individual ELISA tests on serum and meat juice, and pooled samples of serum and meat juice. While *Salmonella* was isolated from the samples of 19 of the 20 commercial farms, the ELISA tests failed to show significant correlation with caecal carriage of *Salmonella* or contamination of

carcasses. However, mean optical density (O.D.) from pools of sera (from 5, 10 or 20 sera) showed a significant correlation with the *Salmonella* status of farm pen faeces. The conclusion of Davies et al. is that while there is a generally poor correlation between serological and bacteriological results, pooled serum or meat juice samples can be used as a cheaper substitute for serological screening of farms for Salmonella than individual samples. Davies et al., therefore, teaches pooling of samples to provide cheaper monitoring, but nothing more.

As stated above, Davies et al. teaches only simple sample pooling to make a classical composite sample for enrichment and then assaying the enriched sample directly. For example, as explained on page 1017 and 1018 (under Laboratory tests), pooled pen faeces samples are added to media and incubated (enriched) prior to assay. Applicant has attached EXHIBITS A and B (presented at the Examiner's interview of 29 January 2009) to facilitate the Examiner's review. Specifically, Davies et al. teaches only classical sample pooling to make a composite sample for enrichment and testing as shown in the diagram of EXHIBIT A. Significantly however, none of the pooled samples of Davies et al. were used after enrichment to prepare the equivalent of a "modular composite sample" as presently claimed by Applicant. Applicant directs the Examiner to review EXHIBIT B, which diagrammatically reproduces the a method according to Applicant's claims.

Specifically, the upper portion of EXHIBIT B illustrates an exemplary preferred embodiment of Applicant's invention as applied to lot testing of food products such as beef trim, in which a plurality of portions (e.g.. 60 independent portions; or a higher or a lower number of portions can be used to increase or decrease the confidence in the results) are collected from each test lot and are placed into a single bag (or other suitable test containers) to provide a respective set of test lot samples (corresponds to steps a) and b) of claim 1). Each test lot sample is then enriched individually (corresponds to step c) of claim 1). A portion (e.g., equal volume portions)

of medium is removed from each of the enriched test lot samples and placed together into a single wet modular composite sample (e.g., test tube) (corresponds to step d) of claim 1). The wet composite is then tested (corresponds to step e) of claim 1). Not shown in the diagram is an optional incubation/enrichment step between the Modular Composite Sample and the Enriched Modular Composite Sample. If a negative test result form microbial agents or organisms is obtained with respect to the modular composite sample, all of the test lot members of the composite are deemed to be negative for the pathogen of interest. On the other hand, if a positive result is obtained on the modular composite sample, samples from each of the individual enriched test lot samples (retained) that were used to prepare to the wet modular composite sample are individually tested (e.g., using the same test protocol or an alternate protocol with at least the same level of sensitivity).

Davies et al. **does not** teach, suggest, or perform, for example steps 3 and 4 of the diagram, which correspond to preparation and testing of a modular composite sample as in Applicant's claim 1, steps d) and e). Likewise in Davies et al., pooled serum and meat juice samples were tested individually and as pools, but these were not enriched but rather assayed directly by ELISA.

Therefore, while the method of Davies et al. provides, as intended, merely a cheaper way of assaying by making classical pooled samples (composite samples), Davies et al. does not make modular composite samples from enriched pooled samples. Thus, for example in Davies et al., for the pens of each of 20 commercial pig finishing farms, one pooled sample was made for each specific farm pen, and the samples were separately submitted for analysis (see Davies et al., page 1017, column 2, first full paragraph). There was, however, no formation of a overall modular composite sample comprising aliquots of the 20 farm-specific pooled pen samples (or enriched farm-specific pooled pen samples). Thus, while Davies et al. practices assay of classic pooled pen samples for efficiency, Davies et al. did not practice or teach the presently claimed methods.

By way of further illustration of the distinctions of the presently claimed methods, application of the present methods to the problem of Davies et al., for example, would involve enrichment of each of the 20 farm-specific pooled pen samples (and retention of the enrichments), followed by formation of an overall modular composite sample comprising aliquots of the 20 enriched farm-specific pooled pen samples, and assay of the modular composite sample (or assay of an enriched modular composite sample)—resulting in a much greater efficiency than provided for by classical methods of Davies et al., because using Applicant's method one would not have had to initially assay each of the 20 enriched farm-specific pooled pen samples, and would rather have needed to assay them only in the case where the single modular composite sample was determined to be positive for a particular target microorganism.

Applicant has, nonetheless, amended independent claims 1 and 20 as suggested by the Examiner and the Examiner's supervisor, to recite "wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions" and further reciting separate test lot samples, which amendments serve to further distinguish the initial enrichment of separate test lot samples, in relation to the subsequent "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample."

Applicant respectfully contends, therefore, that the teachings of Davies et al. are fundamentally distinguished from the presently claimed subject matter, and respectfully request withdrawal of the Examiner's rejection of claims 1, 3-9, 13-26, 29-31, and 34, under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 103

Kuo et al., in view of Budiman et al., Davies et. al., and Skov et al.:

The Examiner has rejected claims 1, 3-27, 29-31, and 33-34, under 35 U.S.C. § 103(a), as

allegedly being obvious in view of Kuo et al. (*Journal of Pharmaceutical and Biomedical Analysis* 16:837-846, 1998) in view of Budiman et al. (Theoretical and Applied Genetics, 108:190-196, 2004) and further in view of Davies et al. (*supra*) and Skov et al.(*supra*).

Specifically, the Examiner states that Kuo et al. teaches the concept of a method of individual sampling and pooled sampling to obtain pharmacokinetic data of the effect of drugs. To preclude the possibility of cross reactions occurring between multiple drugs (C1-C6) given to a given animal, a given dose of each drug compound is given to individual animals (three individual animals are used for each drug compound C1-C6), serial blood samples were collected at 0.5, 1, 2, 4, and 8 h post-dose from each animal and placed into separate tubes. Plasma was separated from the red cells and stored until analysis. Pooled samples were then made by combining 100 microliter aliquots taken from one of the three 0.5 h samples corresponding to each drug to provide pooled samples of 600 microliters. For each time point, three such pooled samples were prepared. Kuo et al. drew the conclusion that several drugs would be identified as the highest to lowest effective, and that a pooled sample analysis followed by one on one sample analysis will best serve the purpose of establishing pharmacokinetics. The Examiner states that while Kuo et al. is silent about a DNA-based method, analysis of test lots comprising meat or poultry product (e.g., beef, bison, pork, sheep) and enrichment for a bacterial organism (e.g., *Escherichia coli*, *Listeria* or *Salmonella*), Budiman et al. nonetheless teaches DNA-based analysis of pooled and individual samples, Davies et al. nonetheless teaches pig herds (as discussed herein above in this Response and Amendment), and Skov et al. nonetheless teaches collected individual and pooled samples (as discussed herein above in this Response and Amendment).

