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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	07/28/2020	10724068	0066090-003US2	5392

22504 7590 07/08/2020

DAVIS WRIGHT TREMAINE, LLP/SEATTLE
IP DOCKETING DEPT.
DAVIS WRIGHT TREMAINE LLP
920 FIFTH AVE., SUITE 3300
SEATTLE, WA 98104-1610

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 23 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 Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Mansour Samadpour, Lake Forest Park, WA;
Institute for Environmental Health, Inc., Lake Forest Park, WA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Please amend the paragraph at page 20, lines 17-24, as follows:

Yet further alternate embodiments provide a method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising: obtaining a test sample at a first location, the sample being solid, semi-solid or liquid; diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample; incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

Change(s) applied to document, Please amend the paragraph at page 21, lines ¹⁶⁻²¹~~23-26~~, as follows:

/M.J.O./
5/18/2020 Samples testable according to the present invention include, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, ~~[[etc]]~~ etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

Please amend the paragraphs at page 24, lines 5-21, as follows:

In preferred embodiments, the present inventive methods encompass the detection of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species* species, *Staphylococcus* ~~[[spp]]~~ spp. Additionally, other pathogens and pathogenic agents are encompassed within the present invention, including, but not limited to

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

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.

22504 7590 04/01/2020
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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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392

TITLE OF INVENTION: ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	07/01/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
SWARTZ, RODNEY P	1645	424-234100

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 03-09 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 04-0258

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Barry L. Davison/

Date June 19, 2020

Typed or printed name Barry L. Davison, Ph.D., J.D.

Registration No. 47,309

Electronic Acknowledgement Receipt

EFS ID:	39775221
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-JUN-2020
Filing Date:	15-DEC-2017
Time Stamp:	15:13:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 1000
RAM confirmation Number	E20206IF14013430
Deposit Account	040258
Authorized User	Janet Berdine

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

National Beef Ex. 1008

Page 4 of 239

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)	2020-06-19_0066090-003US2_Issue_Fee_Transmittal.pdf	236082	no	1
			2c1917a388ddbaaf5d88c4eb739830a68971d529		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30526	no	2
			d7ac691295c4fef45fdb894ddcb68bc55e33b360		
Warnings:					
Information:					
Total Files Size (in bytes):			266608		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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 04/01/2020
DAVIS WRIGHT TREMAINE, LLP/SEATTLE
IP DOCKETING DEPT.
DAVIS WRIGHT TREMAINE LLP
920 FIFTH AVE., SUITE 3300
SEATTLE, WA 98104-1610

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 04/01/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392

TITLE OF INVENTION: ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1000	\$0.00	\$0.00	\$1000	07/01/2020

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 ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
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By fax, send to: (571)-273-2885

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SEATTLE, WA 98104-1610

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(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392

TITLE OF INVENTION: ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES

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EXAMINER	ART UNIT	CLASS-SUBCLASS
SWARTZ, RODNEY P	1645	424-234100

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☐ 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 03-09 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,

1 _____

(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.

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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

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☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

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☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392
22504	7590	04/01/2020	EXAMINER	
DAVIS WRIGHT TREMAINE, LLP/SEATTLE IP DOCKETING DEPT. DAVIS WRIGHT TREMAINE LLP 920 FIFTH AVE., SUITE 3300 SEATTLE, WA 98104-1610			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 04/01/2020				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B 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 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, 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.

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 disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Notice of Allowability	Application No. 15/844,407	Applicant(s) Samadpour, Mansour	
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645	AIA (FITF) Status No

-- 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 3-19-2020.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov**.

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

Certified copies:

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.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ 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. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	5. ☐ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☒ Other <u>Detailed Action</u> .
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/Rodney P Swartz, Ph.D./
Primary Examiner, Art Unit 1645

Continuation of 3. The allowed claim(s) is/are: 1,5,7,9-15,17 and 19-31

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. Applicant's Response to Office Action, received 3-19-2020, is acknowledged. Claims 1, 10, and 20 have been amended. The submitted Terminal Disclaimer has been reviewed and approved.
3. Claims 1, 5, 7, 9-15, 17, and 19-31 are pending and under consideration.

Rejections/Objections Withdrawn

4. The objection to claim 10 is withdrawn in light of the claim amendment.
5. The objection to claim 20 is withdrawn in light of the claim amendment.
6. The rejection of claim 1 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe" in lines 8, 9, 10, 12, and 13, is withdrawn in light of the claim amendment.
7. The rejection of claims 1, 5, 7, 9-13, 22, 24, and 26-28 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for how one detects a particular pathogen or other microbe when the assay steps are drawn only to bacteria, is withdrawn in light of the claim amendments.
8. The rejection of claim 5 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
9. The rejection of claim 9 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.

10. The rejection of claim 10 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
11. The rejection of claim 11 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
12. The rejection of claim 24 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
13. The rejection of claim 26 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
14. The rejection of claim 27 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, insufficient antecedent basis for the limitation "particular bacterial pathogen or bacterial microbe", is withdrawn in light of the claim amendments.
15. The rejection of claims 1, 5, 7, 9-13, 22, 24, and 26-28 on the grounds of nonstatutory double patenting as being unpatentable over claims 1, 4-10, 17, 19, and 21-23 of U.S. Patent No. 9,845,486, is withdrawn in light of the approved and entered Terminal Disclaimer.
16. The rejection of claims 14, 15, 17, 19-21, 23, 25, and 29-31 on the grounds of nonstatutory double patenting as being unpatentable over claims 11-16, 18, 20, and 24-26 of U.S. Patent No. 9,845,486, withdrawn in light of the approved and entered Terminal Disclaimer.
17. The rejection of claims 1, 5, 7, 9-13, 22, 24, and 26-28 on the grounds of nonstatutory double patenting as being unpatentable over claims 1-11, 18, 20, and 22-23 of

U.S. Patent No. 7,531,163, is withdrawn in light of the approved and entered Terminal Disclaimer.

Conclusion

18. Claims 1, 5, 7, 9-15, 17, and 19-31 are allowed.
19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for 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 (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.

/Rodney P Swartz, Ph.D./
Primary Examiner, Art Unit 1645
March 25, 2020

<i>Index of Claims</i> 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

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

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	12/16/2019	03/25/2020							
	1	✓	=							
	2	-	-							
	3	-	-							
	4	-	-							
	5	✓	=							
	6	-	-							
	7	✓	=							
	8	-	-							
	9	✓	=							
	10	✓	=							
	11	✓	=							
	12	✓	=							
	13	✓	=							
	14	✓	=							
	15	✓	=							
	16	-	-							
	17	✓	=							
	18	-	-							
	19	✓	=							
	20	✓	=							
	21	✓	=							
	22	✓	=							
	23	✓	=							
	24	✓	=							
	25	✓	=							
	26	✓	=							
	27	✓	=							
	28	✓	=							
	29	✓	=							
	30	✓	=							
	31	✓	=							

Search Notes 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

CPC - Searched*		
Symbol	Date	Examiner
A61K 39/02	12/16/2019	RPS
C12Q 1/00	12/16/2019	RPS
Go1N 33/53	12/16/2019	RPS
C12N 1/00		

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
424	9.1, 130.1, 164.1, 184.1, 234.1	12/16/2019	RPS
435	4, 7.2, 243	12/16/2019	RPS

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PALM - inventor names; EAST; biosis caba caplus embase japio medline pctfull scisearch	12/16/2019	RPS
reviewed prosecution and prior searches	03/25/2020	RPS

/Rodney P Swartz, Ph.D./ Primary Examiner, Art Unit 1645	
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<i>Search Notes</i> 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
see Issue Classification		03/25/2020	RPS

/Rodney P Swartz, Ph.D./ Primary Examiner, Art Unit 1645	
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Issue Classification 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

CPC						
Symbol					Type	Version
C12Q	/	1	/	04	F	2013-01-01
C12Q	/	1	/	6806	I	2013-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	24	
/Rodney P Swartz, Ph.D./	25 March 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61K	/	39	/ 02
C12Q	/	1	/ 00
G01N	/	33	/ 53
NON-CLAIMED			
	/		/

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
424	234.1

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
424	9.1	130.1	164.1	184.1		
435	4	7.2	243			

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	24	
/Rodney P Swartz, Ph.D./	25 March 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

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

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 24	
/Rodney P Swartz, Ph.D./ Primary Examiner, Art Unit 1645 (Primary Examiner) _____ (Date) 25 March 2020		O.G. Print Claim(s) 1	O.G. Print Figure none



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BIB DATA SHEET

CONFIRMATION NO. 5392

SERIAL NUMBER 15/844,407	FILING or 371(c) DATE 12/15/2017 RULE	CLASS 424	GROUP ART UNIT 1645	ATTORNEY DOCKET NO. 0066090-003US2	
APPLICANTS Institute for Environmental Health, Inc., Lake Forest Park, WA INVENTORS Mansour Samadpour, Lake Forest Park, WA; ** CONTINUING DATA ***** This application is a CON of 12/360,646 01/27/2009 PAT 9845486 which is a CON of 10/848,253 05/17/2004 PAT 7531163 which claims benefit of 60/470,975 05/16/2003 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 01/08/2018					
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and /RODNEY P SWARTZ, PhD/ Acknowledged Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY WA	SHEETS DRAWINGS 11	TOTAL CLAIMS 24	INDEPENDENT CLAIMS 2
ADDRESS DAVIS WRIGHT TREMAINE, LLP/SEATTLE IP DOCKETING DEPT. DAVIS WRIGHT TREMAINE LLP 920 FIFTH AVE., SUITE 3300 SEATTLE, WA 98104-1610 UNITED STATES					
TITLE ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES					
FILING FEE RECEIVED 2060	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour

Filing Date: December 15, 2017

Application No.: 15/844,407

Confirmation No.: 5392

For: ENRICHMENT METHODS FOR THE DETECTION
OF PATHOGENS AND OTHER MICROBES

Art Unit: 1645

Examiner: Rodney P. Swartz

Docket: 0066090-003US2

Date: March 19, 2020

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 an Office Action dated December 19, 2019, for the above-identified patent application.

Please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of the claims, which begins on page 9 of this paper.

Remarks/Arguments begin on page 16 of this paper.

IN THE SPECIFICATION

Per the Examiner's request, please amend the Specification as follows:

Please amend the paragraph at page 1, lines 14-20, as follows:

The present invention, in various aspects, relates generally to improving the efficiency of producing foods , and the safety and quality of food products, including but not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, [[etc]] etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, [[etc]] etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols. More specifically, embodiments of the present invention relate to novel methods for pathogen testing and detection at a site that is remote from a site of which samples are taken.

Please amend the paragraph at page 2, lines 1-15, as follows:

Most regulatory agencies require, and customers demand specific testing for pathogens that are common to specific food types, and agricultural products, that are capable of *in vivo* multiplication. Rapid and accurate methods for detection of foodborne and waterborne pathogens are essential, particularly in the context of food manufacturing processes, pharmaceutical industry, drinking water and wastewater utilities, management of fisheries resources and bodies of water (recreational, [[etc]] etc.). The same applies to the general detection of human, animal and plant pathogens, and in general to any kind of bacterial, viral, fungal, and parasitic pathogens that are capable of *in vivo* multiplication, and their indicator organisms. Many manufacturers and utilities have, consequently, had to build in-house labs to expedite the testing, or lose valuable time waiting for test results when samples are shipped out

to outside labs. The same is true for the utility industry (water and wastewater), and the pharmaceutical industry. Furthermore, using art-recognized and current standard methods, the cost of enrichment media used to expand the numbers of one or more particular pathogens to detectable levels, can be substantial.

Please amend the paragraph at page 8, lines 9-19, as follows:

Clostridium. Fach, et al. (*Appl. Environ. Microbiol.* 61:389-92, 1995), incubate 10 g of food samples (raw/cooked beef, raw/cooked pork, and raw fish) in 90 ml of Trypticase yeast extract glucose for the detection of *Clostridium* ~~[[spp]]~~ spp. Similarly, Dahlenborg et al. (*Appl. Environ. Microbiol.* 67:4781-8, 2001) incubate 10 g of feces in 90 ml of tryptone-peptone-glucose-yeast extract to select for *C. botulinum*.

Specilaized, selective media. Additionally, various specialized *selection* media (and agar) are known and used in the art. Such media comprises one or more anti-microbial reagents (e.g., tellurite and cefixime that selectively suppress particular (e.g., normal) flora growth and interference therefrom, to enhance the ability to detect, for example a slower growing pathogen (e.g., ~~E. coli~~ E. coli O157:H7). Such anti-microbial reagents, while having utility, nonetheless add even more expense to the media.

Please amend the paragraphs at page 9, lines 15, through page 10, line 3, as follows:

There is a pronounced need in the art for accurate and efficient methods for testing samples at a remote location, including but not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, ~~[[etc]]~~ etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection

protocols.

SUMMARY OF THE INVENTION

The present invention provides novel enrichment, testing and detection methods for detection of pathogens or other microbes in food, water, wastewater, sludge, pharmaceutical, industrial samples, and the like. The methods are also applicable to testing samples including, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, [[etc]] etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

Please amend the paragraph starting at page 15, line 26, through page 16, line 8, as follows:

“Sampling” or “obtaining samples” refers to obtaining, in a form suitable for pathogen/microbe testing purposes, a sample of the pathogens and/or other microbes of interest present on or within various samples. Samples testable according to the present invention include, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, [[etc]] etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols. Samples, include environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

Please amend the paragraph at page 17, lines 17-26, as follows:

Preferably, the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species species*, *Staphylococcus* ~~[[spp.]] spp.~~; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; indicator molecules including glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions), including bovine spongiform encephalopathy (BSE) agents, scrapie, chronic wasting disease; and combinations thereof.

Please amend the paragraph at page 19, line 25, through page 20, line 5, as follows:

Preferably, the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species species*, *Staphylococcus* ~~[[spp.]] spp.~~; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; indicator molecules including glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions), including bovine spongiform encephalopathy (BSE) agents, scrapie, chronic wasting disease; and combinations thereof.

Please amend the paragraph at page 20, lines 17-24, as follows:

Yet further alternate embodiments provide a method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising: obtaining a test sample at a first location, the sample being solid, semi-solid or liquid; diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample; incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

Please amend the paragraph at page 21, lines 23-26, as follows:

Samples testable according to the present invention include, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, [[etc]] etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

Please amend the paragraphs at page 24, lines 5-21, as follows:

In preferred embodiments, the present inventive methods encompass the detection of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species species*, *Staphylococcus* [[spp]] spp. Additionally, other pathogens and pathogenic agents are encompassed within the present invention, including, but not limited to

other frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms (total heterotrophes, generic *E. coli*, total and fecal coliforms, enterococcus, [[etc]] etc.); and spoilage organisms (*Pseudomonas*, [[etc]] etc.), and indicator molecules such as glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions) (e.g., bovine spongiform encephalopathy (BSE) agents, scrapie (sheep), chronic wasting disease (e.g., deer, Elk).

Preferably, the detected microbe is: a pathogen including, but not limited to, *Escherichia coli* O157:H7 (*E. coli* O157:H7), *Listeria* Listeria, *Salmonella* Salmonella, EHEC, *Campylobacter* Campylobacter, *Staphylococcus* Staphylococcus, pathogenic ~~Clostridia~~ Clostridia species, and other frank, or opportunistic pathogens; a spoilage organism including, but not limited to, ~~clostridia~~ Clostridia and ~~pseudomonas~~ Pseudomonas species; or an indicator organism including, but not limited to, generic *E. coli*, fecal coliforms, total coliforms, etc. More preferably, the pathogen is *Escherichia coli* O157:H7 (*E. coli* O157:H7).

Please amend paragraphs at page 25, lines 4-15, as follows:

Reveal® test kits are available from Neogen Corporation, Lansing, MI., and comprise an ELISA test that combines an immunoassay with chromatography in a lateral flow device (Reveal® test kits are available for *E. coli* O157:H7, *Salmonella*, *Listeria* [[spp.]] spp. and *Listeria monocytogenes*);

VIP® test kits are available from BioControl, Bellevue, WA., and comprise an ELISA test that is expressed as a lateral flow antibody-chromogen immunoprecipitate assay (VIP® test kits are available for EHEC, *Salmonella* Salmonella, *Listeria* Listeria spp. and *Listeria* ~~monocytogenes~~ Listeria monocytogenes);

Application No. 15/884,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Application Filing Date: December 15, 2017
Office Action Dated: December 19, 2019
Date of Amendment: March 19, 2020
Examiner: Rodney P. Swartz

BAX® Qualicon test kits are available from DuPont, Wilmington, DE., wherein, using the BAX® system, samples are enriched and then lysed to release DNA, which is amplified using PCR techniques, and detected using a fluorescent signal (BAX® test kits are available for *E. coli* O157:H&, *Salmonella*, *Listeria* [[*spp.*]] spp. and *Listeria monocytogenes*, and ~~*enterobaeter*~~ *Enterobacter sakazakii*); and

IN THE CLAIMS:

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

1. (Currently amended) A method for detection of a particular bacterial pathogen or ~~other-bacterial~~ microbe, comprising:

- obtaining a test sample, the sample being solid or semi-solid;
- diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution;
- incubating, in an incubator, the diluted sample at an optimal temperature for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and
- determining, by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

2-4. (Cancelled)

5. (Previously presented) The method of claim 1, wherein the optimal temperature is within the optimal growth temperature range of the particular bacterial pathogen or bacterial microbe in the liquid enrichment medium.

6. (Cancelled)

7. (Previously presented) The method of claim 5, wherein the optimal temperature range is from about 25°C to about 45°C.

8. (Cancelled)

9. (Previously presented) The method of claim 1, wherein the assay suitable for detection of the particular bacterial pathogen or bacterial microbe is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular bacterial pathogen or bacterial microbe, and combinations thereof.

10. (Currently amended) The method of claim 1, wherein the particular bacterial pathogen or bacterial microbe is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinia*, *Campylobacter*, *Clostridial* ~~species~~ species, *Staphylococcus* ~~spp-ssp.~~, frank and opportunistic bacteria, indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

11. (Previously presented) The method of claim 10, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7, or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*.

12. (Previously presented) The method of claim 1, wherein obtaining the test sample comprises obtaining a standard Lot-unit sample.

13. (Previously presented) The method of claim 1, wherein the test sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples, industrial samples, pharmaceutical samples, bio-solid samples, air samples, samples taken by spore traps, settled dust, impingers, or filtration, and combinations thereof.

14. (Previously presented) A method for detection of a particular bacterial pathogen or bacterial microbe, comprising:

- obtaining a liquid test sample;
- diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.) or lesser dilution, or not diluting the sample;
- incubating, in an incubator, the diluted or the not diluted test sample at an optimal temperature for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and
- determining, by assaying the diluted or the not diluted test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

15. (Previously presented) The method of claim 14, wherein the optimal temperature is within the optimal growth temperature range of the particular bacterial pathogen or bacterial microbe in the liquid enrichment medium.

16. (Cancelled)

17. (Previously presented) The method of claim 15, wherein the optimal temperature range is from about 25°C to about 45°C.

18. (Cancelled)

19. (Previously presented) The method of claim 14, wherein the assay suitable for detection of the particular bacterial pathogen or bacterial microbe contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with the particular bacterial pathogen or bacterial microbe, and combinations thereof.

20. (Currently amended) The method of claim 14, wherein the particular bacterial pathogen or bacterial microbe is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial* ~~species~~species, *Staphylococcus*

~~ssp-ssp~~; frank and opportunistic bacterial, indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

21. (Previously presented) The method of claim 20, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157: or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*.

22. (Previously presented) The method of claim 1, wherein the test sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods, environmental samples, soil, sludge, surface samples, samples taken by impingers and filtration, pharmaceuticals, and samples analyzed using enrichment-detection protocols.

23. (Previously presented) The method of claim 14, wherein the liquid test sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

24. (Previously presented) The method of claim 1, wherein the diluting comprises addition to the test sample of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

25. (Previously presented) The method of claim 14, wherein the diluting comprises addition to the test sample of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

26. (Previously presented) The method of claim 1, wherein the obtaining and diluting of the solid or semi-solid sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location.

27. (Previously presented) The method of claim 26, further comprising addition to the test sample, prior to or during the incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

28. (Previously presented) The method of claim 26, wherein the second location is an in-house or local lab, or a remote location.

29. (Previously presented) The method of claim 14, wherein the obtaining and diluting of the liquid test sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location.

30. (Previously presented) The method of claim 29, further comprising addition to the test sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

31. (Previously presented) The method of claim 29, wherein the second location is an in-house or local lab, or a remote location.

REMARKS

Claims 1, 5, 7, 9-15, 17, and 19-31 are pending.

Claims 10 and 20 stand objected to.

Claim 1, 5, 7, 9-15, 17, and 19-31 are under examination and stand rejected.

Claims 1, 10, and 20 have been amended herein.

The Specification stands objected to.

No new matter has been added.

Formalities

Drawings. Applicant thanks the Examiner for acceptance of the drawings.

IDS: Applicant thanks the Examiner for considering Applicant's Information Disclosure Statement (IDS) dated December 20, 2017.

Specification Objection

The Specification stands objected to because of alleged informalities as stated in the Office Action. The Applicant has amended the Specification, including for consistency, as requested by the Examiner. No new matter has been added.

Claim Objection

Claims 10 and 20 stand objected to because of alleged informalities. Specifically, the Examiner states that in claims 10 and 20, the word "species" and the abbreviation "spp." should not be in italics.

Claims 10 and 20 have been amended accordingly.

Applicant, therefore, respectfully requests withdrawal of the objection.

Rejection of Claims Under 35 U.S.C. § 112

Claim 1 stands rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, because the claim allegedly recites "particular bacterial pathogen or bacterial microbe," for which there is no antecedent basis in the preamble.

Applicant has amended the preamble of claim 1 to recite “particular bacterial pathogen or bacterial microbe” in place of “particular pathogen or other microbe” to provide proper antecedent basis throughout the claims. The amendment is consistent with the language of underlying U.S. Patent 9,845,486.

Applicant, therefore, respectfully requests withdrawal of the rejection.

Claims 1, 5, 7, 9-13, 22, 24, and 26-28 stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph as allegedly being indefinite because the scope of “a particular pathogen or other microbe,” recited in the preamble of claim 1, encompasses any microorganism and it is thus unclear how one detects a particular pathogen or other microbe when the assay steps are drawn only to bacteria.

Applicant, as described above, has amended the preamble of claim 1 to recite “particular bacterial pathogen or bacterial microbe” in place of “particular pathogen or other microbe” to provide proper antecedent basis throughout the claims.

Applicant, therefore, respectfully requests withdrawal of the rejection.

Nonstatutory Type Double Patenting

The Examiner rejected claims 1, 5, 7, 9-13, 22, 24, and 26-28 on the ground of nonstatutory type double patenting as allegedly being unpatentable over claims 1, 4-10, 17, 19, and 21-23 of U.S. Patent No. 9,845,486.

The Examiner also rejected claims 14, 15, 17, 19-21, 23, 25, and 29-31 on the ground of nonstatutory type double patenting as allegedly being unpatentable over claims 11-16, 18, 20, and 24-26 of U.S. Patent No. 9,845,486.

The Examiner further rejected claims 1, 5, 7, 9-13, 22, 24, and 26-28 on the ground of nonstatutory type double patenting as allegedly being unpatentable over claims 1-11, 18, 20, 22, and 23 of U.S. Patent No. 7,531,163.

Applicant provides herewith an executed Terminal Disclaimer in view of U.S. Patent

Application No. 15/884,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Application Filing Date: December 15, 2017
Office Action Dated: December 19, 2019
Date of Amendment: March 19, 2020
Examiner: Rodney P. Swartz

Nos. 9,845,486 and 7,531,163.

Applicant, therefore, respectfully requests withdrawal of the rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Preliminary Amendment provided herein and allowance of all claims.

Any required excess claim fees or extension of time fees are submitted electronically herewith. Further, the Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 04-0258.

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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920 Fifth Avenue, Suite 3300
Seattle, Washington 98104-1610
Telephone: 206-757-8023
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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:	38919700
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-MAR-2020
Filing Date:	15-DEC-2017
Time Stamp:	21:27:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2020-03-19_0066090-003US2_Amendment_After_NonFinal_Rejection.pdf	211066 dfc4f5a2b117440fbd0f0cc9a7e617d6fe4b9ea3	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	8
	Claims	9	15
	Applicant Arguments/Remarks Made in an Amendment	16	18

Warnings:

Information:

Total Files Size (in bytes):	211066
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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.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	15844407	
Filing Date	15-Dec-2017	
First Named Inventor	Mansour Samadpour	
Attorney Docket Number	0066090-003US2	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
Institute for Environmental Health, Inc.	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 7531163 9845486 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.		

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

☐ Small Entity

☐ Micro Entity

☒ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made 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 so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 47309

☐ A sole inventor

☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

☐ A joint inventor; all of whom are signing this request

Signature	/Barry L. Davison/
Name	Barry L. Davison

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15844407

Filing Date: 15-Dec-2017

Applicant/Patent under Reexamination: Samadpour

Electronic Terminal Disclaimer filed on March 19, 2020

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	38916687
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-MAR-2020
Filing Date:	15-DEC-2017
Time Stamp:	21:05:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	E20203IL05300741
Deposit Account	040258
Authorized User	Janet Berdine

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

National Beef Ex. 1008

Page 46 of 239

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33443	no	2
			bc21b36a9eac8218605c974c7f59aa9b75f83231		

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30648	no	2
			79b6c176dceae50a07f8e0bfa01807d616b0a1		

Warnings:

Information:

Total Files Size (in bytes):			64091
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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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392
22504	7590	12/19/2019	EXAMINER	
DAVIS WRIGHT TREMAINE, LLP/SEATTLE IP DOCKETING DEPT. DAVIS WRIGHT TREMAINE LLP 920 FIFTH AVE., SUITE 3300 SEATTLE, WA 98104-1610			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			12/19/2019	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@dwt.com

Office Action Summary

Application No.

15/844,407

Applicant(s)

Samadpour, Mansour

Examiner

RODNEY P SWARTZ, Ph.D.

Art Unit

1645

AIA (FITF) Status

No

-- 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 MONTHS 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 9-19-2019.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ 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*

5) ☒ Claim(s) 1,5,7,9-15,17 and 19-31 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1,5,7,9-15,17 and 19-31 is/are rejected.

8) ☒ Claim(s) 10 and 20 is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

11) ☒ The drawing(s) filed on 12-15-2017 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).

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).

Certified copies:

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)).

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☒ Other: Detailed Action.

Paper No(s)/Mail Date 12/20/2017.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. Applicant's Response to Notice of Non-Compliant Amendment, received 9-19-2019, is acknowledged.

Claims 1, 5, 7, 9, 10, 11, 12, 13, 14, 15, 17, 19, 20, 21, 22, 23, 24, 25, 26, and 27 have been amended. Claims 2, 3, 4, 6, 8, 16, and 18 have been canceled. New claims 28, 29, 30, and 31 have been added.

3. Claims 1, 5, 7, 9-15, 17, 19-31 are pending and under consideration.

Specification

4. The disclosure is objected to because of the following informalities:

Page 8, line 18, "E. coli" should be in italics.

Page 9, lines 19 and 26, "etc." should not have a period to be consistent with the first forms presented.

Page 10, line 16, "etc." should not have a period to be consistent with the first forms presented.

Page 14, lines 19 and 21, "etc." should not have a period to be consistent with the first forms presented.

Page 16, lines 5 and 25, "etc." should not have a period to be consistent with the first forms presented.

Page 17, line 20, "*species*" should not be in italics; line 21, "*spp.*" should not be in italics.

Page 20, line 1, "*species*" should not be in italics; line 21, "*spp.*" should not be in italics.

Page 21, line 20, "etc." should not have a period to be consistent with the first forms presented.

Page 24, line 9, "*species*" should not be in italics, and, "*spp.*" should not be in italics; lines 17-19, all bacterial names should be in italics.

Page 25, line 6, "*spp.*" should not be in italics; line 10, all bacterial names should be in italics; line 14, "*spp.*" should not be in italics, and, "*enterobacter*" should be "*Enterobacter*".

Appropriate correction is required.

Claim Objections

5. Claim 10 is objected to because of the following: line 5, "*species*" should not be in italics; line 6, "*spp.*" should not be in italics; Appropriate correction is required.

6. Claim 20 is objected to because of the following: line 5, "*species*" should not be in italics; line 6, "*spp.*" should not be in italics; Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
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.

8. Claim 1 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in lines 8, 9, 10, 12, and 13.

There is insufficient antecedent basis for this limitation in the claim because the preamble, line 1, is drawn to "particular pathogen or other microbe", not just bacterial.

9. Claims 1, 5, 7, 9-13, 22, 24, and 26-28 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 1 is drawn to A method for detection of a particular pathogen or other microbe, comprising:

- obtaining a test sample, the sample being solid or semi-solid;
- diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution;
- incubating, in an incubator, the diluted sample at an optimal temperature for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe: and
- determining, by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

The scope of "a particular pathogen or other microbe" encompass any microorganism. Thus, it is unclear how one detects a particular pathogen or other microbe when the assay steps are drawn only to bacteria.

Claims 5, 7, 9-13, 22, 24, and 26-28 depend from claim 1, but do not clarify the issue.

10. Claim 5 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in lines 2-3.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 5 depends, is drawn to "particular pathogen or other microbe", not just bacterial.

11. Claim 9 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in lines 2, and 7-8.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 9 depends, is drawn to "particular pathogen or other microbe", not just bacterial.

12. Claim 10 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in lines 1-2.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 10 depends, is drawn to "particular pathogen or other microbe", not just bacterial.

13. Claim 11 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in lines 1-2.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 11 ultimately depends, is drawn to "particular pathogen or other microbe", not just bacterial.

14. Claim 24 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in line 6.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 24 depends, is drawn to "particular pathogen or other microbe", not just bacterial.

15. Claim 26 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in line 8.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 26 depends, is drawn to "particular pathogen or other microbe", not just bacterial.

16. Claim 27 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the claim recites the limitation "particular bacterial pathogen or bacterial microbe" in line 5.

There is insufficient antecedent basis for this limitation in the claim because the preamble of claim 1, from which claim 27 ultimately depends, is drawn to "particular pathogen or other microbe", not just bacterial.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is

appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(I)(1) - 706.02(I)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

18. Claims 1, 5, 7, 9-13, 22, 24, and 26-28 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 4-10, 17, 19, and 21-23 of U.S. Patent No. 9,845,486.

Although the claims at issue are not identical, they are not patentably distinct from each other because they are drawn to the same methods with overlapping ratio of sample to diluent. Instant claim 1 recites a dilution ratio of about 1:0.1 to about 1:9 or lesser dilution while claim 1 of U.S. Pat. No. 9,845,486 recites a dilution ratio of about 1:0.1 to about 1:5 or lesser dilution. Thus, at least one embodiment in both sets of claims is identical.

19. Claims 14, 15, 17, 19-21, 23, 25, and 29-31 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 11-16, 18, 20, and 24-26 of U.S. Patent No. 9,845,486.

Although the claims at issue are not identical, they are not patentably distinct from each other because they are drawn to the same methods with overlapping ratio of sample to diluent. Instant claim 14 recites a dilution ratio of about 1:0.1 to about 1:9 or lesser dilution while claim 11 of U.S. Pat. No. 9,845,486 recites a dilution ratio of about 1:0.1 to about 1:5 or lesser dilution. Thus, at least one embodiment in both sets of claims is identical.

20. Claims 1, 5, 7, 9-13, 22, 24, and 26-28 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11, 18, 20, and 22-23 of U.S. Patent No. 7,531,163.

Although the claims at issue are not identical, they are not patentably distinct from each other because they are drawn to the same methods with overlapping ratio of sample to diluent. Instant claim 1 recites a dilution ratio of about 1:0.1 to about 1:9 or lesser dilution while claim 1 of U.S. Pat. No. 7,531,163 recites a dilution ratio of about 1:0.1 to about 1:2 or lesser dilution. Thus, at least one embodiment in both sets of claims is identical.

Conclusion

21. No claims are allowed.
22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for 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 (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.

/Rodney P Swartz, Ph.D./
Primary Examiner, Art Unit 1645
December 16, 2019

<i>Notice of References Cited</i>	Application/Control No. 15/844,407		Applicant(s)/Patent Under Reexamination Samadpour, Mansour	
	Examiner RODNEY P SWARTZ, Ph.D.		Art Unit 1645	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7531163-B2	05-2009	Samadpour; Mansour	C12Q1/6806	424/9.1
*	B	US-9845486-B2	12-2017	Samadpour; Mansour	C12Q1/6806	1/1
	C					
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	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.

<i>Index of Claims</i> 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

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

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	12/16/2019								
	1	✓								
	2	-								
	3	-								
	4	-								
	5	✓								
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	31	✓								

Search Notes 	Application/Control No. 15/844,407	Applicant(s)/Patent Under Reexamination Samadpour, Mansour
	Examiner RODNEY P SWARTZ, Ph.D.	Art Unit 1645

CPC - Searched*		
Symbol	Date	Examiner
A61K 39/02	12/16/2019	RPS
C12Q 1/00	12/16/2019	RPS
Go1N 33/53	12/16/2019	RPS
C12N 1/00		

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
424	9.1, 130.1, 164.1, 184.1, 234.1	12/16/2019	RPS
435	4, 7.2, 243	12/16/2019	RPS

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
PALM - inventor names; EAST; biosis caba caplus embase japio medline pctfull scisearch	12/16/2019	RPS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/Rodney P Swartz, Ph.D./ Primary Examiner, Art Unit 1645	
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CONFIRMATION NO. 5392

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
15/844,407	12/15/2017	424	1645	0066090-003US2		
RULE						
APPLICANTS Institute for Environmental Health, Inc., Lake Forest Park, WA INVENTORS Mansour Samadpour, Lake Forest Park, WA; ** CONTINUING DATA ***** This application is a CON of 12/360,646 01/27/2009 PAT 9845486 which is a CON of 10/848,253 05/17/2004 PAT 7531163 which claims benefit of 60/470,975 05/16/2003 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 01/08/2018						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and /RODNEY P SWARTZ, PhD/ Acknowledged Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY WA	SHEETS DRAWINGS 11	TOTAL CLAIMS 24	INDEPENDENT CLAIMS 2
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TITLE ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES						
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	1645
Examiner Name	Swartz
Attorney Docket Number	0066090-003US2

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	6060266	A	2000-05-09	Naqui			
	2	7531163	B2	2009-05-12	Samadpour			
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

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
	1	ALBIZO, et al., "Use of the Antiserum-Agar Plate Technique for Specific Identification and Isolation of Pasteurella pestis," Applied Microbiology 16(8):1114-1119, August 1968.	
	2	Bacteriological Analytical Manual Online (U.S. Food & Drug Administration, Center for Food Safety & Applied Nutrition) Chapters 4, 4a, 5, 6, 7, 9, and 10, 146 pages.	
	3	BHADURI, S., et al., "Use of a Single Procedure for Selective Enrichment, Isolation, and Identification of Plasmid-Bearing Virulent Yersinia Enterocolitica of Various Serotypes from Pork Samples," Applied and Environmental Microbiology 63:1657-1660, 1997.	
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First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

11	NG, S.P., et al., "Detection and Serogroup Differentiation of Salmonella spp. in Food Within 30 Hours by Enrichment-Immunoassay With a T6 Monoclonal Antibody Capture Enzyme-Linked Immunosorbent Assay," Applied and Environmental Microbiology 62:2294-2302, 1996.
12	NORTON, D.M., et al., "Molecular Studies on the Ecology of Listeria monocytogenes in the Smoked Fish Processing Industry," Applied and Environmental Microbiology 67:198-205, 2001.
13	PADHYE, N.V., and M.P. DOYLE, "Rapid Procedure for Detecting Enterohemorrhagic Escherichia coli O157:H7 in Food," Applied and Environmental Microbiology 57:2693-2698, 1991.
14	PIGNATO, S., et al., "Evaluation of New Culture Media for Rapid Detection and Isolation of Salmonellae in Foods," Applied and Environmental Microbiology 61:1996-1999, 1995.
15	ROBERTSON, J.A., and M.H. Chen, "Effects of Manganese on the Growth and Morphology of Ureaplasma Urealyticum," Journal of Clinical Microbiology 19(6):857-864, June 1984.
16	RYSER, E.T., et al., "Recovery of Different Listeria Ribotypes From Naturally Contaminated, Raw Refrigerated Meat and Poultry Products With Two Primary Enrichment Media," Applied and Environmental Microbiology 62:1781-1787, 1996.
17	ZHAO, T., et al., "Prevalence of Enterohemorrhagic Escherichia coli O157:H7 in a Survey of Dairy Herds," Applied and Environmental Microbiology 61:1290-1293, 1995.
18	SAMADPOUR, M., "Dry and Semidry Enrichment for the Detection of Foodborne Patogens," U.S. Patent Application No. 60/470,975, filed May 16, 2003.

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Rodney P Swartz, Ph.D./	Date Considered	12/16/2019
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*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.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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/	Date (YYYY-MM-DD)	2017-12-20
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47,309

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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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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1377	"detect pathogen"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/16 16:29
L2	14160	"solid sample" or "semi-solid sample"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/16 16:30
L3	33	I1 and I2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/16 16:30
L4	67	"liquid enrichment medium"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/16 16:30
L5	5	I3 and I4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/16 16:30

12/ 16/ 2019 4:31:08 PM

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=> file biosis caba caplus embase japio lifesci medline scisearch
=> = samadpour mansour/au
E1      171      SAMADPOUR M/AU
E2      1        SAMADPOUR M */AU
E3      101 ---> SAMADPOUR MANSOUR/AU
E4      1        SAMADPOUR MANSOUR DR/AU
E5      1        SAMADPOUR MANSUR/AU
E6      6        SAMADPOUR MOTALEBI M/AU
E7      2        SAMADPOUR MOTALEBI MANSOUR/AU
E8      1        SAMADPOUR N/AU
E9      1        SAMADPOUR S/AU
E10     2        SAMADPOURMOTALEBI M/AU
E11     1        SAMADU KONE A/AU
E12     1        SAMADURA M/AU

=> s e1-e7 and (pathogen? or microb? or bacter? or virus)
4 FILES SEARCHED...
L1      222 ("SAMADPOUR M"/AU OR "SAMADPOUR M */AU OR "SAMADPOUR MANSOUR"/A
U OR "SAMADPOUR MANSOUR DR"/AU OR "SAMADPOUR MANSUR"/AU OR "SAMA
DPOUR MOTALEBI M"/AU OR "SAMADPOUR MOTALEBI MANSOUR"/AU) AND
(PATHOGEN? OR MICROB? OR BACTER? OR VIRUS)

=> dup rem l1
PROCESSING COMPLETED FOR L1
L2      69 DUP REM L1 (153 DUPLICATES REMOVED)

=> s l2 and (cultur? or incubat?)
L3      16 L2 AND (CULTUR? OR INCUBAT?)

=> s l3 and (1:10)
L4      0 L3 AND (1:10)

=> d l3 bib ab kwic 1-
YOU HAVE REQUESTED DATA FROM 16 ANSWERS -- CONTINUE? Y/(N):y

L3      ANSWER 1 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
AN      2009:384334 BIOSIS <<LOGINID::20101214>>
DN      PREV200900385437
TI      Enrichment methods for the detection of ***pathogens*** and other
***microbes*** .
AU      ***Samadpour, Mansour*** [Inventor]; Anonymous
CS      Seattle, WA USA
ASSIGNEE: Institute for Environmental Health Inc
PI      US 07531163 20090512
SO      Official Gazette of the United States Patent and Trademark Office Patents,
(MAY 12 2009)
CODEN: OGUPE7. ISSN: 0098-1133.
DT      Patent
LA      English
ED      Entered STN: 24 Jun 2009
Last Updated on STN: 24 Jun 2009
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

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semi-solid sample or liquid) at the first location at a ratio of about 1:0 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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 additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless ***incubated*** during transit to the test location.

TI Enrichment methods for the detection of ***pathogens*** and other ***microbes***.

AU ***Samadpour, Mansour*** [Inventor]; Anonymous

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 . . . 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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 additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless ***incubated*** during transit to the test location.

IT Methods & Equipment

enrichment ***culture*** -based food sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based water sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based wastewater sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based industrial sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based pharmaceutical sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based botanical sample- ***microbial*** detection: applied and field techniques; enrichment ***culture*** -based environmental sample- ***microbial*** detection: applied and field techniques

L3 ANSWER 2 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN

AN 2008:266483 BIOSIS <<LOGINID::20101214>>

DN PREV200800261325

TI Thermal inactivation D- and z-values of multidrug-resistant and non-multidrug-resistant Salmonella serotypes and survival in ground beef exposed to consumer-style cooking.

AU Stopforth, J. D.; Suhaim, R.; Kottapalli, B.; Hill, W. E.;

Samadpour, M. [Reprint Author]

CS Inst Environm Hlth Inc, 15300 Bothell Way NE, Seattle, WA 98155 USA

mansour@u.washington.edu

SO Journal of Food Protection, (MAR 2008) Vol. 71, No. 3, pp. 509-515.

CODEN: JFPRDR. ISSN: 0362-028X.

DT Article

LA English

ED Entered STN: 9 Apr 2008
Last Updated on STN: 9 Apr 2008

AB There has been speculation that multidrug-resistant (MDR) strains are generated by subtherapeutic antibiotic use in food animals and that such strains result in increased resistance to lethality by food processes such as heat and irradiation. The objective of this study was to evaluate the heat resistance of 20 strains, namely an MDR and a non-multidrug-resistant (NMDR) strain of each of 10 Salmonella serotypes isolated from cattle or cattle environments. MDR and NMDR Salmonella serotypes studied included Montevideo, Typhimurium, Anatum, Muenster, Newport, Mbandaka, Dublin, Reading, Agona, and Give. For phase 1, stationary-phase ***cultures*** of the strains were aliquoted into sterile capillary tubes and immersed in a temperature-controlled water bath at 55, 60, 65, and 70 degrees C for appropriate times. Survivor curves were plotted for each temperature, and a best-fit linear regression was derived for each temperature. D-values (decimal reduction times) and z-values (changes in temperature required to change the D-values) were calculated for each strain. Although there was no overall significant difference in the heat resistance of MDR and NMDR serotypes, NMDR serotypes generally appeared to have slightly higher heat resistance than MDR serotypes, especially at 55 and 60 degrees C. The highest relative heat resistance (highest z-values) was exhibited by Salmonella Anatum. Notably, the relative heat resistance of NMDR Salmonella Agona was similar to that of NMDR Salmonella Anatum and had the highest D-values at all four temperatures. For phase 11, three serotypes (regardless of resistance profile) with the highest relative heat resistance and their drug-resistant counterparts were selected for thermal inactivation in ground beef patties cooked to endpoint temperatures. Salmonella Agona was able to survive in ground beef cooked to an internal temperature of 71 degrees C. Results of these studies suggest drug resistance does not affect the heat resistance of Salmonella and that serotype or strain is an important consideration in risk assessment of the ***pathogen*** with regard to survival at cooking temperatures.

AU Stopforth, J. D.; Suhaim, R.; Kottapalli, B.; Hill, W. E.;
Samadpour, M. [Reprint Author]

AB. . . NMDR Salmonella serotypes studied included Montevideo, Typhimurium, Anatum, Muenster, Newport, Mbandaka, Dublin, Reading, Agona, and Give. For phase 1, stationary-phase ***cultures*** of the strains were aliquoted into sterile capillary tubes and immersed in a temperature-controlled water bath at 55, 60, 65, . . . affect the heat resistance of Salmonella and that serotype or strain is an important consideration in risk assessment of the ***pathogen*** with regard to survival at cooking temperatures.

IT Major Concepts
Pharmacology; Infection; Methods and Techniques; Foods

IT Diseases
Salmonella infection: ***bacterial*** disease, infectious disease, etiology

IT Chemicals & Biochemicals
antibiotic: antibacterial-drug, antiinfective-drug

ORGN . . .
Animals, Artiodactyls, Chordates, Mammals, Nonhuman Vertebrates, Nonhuman Mammals, Vertebrates

ORGN Classifier
Enterobacteriaceae 06702

Super Taxa

Facultatively Anaerobic Gram-Negative Rods; Eubacteria;

Bacteria ; Microorganisms

Organism Name

Salmonella (genus): ***pathogen*** , contaminant,
strain-Typhimurium, strain-Montevideo, strain-Reading, strain-Muenster,
strain-Mbandaka, strain-Give, strain-Anatum, strain-Agona,
strain-Dublin, strain-Newport

Taxa Notes

Bacteria , Eubacteria, Microorganisms

L3 ANSWER 3 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
AN 2006:260972 BIOSIS <<LOGINID::20101214>>
DN PREV200600258565
TI Incidence of enterohemorrhagic Escherichia coli, Escherichia coli O157,
Salmonella, and Listeria monocytogenes in retail fresh ground beef,
sprouts, and mushrooms.
AU ***Samadpour, M.*** [Reprint Author]; Barbour, M. W.; Nguyen, T.; Cao,
T.-M.; Buck, F.; Depavia, G. A.; Mazengia, E.; Yang, P.; Alfi, D.; Lopes,
M.; Stopforth, J. D.
CS Inst Environm Hlth Inc, Seattle, WA 98155 USA
mansour@u.washington.edu
SO Journal of Food Protection, (FEB 2006) Vol. 69, No. 2, pp. 441-443.
CODEN: JFPRDR. ISSN: 0362-028X.
DT Article
LA English
ED Entered STN: 3 May 2006
Last Updated on STN: 3 May 2006
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-month 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 positive for EHEC, and 20 (1.1%) of these were
positive 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 positive 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 positive for Salmonella and none
were positive for L. monocytogenes. Among the 100 mushroom samples, 4
(4.0%) were positive for EHEC but none of these 4 samples were positive
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.
AU ***Samadpour, M.*** [Reprint Author]; Barbour, M. W.; Nguyen, T.; Cao,
T.-M.; Buck, F.; Depavia, G. A.; Mazengia, E.; Yang, P.; Alfi, . . .
AB. . . mushrooms (100 samples), and sprouts (200 samples) were collected
over a 12-month 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. . .
ORGN Classifier
Enterobacteriaceae 06702
Super Taxa

Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
 Bacteria ; Microorganisms

Organism Name
 Salmonella (genus): contaminant
 Escherichia coli (species): contaminant, strain-O157

Taxa Notes
 Bacteria , Eubacteria, Microorganisms

ORGN Classifier
 Regular Nonsporing Gram-Positive Rods 07830

Super Taxa
 Eubacteria; ***Bacteria*** ; Microorganisms

Organism Name
 Listeria monocytogenes (species): contaminant

Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L3 ANSWER 4 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 2004:158131 BIOSIS <<LOGINID::20101214>>
 DN PREV200400144931
 TI Outbreak of Pseudomonas aeruginosa infections caused by commercial
 piercing of upper ear cartilage.
 AU Keene, William E. [Reprint Author]; Markum, Amy C.; ***Samadpour,***
 *** Mansour***

CS Acute and Communicable Disease Program, Oregon Department of Human
 Services, 800 NE Oregon St, Suite 772, Portland, OR, 97232, USA
 william.e.keene@state.or.us

SO JAMA (Journal of the American Medical Association), (February 25 2004)
 Vol. 291, No. 8, pp. 981-985. print.
 ISSN: 0098-7484 (ISSN print).

DT Article
 LA English
 ED Entered STN: 17 Mar 2004
 Last Updated on STN: 17 Mar 2004

AB Context: Sporadic infections following ear piercing are well documented,
 but common-source outbreaks are rarely recognized. Objective: To
 investigate reports of auricular chondritis subsequent to commercial ear
 piercing. Design, Setting, and Subjects: Outbreak investigation by Oregon
 public health agencies, including cohort study of persons pierced at a
 jewelry kiosk in August-September 2000, environmental sampling, and
 molecular subtyping of isolates. Confirmed cases had Pseudomonas
 aeruginosa ***cultured*** from ear wounds. Suspected cases had signs
 and symptoms of external ear infection, including drainage of pus or blood
 for at least 14 days. Main Outcome Measures: Risk factors for infection
 and comparison of ***bacterial*** isolates by molecular subtyping.
 Results: From 186 piercings in 118 individuals, we identified 7 confirmed
 P. aeruginosa infections and 18 suspected infections. Confirmed cases
 were 10 to 19 years old. Most were initially treated with antibiotics
 ineffective against Pseudomonas. Four were hospitalized, 4 underwent
 incision and drainage surgeries (1 as an outpatient), and several were
 cosmetically deformed. Upper ear cartilage piercing was more likely to
 result in either confirmed or suspected infection than was lobe piercing
 (confirmed: RR undefined, P<.001; suspected: RR, 3.6; 95% confidence
 interval, 1.5-8.5). All persons with confirmed infections had their ear
 cartilage pierced with an open, spring-loaded piercing gun. Patient
 isolates were indistinguishable by molecular subtyping, and matching
 isolates were recovered from a disinfectant bottle and nearby sink. At
 least 1 worker admitted sometimes spraying the disinfectant on the ear

studs before piercing. Conclusions: Ear cartilage piercing is inherently more risky than lobe piercing. Clinicians should respond aggressively to potential auricular chondritis and consider *Pseudomonas* a possible cause pending ***culture*** results.

AU Keene, William E. [Reprint Author]; Markum, Amy C.; ***Samadpour,***
 *** Mansour***

AB. . . pierced at a jewelry kiosk in August-September 2000, environmental sampling, and molecular subtyping of isolates. Confirmed cases had *Pseudomonas aeruginosa* ***cultured*** from ear wounds. Suspected cases had signs and symptoms of external ear infection, including drainage of pus or blood for at least 14 days. Main Outcome Measures: Risk factors for infection and comparison of ***bacterial*** isolates by molecular subtyping. Results: From 186 piercings in 118 individuals, we identified 7 confirmed *P. aeruginosa* infections and 18. . . more risky than lobe piercing. Clinicians should respond aggressively to potential auricular chondritis and consider *Pseudomonas* a possible cause pending ***culture*** results.

IT . . . Concepts
 Infection; Public Health (Allied Medical Sciences)

IT Parts, Structures, & Systems of Organisms
 ear cartilage: skeletal system

IT Diseases
 bacterial chondritis: ***bacterial*** disease, ear disease

ORGN . . .

Taxa Notes
 Animals, Chordates, Humans, Mammals, Primates, Vertebrates

ORGN Classifier
Pseudomonadaceae 06508
 Super Taxa
 Gram-Negative Aerobic Rods and Cocci; Eubacteria; ***Bacteria*** ;
 Microorganisms

Organism Name
Pseudomonas aeruginosa (species): ***pathogen***

Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L3 ANSWER 5 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 2004:130256 BIOSIS <<LOGINID::20101214>>
 DN PREV200400130915

TI Phenotypic library-based ***microbial*** source tracking methods:
 Efficacy in the California collaborative study.

AU Harwood, Valerie J. [Reprint Author]; Wiggins, Bruce; Hagedorn, Charles;
 Ellender, R. D.; Gooch, Jan; Kern, James; ***Samadpour, Mansour*** ;
 Chapman, Annie C. H.; Robinson, Brian J.; Thompson, Brian C.

CS Department of Biology, University of South Florida, 4202 E. Fowler Ave,
 SCA 110, Tampa, FL, 33620, USA

SO Journal of Water and Health, (December 2003) Vol. 1, No. 4, pp. 153-166.
 print.
 ISSN: 1477-8920 (ISSN print).

DT Article

LA English

ED Entered STN: 3 Mar 2004
 Last Updated on STN: 3 Mar 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 (approx 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.

- TI Phenotypic library-based ***microbial*** source tracking methods:
Efficacy in the California collaborative study.
- AU Harwood, Valerie J. [Reprint Author]; Wiggins, Bruce; Hagedorn, Charles;
Ellender, R. D.; Gooch, Jan; Kern, James; ***Samadpour, Mansour*** ;
Chapman, Annie C. H.; Robinson, Brian J.; Thompson, Brian C.
- 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, . . .
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. . .
- IT Methods & Equipment
Kirby-Bauer antibiotic susceptibility testing: applied and field
techniques, ***culturing*** techniques, laboratory techniques;
antibiotic resistance analysis: applied and field techniques,
culturing techniques, laboratory techniques; phenotypic
library-based ***microbial*** source tracking: applied and field
techniques; phenotypic subtyping: applied and field techniques
- IT Miscellaneous Descriptors
fecal contamination; minimum detectable percentage; . . .
- ORGN . . .
(common)
- Taxa Notes
Animals, Birds, Chordates, Nonhuman Vertebrates, Vertebrates
- ORGN Classifier
Enterobacteriaceae 06702
Super Taxa
Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
Bacteria ; Microorganisms
- Organism Name
E. coli (common) [Escherichia coli (species)]: contaminant
fecal coliform (common): contaminant

Taxa Notes
 Bacteria , Eubacteria, Microorganisms
 ORGN Classifier
 Gram-Positive Cocci 07700
 Super Taxa
 Eubacteria; ***Bacteria*** ; Microorganisms
 Organism Name
 Enterococcus (genus): contaminant
 Streptococcus (genus): contaminant
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms
 ORGN Classifier
 Hominidae 86215
 Super Taxa
 Primates; Mammalia; Vertebrata; Chordata; Animalia
 Organism Name
 human (common)
 Taxa Notes
 Animals, . . .