The Examiner, based on this, concludes that one of ordinary skill in the art would have been motivated to combine the teachings from Kuo et al. with those from Budiman et al., Davies et al., and Skov et al. to obtain a method to sample, test, and validate a plurality of samples in a

single point product lot an pooled sample lots with respect to *Salmonella* in meat and poultry samples.

Applicant's traversal:

Applicant respectfully traverses the rejection, based on the current claim amendments and on the fact that the limited teachings of Kuo et al. have been misconstrued in relation to Applicant's claimed invention. In fact, Kuo et al., alone or in combination with the other asserted art, does not teach or suggest all the elements of the presently claimed subject matter, because Kuo et al. does not teach or suggest enrichment of a "test lot sample" (as recited in present claim 1 steps b) and c)) **for use in** preparing a "modular composite sample" (as recited in present claim 1d). Budiman et al., Davies et al., and Skov et al. do not make up for these deficiencies of Kuo et al. and, therefore, do not support a *prima facie* case of obviousness in combination with Kuo et al.

Analysis:

Despite reliance by the Examiner on other references for "enrichment," Kuo et al. still only teaches classical sample pooling (600 microliter pooled sample, comprising one 100 micro liter aliquot from each of six individual serum samples) to make a classical composite sample (and in this case with no enrichment) and then assaying the classical composite sample directly (see Applicant's Exhibit A attached hereto), which, compared to Applicant's novel scheme, actually falls short of preparation of even a "test lot sample" as presently claimed, because a plurality of portions has not been taken from each test lot (in the Kuo et al. case, from each animal) to make a pooled sample, and rather the pooled sample of Kuo et al. is a pooled sample of single sample portions taken from individual test lots (individual animals). However, even if, *arguendo*, the pooled sample of Kuo et al. is construed, as urged by the Examiner to be equivalent to one of Applicant's "test lot samples," the Kuo et al. pooled samples are **not** "modular composite samples" as presently claimed, and there is a complete absence of preparing and assaying a

modular composite sample as presently claimed (see Applicant's Exhibit B attached hereto) that allows, in the case of a positive testing modular composite sample, for returning to assay the retained enriched test lot samples (retained pool samples) to determine which enriched test lot samples contributed to the positive result such that positive enriched test lots are rejected while negative test lots are accepted. While Kuo et al. might be practiced to retain the original individual rat-specific serum samples, thereby providing the ability to assay individual rat samples if desired in addition to assaying of the pooled sample, the pooled samples of Kuo et al. are not "modular composite samples" and the individual samples of rat serum are not "test lot samples" as disclosed and claimed by the present Applicant. Modular composite samples, as disclosed and claimed herein, are in effect pools of pools, and the pools of Kuo et al. are but pools of individual samples, each sample from an individual rat—and even here they are not even true test lot samples as disclosed and claimed by the present Applicant.

By way of further illustration of the distinctions of the presently claimed methods, although the facts and subject matter of Kuo et al. do not provide for enrichment, application of the present methods in the context of the problem of Kuo et al., for example, might involve forming, for each different administered drug candidate compound, a respective test lot sample, in each case comprising a plurality of samples (e.g., 0.5 h time points) taken from a plurality of animals all receiving the same drug (a drug group of animals) to provide a respective set of "test lot samples" (a test lot pool) for each different drug, followed by making a modular composite sample comprising an aliquot from each of the respective drug test lot samples (that is, making a pool of pools) and analyzing of the modular composite sample for a particular characteristic. Where the target characteristic is identified in the modular composite sample, it would be possible to go back and assay each of the respective test lot samples to determine which drug group or groups was responsible for the desired characteristic. In cases where it is desirable to correlate a

target characteristic with action of a particular drug, application of Applicant's method would enable the use of larger animal cohorts while reducing the number of assays required, yet retaining to ability identify the particular drug group(s) giving rise to the characteristic being assayed. However, this is not what Kuo et al. teaches, and rather, as stated above, Kuo et al. teaches that serial blood samples were collected at 0.5, 1, 2, 4, and 8 h post-dose from each animal and placed into separate tubes. Pooled samples were then made by combining 100 microliter aliquots taken from one of the three 0.5 h samples corresponding to each drug to provide pooled samples of 600 microliters. Thus, Kuo et al. teaches only classical pooling (composite sample), and does not teach or suggest the instantly claimed subject matter. In fact, not only does Kuo et al. not teach or suggest a true "test lot sample" in the present sense (rather only a pool of single samples each from a different individual), Kuo et al. also does not teach or suggest "modular composite samples" as disclosed and claimed by the present Applicant. Modular composite samples, as disclosed and claimed herein, are in effect "pools of pools" and the pools of Kuo et al. are but pools of individual samples, each sample from an individual rat.

Moreover, While Budiman et al., Davies et al., and Skov et al. provide teaching in the area of DNA methods, *Salmonella* assays, they do not remedy the above described deficiencies of Kuo et al. with respect to the absence of teachings for modular composite samples. Both Davies et al. and Skov et al. have been discussed and rebutted in detail in the prosecution record with respect to the absence of teachings of modular composite samples, and Budiman et al. is relied on by the Examiner only for DNA-based analysis.

Finally, there would have been no motivation to combine Budiman et al., Davies et al., and Skov et al. with Kuo et al., because the subject matter of Kuo et al. is not amenable to enrichment.

Applicant has, nonetheless, amended independent claims 1 and 20 as suggested by the Examiner and the Examiner's supervisor, to recite "wherein each test lot is separately~~the~~

~~assemblage can be~~ sampled by taking said plurality of portions" and further reciting separate test lot samples, which amendments serve to further distinguish the initial enrichment of separate test lot samples, in relation to the subsequent "removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample".