L3 ANSWER 6 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 2003:113106 BIOSIS <<LOGINID::20101214>>
 DN PREV200300113106
 T1 Diversity, frequency, and persistence of Escherichia coli O157 strains
 from range cattle environments.
 AU Renter, David G. [Reprint Author]; Sargeant, Jan M.; Oberst, Richard D.;
 Samadpour, Mansour
 CS Agri-Food Surveillance Systems Branch, Alberta Agriculture, Food and Rural
 Development, 6909 116 Street, First Floor, O. S. Longman Building,
 Edmonton, AB, T6H 4P2, Canada
 David.Renter@gov.ab.ca
 SO Applied and Environmental Microbiology, (January 2003) Vol. 69, No. 1, pp.
 542-547. print.
 ISSN: 0099-2240 (ISSN print).
 DT Article
 LA English
 ED Entered STN: 26 Feb 2003
 Last Updated on STN: 26 Feb 2003
 AB Genetic diversity, isolation frequency, and persistence were determined
 for Escherichia coli O157 strains from range cattle production
 environments. Over the 11-month study, analysis 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 preparations revealed 79 unique patterns (XbaI-PFGE
 subtypes) from 235 typeable isolates confirmed to be E. coli O157. By
 analyzing up to three isolates per positive 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 months 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 molecular epidemiology of *E. coli* O157 previously described for confined cattle operations is also evident in extensively managed range cattle environments.

AU Renter, David G. [Reprint Author]; Sargeant, Jan M.; Oberst, Richard D.;
 Samadpour, Mansour

AB. . . 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. . .

IT Miscellaneous Descriptors
 bacterial diversity: studies; ***bacterial*** frequency: studies; ***bacterial*** persistence: studies; cattle industry; cattle production; molecular epidemiology; range cattle environments; ***bacteriological*** studies

ORGN . . .
 Animals, Chordates, Mammals, Marsupials, Nonhuman Vertebrates, Nonhuman Mammals, Vertebrates

ORGN Classifier
 Enterobacteriaceae 06702
 Super Taxa
 Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
 Bacteria ; Microorganisms

Organism Name
 Escherichia coli (species): ***pathogen*** , O157 strains

Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L3 ANSWER 7 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 2000:522270 BIOSIS <<LOGINID::20101214>>
 DN PREV200000522270
 TI A prospective study of asymptomatic ***bacteriuria*** in sexually active young women.

AU Hooton, Thomas M. [Reprint author]; Scholes, Delia; Stapleton, Ann E.; Roberts, Pacita L.; Winter, Carol; Gupta, Kalpana; ***Samadpour,***
 *** Mansour*** ; Stamm, Walter E.

CS Harborview Medical Center, 325 Ninth Ave., Seattle, WA, 98104, USA
 SO New England Journal of Medicine, (October 5, 2000) Vol. 343, No. 14, pp. 992-997. print.
 CODEN: NEJMAG. ISSN: 0028-4793.

DT Article
 LA English
 ED Entered STN: 29 Nov 2000
 Last Updated on STN: 11 Jan 2002

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 10⁵ 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 (HMO). 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 HMO 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.

TI A prospective study of asymptomatic ***bacteriuria*** in sexually active young women.

AU Hooton, Thomas M. [Reprint author]; Scholes, Delia; Stapleton, Ann E.; Roberts, Pacita L.; Winter, Carol; Gupta, Kalpana; ***Samadpour,***
*** Mansour***; Stamm, Walter E.

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 105 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 (HMO). 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. . . and 6 percent (95 percent confidence interval, 5 percent to 8 percent) among women in the HMO 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.

IT Major Concepts

Infection; Urology (Human Medicine, Medical Sciences); Epidemiology (Population Studies)

IT Diseases

asymptomatic ***bacteriuria*** : ***bacterial*** disease, urologic disease, natural history, ***pathogenesis***, prevalence, risk factors

IT Diseases

symptomatic urinary tract infection: ***bacterial*** disease,
urologic disease, risk factors

ORGN Classifier
Enterobacteriaceae 06702
Super Taxa
Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
Bacteria ; Microorganisms
Organism Name
Escherichia coli: genotype, ***pathogen***
Taxa Notes
Bacteria , Eubacteria, Microorganisms

ORGN Classifier
Hominidae 86215
Super Taxa
Primates; Mammalia; Vertebrata; Chordata; Animalia
Organism Name
human: adolescent, adult, female, host, . . .

L3 ANSWER 8 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
AN 2000:505780 BIOSIS <<LOGINID::20101214>>
DN PREV200000505780
TI Ribotype characterization of E. coli asymptomatic ***bacteriuria***
(ASB) strains in young sexually active women.
AU Hooton, Thomas M. [Reprint author]; Scholes, Delia; Stapleton, Ann;
Roberts, Pacita L.; Winter, Carol; Gupta, Kalpana; ***Samadpour,***
*** Mansour*** ; Stamm, Walter E.
CS Group Health Cooperative, Seattle, WA, USA
SO 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.
DT Conference; (Meeting)
Conference; Abstract; (Meeting Abstract)
LA English
ED Entered STN: 22 Nov 2000
Last Updated on STN: 11 Jan 2002
TI Ribotype characterization of E. coli asymptomatic ***bacteriuria***
(ASB) strains in young sexually active women.
AU Hooton, Thomas M. [Reprint author]; Scholes, Delia; Stapleton, Ann;
Roberts, Pacita L.; Winter, Carol; Gupta, Kalpana; ***Samadpour,***
*** Mansour*** ; Stamm, Walter E.
IT . . .
Gynecology (Human Medicine, Medical Sciences)
IT Parts, Structures, & Systems of Organisms
urine: excretory system
IT Diseases
E. coli asymptomatic ***bacteriuria*** , Escherichia coli
asymptomatic ***bacteriuria***
IT Diseases
UTI: infectious disease, urologic disease, urinary tract infection
Urinary Tract Infections (MeSH)
IT Methods & Equipment
restriction fragment length polymorphism: analytical method,
restriction fragment mapping, ribotyping method; ribotype
characterization: analytical method; urine ***culture*** : cell
culture method
IT Miscellaneous Descriptors

Meeting Abstract
 ORGN Classifier
 Enterobacteriaceae 06702
 Super Taxa
 Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
 Bacteria ; Microorganisms
 Organism Name
 E. coli [Escherichia coli]: ***pathogen***
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

ORGN Classifier
 Hominidae 86215
 Super Taxa
 Primates; Mammalia; Vertebrata; Chordata; Animalia
 Organism Name
 human: adolescent, adult, female, host, . . .

L3 ANSWER 9 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 1998:417616 BIOSIS <<LOGINID::20101214>>
 DN PREV199800417616
 TI Occurrence of Escherichia coli O157:H7, other Shiga-like toxin-producing
 E. coli, and Salmonella in retail fresh ground beef.
 AU ***Samadpour, M.*** ; Yang, P.; Buck, F.; Ammerman, S.; Depavia, G.;
 Mazengia, E.; Alfi, D. [Reprint author]; Barbour, W. M.
 CS Dep. Environ. Health, Univ. Washington, Seattle, WA, USA
 SO 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.
 DT Conference; (Meeting)
 Conference; Abstract; (Meeting Abstract)
 Conference; (Meeting Poster)
 LA English
 ED Entered STN: 2 Oct 1998
 Last Updated on STN: 2 Oct 1998
 AU ***Samadpour, M.*** ; Yang, P.; Buck, F.; Ammerman, S.; Depavia, G.;
 Mazengia, E.; Alfi, D. [Reprint author]; Barbour, W. M.
 IT Methods & Equipment
 enrichment ***culture*** : food contaminant detection method; micro
 restriction fingerprinting: food contaminant detection method; PCR
 [polymerase chain reaction]: food contaminant detection method
 IT. . .

ORGN Classifier
 Enterobacteriaceae 06702
 Super Taxa
 Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
 Bacteria ; Microorganisms
 Organism Name
 Escherichia-coli: O157:H7, Shiga-like toxin-producing, food
 contaminant, ***pathogen***
 Salmonella: food contaminant, ***pathogen***
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L3 ANSWER 10 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on

STN
AN 1993:96168 BIOSIS <<LOGINID::20101214>>
DN PREV199395051364
TI Laboratory aspects of Mycobacterium genavense, a proposed species isolated from AIDS patients.
AU Coyle, Marie B. [Reprint author]; Carlson, La Donna C.; Wallis, Carolyn K.; Leonard, Rebecca B.; Raisys, Vidmantas A.; Kilburn, James O.; ***Samadpour, Mansur*** ; Boettger, Erik C.
CS Dep. Lab. Med., Harborview Med. Cent., Univ. Washington, Seattle, Washington 98104, USA
SO Journal of Clinical Microbiology, (1992) Vol. 30, No. 12, pp. 3205-3212. CODEN: JCMIDW. ISSN: 0095-1137.
DT Article
LA English
ED Entered STN: 9 Feb 1993
Last Updated on STN: 10 Feb 1993
AB "Mycobacterium genavense" is a proposed new species recently reported to cause disseminated infections in 18 patients with AIDS in Europe. We have recovered "M. genavense" as slowly growing fastidious mycobacteria in blood ***cultures*** of seven patients with AIDS. In the original studies of "M. genavense", the fastidious organism grew only in BACTEC 13A vials. The Seattle, Washington, isolates of "M. genavense" also failed to grow when subcultured from 13A vials to routine solid media, but dysgonic colonies were produced on Middlebrook 7H11 agar supplemented with mycobactin J. The mycolic acid pattern of patients' isolates closely resembled that of the type strain of Mycobacterium simiae when analyzed by one- and two-dimensional thin-layer chromatography and by high-performance liquid chromatography. Whole-cell fatty acid analyses by gas-liquid chromatography distinguished the isolates from M. simiae but misidentified them as Mycobacterium fortuitum. Sequence determinations of the hypervariable regions of the 16S rRNA gene indicate that these organisms belong to the recently proposed new species "M. genavense". Growth from Middlebrook 7H11 agar supplemented with mycobactin J consistently yielded positive tests for catalase (semiquantitative and at 68 degree C), pyrazinamidase, and urease which enable mycobacteriology laboratories to presumptively identify "M. genavense" without nucleic acid analyses. The failure of "M. genavense" to grow on conventional mycobacterial solid media suggests that mycobacterial blood ***cultures*** should include a broth medium ***incubated*** for at least 8 weeks.
AU . . Marie B. [Reprint author]; Carlson, La Donna C.; Wallis, Carolyn K.; Leonard, Rebecca B.; Raisys, Vidmantas A.; Kilburn, James O.; ***Samadpour, Mansur*** ; Boettger, Erik C.
AB. . . infections in 18 patients with AIDS in Europe. We have recovered "M. genavense" as slowly growing fastidious mycobacteria in blood ***cultures*** of seven patients with AIDS. In the original studies of "M. genavense", the fastidious organism grew only in BACTEC 13A. . . without nucleic acid analyses. The failure of "M. genavense" to grow on conventional mycobacterial solid media suggests that mycobacterial blood ***cultures*** should include a broth medium ***incubated*** for at least 8 weeks.
ORGN . . .
Taxa Notes
Animals, Chordates, Humans, Mammals, Primates, Vertebrates
ORGN Classifier
Mycobacteriaceae 08881
Super Taxa
Mycobacteria; Actinomycetes and Related Organisms; Eubacteria;

Bacteria ; Microorganisms
 Organism Name
 Mycobacterium fortuitum
 Mycobacterium genavense
 Mycobacterium simiae
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms
 ORGN Classifier
 Retroviridae 03305
 Super Taxa
 DNA and RNA Reverse Transcribing Viruses; Viruses; Microorganisms
 Organism Name
 Retroviridae
 Taxa. . .

L3 ANSWER 11 OF 16 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on
 STN
 AN 1990:310473 BIOSIS <<LOGINID::20101214>>
 DN PREV199090029440; BA90:29440
 TI EVALUATION OF DNA PROBES FOR DETECTION OF SHIGA-LIKE TOXIN PRODUCING
 ESCHERICHIA-COLI IN FOOD AND CALF FECAL SAMPLES.
 AU ***SAMADPOUR M*** [Reprint author]; LISTON J; ONGERTH J E; TARR P I
 CS INST FOOD SCI TECHNOL, SCH FISHERIES, UNIV WASH, SEATTLE, WASH 98195, USA
 SO Applied and Environmental Microbiology, (1990) Vol. 56, No. 5, pp.
 1212-1215.
 CODEN: AEMIDF. ISSN: 0099-2240.
 DT Article
 FS BA
 LA ENGLISH
 ED Entered STN: 10 Jul 1990
 Last Updated on STN: 10 Jul 1990
 AB The use of DNA probes for Shiga-like toxin I (SLT-I) and SLT-II for
 detection of SLT-producing Escherichia coli (SLTEC) in foods and calf
 fecal samples was evaluated. Enrichment ***cultures*** were prepared
 from food or fecal samples. Colonies formed by plating of enrichment
 cultures were probed for SLTEC by colony hybridization.
 Alternatively, enrichment ***cultures*** were analyzed for SLTEC
 presence by dot blot. The lowest detected concentration of SLTEC in
 sample homogenates inoculated with E. coli O157:H7 corresponded to 1.3
 CFU/g of sample. Of the 44 food samples and 28 fecal samples from dairy
 calves tested by the colony hybridization method, 4 food samples,
 including ground beef, raw goat milk, blueberries, and surimi-based
 delicatessen salad, and 9 calf fecal samples were positive with the SLT
 probes. The dot blot technique yielded results within 48 h and can be
 used as a fast and sensitive method of detection for SLTEC in foods an
 calf fecal samples. The colony hybridization technique took 3 to 4 days
 but permits recovery of the positive colonies when desired.
 AU ***SAMADPOUR M*** [Reprint author]; LISTON J; ONGERTH J E; TARR P I
 AB. . . I (SLT-I) and SLT-II for detection of SLT-producing Escherichia coli
 (SLTEC) in foods and calf fecal samples was evaluated. Enrichment
 cultures were prepared from food or fecal samples. Colonies
 formed by plating of enrichment ***cultures*** were probed for SLTEC
 by colony hybridization. Alternatively, enrichment ***cultures***
 were analyzed for SLTEC presence by dot blot. The lowest detected
 concentration of SLTEC in sample homogenates inoculated with E.. . .
 IT Miscellaneous Descriptors
 BACTERIA MICROORGANISM GENETICS METHODS FOOD PRODUCTS

ORGN Classifier

Enterobacteriaceae 06702

Super Taxa

Facultatively Anaerobic Gram-Negative Rods; Eubacteria;

Bacteria ; Microorganisms

Taxa Notes

Bacteria , Eubacteria, Microorganisms

L3 ANSWER 12 OF 16 CAPLUS COPYRIGHT 2010 ACS on STN

AN 2009:1475567 CAPLUS <<LOGINID::20101214>>

DN 151:546146

TI Method and kit for confirming the presence of an analyte such as

microbial analyte

IN ***Samadpour, Mansour***

PA Institute for Environmental Health, Inc., USA

SO U.S. Pat. Appl. Publ., 6pp., Cont.-in-part of U.S. Ser. No.107,458.

CODEN: USXXCO

DT Patent

LA English

FAN.CNT 3

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	US 20090291446	A1	20091126	US 2009-430804	20090427
	US 20060115824	A1	20060601	US 2005-107458	20050415
PRAI	US 2004-562302P	P	20040415		
	US 2005-107458	A2	20050415		
	US 2008-47999P	P	20080425		

AB The invention provides methods and kits for the rapid confirmation of an initial analyte test result. In a preferred embodiment, the process confirms the presence of a given ***microbial*** target in a mixed ***culture*** , or a mixed enrichment media, even when the competing organisms in the mix belong to related species, or are various biotypes of the same species.

OSC.G 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)

TI Method and kit for confirming the presence of an analyte such as

microbial analyte

IN ***Samadpour, Mansour***

AB . . . rapid confirmation of an initial analyte test result. In a preferred embodiment, the process confirms the presence of a given ***microbial*** target in a mixed ***culture*** , or a mixed enrichment media, even when the competing organisms in the mix belong to related species, or are various. . .

IT Magnetic materials

(beads; method and kit for confirming the presence of an analyte such as ***microbial*** analyte using magnetic beads coated with antibody and multiplex PCR)

IT ***Culture*** media

(enrichment; method and kit for confirming the presence of an analyte such as ***microbial*** analyte using magnetic beads coated with antibody and multiplex PCR)

IT Absorbents

Body fluid

Dyes

Escherichia coli

Filters

Microorganism

Polymerase chain reaction

Size-exclusion chromatography
Test kits
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)
IT DNA
Gene, ***microbial***
RL: ANT (Analyte); ANST (Analytical study)
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)
IT Nucleic acids
RL: ANT (Analyte); ARG (Analytical reagent use); ANST (Analytical study);
USES (Uses)
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)
IT Nucleotides
Primers (nucleic acid)
RL: ARG (Analytical reagent use); ANST (Analytical study); USES (Uses)
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)
IT Polymerase chain reaction
(multiplex; method and kit for confirming the presence of an analyte
such as ***microbial*** analyte using magnetic beads coated with
antibody and multiplex PCR)
IT Cytolysis
(of ***bacterial*** cell; method and kit for confirming the
presence of an analyte such as ***microbial*** analyte using
magnetic beads coated with antibody and multiplex PCR)
IT Antibodies and Immunoglobulins
RL: ARG (Analytical reagent use); ANST (Analytical study); USES (Uses)
(on magnetic beads; method and kit for confirming the presence of an
analyte such as ***microbial*** analyte using magnetic beads coated
with antibody and multiplex PCR)
IT Membranes, nonbiological
(porous; method and kit for confirming the presence of an analyte such
as ***microbial*** analyte using magnetic beads coated with
antibody and multiplex PCR)
IT 9012-90-2, DNA polymerase
RL: ARG (Analytical reagent use); ANST (Analytical study); USES (Uses)
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)
IT 9012-36-6, Agarose
RL: BUU (Biological use, unclassified); BIOL (Biological study); USES
(Uses)
(method and kit for confirming the presence of an analyte such as
microbial analyte using magnetic beads coated with antibody
and
multiplex PCR)

L3 ANSWER 13 OF 16 CAPLUS COPYRIGHT 2010 ACS on STN
 AN 2009:1329801 CAPLUS <<LOGINID::20101214>>
 DN 151:468821
 TI Method for confirming the presence of an ***microbial*** analyte
 IN ***Samadpour, Mansour***
 PA IEH Laboratories and Consulting Group, USA
 SO PCT Int. Appl., 15pp.
 CODEN: FLXXD2
 DT Patent
 LA English
 FAN.CNT 3

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	WO 2009132354	A2	20091029	WO 2009-US41839	20090427
	WO 2009132354	A3	20100107		
	W:	AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW			
	RW:	AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, 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, AP, EA, EP, OA			

PRAI US 2008-47999P P 20080425

AB The invention provides methods and kits for the rapid confirmation of an initial analyte test result. In a preferred embodiment, the process confirms the presence of a given ***microbial*** target in a mixed ***culture***, or a mixed enrichment media, even when the competing organisms in the mix belong to related species, or are various biotypes of the same species.

TI Method for confirming the presence of an ***microbial*** analyte
 IN ***Samadpour, Mansour***

AB . . . rapid confirmation of an initial analyte test result. In a preferred embodiment, the process confirms the presence of a given ***microbial*** target in a mixed ***culture***, or a mixed enrichment media, even when the competing organisms in the mix belong to related species, or are various.

ST ***pathogenic*** microorganism food gene PCR kit

IT Escherichia coli
 (O157; PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT Food
 Food analysis
 Food contamination
 Microorganism
 Pathogen
 Size-exclusion chromatography
 Test kits
 (PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT Gene, ***microbial***
 RL: ANT (Analyte); ANST (Analytical study)

(PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT Antibodies and Immunoglobulins
 RL: ARG (Analytical reagent use); ANST (Analytical study); USES (Uses)
 (PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT DNA
 RL: BSU (Biological study, unclassified); BIOL (Biological study)
 (PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT ***Culture*** media
 (enrichment; PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

IT Escherichia coli
 (enterotoxigenic; PCR method for confirming presence of
 pathogenic ***microbial*** contamination of food)

IT Polymerase chain reaction
 (multiplex; PCR method for confirming presence of ***pathogenic***
 microbial contamination of food)

L3 ANSWER 14 OF 16 CAPLUS COPYRIGHT 2010 ACS on STN

AN 2004:1036550 CAPLUS <<LOGINID::20101214>>

DN 141:422061

TI Enrichment methods for the detection of ***pathogens*** and other
 microbes

IN ***Samadpour, Mansour***

PA Institute for Environmental Health, Inc., USA

SO U.S. Pat. Appl. Publ., 25 pp.

CODEN: USXXCO

DT Patent

LA English

FAN.CNT 1

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	US 20040241644	A1	20041202	US 2004-848253	20040517
	US 7531163	B2	20090512		
	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				
	US 20090269760	A1	20091029	US 2009-360646	20090127
PRAI	US 2003-470975P	P	20030516		
	US 2004-848253	A1	20040517		
	WO 2004-US15659	W	20040517		

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

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 dild. (e.g., in the case of a solid or semi-solid sample. or liq.) at the first location at a ratio of about 1:0 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) or greater. The dild. sample is ***incubated*** at an optimal temp. 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 diln. 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.

TI Enrichment methods for the detection of ***pathogens*** and other ***microbes***

IN ***Samadpour, Mansour***

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. . . 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) or greater. The dild. sample is ***incubated*** at an optimal temp. 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 diln. 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.

ST enrichment detection ***pathogen*** ***microbe***

IT DNA microarray technology
Escherichia coli
Food analysis
Nucleic acid hybridization
Pharmaceutical analysis
Wastewater
(enrichment methods for detection of ***pathogens*** and other ***microbes***)

IT DNA
RL: ANT (Analyte); BSU (Biological study, unclassified); ANST (Analytical study); BIOL (Biological study)
(enrichment methods for detection of ***pathogens*** and other ***microbes***)

L3 ANSWER 15 OF 16 EMBASE COPYRIGHT (c) 2010 Elsevier B.V. All rights reserved on STN

AN 2005035761 EMBASE <<LOGINID::20101214>>

TI Is acute uncomplicated urinary tract infection a foodborne illness, and are animals the source?.

AU Hooton, Thomas M., Dr. (correspondence)

CS University of Washington, School of Medicine, Seattle, WA, United States.
hooton@u.washington.edu

AU Hooton, Thomas M., Dr. (correspondence)

CS Harborview Medical Center, 325 Ninth Ave., Seattle, WA 98104-5109, United States. hooton@u.washington.edu

AU ***Samadpour, Mansour***

CS Institute for Environmental Health, Seattle, WA, United States.

SO Clinical Infectious Diseases, (15 Jan 2005) Vol. 40, No. 2, pp. 258-259.
Refs: 10
ISSN: 1058-4838 CODEN: CIDIEL

CY United States

DT Journal; Note

FS 028 Urology and Nephrology
037 Drug Literature Index
004 Microbiology: Bacteriology, Mycology, Parasitology and Virology
046 Environmental Health and Pollution Control
006 Internal Medicine

LA English

ED Entered STN: 4 Feb 2005
Last Updated on STN: 4 Feb 2005

AU ***Samadpour, Mansour***

CS Institute for Environmental Health, Seattle, WA, United States.

CT Medical Descriptors:
acute disease
antibiotic resistance
bacterial colonization
bacterial transmission
bacterium isolation
bladder
cluster analysis
*cystitis: ET, etiology
Escherichia coli
*food contamination
gastrointestinal tract
human
multidrug resistance
nonhuman
note
polymerase chain reaction
priority journal
*pyelonephritis: ET, etiology
sewage
sexual intercourse
*urinary tract infection: ET, etiology
urine culture
vagina
cotrimoxazole

L3 ANSWER 16 OF 16 EMBASE COPYRIGHT (c) 2010 Elsevier B.V. All rights reserved on STN

AN 1992369118 EMBASE <<LOGINID::20101214>>

TI Laboratory aspects of 'Mycobacterium genavense,' a proposed species isolated from AIDS patients.

AU Coyle, M.B. (correspondence); Carlson, L.D.C.; Wallis, C.K.; Leonard, R.B.; Raisys, V.A.; Kilburn, J.O.; ***Samadpour, M.*** ; Bottger, E.C.

CS Department of Laboratory Medicine, Harborview Medical Center, University of Washington, Seattle, WA 98104, United States.

SO Journal of Clinical Microbiology, (1992) Vol. 30, No. 12, pp. 3206-3212.
ISSN: 0095-1137 CODEN: JCMIDW

CY United States

DT Journal; Article

FS 004 Microbiology: Bacteriology, Mycology, Parasitology and Virology

LA English

SL English

ED Entered STN: 10 Jan 1993

Last Updated on STN: 10 Jan 1993

AB 'Mycobacterium genavense' is a proposed new species recently reported to cause disseminated infections in 18 patients with AIDS in Europe. We have recovered 'M. genavense' as slowly growing fastidious mycobacteria in blood ***cultures*** of seven patients with AIDS. In the original studies of 'M. genavense,' the fastidious organism grew only in BACTEC 13A vials. The Seattle, Washington, isolates of 'M. genavense' also failed to grow when subcultured from 13A vials to routine solid media, but dysgonic colonies were produced on Middlebrook 7H11 agar supplemented with mycobactin J. The mycolic acid pattern of patients' isolates closely resembled that of the type strain of Mycobacterium simiae when analyzed by one- and two-dimensional thin-layer chromatography and by high-performance liquid chromatography. Whole-cell fatty acid analyses by gas-liquid chromatography distinguished the isolates from M. simiae but misidentified them as Mycobacterium fortuitum. Sequence determinations of the hypervariable regions of the 16S rRNA gene indicate that these organisms belong to the recently proposed new species 'M. genavense.' Growth from Middlebrook 7H11 agar supplemented with mycobactin J consistently yielded positive tests for catalase (semiquantitative and at 68.degree.C), pyrazinamidase, and urease which enable mycobacteriology laboratories to presumptively identify 'M. genavense' without nucleic acid analyses. The failure of 'M. genavense' to grow on conventional mycobacterial solid media suggests that mycobacterial blood ***cultures*** should include a broth medium ***incubated*** for at least 8 weeks.

AU Coyle, M.B. (correspondence); Carlson, L.D.C.; Wallis, C.K.; Leonard, R.B.; Raisys, V.A.; Kilburn, J.O.; ***Samadpour, M.***; Bottger, E.C.

CS Department of Laboratory Medicine, Harborview Medical Center, University of Washington, Seattle, WA 98104, United States.. . .

AB . . . infections in 18 patients with AIDS in Europe. We have recovered 'M. genavense' as slowly growing fastidious mycobacteria in blood ***cultures*** of seven patients with AIDS. In the original studies of 'M. genavense,' the fastidious organism grew only in BACTEC 13A. . . . without nucleic acid analyses. The failure of 'M. genavense' to grow on conventional mycobacterial solid media suggests that mycobacterial blood ***cultures*** should include a broth medium ***incubated*** for at least 8 weeks.

CT Medical Descriptors:

*acquired immune deficiency syndrome
article

bacterium isolation

blood culture

controlled study

gas liquid chromatography

gene sequence

high performance liquid chromatography

laboratory test

lipid analysis

*mycobacterium

nonhuman

nucleic acid analysis
priority journal
sequence homology
*strain difference
thin layer chromatography
catalase: EC, endogenous. . .