Applicant, therefore, respectfully requests withdrawal of the Examiner's rejection based on the rebuttal arguments described herein above with respect to Kuo et al., Davies et al., Skov et al., and Budiman et al.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Response and Amendment and allowance of all claims as presented and amended herein. The Examiner is encouraged to phone Applicant's attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

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EXHIBIT A

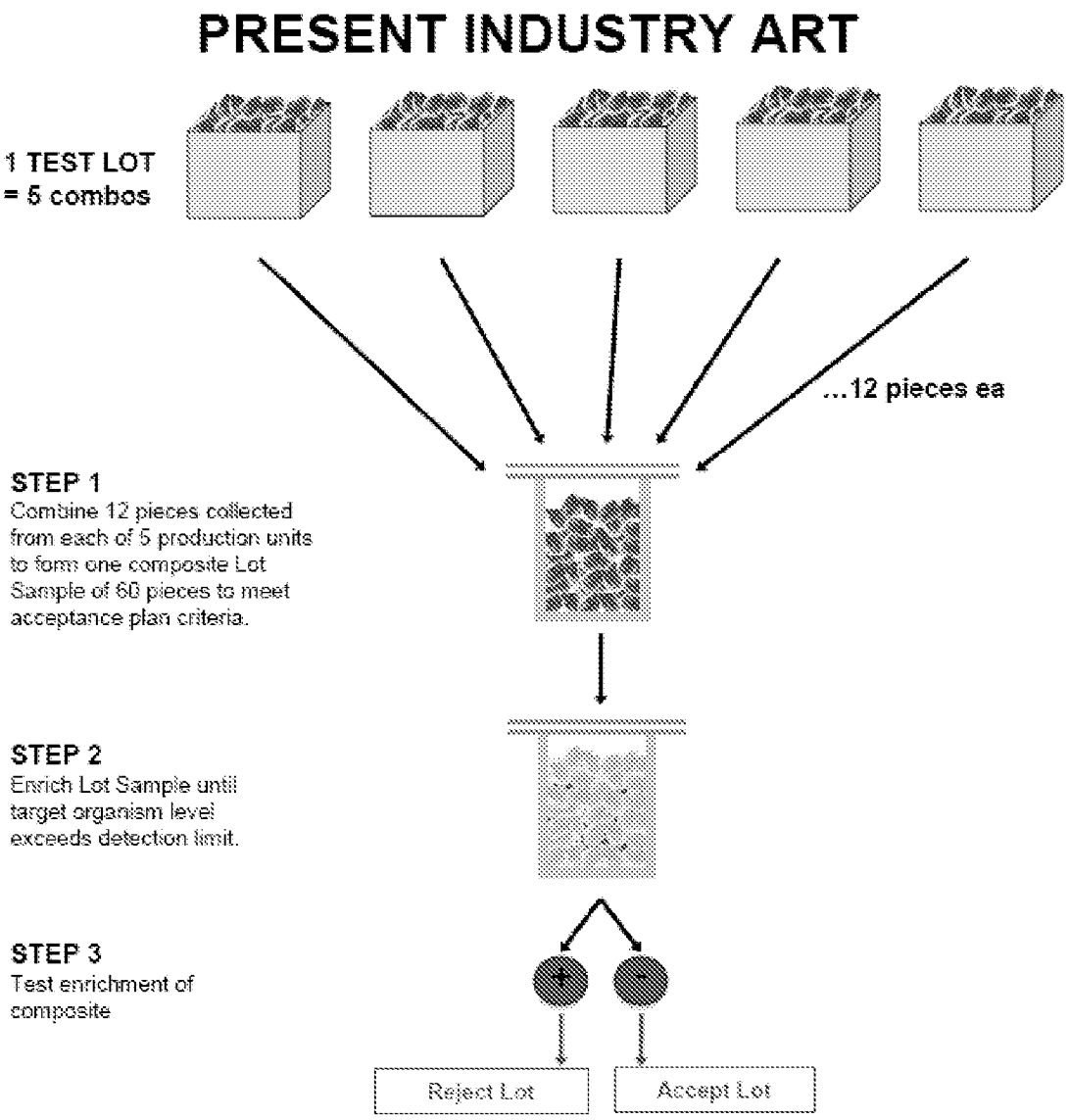

PRESENT INDUSTRY ART
1 TEST LOT
= 5 combos
...12 pieces ea
STEP 1
Combine 12 pieces collected from each of 5 production units to form one composite Lot Sample of 60 pieces to meet acceptance plan criteria.
STEP 2
Enrich Lot Sample until target organism level exceeds detection limit.
STEP 3
Test enrichment of composite
+
-
Reject Lot
Accept Lot

EXHIBIT B

CURRENT INVENTION

1 TEST LOT = 1 combo, 5 Lots tested simultaneously

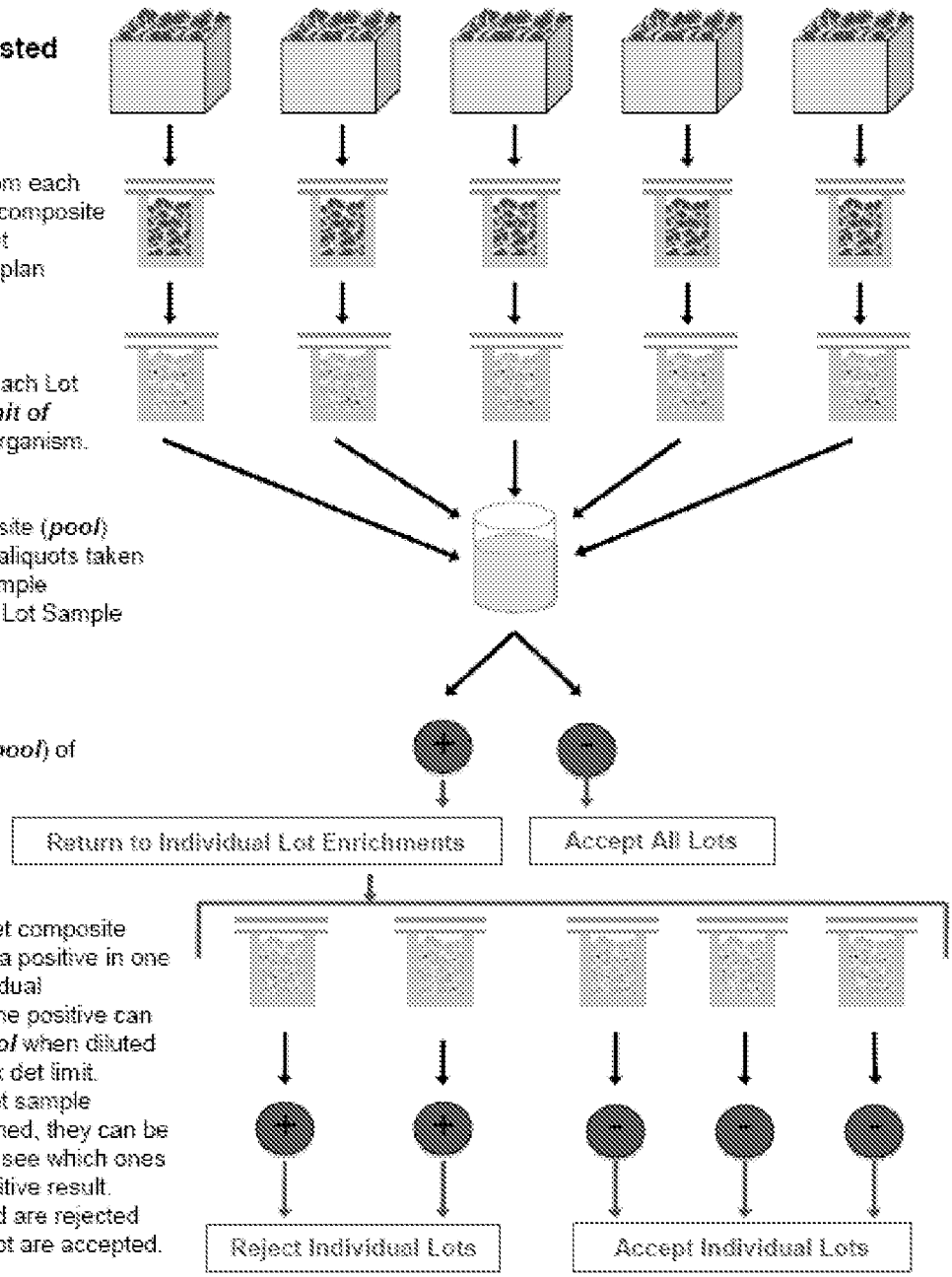
STEP 1
Collect 60 portions from each Lot to form individual composite Lot Samples and meet acceptance sampling plan criteria.