=> s stool? and (pathogen? or microb? or bacter? or virus) and (incubat? or cultur?)

L5 16297 STOOL? AND (PATHOGEN? OR MICROB? OR BACTER? OR VIRUS) AND (INCUBAT? OR CULTUR?)

=> s l5 and dilut? and (1:10)

L6 19 L5 AND DILUT? AND (1:10)

=> dup rem l6

PROCESSING COMPLETED FOR L6

L7 12 DUP REM L6 (7 DUPLICATES REMOVED)

=> d bib ab kwic 1-

YOU HAVE REQUESTED DATA FROM 12 ANSWERS - CONTINUE? Y/(N):y

L7 ANSWER 1 OF 12 SCISEARCH COPYRIGHT (c) 2010 The Thomson Corporation on STN

AN 2008:538992 SCISEARCH <<LOGINID::20101214>>

GA The Genuine Article (R) Number: 288KN

TI Investigation of various tissue ***culture*** monolayers sensitivity in detection of Clostridium difficile toxin

AU Salari, M. H. (Reprint)

CS Univ Tehran, Sch Publ Hlth Med Sci, Dept Pathobiol, Tehran, Iran (Reprint)

AU Badami, N.; Sadeghifard, N.; Harati, F. Amin

CS E-mail: msalari2000@yahoo.com

CYA Iran

SO IRANIAN JOURNAL OF PUBLIC HEALTH, (2008) Vol. 37, No. 1, pp. 99-102. ISSN: 0304-4556.

PB TEHRAN UNIV MEDICAL SCIENCES, P O BOX 14155-6451, TEHRAN, 00000, IRAN.

DT Article; Journal

FS SOCSEARCH

LA English

REC Reference Count: 18

ED Entered STN: 1 May 2008

Last Updated on STN: 1 May 2008

ABSTRACT IS AVAILABLE IN THE ALL AND IALL FORMATS

AB Background: Clostridium difficile is the most common cause of nosocomial diarrhea. It is usually a consequence of antibiotic treatment, but sporadic cases can occur. The purpose of this study was to investigate five tissue ***culture*** monolayers sensitivity in detection of C difficile-toxin.

Methods: A total of 402 ***stool*** samples from patients with nosocomial diarrhea hospitalized in three hospitals of Tehran University of Medical Sciences (TUMS) were collected. The samples were

cultured on a selective cycloserine cefoxitin fructose agar (CCFA)

and ***incubated*** in anaerobic conditions, at 37 degrees C for 4 days. Isolates were characterized to species level by conventional biochemical tests. ***Bacterial*** cytotoxicity was assayed on five

tissue ***culture*** monolayers.

Results: Our findings show that of the total patients, 24 toxigenic *C. difficile* (6%) were isolated. All 24 *C. difficile* toxins showed cytotoxic effect at $\geq$ ***1*** ; ***10*** ***dilution*** on Hela, Hep2, Vero, McCoy and Mdck cells after 16, 20, 24, 24 and 30 hours, respectively. *C. difficile* toxin showed cytotoxic effect at $\geq$ 1: 100 ***dilutions*** only on Hela cell monolayer after 48 hours.

Conclusion: Hela cell monolayer may be a satisfactory substitute for the detection of *C. difficile* toxin in clinical specimens.

TI Investigation of various tissue ***culture*** monolayers sensitivity in detection of *Clostridium difficile* toxin

AB . . . a consequence of antibiotic treatment, but sporadic cases can occur. The purpose of this study was to investigate five tissue ***culture*** monolayers sensitivity in detection of *C. difficile*-toxin.

Methods: A total of 402 ***stool*** samples from patients with nosocomial diarrhea hospitalized in three hospitals of Tehran University of Medical Sciences (TUMS) were collected. The samples were ***cultured*** on a selective cycloserine cefoxitin fructose agar (CCFA) and ***incubated*** in anaerobic conditions, at 37 degrees C for 4 days. Isolates were characterized to species level by conventional biochemical tests. ***Bacterial*** cytotoxicity was assayed on five tissue ***culture*** monolayers.

Results: Our findings show that of the total patients, 24 toxigenic *C. difficile* (6%) were isolated. All 24 *C. difficile* toxins showed cytotoxic effect at $\geq$ ***1*** ; ***10*** ***dilution*** on Hela, Hep2, Vero, McCoy and Mdck cells after 16, 20, 24, 24 and 30 hours, respectively. *C. difficile* toxin showed cytotoxic effect at $\geq$ 1: 100 ***dilutions*** only on Hela cell monolayer after 48 hours.

Conclusion: Hela cell monolayer may be a satisfactory substitute for the detection. . .

ST Author Keywords: patients; diarrhea; *Clostridium difficile*; toxin; CPe; various tissue ***culture***

L7 ANSWER 2 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN DUPLICATE 1

AN 2005:242184 BIOSIS <<LOGINID::20101214>>

DN PREV200510030973

TI Rapid detection of diarrheagenic *E. coli* by real-time PCR.

AU Bischoff, C.; Luethy, J.; Altwegg, M.; Baggi, F. [Reprint Author]

CS Univ Zurich, Dept Med Microbiol, Gloriastr 30-32, CH-8028 Zurich, Switzerland
fbaggi@bluewin.ch

SO Journal of Microbiological Methods, (JUN 2005) Vol. 61, No. 3, pp. 335-341.
CODEN: JMI MDQ. ISSN: 0167-7012.

DT Article

LA English

ED Entered STN: 29 Jun 2005
Last Updated on STN: 29 Jun 2005

AB Enterovirulent *Escherichia coli* are among the most important causes of acute diarrhea in developing as well as in developed countries. We have adapted classical PCR to detect these organisms in ***stool*** specimens to real-time PCR using the LightCycler (R) (LC) SYBR Green format followed by melting curve analysis. With only two different cycling protocols we could detect enteropathogenic *E. coli* (EPEC) and verocytotoxin-producing *E. coli* (VTEC) (duplex assay for both Verotoxin 1

(VT1) and Verotoxin 2 (VT2)) in one run and enteroaggregative *E. coli* (EAEC), enteroinvasive *E. coli* (EIEC) and enterotoxigenic *E. coli* (ETEC) (duplex assay detecting both heat-stable enterotoxin (ST) and heat-labile enterotoxin (LT)) in another run. Using serial ***dilutions*** of control strains, the LC proved to be clearly more sensitive than conventional PCR for five out of seven investigated targets: VTEC (VT1 and VT2), ETEC (ST and LT) and EIEC. For EPEC and EAEC, LC and conventional PCR had identical sensitivities. With ***stool*** samples, we found an optimal agreement between LC-PCR and the conventional PCR when samples were tested in a ***1*** : ***10*** ***dilution***. Only one specimen was discrepant, being repetitively positive for VT by LightCycler (R) but not by conventional PCR. Given the significantly higher sensitivity of the LC-PCR for the VT target (up to a 10⁽⁻⁴⁾

dilution factor by melting curve analysis and up to a 10⁽⁻⁶⁾ ***dilution*** factor following gel electrophoresis), this is probably

a

false negative result by conventional PCR. We conclude that LightCycler (R) PCR is more rapid, easier than and at least as sensitive as our conventional PCR for the detection of enterovirulent *E. coli* in ***stool*** specimens after ***culture*** on MacConkey. (c) 2004 Elsevier B.V. All rights reserved.

AB. . . acute diarrhea in developing as well as in developed countries. We have adapted classical PCR to detect these organisms in ***stool*** specimens to real-time PCR using the LightCycler (R) (LC) SYBR Green format followed by melting curve analysis. With only two. . . enterotoxigenic *E. coli* (ETEC) (duplex assay detecting both heat-stable enterotoxin (ST) and heat-labile enterotoxin (LT)) in another run. Using serial ***dilutions*** of control strains, the LC proved to be clearly more sensitive than conventional PCR for five out of seven investigated. . . and VT2), ETEC (ST and LT) and EIEC. For EPEC and EAEC, LC and conventional PCR had identical sensitivities. With ***stool*** samples, we found an optimal agreement between LC-PCR and the conventional PCR when samples were tested in a ***1*** : ***10*** ***dilution***. Only one specimen was discrepant, being repetitively positive for VT by LightCycler (R) but not by conventional PCR. Given the significantly higher sensitivity of the LC-PCR for the VT target (up to a 10⁽⁻⁴⁾ ***dilution*** factor by melting curve analysis and up to a 10⁽⁻⁶⁾ ***dilution*** factor following gel electrophoresis), this is probably a false negative result by conventional PCR. We conclude that LightCycler (R) PCR. . . rapid, easier than and at least as sensitive as our conventional PCR for the detection of enterovirulent *E. coli* in ***stool*** specimens after ***culture*** on MacConkey. (c) 2004 Elsevier B.V. All rights reserved.

IT Major Concepts

Methods and Techniques; Infection

IT Parts, Structures, & Systems of Organisms

stool : digestive system

IT Diseases

acute diarrhea: digestive system disease

Diarrhea (MeSH)

IT Chemicals & Biochemicals

verocytotoxin

ORGN Classifier

Enterobacteriaceae 06702

Super Taxa

Facultatively Anaerobic Gram-Negative Rods; Eubacteria;

Bacteria ; Microorganisms

Organism Name

Escherichia coli (species): ***pathogen***

Taxa Notes

Bacteria , Eubacteria, Microorganism

L7 ANSWER 3 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
DUPLICATE 2
AN 1999:432006 BIOSIS <<LOGINID::20101214>>
DN PREV199900432006
TI Direct detection of vanA and vanB genes in clinical specimens for rapid
identification of vancomycin resistant enterococci (VRE) using multiplex
PCR.
AU Petrich, A. K. [Reprint author]; Luinstra, K. E.; Groves, D.; Chernesky,
M. A.; Mahony, J. B.
CS St Joseph's Hospital, 50 Charlton Ave. East, L424, St Luke's Wing,
Hamilton, ON, L8N 4A6, Canada
SO Molecular and Cellular Probes, (Aug., 1999) Vol. 13, No. 4, pp. 275-281.
print.
ISSN: 0890-8508.
DT Article
LA English
ED Entered STN: 18 Oct 1999
Last Updated on STN: 18 Oct 1999
AB Surveillance for vancomycin resistant enterococci (VRE) by ***culture***
can be labour intensive and time consuming. We have developed a multiplex
polymerase chain reaction (MPCR) which can be performed directly on the
clinical specimen. The assay allows sensitive detection of enterococci
with vanA- and vanB- mediated resistance to vancomycin. DNA was purified
from ***stool*** and rectal specimens using the XTRAXTM DNA Extraction
Kit (Gull Labs). Multiplex PCR amplified vanA and vanB targets were
detected using a microtiter plate EIA. Two-hundred specimens were tested
by routine ***culture*** and MPCR. ***Culture*** identified 44
VRE isolates and MPCR detected 38 of the 44 ***culture*** positives.
Multiplex PCR detected three additional positive VRE specimens missed by
culture for a sensitivity and specificity of 86.4 and 98.1%,
respectively. When the presence of PCR inhibitors was addressed in the
six ***culture*** positive/MPCR negative specimens, four additional
VRE positive specimens were detected. Performing MPCR on the original
specimens and on a ***1*** : ***10*** ***dilution*** of all
specimens to minimize the effect of inhibitors gave a sensitivity and
specificity of 95.5 and 98.1%, respectively. Multiplex PCR with
confirmation by microtiter plate hybridization could be completed in 8 h
compared with 24-48 h required for ***culture*** .
AB Surveillance for vancomycin resistant enterococci (VRE) by ***culture***
can be labour intensive and time consuming. We have developed a multiplex
polymerase chain reaction (MPCR) which can be performed. . . specimen.
The assay allows sensitive detection of enterococci with vanA- and vanB-
mediated resistance to vancomycin. DNA was purified from ***stool***
and rectal specimens using the XTRAXTM DNA Extraction Kit (Gull Labs).
Multiplex PCR amplified vanA and vanB targets were detected using a
microtiter plate EIA. Two-hundred specimens were tested by routine
culture and MPCR. ***Culture*** identified 44 VRE isolates
and MPCR detected 38 of the 44 ***culture*** positives. Multiplex PCR
detected three additional positive VRE specimens missed by ***culture***
for a sensitivity and specificity of 86.4 and 98.1%, respectively. When
the presence of PCR inhibitors was addressed in the six ***culture***
positive/MPCR negative specimens, four additional VRE positive specimens

were detected. Performing MPCR on the original specimens and on a
1 : ***10*** ***dilution*** of all specimens to minimize
the effect of inhibitors gave a sensitivity and specificity of 95.5 and
98.1%, respectively. Multiplex PCR with confirmation by microtiter plate
hybridization could be completed in 8 h compared with 24-48 h required for
culture.

ORGN Classifier

Gram-Positive Cocci 07700

Super Taxa

Eubacteria; ***Bacteria*** ; Microorganisms

Organism Name

enterococci: rapid identification, vancomycin resistant

Taxa Notes

Bacteria , Eubacteria, Microorganisms

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DUPLICATE 3

AN 1996:361289 BIOSIS <<LOGINID::20101214>>

DN PREV199699083645

TI New colonization pattern of the neonate without antimicrobial therapy
during the first 7 days of life: Enterobacteriaceae, enterococci,
staphylococci.

AU Borderon, J. C.; Lionnet, C.; Rondeau, C.; Suc, A. L.; Laugier, J.; Gold,
F.

CS Cent. de Ped. Gatiens de Clocheville, 49 rue Beranger, 37000 Tours, France

SO Pathologie Biologie, (1996) Vol. 44, No. 5, pp. 416-422.

CODEN: PABIAQ. ISSN: 0369-8114.

DT Article

LA French

ED Entered STN: 14 Aug 1996

Last Updated on STN: 15 Aug 1996

AB Last years, it became obvious that the colonization pattern described in
1976-1978 was no more valid: early colonization by Enterobacteriaceae at
the 2-3 rd day of life in all newborns, with constant presence of
antibioresistant strains even in non treated newborns. To establish the
new pattern of colonization, the same quantitative method of
dilution and ***culture*** on selective media was used daily
from day 1 to day 7 (5 days only for M). The number of
Enterobacteriaceae, enterococci and staphylococci was determined in the
stools of 10 newborns in the Maternity unit (=M) (term 40 weeks +
1, birth weight 3 356 g + 383), 10 in the Premature nursery (=P) (term
34.9 weeks + 1, birth weight 2 457 g + 676), and 14 in the Neonatal
intensive care unit (=R) (term 35.2 weeks + 3.8, birth weight 2457 g +
763). The results establish that colonization by Enterobacteriaceae is no
more constant at D3. It could be demonstrated only in 8/10 M, ***1***
/ ***10*** P, and 6/14 R (statistically different - p lt 0.01 between M
and P). At D5, 9/10 M, 5/10 P, 10/14 R, and at D7, 6/10 P and 10/14 R
were colonized. Resistant Enterobacteriaceae (Escherichia coli,
Klebsiella pneumoniae, Enterobacter cloacae) could be found in only 3/10
M, 4/10 P and 6/14 R. Enterococci could be found in 1 newborn M, 2 P and
7 newborns R. Staphylococci appeared earlier: all newborns M, P and R
were colonized at D2, 4 and 5 respectively. These ***bacteria*** were
coagulase negative, associated with Staphylococcus aureus in 3 P. Our
hypothesis is that late colonization with Enterobacteriaceae and
enterococci is due to the improvement of hygiene procedures and due to the
decontaminating effect of antibiotics in other treated newborns
(Enterobacteriaceae by 3 rd generation cephalosporin and enterococci by

pharyngeal vancomycin).

AB. . . of antibiotic-resistant strains even in non-treated newborns. To establish the new pattern of colonization, the same quantitative method of ***dilution*** and ***culture*** on selective media was used daily from day 1 to day 7 (5 days only for M). The number of Enterobacteriaceae, enterococci and staphylococci was determined in the ***stools*** of 10 newborns in the Maternity unit (=M) (term 40 weeks + 1, birth weight 3 356 g + 383),. . . results establish that colonization by Enterobacteriaceae is no more constant at D3. It could be demonstrated only in 8/10 M, ***1*** / ***10*** P, and 6/14 R (statistically different - p lt 0.01 between M and P). At D5, 9/10 M, 5/10 P,. . . newborns R. Staphylococci appeared earlier: all newborns M, P and R were colonized at D2, 4 and 5 respectively. These ***bacteria*** were coagulase negative, associated with Staphylococcus aureus in 3 P. Our hypothesis is that late colonization with Enterobacteriaceae and enterococci. . .

ORGN Classifier

Enterobacteriaceae 06702

Super Taxa

Facultatively Anaerobic Gram-Negative Rods; Eubacteria;

Bacteria ; Microorganisms

Organism Name

Enterobacter cloacae

Escherichia coli

Klebsiella pneumoniae

Taxa Notes

Bacteria , Eubacteria, Microorganisms

ORGN Classifier

Gram-Positive Cocci 07700

Super Taxa

Eubacteria; ***Bacteria*** ; Microorganisms

Organism Name

gram-positive cocci

Enterococcus

Taxa Notes

Bacteria , Eubacteria, Microorganisms

ORGN Classifier

Hominidae 86215

Super Taxa

Primates; Mammalia; Vertebrata; Chordata; Animalia

Organism Name

human

Taxa Notes

Animals, Chordates, Humans, Mammals, Primates, Vertebrates

ORGN Classifier

Micrococcaceae 07702

Super Taxa

Gram-Positive Cocci; Eubacteria; ***Bacteria*** ; Microorganisms

Organism Name

Staphylococcus

Taxa Notes

Bacteria , Eubacteria, Microorganisms

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AN 0047332670 EMBASE <<LOGINID::20101214>>

TI Symposium on viral hepatitis. The natural history of infectious hepatitis.

AU Krugman, S. (correspondence); Ward, R.; Giles, J.P.
CS Dept. of Ped., New York Univ., Sch. of Med., New York, NY, United States.
SO American Journal of Medicine, (1962) Vol. 32, No. 5, pp. 717-728.
ISSN: 0002-9343
DT Journal; Article
FS CLASSIC
LA English
SL English
ED Entered STN: Jun 2010
Last Updated on STN: Jun 2010
AB Experiments carried out since 1956 in an institute for mentally defective children are discussed. In certain pooled ***stools*** the minimum infective dose was 0.1 g. and the 50% endpoint of infectivity between 1 and 2 g. of ***stool***. The ***incubation*** period was between 39 and 49 days. It was also shown that infectious hepatitis was infective during the latter part of the ***incubation*** period (faeces). The ***virus*** is also present in the blood in the pre-icteric phase. In some pooled sera 0.025 ml. was highly infective; the 50% infectivity endpoint was 0.25 ml. of a ***1*** : ***10*** ***dilution*** of this serum. In one case viraemia existed without any clinical symptoms of hepatitis. In general an attack of infectious hepatitis is followed by a solid immunity. In this institute, from a total of 697 observed cases of infectious hepatitis in 4.5% a second attack was observed. The authors discuss some possible explanation of this phenomenon. The most interesting is the existence of multiple, immunologically distinct types of hepatitis ***virus***. A dose of 0.06 ml. .gamma.-globulin per lb. body weight, prevented icteric hepatitis for 5 months; it did not prevent the infection as such. Patients who received .gamma.-globulin are therefore potential spreaders of the infection.
AB Experiments carried out since 1956 in an institute for mentally defective children are discussed. In certain pooled ***stools*** the minimum infective dose was 0.1 g. and the 50% endpoint of infectivity between 1 and 2 g. of ***stool***. The ***incubation*** period was between 39 and 49 days. It was also shown that infectious hepatitis was infective during the latter part of the ***incubation*** period (faeces). The ***virus*** is also present in the blood in the pre-icteric phase. In some pooled sera 0.025 ml. was highly infective; the 50% infectivity endpoint was 0.25 ml. of a ***1*** : ***10*** ***dilution*** of this serum. In one case viraemia existed without any clinical symptoms of hepatitis. In general an attack of infectious. . . discuss some possible explanation of this phenomenon. The most interesting is the existence of multiple, immunologically distinct types of hepatitis ***virus***. A dose of 0.06 ml. .gamma.-globulin per lb. body weight, prevented icteric hepatitis for 5 months; it did not prevent. . .
CT Medical Descriptors:
blood
body weight
child
dilution
feces
hepatitis
hepatitis virus
*history
immunity
incubation time
infection
*infectious hepatitis

patient
serum
solid
viremia
virus
virus hepatitis
immunoglobulin

L7 ANSWER 6 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
AN 1963:7103 BIOSIS <<LOGINID::20101214>>
DN PREV19634100007103; BA41:7103
TI A modification in the method of studying ***pathogenic*** Escherichia
coli Referat. Zhur., Biol., 1962, No. 7B367. (Translation).
Original Title: Modifikatsiya metodiki issledovaniya na patogennye
kischechnye palochki Referat. Zhur., Biol., 1962, No. 7B367. (Translation).
AU AGAFANOVA, L. I.
SO LAB DELO, (1961) Vol. 9, pp. 37-38.
DT Article
FS BA
LA Unavailable
ED Entered STN: May 2007
Last Updated on STN: May 2007
AB An initial ***stool*** ***culture*** was made on a slant with Endo
medium and cultivated for 18 to 20 hrs. in an ***incubator***. The
microbial colonies were suspended in a "condensation fluid", and
the agglutination reaction was done on glass with a mixture of sera
against ***pathogenic*** Escherichia coli (026B6, 055B5, 0111B4 and
145) ***diluted*** to 1:5- ***1*** : ***10***. The proposed
method resulted in a decrease in work and materials while increasing the
growth of colonies. ABSTRACT AUTHORS: Translator
TI A modification in the method of studying ***pathogenic*** Escherichia
coli Referat. Zhur., Biol., 1962, No. 7B367. (Translation).
Original Title: Modifikatsiya metodiki issledovaniya na patogennye
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AB An initial ***stool*** ***culture*** was made on a slant with Endo
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against ***pathogenic*** Escherichia coli (026B6, 055B5, 0111B4 and
145) ***diluted*** to 1:5- ***1*** : ***10***. The proposed
method resulted in a decrease in work and materials while increasing the
growth of colonies. ABSTRACT AUTHORS: Translator
IT Major Concepts
Bacteriology
IT Parts, Structures, & Systems of Organisms
stool : digestive system; sera: blood and lymphatics
ORGN Classifier
Enterobacteriaceae 06702
Super Taxa
Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
Bacteria ; Microorganisms
Organism Name
Escherichia coli (species)
Taxa Notes
Bacteria , Eubacteria, Microorganisms

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AN 0047396124 EMBASE <<LOGINID::20101214>>

TI Studies on poliomyelitis in Japan. I. Isolation of polioviruses and the age distribution of neutralizing antibodies in urban populations.

AU Kono, R. (correspondence); Ashihara, Y.; Kawakami, K.; Matsumiya, T.; Hirayama, M.; Kubota, H.; Tatsumi, M.

CS Dept. of Publ. Hlth. Microbiol., Inst. of Publ. Hlth., Tokyo, Japan.

SO American journal of hygiene, (1958) Vol. 67, No. 2, pp. 135-153.
ISSN: 0096-5294

DT Journal; Article

FS CLASSIC

LA English

SL English

ED Entered STN: Jun 2010
Last Updated on STN: Jun 2010

AB In Japan, from 1954 to 1956, by means of human embryonic skin-muscle tissue ***culture***, 90 strains of cytopathogenic agents were isolated, mostly from the ***stools*** of patients with paralytic poliomyelitis. Thirteen were untypable. 55 were type I, 13 type II, and 9 type III. During this period 70 to 80% of the agents causing paralytic poliomyelitis belonged to type I. Neutralization tests with 100 TCD50 of 3 types of polio ***virus*** against undiluted and ***diluted*** (***1*** : ***10***) sera from healthy individuals were made on 209 serum specimens from Tokyo and 169 from Osaka. The percentage positive was lowest at 6 to 11 months after birth, but increased rapidly to reach the adult level (80-100%) at about 4 to 6 yr. of age. This pattern of the age distribution of antibodies is almost identical to those obtained in Cairo and French Morocco. In the case of ***diluted*** sera, the final level was attained in 60 to 80%, so that about 20% of immune adults were considered to have antibody titres of less than ***1*** : ***10***. 46% of the paralytic cases occurred in infants under 1 year of age in Tokyo in 1955, coinciding with a steep increase of neutralizing antibodies. This means that paralytic sequelae are most likely to occur following a primary infection without protection of antibody. Analysis of antibody for one or more types of polio ***virus*** in various age groups shows that infection by any one type interferes with heterotypic infection: in other words, there is some degree of cross-immunity between heterotypes. Antibody titres of the pooled sera which were composed of equal quantities of sera from individuals belonging to the same age group were at their minimum levels (antibody titre against types II and III were zero and against type I were 1:3 to 1:8) under 1 year of age, rose to maximum levels (1:64 to 1:128) by 4 to 6 yr., then declined a little and thereafter remained at a level of 1:16 to 1:32 in Tokyo and Osaka.