STEP 2
Enrich and incubate each Lot Sample to ***N x the limit of detection*** for target organism.

STEP 3
Prepare a wet composite (*pool*) from *N - 1* equal size aliquots taken from individual Lot sample enrichments. Retain Lot Sample enrichments.

STEP 4
Test wet composite (*pool*) of enrichment cultures

STEP 5
A positive signal in wet composite (*pool*) is the result of a positive in one or more original individual enrichments. Even one positive can be detected in the *pool* when diluted because N/(N-1) > 1 x det limit. Because individual Lot sample enrichments are retained, they can be immediately tested to see which ones contributed to the positive result. Those that contributed are rejected while those that did not are accepted.



Electronic Acknowledgement Receipt

EFS ID:	4825536
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	George Charles Rondeau/Judy Redmayne
Filer Authorized By:	George Charles Rondeau
Attorney Docket Number:	66090-29
Receipt Date:	19-FEB-2009
Filing Date:	08-AUG-2005
Time Stamp:	19:04:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		66090_29_AMD.pdf	347390 68ea7969677222d18edc317289e93dcc08c8750d	yes	24

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	24
Warnings:			
Information:			
	Total Files Size (in bytes):	347390	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

22504 7590 04/03/2009

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1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 04/03/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

TITLE OF INVENTION: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22504 7590 04/03/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

TITLE OF INVENTION: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
SRIVASTAVA, KAILASH C	1657	435-034000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 04/03/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 04/03/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 310 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 310 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment After Final filed 02/19/2009*.

2. ☒ The allowed claim(s) is/are *1 and 3-34*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *03042009* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☒ Other *Claims amendment of 02/19/2009*.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Kailash C. Srivastava, Examiner*. (3)_____.

(2) *Dr. Barry L. Davison*. (4)_____.

Date of Interview: *04 March 2009*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: *NONE*.

Claim(s) discussed: *Those of Record*.

Identification of prior art discussed: *That of Record*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Applicant's Representative authorized the Examiner to amend Claims 1, 7-10 and 20 to bring the pending Claims in the instant application in a better condition of allowability* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

EXAMINER'S AMENDMENT AND COMMENTS

1. The response and amendment filed 19 February 2009 to Office Action mailed 05 January 2009 is acknowledged and entered.

Withdrawal of Rejections based on Applicant's Amendments

2. In view of remarks and amendments to claims filed 19 February 2009, following rejections in Office Action mailed 05 January 2009 are hereby withdrawn.

- Anticipatory rejection to Claims 1, 3-9, 13-26, 29, 31 and 34 under 35 U.S.C. § 102(a) as anticipated by Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology, Volume 95, Pages1016–1025).

- Obviousness rejection to Claims 1, 3-27, 29-31 and 33-34 under 35 U.S.C. §103(a) as obvious over combined teachings from Kuo et al., (1998. Sample pooling to expedite bioanalysis and pharmacokinetic research, Journal of Pharmaceutical and Biomedical Analysis 16 (1998) 837–846) in view of Budiman et al. (2004. Localization of jointless-2 gene in the centromeric region of tomato chromosome 12 based on high resolution genetic and physical mapping, Theoretical and Applied Genetics, Volume 108, Pages: 190–196) and further in view of Davies et al., (2003.Evaluation of the use of pooled serum, pooled muscle tissue fluid (meat juice) and pooled feces for monitoring pig herds for *Salmonella*, Journal of Applied Microbiology 2003, Volume 95, Pages1016–1025) and Skov et al., (1999. Evaluation of Sampling Methods for the detection of *Salmonella* in broiler flocks, Journal of Applied Microbiology, Volume 86, Pages 695-700).

Claims Status

3. Claim 2 has been cancelled.

4. Claims 1, 6, 8, 10-12, 14-22, 26, 29 and 32-34 have currently been amended.

5. Claims 1 and 3-34 are currently pending and are examined on merits.

Examiner's Amendment

6. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 04 March 2009 with Dr. Barry L. Davison, Applicants' Representative.

In the Claims:

Please amend the following claims in the instant application.

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual

separate test lots ~~may nonetheless yet be~~ are validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining ~~a negative~~ test result for each test lot.

2. (Cancelled)

7. (Currently amended) The method of Claim 1, wherein testing of the modular composite sample, using a suitable detection assay further comprises ~~use of~~ a concentration step to concentrate the microbial agent or organism.

8. (Currently amended)The method of Claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples are further tested, such further testing comprises ~~use of~~ the more sensitive protocol.

9. (Currently amended) The method of Claim 8, wherein the more sensitive protocol further comprises ~~use of~~ a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol that is used to test the modular composite sample.

10. (Currently amended) The method of claim 1, further comprising, forming an additional modular composite sample from the set of enriched separate test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing ~~status~~ result.

20. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more production specimens, wherein each single-unit production lot is separately sampled by taking said plurality of portions thereof;

b) combining the collected plurality of product portions corresponding to each of the separate single-unit production lots to provide a corresponding set of separate single-unit production lot samples, wherein each separate single-unit production lot sample is

attributed to a particular corresponding separate single-unit production lot;

c) incubating the set of separate single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate single-unit production lot samples, to provide a set of separate single-unit production lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate single-unit production lot samples are validated, and wherein when such testing is positive, individual separate single-unit production lots ~~may nonetheless yet be~~ are validated by further testing of a portion of the respective enriched separate single-unit production lot sample using the same or a more sensitive protocol and obtaining ~~a negative~~ test result for each single-unit production lot.

7. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. Claims 1and 3-34 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava
Patent Examiner
Art Unit 1657
(571) 272-0923

07 March 2009

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11199871	SAMADPOUR, MANSOUR
	Examiner	Art Unit
	Kailash C Srivastava	1657

SEARCHED

Class	Subclass	Date	Examiner
Performed Partial Search in WEST	Performed Partial Search in WEST	01/02/2008	KCS
NONE	NONE	01/02/2008	KCS
Updated Partial Search in WEST	Updated Partial Search in WEST	08/17/2008	KCS
NONE	NONE	08/17/2008	KCS
pdated Partial Search in WEST	Updated Partial Search in WEST	12/26/2008	KCS
NONE	NONE	12/26/2008	KCS
Updated Partial Search in WEST	Updated Partial Search in WEST	3/9/2009	KCS
435	32, 34, 36, 38, 39, 40, 849	3/9/2009	KCS

SEARCH NOTES

Search Notes	Date	Examiner
WEST SEARCH: DWPI, EPAB, JPAB, PGPB. USOC, USPT	01/02/2008	KCS
STN SEARCH: AGRICOLA, BIOSIS, EMBASE, HCAPLUS, MEDLINE,	10/31/2007	KCS
Search Strategy:E.coli, Samadpour, test sample, validat, test lot, quality assurance method, sampl, scrren, portion, Salmonella, Screen, coliform, count, control, protocol, safety, food	01/02/2008	KCS
Perform Inventor Search	01/02/2008	KCS
Verified priority data and information (e.g., 60/599,473 filed 08/06/2004).	01/02/2008	KCS
Google Search: EPA method for water analysis, Method 1622, Giardia, Cryptosporidium	01/03/3008	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.	08/17/2008	KCS
Updated Google Search	08/17/2008	KCS
Updated Inventor Search	8/17/2008	KCS
Consulted strategy to upgrade search and strategy for Office Action with Dr. Weber	7/8/2008	KCS

/Kailash C Srivastava/ Examiner.Art Unit 1657	

SEARCH NOTES

Search Notes	Date	Examiner
Consulted strategy to upgrade search and strategy for Office Action with Dr. Weber	12/09/2008	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.Additional terms searched- mixed lot composxite sample	12/26/2008	KCS
Updated Inventor Search	12/26/2008	KCS
Confirmedpriority data and information (e.g., 60/599,473 filed 08/06/2004).	3/9/2009	KCS
Updated Search in WESt with the above-described strategy and additionally pork, meat, poultry, fish, sea food because of the amendment to the claims and additional claims that have not changed the invention scope.Additional terms searched- mixed lot composxite sample	3/9/2009	KCS
Updated Inventor Search	3/9/2009	KCS

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
Updated Partial Search in WEST	Updated Partial Search in WEST	3/9/2009	KCS
435	32, 34, 36, 38, 39, 40, 849	3/9/2009	KCS

/Kailash C Srivastava/ Examiner.Art Unit 1657	

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11199871	SAMADPOUR, MANSOUR
Examiner	**Art Unit**
Kailash C Srivastava	1657

ORIGINAL	
CLASS	SUBCLASS
435	34

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
435	32	36	38	39	40
435	849				

INTERNATIONAL CLASSIFICATION										
CLAIMED					NON-CLAIMED				
C	1	2	Q	1 / 24 (2006.01.01)	C	1	2	Q	1 / 10 (2006.01.01)
C	1	2	Q	1 / 04 (2006.01.01)	C	1	2	Q	1 / 14 (2006.01.01)
C	1	2	Q	1 / 06 (2006.01.01)	C	1	2	Q	1 / 20 (2006.01.01)
C	1	2	Q	1 / 08 (2006.01.01)					

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	14	17	26	33										
	2	15	18	28	34										
2	3	16	19												
27	4	17	20												
3	5	18	21												
4	6	31	22												
5	7	19	23												
6	8	20	24												
30	9	21	25												
7	10	22	26												
8	11	23	27												
9	12	29	28												
10	13	24	29												
11	14	32	30												
12	15	33	31												
13	16	25	32												

/Kailash C Srivastava/ Examiner.Art Unit 1657 (Assistant Examiner)	03/07/2009 (Date)	**Total Claims Allowed:** 33	
/JON P WEBER/ Supervisory Patent Examiner.Art Unit 1656/7 (Primary Examiner)	03/13/2009 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mansour Samadpour	Please enter the instant AMendment After Final
Serial No.:	11/199,871	/Kailash C. Srivastava/03/03/3009
Filed:	08 August 2005	Patent Examiner Art nit 1657
For:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS	
Examiner:	Kailash C. Srivastava	
Art Unit:	1657	
Docket No.:	66090-29	
Date:	19 February 2009	

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 C.F.R. § 1.116

Sir:

This is a RESPONSE AND AMENDMENT in reply to a final Office Action dated 05 January 2009 in the above identified application. No fees are deemed necessary.

Kindly amend the above-identified patent application as follows:

Application No.:	11/199,871
Attorney Docket No.:	66090-29
First Applicant's Name:	Mansour Samadpour
Application Filing Date:	08 August 2005
Office Action Dated:	05 January 2009
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Examiner:	Kailash C. Srivastava

IN THE CLAIMS:

Applicant, pursuant to 37 C.F.R. § 1.121, submits the following amendments to the claims:

1. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately ~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lot samples are validated, and wherein when such testing is positive, individual separate test lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result.

2. (Cancelled)

3. (Original) The method of claim 1, wherein the test lot is a single-unit production lot, comprised of operationally-linked product specimens.

4. (Original) The method of claim 3, wherein product specimens are synonymous with product portions.

5. (Original) The method of claim 1, further comprising incubating the modular composite sample of d), prior to testing in e).

6. (Currently amended) The method of claim 1, wherein incubating each separate test lot sample in c) comprises incubating each separate test lot sample with enrichment medium suitable to enrich for the target microbial agent or organism, ~~to the sample,~~ and wherein removing in d) comprises removing a portion of the enrichment medium from each enriched separate test lot sample and combining the removed portions to provide a modular composite sample.