AB In Japan, from 1954 to 1956, by means of human embryonic skin-muscle tissue ***culture***, 90 strains of cytopathogenic agents were isolated, mostly from the ***stools*** of patients with paralytic poliomyelitis. Thirteen were untypable. 55 were type I, 13 type II, and 9 type III. During. . . of the agents causing paralytic poliomyelitis belonged to type I. Neutralization tests with 100 TCD50 of 3 types of polio ***virus*** against undiluted and ***diluted*** (***1*** : ***10***) sera from healthy individuals were made on 209 serum specimens from Tokyo and 169 from Osaka. The percentage positive was. . . the age distribution of antibodies is almost identical to those obtained in Cairo and French Morocco. In the case of ***diluted*** sera, the final level was attained in 60 to 80%, so that about 20% of immune adults were considered to have antibody titres of less than

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CT Medical Descriptors:

adult
 *age distribution
 antibody titer
 feces
 groups by age
 human
 immunity
 infant
 infection
 *Japan
 Morocco
 muscle tissue
 patient
 *poliomyelitis
 ****Poliomyelitis virus***
 primary infection
 protection
 serodiagnosis
 serum
 skin
 tissue culture
 *urban population
 antibody
 *neutralizing antibody

L7 ANSWER 8 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 1957:21997 BIOSIS <<LOGINID::20101214>>
 DN PREV19573100022044; BA31:22044
 TI A simple synthetic medium for the selective growth of Lactobacillus bifidus.
 Original Title: Ein einfacher vollsynthetischer Selektivahrboden ftir den Lactobacillus bifidus.
 AU PETULY, F.
 CS Zool. Inst. U. Graz., Vienna
 SO ZENTRALBL BAKT ABT I ORIG, (1956) Vol. 166, No. 1, pp. 95-99.
 DT Article
 FS BA
 LA Unavailable
 ED Entered STN: May 2007
 Last Updated on STN: May 2007
 AB A simple agar medium for the selective isolation and growth of Lacto-bacillus bifidus (LB) from the ***stool*** of breast-fed, bottle-fed infants, and of adults is reported. It is a synthetic 2% agar medium with 3.5% lactose. In addition it contains per 100 ml medium: K2HPO4 0.25 g, ammoniumacetate 0.2 g, Tween 80 0.1 g, cystin 0.02 g, Ca-pantothenate 40 [mu]g, biotin 0.4 ug, MgSO4.7H2O 0.25 g, FeSO4.7H2O. 0.625 mg, MnSO4.4H2O 0.425 mg, NaCl 0.625 mg, vitamin C 1 [mu]g. Very high ***dilutions*** of the fecal material; ***1*** : ***10*** ,000,000, 1: 1000,000,000 or higher are plated out. After 1-2 days LB, if present, grows in practically pure ***culture*** . The LB problem is

discussed. ABSTRACT AUTHORS: Ivan Saphra

AB A simple agar medium for the selective isolation and growth of Lacto-bacillus bifidus (LB) from the ***stool*** of breast-fed, bottle-fed infants, and of adults is reported. It is a synthetic 2% agar medium with 3.5% lactose. In. . . [mulg, biotin 0.4 ug, MgSO4.7H2O 0.25 g, FeSO4.7H2O. 0.625 mg, MnSO4.4H2O 0.425 mg, NaCl 0.625 mg, vitamin C 1 [mulg. Very high ***dilutions*** of the fecal material; ***1*** : ***10*** ,000,000, 1: 1000,000,000 or higher are plated out. After 1-2 days LB, if present, grows in practically pure ***culture***. The LB problem is discussed. ABSTRACT AUTHORS: Ivan Saphra

IT Major Concepts
 Bacteriology

IT Parts, Structures, & Systems of Organisms
 stool : digestive system

IT Chemicals & Biochemicals
 lactose; biotin; ammoniumacetate; Tween 80

ORGN Classifier
 Regular Nonsporing Gram-Positive Rods 07830
 Super Taxa
 Eubacteria; ***Bacteria*** ; Microorganisms
 Organism Name
 Lactobacillus bifidus (species)
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L7 ANSWER 9 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN
 AN 1952:1499 BIOSIS <<LOGINID::20101214>>
 DN PREV19522600001502; BA26:1502
 TI The effect of terramycin on the intestinal flora.
 AU RIVERA, JOSE A.; SBOROV, VICTOR M.
 CS Army Med. Center, Washington 12, D.C.
 SO GASTROENTEROL, (1951) Vol. 17, No. 4, pp. 546-550.
 DT Article
 FS BA
 LA Unavailable
 ED Entered STN: May 2007
 Last Updated on STN: May 2007

AB Five patients with chronic viral hepatitis and 2 with hepatic cirrhosis were given daily oral doses of 2-4 g. of terramycin HCl daily in varying schedules. A daily specimen of feces from each patient was examined by direct smear. Routine ***cultures*** and ***bacterial*** counts were carried out every other day in the preliminary control period, during the treatment period, and in the period after withdrawal of terramycin. In the group receiving 4 g. per day, the treatment was continued for a 38-day period. 48 hrs. after the initiation of therapy there was noted a sharp drop in colony counts of both the Gram-positive and -negative organisms. Colony counts remained at zero for 38 days. With discontinuance of therapy there was a return to previous counts within a 6-day period. There was only an incomplete suppression of the fecal colony counts, both of the Gram-positive and -negative groups in the patients receiving 2 g. per day. With this dosage there was also noted at times a return to the pre-treatment no. of colonies even while under terramycin medication. Smears and ***cultures*** made from the same fecal specimens in the patients receiving both 2 and 4 g. of terramycin daily showed no suppression of either Gram-positive or -negative organisms. Because of the discrepancy between the no. of organisms seen on the smears and that seen on colony growth, it seemed likely that the

concn. of terramycin in the feces was sufficient to suppress colony growth. Colony counts were greatly increased when fecal emulsions of 1:200 ***dilution*** were used, as compared to the standard ***dilution*** of ***1*** : ***10*** . *Candida albicans*, *Proteus vulgaris*, and *Pseudomonas aeruginosa* were not affected by terramycin. The growth of these organisms persisted, and it appeared that these organisms grew better and multiplied more rapidly in an environment in which other enteric organisms had been suppressed. There was observed a striking change in the physical properties of the ***stools*** . They were noted to be odorless a short period after the admn. of even small doses of terramycin. The consistency of the ***stools*** softened and their color was felt to be due to bilirubin which was demonstrated in excessive amounts. There was likewise noted a considerable diminution in the concn. of fecal urobilinogen which paralleled the suppression of the intestinal flora. ABSTRACT AUTHORS: V. M. Sborov

AB. . . terramycin HCl daily in varying schedules. A daily specimen of feces from each patient was examined by direct smear. Routine ***cultures*** and ***bacterial*** counts were carried out every other day in the preliminary control period, during the treatment period, and in the period. . . was also noted at times a return to the pre-treatment no. of colonies even while under terramycin medication. Smears and ***cultures*** made from the same fecal specimens in the patients receiving both 2 and 4 g. of terramycin daily showed no. . . terramycin in the feces was sufficient to suppress colony growth. Colony counts were greatly increased when fecal emulsions of 1:200 ***dilution*** were used, as compared to the standard ***dilution*** of ***1*** : ***10*** . *Candida albicans*, *Proteus vulgaris*, and *Pseudomonas aeruginosa* were not affected by terramycin. The growth of these organisms persisted, and it. . . in which other enteric organisms had been suppressed. There was observed a striking change in the physical properties of the ***stools*** . They were noted to be odorless a short period after the admn. of even small doses of terramycin. The consistency of the ***stools*** softened and their color was felt to be due to bilirubin which was demonstrated in excessive amounts. There was likewise. . .

ORGN Classifier
 Bacteria 05000
 Super Taxa
 Microorganisms
 Organism Name
 intestinal flora (common)
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

ORGN Classifier
 Enterobacteriaceae 06702
 Super Taxa
 Facultatively Anaerobic Gram-Negative Rods; Eubacteria;
 Bacteria ; Microorganisms
 Organism Name
 Proteus vulgaris (species)
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

ORGN Classifier
 Fungi Imperfecti or Deuteromycetes 15500
 Super Taxa
 Fungi; Plantae
 Organism Name

Candida albicans (species)
 Taxa Notes. . .
 Name
 organisms (common)
 enteric organisms (common)
 Taxa Notes
 Organisms
 ORGN Classifier
 Pseudomonadaceae 06508
 Super Taxa
 Gram-Negative Aerobic Rods and Cocci; Eubacteria; ***Bacteria*** ;
 Microorganisms
 Organism Name
 Pseudomonas aeruginosa (species)
 Taxa Notes
 Bacteria , Eubacteria, Microorganisms

L7 ANSWER 10 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on
 STN
 AN 1947:17609 BIOSIS <<LOGINID::20101214>>
 DN PREV19472100017736; BA21:17736
 TI Histoplasmosis in infancy.
 AU Iams, Alexander M.; Keith, Haddow M.
 SO JOUR PEDIATRICS, (1947) Vol. 30, No. 2, pp. 123-128.
 DT Article
 FS BA
 LA Unavailable
 ED Entered STN: May 2007
 Last Updated on STN: May 2007
 AB In an extensive involvement such as reported by the authors in their case
 of an infant 7 months of age, the histoplasmin dermal test was negative to
 dilutions of 1:1000, 1:500, 1:100 and ***1*** : ***10***
 while the mother's histoplasmin intradermal test was positive. The ante
 mortem diagnosis was made. The necropsy findings were invasion of the
 organism in the heart, lungs, liver, spleen, kidneys, adrenals, esophagus,
 large bowel, urinary bladder, lymph nodes, thymus, bone marrow and
 diaphragm. The organism was ***cultured*** from the blood, lungs,
 liver, spleen, kidneys, bone marrow, rectus abdominis muscle, and frontal
 lobe of the brain. During the life of the infant, the tibia bone marrow
 puncture specimen revealed Histoplasma capsulatum in a
 reticulo-endothelial cell, in monocyte, in polymorpho-nuclear leucocyte
 and in the eosinophiles. The infant's negative histoplasmin dermal
 reaction may be considered comparable to that seen with tuberculin in
 miliary tuberculosis. The positive reaction of the infant's mother, with
 no evidence of histoplasmosis, may be postulated in that a previous or
 latent infection may have been present with a possible intra-uterine
 invasion of the infant. Their report is also distinctive in that the
 organism was ***cultured*** for the first time ante mortem from the
 stool , urine, and duodenal drainage. ABSTRACT AUTHORS: Hyman
 Goldstein
 AB. . . by the authors in their case of an infant 7 months of age, the
 histoplasmin dermal test was negative to ***dilutions*** of 1:1000,
 1:500, 1:100 and ***1*** : ***10*** while the mother's histoplasmin
 intradermal test was positive. The ante mortem diagnosis was made. The
 necropsy findings were invasion of. . . lungs, liver, spleen, kidneys,
 adrenals, esophagus, large bowel, urinary bladder, lymph nodes, thymus,
 bone marrow and diaphragm. The organism was ***cultured*** from the

blood, lungs, liver, spleen, kidneys, bone marrow, rectus abdominis muscle, and frontal lobe of the brain. During the. . . been present with a possible intra-uterine invasion of the infant. Their report is also distinctive in that the organism was ***cultured*** for the first time ante mortem from the ***stool***, urine, and duodenal drainage.
 ABSTRACT AUTHORS: Hyman Goldstein

- IT . . . Concepts
 - Infection
- IT Parts, Structures, & Systems of Organisms
 - heart: circulatory system; frontal lobe: nervous system; large bowel: digestive system; ***stool*** : digestive system; spleen: immune system, blood and lymphatics; thymus: blood and lymphatics, immune system, endocrine system; esophagus: digestive system; rectus. . . and lymphatics, immune system; urinary bladder: excretory system; tibia: skeletal system
- IT Diseases
 - Histoplasmosis: fungal disease
- IT Diseases
 - miliary tuberculosis: ***bacterial*** disease
 - Tuberculosis, Miliary (MeSH)
- IT Diseases
 - infection: infectious disease
 - Infection (MeSH)
- IT Diseases
 - latent infection: disease, Infection
- IT Chemicals & Biochemicals
 - tuberculin

L7 ANSWER 11 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on STN

AN 1945:16758 BIOSIS <<LOGINID::20101214>>

DN PREV19451900016859; BA19:16859

TI Agglutination tests in the diagnosis of enteric fever in the inoculated.

AU Wilson, J. F.

SO JOUR HYG, (1945) Vol. 44, No. 2, pp. 129-134.

DT Article

FS BA

LA Unavailable

ED Entered STN: May 2007

Last Updated on STN: May 2007

AB A study of typhoid and paratyphoid A agglutination reactions of 4000 sera from 2707 individuals was carried out in a closed community of an Indian frontier post. 2170 sera were from 1973 normal inoculated and 127 normal uninoculated soldiers; 1689 were from 557 inoculated and 18 uninoculated persons ill with febrile diseases other than enteric fevers; and 140 sera were from 32 cases of enteric fever in recently inoculated individuals. Inoculations had been done with phenolized vaccine containing 1000 [image] 106 typhoid and 750 [image] 106 paratyphoid A and B bacilli. The sera were examined for O and Vi typhoid agglutinins and for paratyphoid A O agglutinins. No carriers were found from 847 ***stool*** and urine ***cultures*** made on 58 individuals who had high O or Vi typhoid agglutinins. One paratyphoid A carrier was found; the serum had a Vi titre of ***1*** : ***10***, but did not react at 1:20 ***dilution*** with either TO or AO antigens. In persons having diseases such as dysentery, malaria, mumps, tuberculosis and sand-fly fever, 9 patients had TO titres > 1:160 and 3 had AO titres > 1:160; 25 had Vi agglutinin titers of 1:20 or over. In enteric fever cases, high O

and Vi titres occurred in a greater proportion of cases. The proportion of high titres in normal inoculated soldiers decreased with passage of time after vaccination. Blood ***cultures*** were regarded as the best method of diagnosis and agglutination titres > 1:80 for TO, > 1:40 for AO or > ***1*** : ***10*** for Vi antigens may be suggestive of infection. No titre for TO, AO or Vi agglutinins nor any particular variation in titres could be considered absolutely diagnostic, such tests being least specific within 6 mos. after vaccination. Of the 32 cases, blood ***cultures*** were positive in 22, and agglutination reactions were suggestive in 16 cases. ABSTRACT AUTHORS: H. D. Vera:

AB. . . were examined for O and Vi typhoid agglutinins and for paratyphoid A O agglutinins. No carriers were found from 847 ***stool*** and urine ***cultures*** made on 58 individuals who had high O or Vi typhoid agglutinins. One paratyphoid A carrier was found; the serum had a Vi titre of ***1*** : ***10*** , but did not react at 1:20 ***dilution*** with either TO or AO antigens. In persons having diseases such as dysentery, malaria, mumps, tuberculosis and sand-fly fever, 9. . . proportion of cases. The proportion of high titres in normal inoculated soldiers decreased with passage of time after vaccination. Blood ***cultures*** were regarded as the best method of diagnosis and agglutination titres > 1:80 for TO, > 1:40 for AO or > ***1*** : ***10*** for Vi antigens may be suggestive of infection.

No titre for TO, AO or Vi agglutinins nor any particular variation. . . could be considered absolutely diagnostic, such tests being least specific within 6 mos. after vaccination. Of the 32 cases, blood ***cultures*** were positive in 22, and agglutination reactions were suggestive in 16 cases. ABSTRACT AUTHORS: H. D. Vera:

IT Major Concepts

 Epidemiology (Population Studies)

IT Parts, Structures, & Systems of Organisms

 Blood: blood and lymphatics; serum: blood and lymphatics; ***stool*** : digestive system; urine: excretory system; sera: blood and lymphatics

IT Diseases

 tuberculosis: ***bacterial*** disease

 Tuberculosis (MeSH)

IT Diseases

 typhoid: ***bacterial*** disease

 Typhoid Fever (MeSH)

IT Diseases

 infection: infectious disease

 Infection (MeSH)

IT Diseases

 enteric fever: disease, Typhoid Fever

IT Diseases

 malaria: parasitic. . .

ORGN Classifier

 Bacteria 05000

 Super Taxa

 Microorganisms

 Organism Name

 bacilli (common)

 Taxa Notes

 Bacteria , Eubacteria, Microorganisms

ORGN Classifier

 Hominidae 86215

 Super Taxa

Primates; Mammalia; Vertebrata; Chordata; Animalia
 Organism Name
 human (common)
 Taxa Notes
 Animals, . . .

L7 ANSWER 12 OF 12 BIOSIS COPYRIGHT (c) 2010 The Thomson Corporation on
 STN

AN 1939:13350 BIOSIS <<LOGINID::20101214>>

DN PREV19391300013448; BA13:13448

TI Erfahrungen mit der "Bacillenträger-Widal-reaktion".

AU KRISTENSEN, MARTIN; JUEL HEN-NINGSEN, E.

SO ZEITSCHR HYG U INFEKTIONSKRANKH, (1938) Vol. 121, No. 2, pp. 129-135.

DT Article

FS BA

LA Unavailable

ED Entered STN: May 2007

Last Updated on STN: May 2007

AB In Denmark during the years 1932-1937 10,000 agglutination tests were
 carried out with the serums of nearly as many persons, using as antigens
 formalinized suspensions of typhoid bacilli and paratyphoid B bacilli in
 the specific phase. ***Dilutions*** of 1:5, ***1*** : ***10*** ,
 and 1:25 were tested, ***incubation*** being at 50[degree] C for 16
 hours. 20% of serums were positive in the lowest ***dilution*** for
 one of the two antigens, 14% for the typhoid and 8% for the para B. Since
 a previous study indicated that with this technique all carriers give a
 positive, reaction, it is proposed that when a search for carriers is made
 this test be performed first and ***stool*** and urine examinations be
 made only on the positive reactors, thus avoiding approximately 80% of the
 work otherwise necessary. ABSTRACT AUTHORS: H. J. Sears

AB. . . nearly as many persons, using as antigens formalinized suspensions
 of typhoid bacilli and paratyphoid B bacilli in the specific phase.
 Dilutions of 1:5, ***1*** : ***10*** , and 1:25 were tested,
 incubation being at 50[degree] C for 16 hours. 20% of serums were
 positive in the lowest ***dilution*** for one of the two antigens, 14%
 for the typhoid and 8% for the para B. Since a previous study. . . a
 positive, reaction, it is proposed that when a search for carriers is made
 this test be performed first and ***stool*** and urine examinations be
 made only on the positive reactors, thus avoiding approximately 80% of the
 work otherwise necessary. ABSTRACT. . .

IT Major Concepts

Immune System (Chemical Coordination and Homeostasis)

IT Parts, Structures, & Systems of Organisms

stool : digestive system; urine: excretory system

IT Diseases

typhoid: ***bacterial*** disease

Typhoid Fever (MeSH)

IT Chemicals & Biochemicals

antigens

ORGN Classifier

Bacteria 05000

Super Taxa

Microorganisms

Organism Name

bacilli (common)

Taxa Notes

Bacteria , Eubacteria, Microorganisms

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour

Filing Date: December 15, 2017

Application No.: 15/844,407

For: ENRICHMENT METHODS FOR THE DETECTION
OF PATHOGENS AND OTHER MICROBES

Art Unit: 1645

Examiner: Rodney P. Swartz

Docket: 0066090-003US2

Date: September 19, 2019

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

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

Sir:

This filing is in response to the Notice of Non-Compliant Amendment dated April 30, 2019, for the above-identified patent application.

Prior to examination on the merits, kindly amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of the claims, which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

A Replacement Abstract is attached hereto as a separate page.

Application No. 15/844,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Notice of Non-Compliant Amendment dated April 30, 2019
Date of Response September 19, 2019
Examiner: Rodney P. Swartz

IN THE SPECIFICATION

A replacement abstract showing the changes made is appended hereto as a separate page.

IN THE CLAIMS:

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

1. (Currently amended) A method for ~~remote~~-detection of a particular pathogen or other microbe, ~~in a solid sample, semi-solid sample or liquid sample~~ comprising:

-obtaining a test sample ~~at a first location~~, the sample being solid, or semi-solid ~~or liquid~~;
-diluting, ~~at the first location~~, the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:2-9 (wt./vol.), ~~or greater~~ lesser dilution;

-incubating, in an incubator, the diluted sample at an optimal temperature ~~in an incubator~~ ~~during transit of the diluted sample to a second location that is a remote test location~~ for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and

-determining, ~~at the remote test location~~, by assaying the diluted incubated test sample, or a portion thereof, with ~~an~~ the assay suitable to detect the particular pathogen or ~~other bacterial~~ microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

2-4. (Cancelled)

5. (Currently amended) The method of claim 1, wherein the optimal temperature is within, ~~or substantially within~~, the optimal growth temperature range of the particular bacterial pathogen or ~~other bacterial~~ microbe in the ~~particular~~ liquid enrichment medium.

6. (Cancelled)

7. (Currently amended) The method of claim 5, wherein the optimal temperature range is from about 25°C to about 45°C.

8. (Cancelled)

9. (Currently amended) The method of claim 1, wherein the assay suitable for detection of the particular bacterial pathogen or microbial contamination bacterial microbe is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays~~, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

10. (Currently amended) The method of claim 1, wherein the particular bacterial pathogen or bacterial microbe ~~or pathogen~~ is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens~~; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including ~~Pseudomonas~~ *Pseudomonas*; and combinations thereof.

11. (Currently amended) The method of claim 10, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7, or H negative), ~~*Salmonella*, *Listeria*~~ *Salmonella*, *Listeria*, EHEC, and ~~*Campylobacter*~~ *Campylobacter*.

12. (Currently amended) The method of claim 1, wherein obtaining ~~a the test sample is~~ comprises obtaining a standard Lot-unit sample.

13. (Currently amended) The method of claim 1, wherein the test sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples, industrial samples, pharmaceutical samples, ~~water samples, wastewater samples, bio-solid samples, air samples, samples taken by spore traps, settled dust, impingers, or filtration~~filtration), and combinations thereof.

14. (Currently amended) A method for ~~remote~~-detection of a particular bacterial pathogen or other bacterial microbe in a liquid sample comprising:

~~-obtaining a liquid test sample at a first location;~~
-diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt/vol.) or lesser dilution, or not diluting the sample;

~~-incubating, in an incubator, the diluted or the not diluted test sample at an optimal temperature in an incubator during transit of the diluted sample to a second location that is a remote test location for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and~~

~~-determining, at the remote test location, by assaying the diluted or the not diluted incubated test sample, or a portion thereof, with an the assay suitable to detect the particular bacterial pathogen or other bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.~~

15. (Currently amended) The method of claim 14, wherein the optimal temperature is within, ~~or substantially within~~, the optimal growth temperature range of the particular bacterial pathogen or ~~other bacterial~~ microbe in the particular liquid enrichment medium.

16. (Cancelled)

17. (Currently amended) The method of claim 15, wherein the optimal temperature range is from about 25°C to about 45°C.

18. (Cancelled)

19. (Currently amended) The method of claim 14, wherein the assay suitable for detection of the particular bacterial pathogenic or ~~microbial~~ bacterial microbe contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays~~, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with the particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

20. (Currently amended) The method of claim 14, wherein the particular bacterial pathogen or bacterial microbe ~~or pathogen~~ is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens~~; indicator organisms

including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including ~~Pseudomonas~~ Pseudomonas; and combinations thereof.

21. (Currently amended) The method of claim 20, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157: or H negative), ~~Salmonella, Listeria~~ Salmonella, Listeria, EHEC, and ~~Campylobacter~~ Campylobacter.

22. (Currently amended) The method of claim 1, ~~where-in~~ wherein the test sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods, environmental samples, soil, sludge, surface samples, samples taken by impingers and filtration, pharmaceuticals, and samples analyzed using enrichment-detection protocols.

23. (Currently amended) The method of claim 14, wherein the liquid test sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

24. (Currently amended) The method of claim 1, ~~further comprising~~ wherein the diluting comprises addition to the test sample, ~~prior to transit of the sample to the second location,~~ of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target~~ organism, particular bacterial pathogen or bacterial microbe, and combinations thereof.

25. (Currently amended) The method of claim 14, ~~further comprising wherein the diluting comprises~~ addition to the ~~test~~ sample, ~~prior to transit of the sample to the second location,~~ of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~ particular bacterial pathogen or bacterial microbe, and combinations thereof.

26. (Currently amended) The method of claim 1, wherein the obtaining and diluting of the solid or semi-solid sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location~~A method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising:~~

~~-obtaining a test sample at a first location, the sample being solid, semi-solid or liquid;~~
~~-diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample;~~
~~-incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and~~
~~-determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.~~

27. (Currently amended) The method of claim 26, further comprising addition to the test sample, prior to or during the incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~ particular bacterial pathogen or bacterial microbe, and combinations thereof.

28. (New) The method of claim 26, wherein the second location is an in-house or local lab, or a remote location.

29. (New) The method of claim 14, wherein the obtaining and diluting of the liquid test sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location.

30. (New) The method of claim 29, further comprising addition to the test sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

31. (New) The method of claim 29, wherein the second location is an in-house or local lab, or a remote location.

REMARKS

This filing is in response to the Notice of Non-Compliant Amendment dated April 30, 2019, for the above-identified patent application. Amendments have been made per the Examiner's request.

Claim Amendments:

Applicant has herein made minor, fully supported preliminary amendments to clarify the claimed subject matter. The amendments, at various points, conform to amendments introduced by the Applicant and accepted by the Examiner in: Applicant's underlying continuation U.S. Patent Application No. 12/360,646, filed January 27, 2009 (that will issue as U.S. Patent No. 9,845,486 on December 19, 2017); and in underlying parent U.S. Application No. 10/848,253 (now U.S. Patent No. 7,531,163). Support for the amendments is found throughout the originally filed Specification and including, in particular, the originally filed claims.

Additionally, independent claims 1 and 14 have been amended to recite "diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution." Support for the amendment is found throughout the originally filed specification where prior art enrichment methods comprise 1:10 dilutions involving the use of substantial volumes of media (see, e.g., present specification at page 2, lines 10-21, etc.). Applicant, by contrast, teaches that the dilutions can be less than 1:10 dilution (see, e.g., present specification at page 14, lines 6-11, etc.; and priority specification 60/470,975 at last paragraph), and include, for example, dilutions of between about 1:0.1 to about 1:2 (wt./vol.), etc., further include dilutions of between about 1:0.1 to about 1:5 (wt./vol.) (i.e., "semi-dry" dilutions, where "semi," as recognized in the art, is half in quantity or value, where a 1:5 dilution is half of the standard 1:10 dilution), and further include dilutions of 1:9 (wt./vol.), or lesser dilution. For example, the specification (at page 13, lines 12-22) teaches that:

"The present novel embodiments provide accurate, cost effective, and timely sampling and testing methods under circumstances where shipping of the sample to a remote testing location is required or desirable. The present invention, in various aspects, allows, *inter alia*, for: (i) savings in the cost of enrichment media/buffers; (ii) the ability to ship the samples economically (**with up to 90% less weight**), and with far less chances of spills (e.g., **because of 90% less liquids in enriched samples**), in specially designed

dry/semi-dry shipping incubators, to remote/distant laboratories; (iii) increased sensitivity in the detection of the target organisms, due to smaller dilution factor; and (iv) the ability to form centralized laboratories (that may be remote from the sampling sites) that use the enrichment/incubation-in shipping concept to provide testing services to distant clients with the ability to report as fast as a local laboratory, and at similar or reduced costs relative to local laboratories” (emphasis added by Applicant).

Given the standard 1:10 dilution in the art (i.e., 1 part sample + 9 parts dilution medium), the statement “with up to 90% less weight” encompasses all values of lesser dilutions (less than 1:10), up to 100% less dilution medium (i.e., up to no dilution medium; “dry” enrichment; just shipping the undiluted sample). The teaching of “with up to 90% less weight...” “because of 90% less liquids in enriched samples” encompasses all incremental percentages up to 90%, including, for example, a 1:9 dilution (that is, 1 part sample + 8 parts dilution medium), which would be 10% less dilution medium relative to the 1:10 prior art, or a lesser dilution.

Additionally, the optional limitations of first and second locations have been deleted from independent claims 1 and 14, and are now represented in *dependent* claims 26-31 (which include new claims 28-31). Support that the first and second location limitations are preferred options, as well as support for remote and local laboratories is found, for example, in the application at page 10, lines 4-15; page 13, lines 5-23; etc. No new matter has been added.

Claim 13 has been amended to correct the spelling of “filtration.”

Deleted claims:

Claims 2-4, 6, 8, 16, and 18 have been cancelled herein without prejudice.

New claims:

New claims 28-31, fully supported, have been added.

Specification Amendments:

The ABSTRACT has been amended to shorten it. Now new matter has been added.

Applicant respectfully contends all claims are allowable as presented herein.

Application No. 15/844,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Notice of Non-Compliant Amendment dated April 30, 2019
Date of Response September 19, 2019
Examiner: Rodney P. Swartz

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Preliminary Amendment provided herein and allowance of all claims.