7. (Original) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of a concentration step to concentrate the microbial agent or organism.

8. (Currently amended) The method of claim 1, wherein testing in e) of the modular composite sample is positive, and wherein the individual separate test lot samples~~lots~~ are further tested, such further testing comprises use of the more sensitive protocol.

9. (Original) The method of claim 8, wherein the more sensitive protocol comprises use of a concentration step to concentrate the microbial agent or organism, in combination with the same test protocol used to test the modular composite sample.

10. (Currently amended) The method of claim 1, further comprising, forming an additional modular composite sample from the set of enriched separate test lot samples of c) and testing the additional modular composite sample, using the same or a different suitable assay, to confirm the testing status.

11. (Currently amended) The method of claim 1, further comprising, forming an additional modular composite sample from an additional enriched separate test lot sample along with any enriched separate test lot samples of c) that test negative in e), and testing the additional modular composite sample, using the same or a different suitable assay.

12. (Currently amended) The method of claim 1, further comprising, where testing of the modular composite sample in e) is negative, forming an additional modular composite sample from the set of enriched separate test lot samples of c), and testing the additional modular composite sample, using a different suitable assay, to confirm the negative testing status.

13. (Previously presented) The method of claim 1, wherein the test lot is selected from the lot group consisting of a single combo, single bin, single pallet, and a production assemblage.

14. (Currently amended) The method of claim 1, wherein the number of separate test lots is from 3 to 10.

15. (Currently amended) The method of claim 1, further comprising, where testing of the modular composite sample is positive, determining which individual separate test lots are positive, application of remedial measures to said separate positive test lots, and validating by further testing of a portion of the respective remediated separate test lots and obtaining a negative test result.

16. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot a number of portions from 5 to 100.

17. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot 30 to 60 portions.

18. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting 30 portions from each separate test lot.

19. (Currently amended) The method of claim 1, wherein, in a), separately collecting said[[a]] plurality of portions from each of said[[a]] plurality of separate test lots comprises separately collecting from each separate test lot about 60 portions.

20. (Currently amended) A method of sampling, testing and validating test lots for microbial contamination, comprising:

a) collecting a plurality of portions from each of a plurality of single-unit production lots, the single-unit production lots each comprising an assemblage of one or more product specimens, wherein each single-unit production lot is separately~~the assemblage can be~~ sampled by taking said plurality of portions thereof;

b) combining the collected plurality of product portions corresponding to each of the separate single-unit production lots to provide a corresponding set of separate single-unit production lot samples, wherein each separate single-unit production lot sample is attributed to a particular corresponding separate single-unit production lot;

c) incubating the set of separate single-unit production lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate single-unit production lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate single-unit production lot samples, to provide a set of separate single-unit production lot samples enriched for the target microbial agent or organism;

d) removing portions of each enriched separate single-unit production lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate single-unit production lot samples are validated, and wherein when such testing is positive, individual separate single-unit production lots may nonetheless yet be validated by further testing of a portion of the respective enriched separate single-unit production lot sample using the same or a more sensitive protocol and obtaining a negative test result.

21. (Currently amended) The method of claim 1, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate test lot samples.

22. (Currently amended) The method of claim 20, wherein removing portions in step d) is removing equal portions, aseptically, so as to preclude contamination of the enriched separate single-unit production lot samples.

23. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria*, *Salmonella* and *Escherichia coli*.

24. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises at least one selected from the group consisting of *Listeria* spp., *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli* O157:H7, coliforms and fecal coliforms.

25. (Previously presented) The method of claim 1, wherein the target microbial agent or organism comprises a spoilage organism.

26. (Currently amended) The method of claim 1, wherein removing portions of each enriched separate test lot sample comprises removing equal volume portions of each enriched separate test lot sample.

27. (Previously presented) The method of claim 1, wherein testing of the modular composite sample, using a suitable detection assay comprises use of at least one of a DNA-based method, an immunochemistry-based method, and a biosensor-based method.

28. (Previously presented) The method of claim 7 wherein the concentration step comprises at least one of immunomagnetic bead separation, and affinity chromatography.

29. (Currently amended) The method of claim 1, wherein the separate test lots are production lots of a meat or poultry product, comprising an assemblage of one or more meat or poultry specimens, respectively.

30. (Previously presented) The method of claim 29, wherein the meat or poultry specimens are meat trim pieces or poultry trim pieces, respectively.

31. (Previously presented) The method of claim 29, wherein the meat is that of beef, pork, sheep or bison.

32. (Currently amended) The method of claim 1, wherein the separate test lots are separate production lots of a fish or seafood product, comprising an assemblage of one or more fish or seafood specimens, respectively.

33. (Currently amended) The method of claim 1, wherein the separate test lots are separate production lots of a ready-to-eat product.

34. (Currently amended) The method of claim 6, wherein the medium comprises a selective agent that will inhibit a competing non-target microbial agent or organism[[s]].

WEST Search History for Application 11199871

Creation Date: 2009030909:41

Query	DB	Op.	Plur.	Thes.	Date
quality control	USPT	ADJ			08-17-2008
composite sample	USPT	ADJ			08-17-2008
(mixed lot) (sample)	USPT	ADJ			08-17-2008
Intermediate sample	USPT	ADJ			08-17-2008
ladder sampl$5	USPT	ADJ			08-17-2008
(mixed lot) same (sample)	USPT	ADJ			08-17-2008
(quality control) same ((mixed lot) same (sample))	USPT	ADJ			08-17-2008
(composite sample) same (Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) same (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (composite sample same Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) same (composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) same (quality control same composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(quality control) same (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control) same (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (Intermediate sample)	USPT	ADJ			08-17-2008
(quality control) and (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (ladder sampl$5)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (composite sample)	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and (quality control same composite sample)	USPT	ADJ			08-17-2008
(stepwise)same (sample analysis)	USPT	ADJ			08-17-2008
(quality control) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008

(ladder sampl$5) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(composite sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
(quality control and Intermediate sample) and ((stepwise)same (sample analysis))	USPT	ADJ			08-17-2008
discriminat$8 same sampl$5	USPT	ADJ			08-17-2008
((stepwise)same (sample analysis)) same (discriminat$8 same sampl$5)	USPT	ADJ			08-17-2008
(stepwise) same (sample analysis)	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) same ((stepwise) same (sample analysis))	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			08-17-2008
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			08-17-2008
(quality control) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Intermediate sample) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(ladder sampl$5) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
((mixed lot) same (sample)) and (discriminat$8 same sampl$5 and composite sample)	USPT	ADJ			08-17-2008
(Pharmaceutical sample)	USPT	ADJ			08-17-2008
(quality control) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(Intermediate sample) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(ladder sampl$5) and (quality control and (Pharmaceutical sample))	USPT	ADJ			08-17-2008
(ladder sampl$5) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008
(composite sample) and ((Pharmaceutical sample))	USPT	ADJ			08-17-2008

(composite sample and (Pharmaceutical sample)) and @pd > 20080817	USPT	ADJ			08-17-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ	YES		08-17-2008
((stepwise) same (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(Intermediate sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(ladder sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ	YES		08-17-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
quality control	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
composite sample	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot)and (sample)		ADJ	YES		08-17-2008

	EPAB, JPAB, DWPI				
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((Pharmaceutical sample))	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
(discriminat$8 and sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((stepwise)and (sample analysis)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ	YES		08-17-2008
quality control	USPT	ADJ			12-26-2008
composite sample	USPT	ADJ			12-26-2008
Intermediate sample	USPT	ADJ			12-26-2008
ladder sampl$5	USPT	ADJ			12-26-2008

(mixed lot) same (sample)	USPT	ADJ			12-26-2008
(composite sample) same (Intermediate sample)	USPT	ADJ			12-26-2008
(quality control) same (composite sample)	USPT	ADJ			12-26-2008
(quality control) and (Intermediate sample)	USPT	ADJ			12-26-2008
(stepwise)same (sample analysis)	USPT	ADJ			12-26-2008
discriminat$8 same sampl$5	USPT	ADJ			12-26-2008
(stepwise) same (sample analysis)	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			12-26-2008
(Pharmaceutical sample)	USPT	ADJ			12-26-2008
(quality control) and ((Pharmaceutical sample))	USPT	ADJ			12-26-2008
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			12-26-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ			12-26-2008
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			12-26-2008
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ			12-26-2008
quality control	EPAB, JPAB, DWPI	ADJ			12-26-2008
composite sample	EPAB, JPAB, DWPI	ADJ			12-26-2008
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ			12-26-2008

(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ			12-26-2008
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ			12-26-2008
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ			12-26-2008
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ			12-26-2008
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ			12-26-2008
sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))	PGPB, USPT	ADJ	YES		12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)))	PGPB, USPT	ADJ	YES		12-26-2008
(pooled same (lot sample))	PGPB, USPT	ADJ	YES		12-26-2008
(pooled same sample)	PGPB, USPT	ADJ	YES		12-26-2008
sample Same (pooled or composite or lot)	PGPB, USPT	ADJ	YES		12-26-2008
((pooled same sample)) same (sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		12-26-2008
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella same sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ	YES		12-26-2008
		ADJ	YES		12-26-2008

(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT				
sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
(pooled and sample)	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
sample and (pooled or composite or lot)	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
((pooled and sample)) and (sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
(sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))) and ((pooled and sample) and sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ	YES		12-26-2008
quality control	USPT	ADJ			03-09-2009
composite sample	USPT	ADJ			03-09-2009
Intermediate sample	USPT	ADJ			03-09-2009
ladder sampl$5	USPT	ADJ			03-09-2009
(mixed lot) same (sample)	USPT	ADJ			03-09-2009
(composite sample) same (Intermediate sample)	USPT	ADJ			03-09-2009
(quality control) same (composite sample)	USPT	ADJ			03-09-2009
(quality control) and (Intermediate sample)	USPT	ADJ			03-09-2009
(stepwise)same (sample analysis)	USPT	ADJ			03-09-2009
discriminat$8 same sampl$5	USPT	ADJ			03-09-2009
(stepwise) same (sample analysis)	USPT	ADJ			03-09-2009
(discriminat$8 same sampl$5) and ((stepwise) same (sample analysis))	USPT	ADJ			03-09-2009
(discriminat$8 same sampl$5) and (composite sample)	USPT	ADJ			03-09-2009

(Pharmaceutical sample)	USPT	ADJ			03-09-2009
(quality control) and ((Pharmaceutical sample))	USPT	ADJ			03-09-2009
(Intermediate sample) and ((Pharmaceutical sample))	USPT	ADJ			03-09-2009
(meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella	USPT	ADJ			03-09-2009
(quality control) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			03-09-2009
(discriminat$8 same sampl$5) and (quality control and (meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			03-09-2009
(composite sample) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella)	USPT	ADJ			03-09-2009
(meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella	EPAB, JPAB, DWPI	ADJ			03-09-2009
quality control	EPAB, JPAB, DWPI	ADJ			03-09-2009
composite sample	EPAB, JPAB, DWPI	ADJ			03-09-2009
(mixed lot)and (sample)	EPAB, JPAB, DWPI	ADJ			03-09-2009
((mixed lot)and (sample))	EPAB, JPAB, DWPI	ADJ			03-09-2009
(mixed lot) and (sample)	EPAB, JPAB, DWPI	ADJ			03-09-2009
(stepwise)and (sample analysis)	EPAB, JPAB, DWPI	ADJ			03-09-2009
discriminat$8 and sampl$5	EPAB, JPAB, DWPI	ADJ			03-09-2009
(Pharmaceutical sample)	EPAB, JPAB, DWPI	ADJ			03-09-2009

((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella) and (quality control)	EPAB, JPAB, DWPI	ADJ			03-09-2009
(composite sample) and (quality control)	EPAB, JPAB, DWPI	ADJ			03-09-2009
(discriminat$8 and sampl$5) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ			03-09-2009
((Pharmaceutical sample)) and ((meat or pork or chicken or beef or bison or sandwich or cold cut) and Salmonella)	EPAB, JPAB, DWPI	ADJ			03-09-2009
sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))	PGPB, USPT	ADJ			03-09-2009
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella) same (sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)))	PGPB, USPT	ADJ			03-09-2009
(pooled same sample)	PGPB, USPT	ADJ			03-09-2009
sample Same (pooled or composite or lot)	PGPB, USPT	ADJ			03-09-2009
((pooled same sample)) same (sample Same (pooled or composite or lot))	PGPB, USPT	ADJ			03-09-2009
((meat or pork or chicken or beef or bison or sandwich or cold cut) same Salmonella same sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ			03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9))) same ((pooled same sample) same sample Same (pooled or composite or lot))	PGPB, USPT	ADJ			03-09-2009
sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))	USOC, EPAB, JPAB, DWPI	ADJ			03-09-2009
(pooled and sample)	USOC, EPAB, JPAB, DWPI	ADJ			03-09-2009
sample and (pooled or composite or lot)	USOC, EPAB,	ADJ			03-09-2009