Any required excess claim fees or extension of time fees are submitted electronically herewith. Further, the Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 04-0258.

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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ABSTRACT OF THE DISCLOSURE

~~The present invention provides novel enrichment, testing and detection methods~~ Methods for enrichment and 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~~ are provided. Certain aspects provide diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution. In ~~preferred-particular~~ aspects, a sample is obtained and diluted 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 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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~~ may be a remote test location for testing. ~~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-particular~~ embodiments, no dilution at the first location is required, and optionally minimal additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless incubated during transit to the test location.

Electronic Acknowledgement Receipt

EFS ID:	37213339
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-SEP-2019
Filing Date:	15-DEC-2017
Time Stamp:	14:04:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2019-09-19_0066090-003US2_Response_to_Notice_of_Non-Compliant_Amendment.pdf	214885 b78df8104b10f64b4c6855c2ac9436862b37b9aa	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Supplemental Response or Supplemental Amendment	1	1
	Specification	2	2
	Claims	3	9
	Applicant Arguments/Remarks Made in an Amendment	10	12
	Abstract	13	13

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30953	no	2
			98c99225309d80da7e12f83769bb5fa35f0a0e35		

Warnings:

Information:

Total Files Size (in bytes):	245838
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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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour

Filing Date: December 15, 2017

Application No.: 15/844,407

For: ENRICHMENT METHODS FOR THE DETECTION
OF PATHOGENS AND OTHER MICROBES

Art Unit: 1645

Examiner: Rodney P. Swartz

Docket: 0066090-003US2

Date: September 19, 2019

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

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

Sir:

This filing is in response to the Notice of Non-Compliant Amendment dated April 30, 2019, for the above-identified patent application.

Prior to examination on the merits, kindly amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of the claims, which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

A Replacement Abstract is attached hereto as a separate page.

Application No. 15/844,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Notice of Non-Compliant Amendment dated April 30, 2019
Date of Response September 19, 2019
Examiner: Rodney P. Swartz

IN THE SPECIFICATION

A replacement abstract showing the changes made is appended hereto as a separate page.

IN THE CLAIMS:

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

1. (Currently amended) A method for ~~remote~~-detection of a particular pathogen or other microbe, ~~in a solid sample, semi-solid sample or liquid sample~~ comprising:

~~-obtaining a test sample at a first location, the sample being solid, or semi-solid or liquid;~~
~~-diluting, at the first location, the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:2-9 (wt./vol.), or greater lesser dilution;~~

~~-incubating, in an incubator, the diluted sample at an optimal temperature ~~in an incubator~~ during transit of the diluted sample to a second location that is a remote test location for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and~~

~~-determining, ~~at the remote test location~~, by assaying the diluted incubated test sample, or a portion thereof, with ~~an~~ the assay suitable to detect the particular pathogen or ~~other~~ bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe~~

2-4. (Cancelled)

5. (Currently amended) The method of claim 1, wherein the optimal temperature is within, ~~or substantially within~~, the optimal growth temperature range of the particular bacterial pathogen or ~~other~~ bacterial microbe in the ~~particular~~ liquid enrichment medium.

6. (Cancelled)

7. (Currently amended) The method of claim 5, wherein the optimal temperature range is from about 25°C to about 45°C.

8. (Cancelled)

9. (Currently amended) The method of claim 1, wherein the assay suitable for detection of the particular bacterial pathogen or microbial contamination bacterial microbe is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays~~, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

10. (Currently amended) The method of claim 1, wherein the particular bacterial pathogen or bacterial microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens~~; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including ~~Pseudomonas~~ *Pseudomonas*; and combinations thereof.

11. (Currently amended) The method of claim 10, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7, or H negative), ~~*Salmonella*, *Listeria*~~ *Salmonella*, *Listeria*, EHEC, and ~~*Campylobacter*~~ *Campylobacter*.

12. (Currently amended) The method of claim 1, wherein obtaining ~~a the test sample is~~ comprises obtaining a standard Lot-unit sample.

13. (Currently amended) The method of claim 1, wherein the test sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples, industrial samples, pharmaceutical samples, ~~water samples, wastewater samples, bio-solid samples, air samples, samples taken by spore traps, settled dust, impingers, or filtration~~filtration), and combinations thereof.

14. (Currently amended) A method for ~~remote~~-detection of a particular bacterial pathogen or other bacterial microbe in a liquid sample comprising:

~~-obtaining a liquid test sample at a first location;~~
-diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt/vol.) or lesser dilution, or not diluting the sample;

~~-incubating, in an incubator, the diluted or the not diluted test sample at an optimal temperature in an incubator during transit of the diluted sample to a second location that is a remote test location for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and~~

~~-determining, at the remote test location, by assaying the diluted or the not diluted incubated test sample, or a portion thereof, with an the assay suitable to detect the particular bacterial pathogen or other bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.~~

15. (Currently amended) The method of claim 14, wherein the optimal temperature is within, ~~or substantially within~~, the optimal growth temperature range of the particular bacterial pathogen or ~~other bacterial~~ microbe in the particular liquid enrichment medium.

16. (Cancelled)

17. (Currently amended) The method of claim 15, wherein the optimal temperature range is from about 25°C to about 45°C.

18. (Cancelled)

19. (Currently amended) The method of claim 14, wherein the assay suitable for detection of the particular bacterial pathogenic or ~~microbial~~ bacterial microbe contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays~~, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with the particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

20. (Currently amended) The method of claim 14, wherein the particular bacterial pathogen or bacterial microbe ~~or pathogen~~ is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens~~; indicator organisms

including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including ~~Pseudomonas~~ Pseudomonas; and combinations thereof.

21. (Currently amended) The method of claim 20, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157: or H negative), ~~Salmonella, Listeria~~ Salmonella, Listeria, EHEC, and ~~Campylobacter~~ Campylobacter.

22. (Currently amended) The method of claim 1, ~~where-in~~ wherein the test sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods, environmental samples, soil, sludge, surface samples, samples taken by impingers and filtration, pharmaceuticals, and samples analyzed using enrichment-detection protocols.

23. (Currently amended) The method of claim 14, wherein the liquid test sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

24. (Currently amended) The method of claim 1, ~~further comprising~~ wherein the diluting comprises addition to the test sample, ~~prior to transit of the sample to the second location,~~ of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target~~ organism, particular bacterial pathogen or bacterial microbe, and combinations thereof.

25. (Currently amended) The method of claim 14, ~~further comprising wherein the diluting comprises~~ addition to the ~~test~~ sample, ~~prior to transit of the sample to the second location,~~ of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~ particular bacterial pathogen or bacterial microbe, and combinations thereof.

26. (Currently amended) The method of claim 1, wherein the obtaining and diluting of the solid or semi-solid sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location~~A method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising:~~

~~-obtaining a test sample at a first location, the sample being solid, semi-solid or liquid;~~
~~-diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample;~~
~~-incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and~~
~~-determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.~~

27. (Currently amended) The method of claim 26, further comprising addition to the test sample, prior to or during the incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~particular bacterial pathogen or bacterial microbe, and combinations thereof.

28. (New) The method of claim 26, wherein the second location is an in-house or local lab, or a remote location.

29. (New) The method of claim 14, wherein the obtaining and diluting of the liquid test sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location.

30. (New) The method of claim 29, further comprising addition to the test sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

31. (New) The method of claim 29, wherein the second location is an in-house or local lab, or a remote location.

REMARKS

This filing is in response to the Notice of Non-Compliant Amendment dated April 30, 2019, for the above-identified patent application. Amendments have been made per the Examiner's request.

Claim Amendments:

Applicant has herein made minor, fully supported preliminary amendments to clarify the claimed subject matter. The amendments, at various points, conform to amendments introduced by the Applicant and accepted by the Examiner in: Applicant's underlying continuation U.S. Patent Application No. 12/360,646, filed January 27, 2009 (that will issue as U.S. Patent No. 9,845,486 on December 19, 2017); and in underlying parent U.S. Application No. 10/848,253 (now U.S. Patent No. 7,531,163). Support for the amendments is found throughout the originally filed Specification and including, in particular, the originally filed claims.

Additionally, independent claims 1 and 14 have been amended to recite "diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution." Support for the amendment is found throughout the originally filed specification where prior art enrichment methods comprise 1:10 dilutions involving the use of substantial volumes of media (see, e.g., present specification at page 2, lines 10-21, etc.). Applicant, by contrast, teaches that the dilutions can be less than 1:10 dilution (see, e.g., present specification at page 14, lines 6-11, etc.; and priority specification 60/470,975 at last paragraph), and include, for example, dilutions of between about 1:0.1 to about 1:2 (wt./vol.), etc., further include dilutions of between about 1:0.1 to about 1:5 (wt./vol.) (i.e., "semi-dry" dilutions, where "semi," as recognized in the art, is half in quantity or value, where a 1:5 dilution is half of the standard 1:10 dilution), and further include dilutions of 1:9 (wt./vol.), or lesser dilution. For example, the specification (at page 13, lines 12-22) teaches that:

"The present novel embodiments provide accurate, cost effective, and timely sampling and testing methods under circumstances where shipping of the sample to a remote testing location is required or desirable. The present invention, in various aspects, allows, *inter alia*, for: (i) savings in the cost of enrichment media/buffers; (ii) the ability to ship the samples economically (**with up to 90% less weight**), and with far less chances of spills (e.g., **because of 90% less liquids in enriched samples**), in specially designed

dry/semi-dry shipping incubators, to remote/distant laboratories; (iii) increased sensitivity in the detection of the target organisms, due to smaller dilution factor; and (iv) the ability to form centralized laboratories (that may be remote from the sampling sites) that use the enrichment/incubation-in shipping concept to provide testing services to distant clients with the ability to report as fast as a local laboratory, and at similar or reduced costs relative to local laboratories” (emphasis added by Applicant).

Given the standard 1:10 dilution in the art (i.e., 1 part sample + 9 parts dilution medium), the statement “with up to 90% less weight” encompasses all values of lesser dilutions (less than 1:10), up to 100% less dilution medium (i.e., up to no dilution medium; “dry” enrichment; just shipping the undiluted sample). The teaching of “with up to 90% less weight...” “because of 90% less liquids in enriched samples” encompasses all incremental percentages up to 90%, including, for example, a 1:9 dilution (that is, 1 part sample + 8 parts dilution medium), which would be 10% less dilution medium relative to the 1:10 prior art, or a lesser dilution.

Additionally, the optional limitations of first and second locations have been deleted from independent claims 1 and 14, and are now represented in *dependent* claims 26-31 (which include new claims 28-31). Support that the first and second location limitations are preferred options, as well as support for remote and local laboratories is found, for example, in the application at page 10, lines 4-15; page 13, lines 5-23; etc. No new matter has been added.

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New claims 28-31, fully supported, have been added.

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The ABSTRACT has been amended to shorten it. Now new matter has been added.

Applicant respectfully contends all claims are allowable as presented herein.

Application No. 15/844,407
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Notice of Non-Compliant Amendment dated April 30, 2019
Date of Response September 19, 2019
Examiner: Rodney P. Swartz

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Preliminary Amendment provided herein and allowance of all claims.

Any required excess claim fees or extension of time fees are submitted electronically herewith. Further, the Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 04-0258.

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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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

ABSTRACT OF THE DISCLOSURE

~~The present invention provides novel enrichment, testing and detection methods~~ Methods for enrichment and 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~~ are provided. Certain aspects provide diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution. In ~~preferred-particular~~ aspects, a sample is obtained and diluted 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 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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~~ may be a remote test location for testing. ~~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-particular~~ embodiments, no dilution at the first location is required, and optionally minimal additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless incubated during transit to the test location.

Electronic Acknowledgement Receipt

EFS ID:	37213588
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-SEP-2019
Filing Date:	15-DEC-2017
Time Stamp:	14:12:38
Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2019-09-19_0066090-003US2_Response_to_Notice_of_Non-Compliant_Amendment.pdf	214885 b78df8104b10f64b4c6855c2ac9436862b37b9aa	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Supplemental Response or Supplemental Amendment	1	1
	Specification	2	2
	Claims	3	9
	Applicant Arguments/Remarks Made in an Amendment	10	12
	Abstract	13	13

Warnings:

Information:

Total Files Size (in bytes):	214885
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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.

Electronic Acknowledgement Receipt

EFS ID:	37213436
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	19-SEP-2019
Filing Date:	15-DEC-2017
Time Stamp:	14:07:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 2200
RAM confirmation Number	E20199IE08238983
Deposit Account	040258
Authorized User	Janet Berdine

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

National Beef Ex. 1008

Page 136 of 239

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (SB06)	fee-info.pdf	30951	no	2
			0f9af509abecaa10b39ff41982c9793957e083307		

Warnings:**Information:**

Total Files Size (in bytes):	30951
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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.

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PLUS Search Results for S/N 15844407, Searched Thu May 09 11:25:45 EDT 2019

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

7531163 90	9518283 57
9845486 90	
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20080182272 90	
20090269760 90	
20180112249 90	
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2	5392
22504	7590	04/30/2019	EXAMINER	
DAVIS WRIGHT TREMAINE, LLP/Seattle			SWARTZ, RODNEY P	
IP Docketing Dept.			ART UNIT	PAPER NUMBER
Davis Wright Tremaine LLP			1645	
920 Fifth Ave., Suite 3300			NOTIFICATION DATE	DELIVERY MODE
SEATTLE, WA 98104-1610			04/30/2019	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@dwt.com

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. The amendment to the claims filed on 12-15-2017 does not comply with the requirements of 37 CFR 1.121(c) because claims 10, 11, 13, 20 has been improperly amended.

In claim 10, last line, non-italicized *Pseudomonas* has been italicized (*Pseudomonas*) without the required markings deleting the non-italicized form and inserting the italicized form.

In claim 11, non-italicized *Salmonella*, *Listeria*, and *Campylobacter* have been italicized (*Salmonella*, *Listeria*, and *Campylobacter*) without the required markings deleting the non-italicized form and inserting the italicized form.

In claim 13, line 6, the end parenthesis ")" has been deleted without the required proper marking.

In claim 20, last line, non-italicized *Pseudomonas* has been italicized (*Pseudomonas*) without the required markings deleting the non-italicized form and inserting the italicized form.

In claim 21, non-italicized *Salmonella*, *Listeria*, and *Campylobacter* have been italicized (*Salmonella*, *Listeria*, and *Campylobacter*) without the required markings deleting the non-italicized form and inserting the italicized form.

3. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Since the reply filed on 12-15-2017 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

4. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for 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 (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.

/Rodney P Swartz, Ph.D./
Primary Examiner, Art Unit 1645
April 25, 2019

***Notice of Non-Compliant
Amendment (37 CFR 1.121)***

Application No.

15/844,407

Applicant(s)

Samadpour, Mansour

Examiner

RODNEY P SWARTZ,
Ph.D.

Art Unit

1645

AIA (FITF) Status

No

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

The amendment document filed on 12/15/2017 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet", "New Sheet", or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: See attached Detailed Correspondence.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

- 1. Applicant is given **no new time period if the non-compliant amendment is an** after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
- 2. Applicant is given **two months** from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Rodney P Swartz, Ph.D./
Primary Examiner, Art Unit 1645

U.S. Patent and Trademark Office
PTOL-324 (11-13)

Notice of Non-Compliant Amendment (37 CFR 1.121)

Part of Paper No. 20190425
National Beef Ex. 1008
Page 143 of 239



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2

CONFIRMATION NO. 5392

PUBLICATION NOTICE



OC00000099080124

22504
DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Title:ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES

Publication No.US-2018-0112249-A1

Publication Date:04/26/2018

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
--------------------	--

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐

The attached application, or

☒United States application or PCT international application number 15/844,407filed on December 15, 2017

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

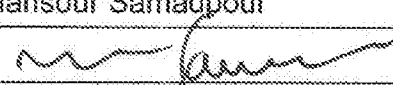
WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Mansour Samadpour

Date (Optional): _____

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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.

Electronic Acknowledgement Receipt

EFS ID:	31600797
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	25-JAN-2018
Filing Date:	15-DEC-2017
Time Stamp:	10:36:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	2018-01-25_0066090-003US2_Declaration.pdf	483776 6177fd5bdb0fddeef681a02431dad0c7d0ea09f9b	no	1

Warnings:

National Beef Ex. 1008

Page 146 of 239

Information:	
Total Files Size (in bytes):	483776
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2

CONFIRMATION NO. 5392

IMPROPER CFR REQUEST



22504
DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Date Mailed: 01/09/2018

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Continuity, Priority Claims, Petitions, and Non-Publication Requests

In response to your request for a corrected Filing Receipt, the Office is unable to comply with your request because:

Improper Benefit Claim(s) to Prior-Filed Provisional Application(s)

The benefit claim(s) to prior-filed provisional application(s) is improper because the instant application was not filed within twelve (12) months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional or international application designating the United States that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application. Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed applications (including an indication of any intermediate application that is directly claiming the benefit of the provisional application and filed with 12 months of the filing date of the provisional application) as required by 37 CFR 1.78.

Alternatively, if the instant application (or intermediate application) was filed within 14 months of the prior provisional application, applicant may file a petition (in the instant application or the intermediate application, as appropriate) to restore the benefit of the provisional application if the delay in filing the instant application (or intermediate application) within the 12 month time period was unintentional. See 37 CFR 1.78 for the requirements of a petition to restore the benefit of the provisional application.

For applications filed on or after September 16, 2012, applicant must submit a corrected application data sheet (ADS) to include a specific reference.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78, the petition fee set forth in 37 CFR 1.17(m), and the required reference are filed.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office

of Data Management, Application Assistance Unit, at
(571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/lkchi/



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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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
15/844,407	12/15/2017	1797	2060	0066090-003US2	24	2

CONFIRMATION NO. 5392

FILING RECEIPT



0000000096520313

22504
DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Date Mailed: 01/09/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Mansour Samadpour, Lake Forest Park, WA;

Applicant(s)

Institute for Environmental Health, Inc., Lake Forest Park, WA

Power of Attorney: The patent practitioners associated with Customer Number 22504

Domestic Priority data as claimed by applicant

This application is a CON of 12/360,646 01/27/2009 PAT 9845486
which is a CON of 10/848,253 05/17/2004 PAT 7531163
which claims benefit of 60/470,975 05/16/2003

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 01/08/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/844,407**

Projected Publication Date: 04/19/2018

Non-Publication Request: No

Early Publication Request: No

Title

ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES

Preliminary Class

436

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/844,407	12/15/2017	Mansour Samadpour	0066090-003US2

CONFIRMATION NO. 5392

INFORMAL NOTICE



22504
DAVIS WRIGHT TREMAINE, LLP/Seattle
IP Docketing Dept.
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

Date Mailed: 01/09/2018

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
Mansour Samadpour

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/mmasfaw/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
15/844,407

APPLICATION AS FILED - PART I

(Column 1)		(Column 2)		SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)			RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A				N/A	280
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A				N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A				N/A	720
TOTAL CLAIMS (37 CFR 1.16(j))	24	minus 20 = *	4			OR	x 80 =	320
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2	minus 3 = *					x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 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).							0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))								0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL			TOTAL	1920

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	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))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
TOTAL ADD'L FEE								OR	TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	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))							OR		
	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 found in the appropriate box in column 1.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		15844407
	Filing Date		2017-12-15
	First Named Inventor	Mansour Samadpour	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		0066090-003US2

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	6060266	A	2000-05-09	Naqui	
	2	7531163	B2	2009-05-12	Samadpour	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

U.S.PATENT APPLICATION PUBLICATIONS						Remove
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					
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²ⁱ	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							
If you wish to add additional Foreign Patent Document citation information please click the Add button								Add
NON-PATENT LITERATURE DOCUMENTS								Remove

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

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
	1	ALBIZO, et al., "Use of the Antiserum-Agar Plate Technique for Specific Identification and Isolation of Pasteurella pestis," Applied Microbiology 16(8):1114-1119, August 1968.	
	2	Bacteriological Analytical Manual Online (U.S. Food & Drug Administration, Center for Food Safety & Applied Nutrition) Chapters 4, 4a, 5, 6, 7, 9, and 10, 146 pages.	
	3	BHADURI, S., et al., "Use of a Single Procedure for Selective Enrichment, Isolation, and Identification of Plasmid-Bearing Virulent Yersinia Enterocolitica of Various Serotypes from Pork Samples," Applied and Environmental Microbiology 63:1657-1660, 1997.	
	4	BUSCH, S.V., and C.W. DONNELLY, "Development of a Repair-Enrichment Broth for Resuscitation of Heat-Injured Listeria Monocytogenes and Listeria Innocua," Applied and Environmental Microbiology 58:14-20, 1992.	
	5	DAHLENBORG, M., et al., "Development of a Combined Selection and Enrichment PCR Procedure for Clostridium botulinum Types B, E, and F and Its Use to Determine Prevalence in Fecal Samples From Slaughtered Pigs," Applied and Environmental Microbiology 67:4781-4788, 2001.	
	6	DAVIES, R.H., et al., "Evaluation of the Use of Pooled Serum, Pooled Muscle Tissue Fluid (Meat Juice) and Pooled Faeces for Monitoring Pig Herds for Salmonella," Journal of Applied Microbiology 95:1016-1025, 2003	
	7	DOYLE, M.P., and J.L. SCHOENI, "Isolation of Escherichia coli O157:H7 from Retail Fresh Meats and Poultry," Applied and Environmental Microbiology 53:2394-2396, 1987.	
	8	FACH, P., et al., "PCR and Gene Probe Identification of Botulinum Neurotoxin A-, B-, E-, F-, and G-Producing Clostridium spp. and Evaluation in Food Samples," Applied and Environmental Microbiology 61:389-392, 1995.	
	9	FOGEL, A., and S.A. PLOTKIN, "Markers of Rubella Virus Strains in RK13 Cell Culture," Journal of Virology 3 (2):157-163, February 1969.	
	10	JIANG, J., et al., "Evaluation of Universal Preenrichment Broth for the Recovery of foodborne Pathogens From Milk and Cheese," Journal of Dairy Science 81:2798-2803, 1998.	

**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

Application Number	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

11	NG, S.P., et al., "Detection and Serogroup Differentiation of Salmonella spp. in Food Within 30 Hours by Enrichment-Immunoassay With a T6 Monoclonal Antibody Capture Enzyme-Linked Immunosorbent Assay," Applied and Environmental Microbiology 62:2294-2302, 1996.
12	NORTON, D.M., et al., "Molecular Studies on the Ecology of Listeria monocytogenes in the Smoked Fish Processing Industry," Applied and Environmental Microbiology 67:198-205, 2001.
13	PADHYE, N.V., and M.P. DOYLE, "Rapid Procedure for Detecting Enterohemorrhagic Escherichia coli O157:H7 in Food," Applied and Environmental Microbiology 57:2693-2698, 1991.
14	PIGNATO, S., et al., "Evaluation of New Culture Media for Rapid Detection and Isolation of Salmonellae in Foods," Applied and Environmental Microbiology 61:1996-1999, 1995.
15	ROBERTSON, J.A., and M.H. Chen, "Effects of Manganese on the Growth and Morphology of Ureaplasma Urealyticum," Journal of Clinical Microbiology 19(6):857-864, June 1984.
16	RYSER, E.T., et al., "Recovery of Different Listeria Ribotypes From Naturally Contaminated, Raw Refrigerated Meat and Poultry Products With Two Primary Enrichment Media," Applied and Environmental Microbiology 62:1781-1787, 1996.
17	ZHAO, T., et al., "Prevalence of Enterohemorrhagic Escherichia coli O157:H7 in a Survey of Dairy Herds," Applied and Environmental Microbiology 61:1290-1293, 1995.
18	SAMADPOUR, M., "Dry and Semidry Enrichment for the Detection of Foodborne Patogens," U.S. Patent Application No. 60/470,975, filed May 16, 2003.

If you wish to add additional non-patent literature document citation information please click the Add button

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	15844407
Filing Date	2017-12-15
First Named Inventor	Mansour Samadpour
Art Unit	
Examiner Name	
Attorney Docket Number	0066090-003US2

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.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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/	Date (YYYY-MM-DD)	2017-12-20
Name/Print	Barry L. Davison, Ph.D., J.D.	Registration Number	47,309

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 records.
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:	31290075
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	20-DEC-2017
Filing Date:	
Time Stamp:	14:53:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2017-12-20_0066090-003US2_DS_Transmittal.pdf	64114 c45bbe32e5e199f66f21314831d5a69a1ca1f3ca	no	1

Warnings:

National Beef Ex. 1008

Page 160 of 239

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	2017-12-20_0066090-003US2_ID DS.pdf	613958	no	5
			e48b9e7442de62500b181f0927e4395f865 55640		
Warnings:					
Information:					
Total Files Size (in bytes):				678072	
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Mansour Samadpour Attorney Docket No.: 0066090-003US2
Application No.: 15/844,407 Confirmation No.: 5392
Filed: December 15, 2017
Title: ENRICHMENT METHODS FOR THE DETECTION
OF PATHOGENS AND OTHER MICROBES

December 20, 2017

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

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Dear Commissioner:

Applicant is aware of the information listed in the attached form that may be material to the prosecution of the above-identified patent application.

This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior U.S. Patent Application No. 12/360,646, filed January 27, 2009. The nonpatent literature references listed on the attached form were submitted to and/or cited by the U.S. Patent and Trademark Office in this prior application and, therefore, are not required to be provided in this application.

As provided for by 37 C.F.R. § 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application. No fee is due at this time in accordance with 37 C.F.R. § 1.97(b).

Respectfully submitted,

/Barry L. Davison/
Barry L. Davison, Ph.D., J.D.
Registration No. 47,309

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Filed herewith
First Named Inventor	Mansour Samadpour
Title	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	0066090-003US2

SIGNATURE of Applicant or Patent Practitioner

Signature	/Barry L. Davison/	Date (Optional)	December 15, 2017
Name	Barry L. Davison, Ph.D., J.D.	Registration Number	47,309
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)	Institute for Environmental Health, Inc.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 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.**

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number

Filing Date

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I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

22504

OR



I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

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The address associated with the above-mentioned Customer Number

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City

State

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Country

Telephone

Email

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Institute for Environmental Health, Inc.



Inventor or Joint Inventor (title not required below)



Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)



Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)



Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Date (Optional)

04/22/2014

Name

Mansour Samadpour

Title

Principal

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.



Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 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.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mansour Samadpour

Filing Date: December 15, 2017

Application No.: Filed herewith

For: ENRICHMENT METHODS FOR THE DETECTION
OF PATHOGENS AND OTHER MICROBES

Art Unit: Not yet assigned

Examiner: Not yet assigned

Docket: 0066090-003US2

Date: December 15, 2017

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

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

Sir:

This is a Preliminary Amendment for the above-identified patent application to accompany the application filed herewith.

Prior to examination on the merits, kindly amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of the claims, which begins on page 3 of this paper.

Remarks/Arguments begin on page 10 of this paper.