	JPAB, DWPI				
((pooled and sample)) and (sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ			03-09-2009
(sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9))) and ((pooled and sample) and sample and (pooled or composite or lot))	USOC, EPAB, JPAB, DWPI	ADJ			03-09-2009
(sample and (enrich$5 and ((pathogenic bacteria) or Salmonella or Listeria$9)) and (pooled and sample) and sample and (pooled or composite or lot)) and @pd > 20081226	USOC, EPAB, JPAB, DWPI	ADJ			03-09-2009
435/34.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/36.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/38.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/39.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/40.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/849.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
435/849.CCLS.	PGPB, USPT	ADJ	YES		03-09-2009
(435/34.CCLS.) AND (435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(435/39.CCLS.) AND (435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(435/38.CCLS.) AND (435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(435/36.CCLS.) AND (435/38.CCLS. AND 435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(435/40.CCLS.) AND (435/36.CCLS. AND 435/38.CCLS. AND 435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009

(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/36.CCLS. AND 435/38.CCLS. AND 435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/38.CCLS. AND 435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/38.CCLS. AND 435/39.CCLS. AND 435/34.CCLS. AND 435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/34.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/36.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/38.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/39.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/40.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009
(sample same (enrich$5 same ((pathogenic bacteria) or Salmonella or Listeria$9)) same (pooled same sample) same sample Same (pooled or composite or lot)) AND (435/849.CCLS.)	PGPB, USPT	ADJ	YES		03-09-2009

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

22504 7590 04/03/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

filed electronically

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Judith E. Redmayne	(Depositor's name)
Judith E. Redmayne	(Signature)
April 8, 2009	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

TITLE OF INVENTION: MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
SRIVASTAVA, KAILASH C	1657	435-034000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Barry L. Davison, Ph.D., J.D.
2 Davis Wright Tremaine LLP
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Institute for Environmental Health, Inc. Lake Forest Park, Washington

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 040258 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date April 8, 2009

Typed or printed name Barry L. Davison, Ph.D., J.D. Registration No. 47,309

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	11199871
Filing Date:	08-Aug-2005
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Filer:	Barry Davison/Judy Redmayne
Attorney Docket Number:	66090-29

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Publ. Fee- early, voluntary, or normal	1504	1	300	300
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	755	755

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1055**

Electronic Acknowledgement Receipt

EFS ID:	5117420
Application Number:	11199871
International Application Number:	
Confirmation Number:	2448
Title of Invention:	MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR CONSTITUENTS
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Judy Redmayne
Filer Authorized By:	Barry Davison
Attorney Docket Number:	66090-29
Receipt Date:	08-APR-2009
Filing Date:	08-AUG-2005
Time Stamp:	12:41:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1055
RAM confirmation Number	8038
Deposit Account	040258
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	66090_29_IF.pdf	54725 f3c6a5d07e806e1d629a889d5f63270c4bd344f5	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	31975 6f203b9ee30f91acb169cd6588d47bc2c74da901	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	86700		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Kindly ***substitute*** the following paragraph for the corresponding paragraph at page 16, lines 14-26:

--In particular aspects, the methods further comprise, where testing of the modular composite sample is positive, determining which individual test lots are positive, and application of remedial measures that are specific to one or more individual test lots that test positive. In particular aspects, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot a number of portions selected from the group consisting of from about 5 to about 100, from about 10 to about 90, from about 20 to about 80, from about 30 to about 70, from about 30 to about 60, and from about 40 to about 50 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 to about 60 portions. Alternatively~~Alternativley~~, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 30 portions. Preferably, separately collecting a plurality of portions from each of a plurality of test lots comprises separately collecting from each test lot about 60 portions.--

Page 18 line 22 to Page 19 line 2 RW 4/9/09

Kindly ***substitute*** the following paragraph for the corresponding paragraph at ~~page 16, lines 14-26:~~

--The product, in this Example I, being produced by this U.S. beef producer was beef trim. The release of the validated 19,280,000~~1,9280,000~~ lbs of beef trim into commerce using the present invention, instead of diverting or downgrading the product, trim, represents a cost savings to the producer of about $2,500,000, relative to prior art methods. Additionally, the testing of the single-unit production lots by augmented testing protocols (representing a 5- to 50-fold increase in

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	05/19/2009	7534584	66090-29	2448

22504 7590 04/29/2009

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 310 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Mansour Samadpour, Seattle, WA;

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/199,871	08/08/2005	Mansour Samadpour	66090-29	2448

22504 7590 03/08/2010

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
03/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/199,871	SAMADPOUR, MANSOUR	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Kailash C. Srivastava,Examiner*. (3)_____.

(2) *Mr. B. Davison, Applicant's Representative*. (4)_____.

Date of Interview: *03/01-2/2010*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: *NONE*.

Claim(s) discussed: *NONE*.

Identification of prior art discussed: *NONE*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Applicant's Representative sought Examiner's advice regarding a third Party filing and Reexamination request. Examiner informed the Representative that the Examiner will consult Examiner's Supervisor and give the Representative information. Subsequently, Examiner advised the Representative that (i) the case will now be handled by the Re-Exam Unit of the Patent Office, (ii) The representative should contact Mr. B. Celsa as the Examiner's Supervisor advised the representative in a voice mail message* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Kailash C Srivastava/ Examiner, Art Unit 1657	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY.DOCKET NO./TITLE	REQUEST ID
11/199,871	08/08/2005	Mansour Samadpour	0066090-008US0	26037

Acknowledgement of Loss of Entitlement to Entity Status Discount

The entity status change request below filed through Private PAIR on 10/04/2016 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

X Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be notification of loss of entitlement to small or micro entity status, as applicable.

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Barry L. Davison/
Name:	Barry L. Davison
Registration Number:	47309

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Western District of Texas on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
6:21-cv-176	2/25/2021	Western District of Texas

PLAINTIFF	DEFENDANT
Institute for Environmental Health, Inc.	Food Safety Net Services, Ltd

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	7,534,584	5/2/2021	Institute for Environmental Health, Inc.
2	8,822,143	9/2/2014	Institute for Environmental Health, Inc.
3	9,637,771	5/2/2017	Institute for Environmental Health, Inc.
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Western District of Texas on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

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PLAINTIFF	DEFENDANT
Institute for Environmental Health, Inc.	Food Safety Net Services, Ltd

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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3	9,637,771	5/2/2017	Institute for Environmental Health, Inc.
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DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT
02/15/2022 - Voluntary Dismissal

CLERK	(BY) DEPUTY CLERK	DATE
Jeannette J. Clack	Jennifer Clark	02/15/2022

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