A Replacement Abstract is attached hereto as a separate page.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

IN THE SPECIFICATION

A replacement abstract showing the changes made is appended hereto as a separate page.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

IN THE CLAIMS:

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

1. (Currently amended) A method for ~~remote~~-detection of a particular pathogen or other microbe, ~~in a solid sample, semi-solid sample or liquid sample~~ comprising:

- obtaining a test sample ~~at a first location~~, the sample being solid, or semi-solid ~~or liquid~~;
- diluting, ~~at the first location~~, the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:2-9 (wt./vol.), or ~~greater~~lesser dilution;
- incubating, in an incubator, the diluted sample at an optimal temperature ~~in an incubator~~ during transit of the diluted sample to a second location that is a remote test location for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and
- determining, ~~at the remote test location~~, by assaying the diluted incubated test sample, or a portion thereof, with ~~an~~ the assay suitable to detect the particular pathogen or ~~other bacterial~~ microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

2-4. (Cancelled)

5. (Currently amended) The method of claim 1, wherein the optimal temperature is within, ~~or substantially within~~, the optimal growth temperature range of the particular bacterial pathogen or ~~other bacterial~~ microbe in the ~~particular~~ liquid enrichment medium.

6. (Cancelled)

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

7. (Currently amended) The method of claim 5, wherein the optimal temperature range is from about 25°C to about 45°C.

8. (Cancelled)

9. (Currently amended) The method of claim 1, wherein the assay suitable for detection of the particular bacterial pathogen or ~~microbial contamination~~ bacterial microbe is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays~~, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

10. (Currently amended) The method of claim 1, wherein the particular bacterial pathogen or bacterial microbe ~~or pathogen~~ is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens~~; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

11. (Currently amended) The method of claim 10, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7, or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

12. (Currently amended) The method of claim 1, wherein obtaining ~~a the test sample is~~ comprises obtaining a standard Lot-unit sample.

13. (Currently amended) The method of claim 1, wherein the test sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples, industrial samples, pharmaceutical samples, ~~water samples, wastewater samples, bio-solid samples,~~ air samples, samples taken by spore traps, settled dust, impingers, or filtration, and combinations thereof.

14. (Currently amended) A method for ~~remote~~-detection of a particular bacterial pathogen or ~~other bacterial~~ microbe, ~~in a liquid sample~~ comprising:

-obtaining a liquid test sample ~~at a first location~~;
-diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.) or lesser dilution, or not diluting the sample;

-incubating, in an incubator, the diluted or the not diluted test sample at an optimal temperature ~~in an incubator during transit of the diluted sample to a second location that is a remote test location~~ for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or bacterial microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and

-determining, ~~at the remote test location,~~ by assaying the diluted or the not diluted ~~incubated~~ test sample, or a portion thereof, with ~~an the~~ an assay suitable to detect the particular bacterial pathogen or other bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

15. (Currently amended) The method of claim 14, wherein the optimal temperature is within, ~~or substantially within,~~ the optimal growth temperature range of the particular bacterial pathogen or other bacterial ~~microbe in the particular liquid~~ enrichment medium.

16. (Cancelled)

17. (Currently amended) The method of claim 15, wherein the optimal temperature range is from about 25°C to about 45°C.

18. (Cancelled)

19. (Currently amended) The method of claim 14, wherein the assay suitable for detection of the particular bacterial pathogen ~~or microbial bacterial microbe~~ contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, ~~bacteriophage detection-based assays,~~ classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with the particular ~~target organisms or groups of target organisms~~ bacterial pathogen or bacterial microbe, and combinations thereof.

20. (Currently amended) The method of claim 14, wherein the particular bacterial pathogen or bacterial ~~microbe or pathogen~~ is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, ~~fungal, viral, parasitic pathogens;~~ indicator organisms

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

21. (Currently amended) The method of claim 20, wherein the particular bacterial pathogen or bacterial microbe is *Escherichia coli* O157:H7 (*E. coli* O157: or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*).

22. (Currently amended) The method of claim 1, ~~where in~~wherein the test sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods, environmental samples, soil, sludge, surface samples, samples taken by impingers and filtration, pharmaceuticals, and samples analyzed using enrichment-detection protocols.

23. (Currently amended) The method of claim 14, wherein the liquid test sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

24. (Currently amended) The method of claim 1, ~~further comprising~~wherein the diluting comprises addition to the test sample, ~~prior to transit of the sample to the second location,~~ of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~ particular bacterial pathogen or bacterial microbe, and combinations thereof.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

25. (Currently amended) The method of claim 14, ~~further comprising~~ wherein the diluting comprises addition to the test sample, ~~prior to transit of the sample to the second location~~, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~ particular bacterial pathogen or bacterial microbe, and combinations thereof.

26. (Currently amended) The method of claim 1, wherein the obtaining and diluting of the solid or semi-solid sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location~~A method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising:~~

- ~~-obtaining a test sample at a first location, the sample being solid, semi-solid or liquid;~~
- ~~-diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample;~~
- ~~-incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and~~
- ~~-determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.~~

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

27. (Currently amended) The method of claim 26, further comprising addition to the test sample, prior to or during the incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the ~~target organism~~particular bacterial pathogen or bacterial microbe, and combinations thereof.

28. (New) The method of claim 26, wherein the second location is an in-house or local lab, or a remote location.

29. (New) The method of claim 14, wherein the obtaining and diluting of the liquid test sample with liquid enrichment medium is at a first location, wherein incubating the diluted sample at an optimal temperature in the incubator is during transit of the diluted sample to a second location that is not the site of sample collection and dilution, and wherein determining by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe, is at the second location.

30. (New) The method of claim 29, further comprising addition to the test sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the particular bacterial pathogen or bacterial microbe, and combinations thereof.

31. (New) The method of claim 29, wherein the second location is an in-house or local lab, or a remote location.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

REMARKS

This is a Preliminary Amendment to accompany the *continuation* application filed herewith.

Claim Amendments:

Applicant has herein made minor, fully supported preliminary amendments to clarify the claimed subject matter. The amendments, at various points, conform to amendments introduced by the Applicant and accepted by the Examiner in: Applicant's underlying continuation U.S. Patent Application No. 12/360,646, filed January 27, 2009 (that will issue as U.S. Patent No. 9,845,486 on December 19, 2017); and in underlying parent U.S. Application No. 10/848,253 (now U.S. Patent No. 7,531,163). Support for the amendments is found throughout the originally filed Specification and including, in particular, the originally filed claims.

Additionally, independent claims 1 and 14 have been amended to recite "diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution." Support for the amendment is found throughout the originally filed specification where prior art enrichment methods comprise 1:10 dilutions involving the use of substantial volumes of media (see, e.g., present specification at page 2, lines 10-21, etc.). Applicant, by contrast, teaches that the dilutions can be less than 1:10 dilution (see, e.g., present specification at page 14, lines 6-11, etc.; and priority specification 60/470,975 at last paragraph), and include, for example, dilutions of between about 1:0.1 to about 1:2 (wt./vol.), etc., further include dilutions of between about 1:0.1 to about 1:5 (wt./vol.) (i.e., "semi-dry" dilutions, where "semi," as recognized in the art, is half in quantity or value, where a 1:5 dilution is half of the standard 1:10 dilution), and further include dilutions of 1:9 (wt./vol.), or lesser dilution. For example, the specification (at page 13, lines 12-22) teaches that:

"The present novel embodiments provide accurate, cost effective, and timely sampling and testing methods under circumstances where shipping of the sample to a remote testing location is required or desirable. The present invention, in various aspects, allows, *inter alia*, for: (i) savings in the cost of enrichment media/buffers; (ii) the ability to ship the samples economically (**with up to 90% less weight**), and with far less chances of spills (e.g., **because of 90% less liquids in enriched samples**), in specially designed

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

dry/semi-dry shipping incubators, to remote/distant laboratories; (iii) increased sensitivity in the detection of the target organisms, due to smaller dilution factor; and (iv) the ability to form centralized laboratories (that may be remote from the sampling sites) that use the enrichment/incubation-in shipping concept to provide testing services to distant clients with the ability to report as fast as a local laboratory, and at similar or reduced costs relative to local laboratories” (emphasis added by Applicant).

Given the standard 1:10 dilution in the art (i.e., 1 part sample + 9 parts dilution medium), the statement “with up to 90% less weight” encompasses all values of lesser dilutions (less than 1:10), up to 100% less dilution medium (i.e., up to no dilution medium; “dry” enrichment; just shipping the undiluted sample). The teaching of “with up to 90% less weight...” “because of 90% less liquids in enriched samples” encompasses all incremental percentages up to 90%, including, for example, a 1:9 dilution (that is, 1 part sample + 8 parts dilution medium), which would be 10% less dilution medium relative to the 1:10 prior art, or a lesser dilution.

Additionally, the optional limitations of first and second locations have been deleted from independent claims 1 and 14, and are now represented in *dependent* claims 26-31 (which include new claims 28-31). Support that the first and second location limitations are preferred options, as well as support for remote and local laboratories is found, for example, in the application at page 10, lines 4-15; page 13, lines 5-23; etc. No new matter has been added.

Deleted claims:

Claims 2-4, 6, 8, 16, and 18 have been cancelled herein without prejudice.

New claims:

New claims 28-31, fully supported, have been added.

Specification Amendments:

The ABSTRACT has been amended to shorten it. Now new matter has been added.

Applicant respectfully contends all claims are allowable as presented herein.

Application No. Filed herewith
Attorney Docket No. 0066090-003US2
First Applicant's Name: Mansour Samadpour
Filing Date: December 15, 2017
Date of Preliminary Amendment: December 15, 2017
Examiner: Not yet assigned

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests entry of the present Preliminary Amendment provided herein and allowance of all claims. 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,
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

ABSTRACT OF THE DISCLOSURE

~~The present invention provides novel enrichment, testing and detection methods.~~ Methods for enrichment and 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~~ are provided. Certain aspects provide diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:9 (wt./vol.), or lesser dilution. In ~~preferred~~ particular aspects, a sample is obtained and diluted 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 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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~~ may be a remote test location for testing. ~~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~~ particular embodiments, no dilution at the first location is required, and optionally minimal additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless incubated during transit to the test location.

**ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS
AND OTHER MICROBES**

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of U.S. Patent Application No. 12/360,646,
5 filed January 27, 2009, to issue as U.S. Patent No. 9,845,486 on December 19, 2017, entitled
“ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER
MICROBES,” which is a continuation application of U.S. Patent Application No. 10/848,253,
filed May 17, 2004, now U.S. Patent No. 7,531,163, entitled “ENRICHMENT METHODS FOR
THE DETECTION OF PATHOGENS AND OTHER MICROBES,” which claims the benefit of
10 priority to U.S. Provisional Patent Application No. 60/470,975, filed May 16, 2003, entitled
“DRY AND SEMIDRY ENRICHMENT FOR THE DETECTION OF FOODBORNE
PATHOGENS,” the disclosures of which are incorporated by reference herein in their entirety.

FIELD OF THE INVENTION

The present invention, in various aspects, relates generally to improving the efficiency of
15 producing foods , and the safety and quality of food products, including but not limited to beef,
pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy
products, dry goods (cereals, etc), and all manners of raw and processed foods, environmental
samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration,
etc), pharmaceuticals, and other types of samples that are to be analyzed using
20 enrichment-detection protocols. More specifically, embodiments of the present invention relate
to novel methods for pathogen testing and detection at a site that is remote from a site of which
samples are taken.

BACKGROUND

Most regulatory agencies require, and customers demand specific testing for pathogens that are common to specific food types, and agricultural products, that are capable of *in vivo* multiplication. Rapid and accurate methods for detection of foodborne and waterborne pathogens are essential, particularly in the context of food manufacturing processes, pharmaceutical industry, drinking water and wastewater utilities, management of fisheries resources and bodies of water (recreational, etc). The same applies to the general detection of human, animal and plant pathogens, and in general to any kind of bacterial, viral, fungal, and parasitic pathogens that are capable of *in vivo* multiplication, and their indicator organisms.

Many manufacturers and utilities have, consequently, had to build in-house labs to expedite the testing, or lose valuable time waiting for test results when samples are shipped out to outside labs. The same is true for the utility industry (water and wastewater), and the pharmaceutical industry. Furthermore, using art-recognized and current standard methods, the cost of enrichment media used to expand the numbers of one or more particular pathogens to detectable levels, can be substantial.

Prior art enrichment methods. Significantly, conventional/standard methods for detection of pathogens in food (dry and liquid) involve diluting the sample 1:10 (wt/v) with media (e.g., sterile media) (or with another diluent, followed immediately by serial dilution into media to provide an effective 1:10 dilution into media), and thus involve the use of substantial volumes of media. 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). Significantly, these protocols have been adopted in the field so that samples (e.g., meat samples) at remote locations are typically diluted 1:10 (wt./vol.), and then shipped under ambient or uncontrolled conditions to a test location, where they are incubated at an optimal temperature and subsequently tested for pathogens.

For example, the following prior art examples comprise enrichment followed by detection of the target organisms in the enriched media, and are based on the use of 1:10 dilution of the sample in an appropriate media/buffer:

Escherichia coli. The assay for the detection of *E. coli* in citrus juices, as described in the
5 Bacteriological Analytical manual (BAM) (United States Food & Drug Administration, and
Center for Food Safety & Applied Nutrition, Bacteriological Analytical Manual, Chapter 4,
Enumeration of *Escherichia coli* and the Coliform Bacteria, September 2002), is carried out in
duplicate. Basically, a 10-mL portion of juice is aseptically inoculated into 90 mL of Universal
Pre-enrichment Broth (UPEB) and incubated at 35°C for 24 h. After enrichment, the sample is
10 mixed and 1 mL is transferred from each UPEB enrichment broth into 9 mL of EC broth
containing a CC disc, and EC/CC broth tubes are incubated at 44.5°C in a circulating water bath
for 24 h. Preferably, *positive* (tube inoculated with a MUG (+) *E. coli* strain) and *negative* (tube
inoculated with *K. pneumoniae*) controls are included. The tubes are checked in the dark and
under long wave UV light. The presence of blue fluorescence in either tube is indicative that *E.*
15 *coli* is present in the sample. Note: the CC discs also contain X-gal, which when cleaved by
 β -galactosidase will yield blue color on or around the disc. This reaction is analogous to
measuring acid/gas production from fermentation of lactose hence, the presence of blue color is
indicative of coliforms. For the detection of *Escherichia coli* O157:H7 in food, 25 g of ground
beef is incubated in 225 ml of selective enrichment medium for 16 to 18 h at 37°C with agitation
20 (Padhye & Doyle, *Appl. Environ. Microbiol.* 57:2693-2698, 1991). Enzyme-linked
immunosorbent assay (ELISA) is used to detect the pathogen from the enriched culture. Doyle
& Schoeni (*Appl. Environ. Microbiol.* 53:2394-2396, 1987) isolated *E. coli* O157:H7 from retail
fresh meats and poultry using the enrichment method whereby 25 g of food sample was added to
225 modified TSB. In the same fashion, fecal sample enrichment was done with modified TSB
25 at 1:10 ratio (Zhao, et al., *Appl. Environ. Microbiol.* 61:1290-1293, 1995).

Salmonella. BAM, 2003 teaches use of 1:9 sample/broth ratio (1: 10 dilution) for
detection of salmonella in meats, meat substitutes, meat by-products, animal substances,

glandular products, and meals (fish, meat, bone). The recommended procedure is as follows: weigh twenty-five gm (25 g) of sample aseptically; add 225 ml of sterile lactose broth and blend for two min.; transfer the homogenized mixture aseptically to a sterile wide-mouth, screw-cap jar (500 ml) or other appropriate container and let stand 60 ± 5 min at room temperature with the container securely capped (blending can be omitted if mixture is powder, ground or comminuted) (lactose broth is added to samples that do not require blending); mix well and check the pH with the help of a test paper; adjust pH, if necessary, to 6.8 ± 0.2 ; add up to 2.25 ml steamed (15 min) Tergitol Anionic 7 and mix well (alternatively, steamed (15 min) Triton X-100 can be used) (the use of surfactants should be limited to initiate foaming); and loosen jar caps 1/4 turn and incubate sample mixtures 24 ± 2 h at 35°C .

Likewise, Pignato, et al. (*Appl. Environ. Microbiol.* 61: 1996–1999, 1995) evaluated new culture media for rapid detection and isolation of salmonellae in foods. The methodology followed was as follows: fifty g of meat samples are taken and minced; 25 g is homogenized for 1 min in a stomacher with 225 ml of Buffered Peptone Water (BPW) and then pre-enriched by incubation for 24 h at 37°C , while 25 g is homogenized with 225 ml of Salmosyst broth and is further pre-enriched by incubation for 6 h at 37°C ; the whole contents of two eggs are homogenized for 30 s in a stomacher and then divided in two aliquots of 50 g each for pre-enrichment with 450 ml of BPW and 450 ml of Salmosyst broth; and an aliquot of 10 ml of BPW is transferred to 100 ml of Müller-Kauffmann tetrathionate broth (M-KTB), for selective enrichment by incubation for 24 and 48 h at 43°C after the preenrichment. For the detection of *Salmonella* spp., 25 g of ground pork is enriched in 225 ml of prewarmed buffered peptone water (Ng, et al., *Appl. Environ. Microbiol.* 62:2294-2302, 1996). The same ratio (1:10) of enrichment was done for infant milk for the detection of *Salmonella* spp.

See also United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition. Bacteriological Analytical Manual, Chapter 5, Salmonella, April 2003.

Shigella sonnei. The conventional culture method for the enrichment of *Shigella sonnei* includes the use of 25 g sample into 225 ml shigella broth, already containing 0.5 µg/ml

novobiocin (United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, Bacteriological Analytical Manual. Chapter 6. Shigella, January 2001). The procedure is as follows: pour supernatant into sterile 500 ml Erlenmeyer flask; adjust pH, to 7.0 ± 0.2 with sterile 1 N NaOH or 1 N HCl; set the flask in an anaerobic jar with fresh catalyst; insert
5 GasPak™ and activate by adding water; incubate the jars in 44.0°C water bath for 20 h; stir the enrichment culture suspension and streak on a MacConkey agar; and incubate for 20 h at 35°C.

Campylobacter. United States Food & drug Administration, and Center for Food safety & Applied Nutrition, Bacteriological Analytical Manual. Chapter 7, Campylobacter, March 2001 (2001) suggests the use of a 1:10 dilution for sample enrichment when high numbers of
10 background flora (with broad species diversity) are present. It is taught that sample dilution helps antibiotics perform more effectively, and campylobacter cells utilize the low-oxygen atmosphere more efficiently.

Listeria. For the prior art enrichment of *Listeria monocytogenes* in composite samples, a composite blend of 50 g (equivalent to 25 g food plus 25 ml basal Buffered *Listeria* enrichment
15 broth (BLEB)) is mixed with a 200 ml amount of basal BLEB. An aliquot (50 ml) of the composite blend is retained, preferably at 5°C and not below 0°C, for possible pathogen enumeration. For non-composited samples, single 25 g analytical portions of food are blended or stomached in 225 ml of basal BLEB and pre-enriched/enriched as per the procedures. A 25 g sample is retained for possible pathogen enumeration and should be stored either frozen, in a
20 non-defrosting freezer or at 5°C.

Ryser, et al. (*Appl. Environ. Microbiol.* 62(5): 1781–1787, 1996), conducted experiments for the recovery of *Listeria ribotypes* from naturally contaminated, raw refrigerated meat and poultry products. A 1:10 sample dilution is used. Paired samples of ground beef, pork sausage, ground turkey, and chicken weighing 25 g are inoculated into 225 ml each of University of
25 Vermont-modified *Listeria* enrichment broth (UVM; Difco Laboratories, Detroit, Mich.) and *Listeria* repair broth (LRB; developed by Busch and Donnelly; Busch & Donnelly, *Appl. Environ. Microbiol.* 58:14–20, 1992), homogenized for 2 min in a Lab-Tek 400 Stomacher

(Tek-mar, Cincinnati, Ohio), and incubated at 30°C. An aliquot of 0.1 ml of each UVM and LRB primary enrichment is inoculated into a separate tube containing 10 ml of Fraser broth after an incubation of 22 to 26 h at 30°C. Following 24 and 40 h of incubation at 35 °C, all secondary enrichments, regardless of color change due to esculin hydrolysis, are streaked onto modified Oxford agar plates. All plates are incubated at 35°C for 24 h, after which two presumptive *Listeria* isolates per sample for each primary enrichment medium are streaked onto brain heart infusion agar plates for purification and incubated at 35°C for 24 h. An additional eight presumptive UVM and LRB *Listeria* isolates per primary enrichment medium from five samples of each of the four products are also streaked onto plates of brain heart infusion agar and similarly incubated.

Likewise, Norton, et al. (*Appl. Environ. Microbiol.* 67(1): 198-205, 2001), use a dilution of 1:10 for the *Listeria* enrichment. Twenty-five-gram portions of raw, in-process, and smoked fish are homogenized in 225 ml of *Listeria* Enrichment Broth (LEB) (Difco Laboratories, Detroit, Mich.) using a Stomacher 400 laboratory blender (Seward Ltd.). Brine solutions, in 25-ml aliquots, are inoculated into 225 ml of LEB. Swabs and transport media are transferred aseptically to 8 ml of LEB. After 24 and 48 h of incubation at 30°C, 0.1 ml of each enrichment culture are plated on Oxford medium containing the Oxford Antimicrobial Supplement (Difco Laboratories), and incubated at 30°C for 48 h. Pure culture isolates used for *hlyA* PCR or BAX system analysis (for confirmation that this system correctly identifies isolates from culture-positive, BAX system-negative samples) are cultured into brain heart infusion broth at 37°C with shaking for 12 to 15 h.

Growth of healthy and heat-injured strains of *Listeria monocytogenes* and *Salmonella* spp. from raw milk was supported by enrichment of sample in the universal pre-enrichment broth. One ml of milk was inoculated into tubes containing 9 ml of pre-enrichment broth (Jiang, et al., *J. Dairy Sci.* 81:7298-72830, 1998).

See also United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition. Bacteriological Analytical Manual, Chapter 10. Detection and enumeration of *Listeria monocytogenes* in foods, January 2003.

Yersinia enterocolitica and *Yersinia pseudotuberculosis*. The simplified procedure for isolating *Yersinia* from food, water, and environmental samples as suggested in Bacteriological Analytical Manual (United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, 2001) is as follows: aseptically weigh 25 g sample into 225 ml Peptone sorbitol bile broth (PSBB). Homogenize for 30 s and incubate at 10°C for 10 days. If high levels of *Yersinia* are expected in product, spread-plate 0.1 ml on MacConkey agar (Doyle, et al., *Appl. Environ. Microbiol.* 42:661-666, 1981, *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, 2001, Weissfeld (Weissfeld & Sonnenwirth, *J. Clin. Microbiol.* 15:508-510, 1982.) *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, 2001) and 0.1 ml on CIN agar (Schiemann, D.A., *Appl. Environ. Microbiol.* 43:14-27, *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition. January 2001, Bacteriological Analytical Manual. Chapter 8, 1982, *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, 2001; Schiemann & Wauters, *Yersinia*, Chapter 27, *Yersinia pseudotuberculosis*, pp. 601-672, *In*: Compendium of Methods for the Microbiological Examination of Foods, 3rd ed., Vanderzant, C., and D.F. Splittstoesser (eds), American Public Health Association, Washington, DC, *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition. January 2001, Bacteriological Analytical Manual, Chapter 8, 1992; *In* United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition) before incubating the broth.

A selective enrichment for plasmid-bearing virulent serotypes of *Yersinia enterocolitica* from pork was developed in which 10 g of samples is incubated with 90 ml of modified Trypticase soy broth (MTSB) (Bhaduri, S., et al., *Appl. Environ. Microbiol.* 63(5):1657-60, 1997). The first 10 ml of MTSB is added to the samples and was allowed to stand for 5 min,

followed by adding the remainder 80 ml of MTSB into the sample bag for a 24 h incubation at 12°C.

Vibrio cholerae. Bacteriological Analytical manual (United States Food & Drug Administration, and Center for Food Safety & Applied Nutrition, Bacteriological Analytical Manual, Chapter 9; Vibrio, July 2001) recommends addition of 225 ml alkaline peptone water (APW) with 25 g of weighed sample into a tarred jar (approximately 500 ml capacity). Seafood or vegetables are blended or cut into small pieces with sterile scissors. The mixed sample is blended for 2 min at high speed, and incubated in APW at $35 \pm 2^\circ\text{C}$ for 6 to 8 h.

Clostridium. Fach, et al. (*Appl. Environ. Microbiol.* 61:389-92, 1995), incubate 10 g of food samples (raw/cooked beef, raw/cooked pork, and raw fish) in 90 ml of Trypticase yeast extract glucose for the detection of *Clostridium spp.* Similarly, Dahlenborg et al. (*Appl. Environ. Microbiol.* 67:4781-8, 2001) incubate 10 g of feces in 90 ml of tryptone-peptone-glucose-yeast extract to select for *C. botulinum*.

Specilaized, selective media. Additionally, various specialized *selection* media (and agar) are known and used in the art. Such media comprises one or more anti-microbial reagents (e.g., tellurite and cefixime that selectively suppress particular (e.g., normal) flora growth and interference therefrom, to enhance the ability to detect, for example a slower growing pathogen (e.g., E. coli O157:H7). Such anti-microbial reagents, while having utility, nonetheless add even more expense to the media.

Therefore, not only is the cost of the sterile media itself significant, but, given the volumes typically involved, the associated shipping costs are also substantial given the large volumes (sample plus media/buffer). Furthermore, the size of the prior art samples (plus media/buffer) make it impractical to ship at an appropriate or optimal temperature (e.g., using temperature-controlled, spill-proof shipping containers/incubators. The inability to take advantage of shipping time for enrichment results in a substantial time delay in obtaining laboratory results. This has forced many industries and entities to either use local testing

facilities, build in-house certifiable testing labs, or accept, a substantial expense, the additional 1-2 days of 'process' time while awaiting test results.

Generally speaking, development of more timely and cost effective sampling, enrichment and testing procedures will make efficient use of the industry's financial resources, and thus will facilitate industry implementation of, and compliance with regulatory guidelines.

Therefore, to provide efficient and cost effective testing methods, and to facilitate industry implementation of and compliance with regulatory guidelines, there is a pronounced need in the art for rapid and efficient methods and apparatus for detection, at test locations that are remote from the site(s) of sampling, of various kinds of bacterial, viral, fungal, and parasitic pathogens that are capable of *in vivo* multiplication.

There is a pronounced need in the art to reduce the time required to obtain meaningful test results from remote test locations.

There is a pronounced need in the art to reduce the costs of obtaining such timely meaningful test results from remote test locations.

There is a pronounced need in the art for accurate and efficient methods for testing samples at a remote location, including but not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, etc), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

SUMMARY OF THE INVENTION

The present invention provides novel enrichment, testing and detection methods for detection of pathogens or other microbes in food, water, wastewater, sludge, pharmaceutical, industrial samples, and the like. The methods are also applicable to testing samples including, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, etc.), and all manners of raw and

processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

In preferred aspects, a sample is obtained at a *first* location and is enriched, based on its intrinsic properties (if water activity and nutrition, pH, are sufficient/proper to support the growth of the target organism), either with no addition of other compounds, or by the addition of minimal amounts of enrichment appropriate media, ranging from 0.1 volume to 1 volume (per wt sample). The samples are then incubated at the appropriate temperature which is selected on the basis of the temperature that allows for the optimal growth of the target organism(s) over the background flora. The samples, after sufficient incubation, are then analyzed for the presence of the pathogen using any number of available methods. Alternatively the enriched samples are incubated at an optimal temperature in an incubator during transit of the diluted sample to a *second* location that is a remote test location. The enriched, incubated sample is received and tested at the second location by assaying the received sample, or a portion thereof, with an assay suitable to detect the pathogen/target microbes.

In alternate preferred embodiments (e.g., liquid samples, juice, etc.), samples are enriched by adjusting their water activity (using sterile water/buffer/enrichment media), nutrient levels, pH, buffering capacity, and possibly addition of selective compounds (that repress the growth of competitive organisms in the samples) to the level that allows for the growth of the target organism, at the first location, followed by incubation and testing at the first location or shipping in transport incubators to a *second* testing location. The novel methods provide accurate, cost effective, and timely sampling and testing methods in-house or under circumstances where shipping of the sample to a remote testing location is required or desirable.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1 and 2 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 1), or an

embodiment of the inventive ‘dry’ method (Fig. 2) for 6 h, and concentrated by Dynabeads[®]. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 3 and 4 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 3), or an embodiment of the inventive ‘dry’ method (Fig. 4), for 7 h, and concentrated by Dynabeads[®]. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 5 and 6 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 5), or an embodiment of the inventive ‘dry’ method (Fig. 6), for 8 h, and concentrated by Dynabeads[®]. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 7 and 8 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 7), or an embodiment of the inventive ‘dry’ method (Fig. 8), for 6 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 9 and 10 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 9), or an embodiment of the inventive ‘dry’ method (Fig. 10), for 7 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 11 and 12 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 11), or an embodiment of the inventive ‘dry’ method (Fig. 12), for 8 h. Numbers 1, 2, 3 were inoculation

levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 13 and 14 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a standard method (Fig. 13), or an embodiment of the inventive 'dry' method (Fig. 14), for 24 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 15 and 16 show amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with a standard method (Fig. 15), or an embodiment of the inventive 'dry' method (Fig. 16), for 6 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 17 and 18 show amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with a standard method (Fig. 17), or an embodiment of the inventive 'dry' method (Fig. 18), for 7 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 19 and 20 show amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with a standard method (Fig. 19), or an embodiment of the inventive 'dry' method (Fig. 20), for 8 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figures 21 and 22 show amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with a standard method (Fig. 21), or an embodiment of the inventive 'dry' method (Fig. 22), for 24 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

DETAILED DESCRIPTION OF THE INVENTION

Prior to the present invention, low-dilution enrichment, transit incubation methods were not known or appreciated in the relevant art. Prior art methods, as summarized herein, under the “Background” section, are based on 1:10 (wt./vol.) dilutions of the sample.

5 In various aspects, the present invention provides novel methods for remote testing of one or more pathogens or other microbes in food, water, wastewater, sludge, pharmaceutical, industrial samples, and the like. In particular aspects, a dry-enrichment or a semi-dry-enrichment process allows for incubation, during transit to a remote testing location, of the food samples either without (e.g., liquid samples) the addition of enrichment media, or with (e.g., solid or
10 semi-solid samples) addition of only relatively small quantities of media and/or supplements, for testing at the remote location of contaminating pathogens or other microbes.

The present novel embodiments provide accurate, cost effective, and timely sampling and testing methods under circumstances where shipping of the sample to a remote testing location is required or desirable. The present invention, in various aspects, allows, *inter alia*, for: (i)
15 savings in the cost of enrichment media/buffers; (ii) the ability to ship the samples economically (with up to 90% less weight), and with far less chances of spills (e.g., because of 90% less liquids in enriched samples), in specially designed dry/semi-dry shipping incubators, to remote/distant laboratories; (iii) increased sensitivity in the detection of the target organisms, due to smaller dilution factor; and (iv) the ability to form centralized laboratories (that may be remote
20 from the sampling sites) that use the enrichment/incubation-in shipping concept to provide testing services to distant clients with the ability to report as fast as a local laboratory, and at similar or reduced costs relative to local laboratories.

According to the present invention, the samples are incubated immediately at the desired incubation temperature, and/or are incubated in transit by shipping the samples in a
25 temperature-controlled shipping container or incubator allowing for incubation at appropriate temperatures within optimal ranges depending on the pathogen’s optimal growth range, and/or optimal competitive growth range.

According to the present invention, for many types of foods, the food itself can be incubated with no addition of inhibitory or supplementary substances. For example, with foods or environmental samples that are in liquid form (e.g., fruit juices and the like), the samples are enriched directly, with or without a concentration step, with or without the addition of supplementary nutrients, inhibitors, or indicators.

In other aspects, with dry and semi-dry foods, the water and/or nutrient activity is adjusted to allow for the growth of the target organism. Addition of supplements depends on the target organism and the nature of the samples which are to be tested. Inventive supplements include water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, etc.

The protocols as described allow for the enrichment of pathogens, or target organisms with minimal increase in volume/weight of the samples. For samples that are to be shipped out, the shipping time can be used to enrich the sample without substantial increase in the weight and volume of the product, also minimizing the probability of spillage and/or cross-contamination. The sensitivity of the method is increased due to the elimination of dilution factor; the sample size has not increased substantially in terms of its volume or weight.

Samples testable according to the present invention include, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, etc.), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols.

Definitions

“Carcass” refers to the body of the livestock after harvest, de-hiding (or, as the case may be, de-feathering, de-skinning, de-scaling), and evisceration. Preferred embodiments relate to beef carcasses, but the present invention encompasses carcasses of pigs, sheep, deer, bison, elk,

poultry (e.g., turkey, chicken) and other animals (e.g., fish) that are killed and processed into products that may contain pathogens and/or other microbes of interest.

Carcass “splitting” refers to splitting of the carcass into portions, including into two half-carcasses or half-carcass portions. In preferred embodiments, splitting refers to splitting into two
5 half-carcass portions.

“Fabrication” refers to the process of cutting-up half-carcass into marketable cuts (e.g., primals, sub-primals, trim).

“Trim” refers to small pieces of meat and fat which are excised during the fabrication process in order to produce primal and subprimal pieces and marketable cuts.

10 “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 to the trim packaging unit. Alternatively raw materials to be tested can be packaged into boxes, bags or other appropriate containers, which can be placed, for example, on pallets.

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

A prior art “Bin-sample” refers to a sample (typically about 75 g), comprised of 1-12 randomly-selected pieces from a single combo-bin. Typically, in prior art sampling plans, the
20 standard manner of collection is to randomly pick five pieces as a comb-bin is being filled.

A prior art “Lot-unit sample” refers to a 375 g *composite* sample, comprised of seventy-five (75) gram samples from each combo-bin of the Lot-unit. In a variation of the typical prior art protocol, the random piece samples from each combo-bin (the Bin-samples) are subjected to grinding, then composite Lot-samples are made from the respective ground
25 Bin-samples.

“Sampling” or “obtaining samples” refers to obtaining, in a form suitable for pathogen/microbe testing purposes, a sample of the pathogens and/or other microbes of interest

present on or within various samples. Samples testable according to the present invention include, but are not limited to beef, pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy products, dry goods (cereals, etc), and all manners of raw and processed foods, environmental samples (water, wastewater, soil, surface samples, samples
5 taken by impingers and filtration, etc.), pharmaceuticals, and other types of samples that are to be analyzed using enrichment-detection protocols. Samples, include environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

For meat products, a sample may correspond to the surface of one or more test locations
10 of the carcass or sub-carcass portion. Any sampling method is encompassed, provided that it is suitable to acquire (or include), at least to some extent, the surface pathogens/microbes. Preferably, the sampling method is by excision, or by blotting, swabbing, sponging, and the like (see under "Samples and Sample Locations, herein below).

Preferred Embodiments

Aspects of the present invention provide a method for remote detection of a pathogen or
15 other microbe in a sample comprising: obtaining a test sample at a first location, the sample being solid or semi-solid; diluting, at the *first* location, the sample with enrichment medium at a ratio of about 1:2.0 (wt./vol.) or greater; incubating the diluted sample at an optimal temperature in an incubator during transit of the diluted sample to a *second* location that is a remote test
20 location; and determining, at the remote test location, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

Preferably, the sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods,
25 environmental samples, soil, surface samples, samples taken by impingers and filtration, etc., pharmaceuticals, and samples analyzed using enrichment-detection protocols.

Preferably, diluting is at a ratio of 1:1 (wt./vol.) or greater. More preferably, diluting is at a ratio of 1:0.5 (wt./vol.) or greater. Alternatively, diluting is at a ratio of 1:0.3 (wt./vol.) or greater, or at a ratio of 1:01 (wt./vol.) or greater (i.e., non-diluted).

Preferably, the optimal temperature is within, or substantially within, the optimal growth temperature range of the pathogen or other microbe in the particular enrichment medium. Preferably, the optimal temperature is within, or substantially within, a temperature range that affords an optimal competitive growth advantage, relative to other microbes present in the sample. Preferably, the optimal temperature range is from about 25 to 45 °C. Preferably, the optimal competitive growth temperature range is from about 30 to about 45°C.

Preferably, the assay suitable for detection of pathogenic or microbial contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, bacteriophage-detection-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular target organisms or groups of target organisms, and combinations thereof.

Preferably, the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinia*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; indicator molecules including glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions), including bovine spongiform encephalopathy (BSE) agents, scrapie, chronic wasting disease; and combinations thereof.

Preferably, the pathogen or microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7).

Preferably, obtaining a sample is obtaining a sample from at least one test location of a carcass or of a split-portion thereof, wherein the test sample is obtained, in the slaughter production process, prior to or during initial chilling of the respective carcass or split-portion thereof. Preferably, the sample is a composite-Lot sample, corresponding to a combination of samples from a plurality of carcasses with a carcass Lot, and wherein the carcass is selected from the carcass group consisting of cattle, sheep, pigs, bison, elk, deer, chicken, turkey, fish and combinations thereof.

In alternative embodiments, supplements are added to the sample, prior to shipping of the sample to the remote testing location. Preferably, supplements are selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators. Such supplements are well known to those of ordinary skill in the relevant art, and include art-recognized micro- (e.g., Zn, Fe and Mn) and macro nutrients (e.g., Na, P, K, Ca, and magnesium and sulfur) (see, e.g., U.S. 5,582,627, incorporated by reference herein in its entirety), and/or carbon skeleton sources or other compounds, including but not limited to: sugar-
-mannose, lactose, dextrose, arylthrose, fructose, fucose, galactose, glucose, gulose, maltose, polysaccharide, raffinose, ribose, ribulose, rutinose, saccharose, stachyose, trehalose, xylose, xylulose, adonose, amylose, arabinose, fructose phosphate, fucose-p, galactose-p, glucose-p, lactose-p, maltose-p, mannose-p, ribose-p, ribulose-p, xylose-p, xylulose-p, deoxyribose, corn steep liquor, whey, corn sugar, corn syrup, maple syrup, grape sugar, grape syrup, beet sugar, sorghum molasses, cane molasses, calcium lignosulfonate; sugar alcohol--adonitol, galactitol, glucitol, maltitol, mannitol, mannitol-p, ribitol, sorbitol, sorbitol-p, xylitol; organic acids--glucuronic acid, a-ketoglutaric acid, galactonic acid, glucaric acid, gluconic acid, pyruvic acid, polygalacturonic acid, saccharic acid, citric acid, succinic acid, malic acid, oxaloacetic acid, aspartic acid, phosphoglyceric acid, fulvic acid, ulmic acid, humic acid; nucleotides and bases--adenosine, adenosine-p, adenosine-p-glucose, uridine, uridine-p, uridine-p-glucose, thymine, thymine-p, cytosine, cytosine-p, guanosine, guanosine-p, guanosine-p-glucose, guanine, guanine-p, NADPH, NADH, FMN, FADH; Buffers--phosphate buffer, acetate buffer, AMP

buffer, calcium tartrate, glycine buffer, phosphate citrate buffer, and tris buffer; and combinations thereof, are also contemplated (*Id*).

Optional addition of complexing agents, including but not limited to citric acid; Ca, K, Na and ammonium lignosulfonates, fulvic acid, ulmic acid, humic acid, Katy-J, EDTA, EDDA, EDDHA, HEDTA, CDTA, PTPA, NTA, and combination thereof, are also contemplated.

In alternate preferred embodiments, the invention provides a method for remote detection of a pathogen or other microbe in a liquid sample comprising: obtaining a liquid sample at a first location; incubating the sample at an optimal temperature in an incubator during transit of the diluted sample to a *second* location that is a remote test location; and determining, at the remote test location, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

Preferably, the optimal temperature is within, or substantially within, the optimal growth temperature range of the pathogen or other microbe in the particular enrichment medium. Preferably, the optimal temperature is within, or substantially within, a temperature range that affords an optimal competitive growth advantage, relative to other microbes present in the sample. Preferably, the optimal temperature range is from about 25 to about 45 °C. Preferably, the optimal competitive temperature range is from about 30 to about 45 °C.

Preferably, detection of pathogenic or microbial contamination is with an assay selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, bacteriophage-detection-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular target organisms or groups of target organisms, and combinations thereof.

Preferably, the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia*

coli (EPEC), *Salmonella*, *Listeria*, *Yersinia*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; indicator molecules including glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions), including bovine spongiform encephalopathy (BSE) agents, scrapie, chronic wasting disease; and combinations thereof.

Preferably, the pathogen or microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7).

Preferably, the liquid sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, pharmaceuticals, and other samples analyzed using enrichment-detection protocols.

Alternatively, the methods comprise addition to the sample, prior to transit of the sample to the second location, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers and combinations thereof. Exemplary supplements are described elsewhere herein.

Yet further alternate embodiments provide a method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising: obtaining a test sample at a first location, the sample being solid, semi-solid or liquid; diluting, at the first location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample; incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

Preferably, the methods further comprise addition to the sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust

the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the target organism, and combinations thereof.

Incubators

Preferred embodiments of the present invention comprise use of an incubator for holding
5 the sample or diluted sample at an optimal temperature, or within an optimal temperature range,
during shipment of the sample to the remote testing location. Suitable incubators are known in
the art. In a preferred embodiment the incubator comprises an enclosure into which bottles
containing sample and enrichment medium/buffer can be placed. Preferably the enclosure is an
insulated container with a removable lid. Preferably, a temperature sensor activates ‘on demand’
10 power to a heating (and/or cooling) element. Preferably, the power supply is a typical 12 v type,
able to work in a vehicle (e.g., off the cigarette lighter, or similar connection). In particular
embodiments, a fan circulates air around the heating (and/or cooling) element. In preferred
embodiments the power source is through a cigarette lighter-type connection within a vehicle.
Preferably, the sample bottles are designed to be leak proof.

15 Samples to be Tested by the Inventive Methods

Samples testable according to the present invention include, but are not limited to beef,
pork, sheep, bison, deer, elk, poultry (e.g., chicken and turkey) and fish, produce, juices, dairy
products, dry goods (cereals, etc), and all manners of raw and processed foods, environmental
samples (water, wastewater, soil, surface samples, samples taken by impingers and filtration,
20 etc.), pharmaceuticals, and other types of samples that are to be analyzed using
enrichment-detection protocols.

Prior Art Trim Testing Methods in the Slaughter Industry

Prior art pathogen-testing plans are actually either trim-testing plans, final product testing
plans, or both, involving random and incomplete sampling at the ‘packing-Lot’ level; that is,
25 testing of trim samples near the end of the production chain (as they enter the bins or after
binning, or testing of the ground products by taking samples at given time intervals. A typical

trim-testing plan involves analysis of ‘five-combo-lot’ units, and comprises analysis of a single composite-Lot sample of about 375 g, prepared by combining five combo-bin samples (about 75 g each), in each case corresponding to one to five randomly-selected pieces from each combo-bin, such that, on average 5-25 pieces representing the five combo-bins are in the composite sample. The combo-bin is comprised of pieces of a plurality of carcasses, and thus the test results under these prior art systems reflect random and incomplete sampling; that is, only a small fraction of the carcasses are represented in the test results, particularly where, as is true of many such plans, only a sub-fraction of the composite-Lot sample is used for the pathogen-testing assay (e.g., when large pieces of trim are collected). For example, for ground beef production, final product testing comprises taking ground beef samples at given time intervals (e.g., every 10-30 minutes) and compositing a number of samples into one composite sample.

Generally, one of several methods of analysis has been used for pathogen detection after sampling at the packing-Lot level: (1) Immunochemical based detection (e.g., ELISA based immunoassays) following enrichment (e.g., for *E. coli* O157:H7); (2) Nucleic acid-based (e.g., DNA-based, such as PCR-analysis) detection methods following enrichment (e.g., for *E. coli* O157:H7), wherein an appropriate medium is inoculated with a composite-Lot sample; and (3) target organisms can be detected by enrichment, followed by immunomagnetic separation followed by plating, immunochemical or DNA based detection. Typically, the levels of sensitivity of most of these methods are set at about 1 colony forming unit (cfu)/25 g of sample.

Typically, to allow time for trim testing results to be obtained, such sampling plans require additional (in addition to initial chilling of the split-carcasses, and the time taken during the processing of the carcasses (fabrication)) ‘holding’ of the trim prior to use. Such holding of the trim will typically add 12 to 24 hrs of extra refrigeration storage time/capacity, and uses up about a day of the product shelf-life.

Trim Testing Methods in the Context of the Present Invention

According to preferred aspects of the present invention, carcasses (e.g., beef, sheep, pigs, deer, elk, bison, poultry, and fish) typically spend up to 24 hours in chilled storage prior to being cut up into, or generating, trim (prior to fabrication), and this is sufficient time to run an adequate detection assay (e.g., presence/absence assays) for microbes or other pathogens. Furthermore, carcass-Lots are identifiable, and carcasses are typically tagged with unique identifiers, and thus, according to the present invention, where a timely and statistically-significant *positive* result (contaminated carcass) is obtained, the respective contaminated carcass-Lot is precluded from entering the fabrication/production chain. Therefore, cross-contamination is reduced or eliminated, where carcasses carrying contamination are removed from the process stream prior to being cut into, or generating, trim (e.g., the possibility of transferring any contamination to equipment such as knives and conveyor belts is reduced or eliminated).

In a preferred aspect, the inventive method comprises splitting of a carcass-Lot to produce a split-carcass-Lot (Lot of split-portions), and obtaining at least one surface test sample from at least one preferred sample location of one or both split-portions, immediately prior to chilling of the split-portions. In a particularly preferred embodiment, at least three distinct surface samples are taken from each half-carcass. The test samples are combined to form a composite-Lot test sample, and the composite-Lot test sample, or a portion thereof is used for determining whether contamination is present by using an assay suitable to detect the microbe or pathogen of interest. Preferably, a carcass-Lot is a group of 50-100 carcasses. Preferably, at least one half of each carcass is surface-sampled (e.g., by excision, blotting, swabbing, or sponging). Preferably, testing is of composite-Lot samples comprising at least 25, at least 50, at least 100, at least 150, at least 200, or at least 300 surface samples (e.g., blotting, swabbing, or sponging, or thinly excised sample slices). Preferably, three to four carcass sampling stations (locations) are established. Preferably, the sampling stations correspond to carcass sites that are most likely, according to the present invention, to be contaminated, based on factors regarding the locations and incident rates of a given pathogen such as *E. coli* O157:H7. Preferably, the test

locations are selected in a random or repeated (rotational) order from the group consisting of rump, brisket, back and flank, and combinations thereof. Preferably, from rump, brisket and/or flank.

Type of Pathogens/Microbes to be Detected

5 In preferred embodiments, the present inventive methods encompass the detection of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinia*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.* Additionally, other pathogens and pathogenic agents are
10 encompassed within the present invention, including, but not limited to other frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms (total heterotrophes, generic *E. coli*, total and fecal coliforms, enterococcus, etc); and spoilage organisms (*Pseudomonas*, etc), and indicator molecules such as glial fibrillary acid protein (GFAP), transmissible spongiform encephalopathy (TSE) agents (prions) (e.g., bovine spongiform
15 encephalopathy (BSE) agents, scrapie (sheep), chronic wasting disease (e.g., deer, Elk).

Preferably, the detected microbe is: a pathogen including, but not limited to, *Escherichia coli* O157:H7 (*E. coli* O157:H7), *Listeria*, *Salmonella*, EHEC, *Campylobacter*, *Staphylococcus*, pathogenic *Clostridial species*, and other frank, or opportunistic pathogens; a spoilage organism including, but not limited to, *Clostridial* and *Pseudomonas species*; or an indicator organism
20 including, but not limited to, generic *E. coli*, fecal coliforms, total coliforms, etc. More preferably, the pathogen is *Escherichia coli* O157:H7 (*E. coli* O157:H7).

Detection Assays

Preferably, the detection assay is selected from the assay group consisting of immunoassays, nucleic acid amplification-based (e.g., PCR-based assays), nucleic acid
25 hybridization-based assays, bio-sensor assays, immunostaining-microscopy based assays, nucleic acid-array-based (e.g., DNA chip-based) assays, bacteriophage detection based assays, classical

microbiology based assays, and chemical/biochemical assays based on the detection of compounds associated with particular groups of target organisms, and combinations thereof. Such assays are well known in the relevant art, and a few exemplary assays are as follows:

Reveal® test kits are available from Neogen Corporation, Lansing, MI., and comprise an ELISA test that combines an immunoassay with chromatography in a lateral flow device (Reveal® test kits are available for *E. coli* O157:H7, *Salmonella*, *Listeria spp.* and *Listeria monocytogenes*);

VIP® test kits are available from BioControl, Bellevue, WA., and comprise an ELISA test that is expressed as a lateral flow antibody-chromogen immunoprecipitate assay (VIP® test kits are available for EHEC, *Salmonella*, *Listeria spp.* and *Listeria monocytogenes*);

BAX® Qualicon test kits are available from DuPont, Wilmington, DE., wherein, using the BAX® system, samples are enriched and then lysed to release DNA, which is amplified using PCR techniques, and detected using a fluorescent signal (BAX® test kits are available for *E. coli* O157:H&, *Salmonella*, *Listeria spp.* and *Listeria monocytogenes*, and *enterobacter sakazakii*); and

TSE (e.g., in cattle sheep and deer) can be tested by testing nervous system tissue (e.g., brain stem) for the respective agents (PrP) using, for example, ELISA assays, such as the Enfer TSE test, manufactured by Enfer Scientific, Newbridge Ireland, and distributed by Abbott Laboratories (Abbott Park, IL; see Abbott Application Note by Klass, et al., 2002, “A test for transmissible spongiform encephalopathy,” incorporated herein by reference).

Carcass Samples and Sample Locations

Sampling, as practiced herein, refers to obtaining, in a form suitable for pathogen/microbe testing purposes, a sample of the pathogens and/or other microbes of interest present on the surface of one or more test locations of the carcass or sub-carcass portion. Any sampling method is encompassed, provided that it is suitable to extract (or include), at least to some extent, the surface pathogens/microbes. Preferably, the sampling method is by excision, or by blotting, swabbing, sponging, and the like. Preferably, in order to produce results which

allow systematic comparisons with additional monitoring of microbial interventions along process line, samples are collected at the rump, brisket, or flank and combinations thereof (see Elder, et al., *PNAS* 97:2999-3003, 2000; Correlation of enterohemorrhagic *Escherichia coli* O157 prevalence in feces, hides, and carcasses of beef cattle during processing).

5 Preferably, obtaining a test sample, or remedial test sample, comprises obtaining one or more surface samples from at least one test location of at least one split-portion, or remedial-split-portion of each carcass. Preferably, the test sample, or remedial test sample, is a surface sample (e.g., swabbed, blotted, sponged, or an excised surface tissue section) corresponding to, or having a surface area of at least 4, at least 6, at least 8, at least 10, at least 12, or at least 16
10 square inches. More preferably, the test sample, or remedial test sample, is a surface sample corresponding to, or having a dimension of about 16 square inches. Preferably, the test sample, or remedial test sample, comprises three, or at least three, such surface samples, each from a distinct location of the split-portion. Preferably, the test location, or remedial test location, is randomly or rotationally selected from the group consisting of sites most likely to harbor
15 microbial pathogens (e.g., rump, brisket, back and flank, and combinations thereof).

In particularly preferred embodiments, a contaminated split-carcass-Lot is subjected to remedial reconditioning. Preferably, reconditioning comprises sanitizing/pasteurizing by hot-water or steam pasteurization, and/or by using an organic acid spray (e.g., lactic-acid spray), etc. Such methods are well known to those of ordinary skill in the relevant art.

20 The present invention will now be further illustrated by reference to the following EXAMPLES. However, it should be noted that these EXAMPLES, like the embodiments described above, are illustrative and are not to be construed as restricting the enabled scope of the invention in any way.

EXAMPLE I

25 (Enrichment methods based on 1:0.5 dilution samples to media were found to be effective)

To compare the effectiveness of dry (1:0.5 meat to media) to standard (1:10) enrichment methods on the growth of *Escherichia coli* O157:H7 and *Salmonella* spp. on experimentally

inoculated meat samples incubated for 6, 7, 8, and 24 h. *E. coli* and *Salmonella* spp. were detected with a multiplex polymerase chain reaction (PCR) technique.

Materials and Methods

Inoculum preparation. Colonies of *E. coli* O157:H7 and *Salmonella typhi* isolated from clinical samples were grown on MacConkey II agar (BD Diagnostic Systems, Sparks, MD) and XLD (BD), respectively. Random colonies of *E. coli* O157 were confirmed with *E. coli* O157 Latex Test Kit (Oxoid, Hampshire, UK). Each pathogen were independently cultured in *E. coli* O157 Bax[®] System media (Dupont Qualicon by Oxoid Ltd., Hampshire, England) at 37 °C for 24 h. Serial dilutions of each inoculum were done separately in 0.1% peptone water (BD). Enumeration was done by plating 1 ml of each dilution on Petrifilm[™] Aerobic Count Plates (3M[™] Microbiology Products, St. Paul, MN). Plates were incubated at 37 °C for up to 48 h. Based on enumeration data, meat trim samples were inoculated with approximately 6.1×10^2 , 9.1×10^1 , and 0.9×10^1 CFU/ml of *E. coli* O157:H7, and 4.1×10^2 , 6.2×10^1 , and 1.0×10^1 CFU/ml of *S. typhi*.

Meat sample. Prepacked meat trim (beef stew) sample was purchased from a local grocery store in Seattle, WA. For standard and dry enrichment methods, 25 g and 100 g of duplicate samples were placed in whirl-pack bags, respectively. Meat samples were inoculated with three concentrations of *E. coli* O157:H7 and *S. typhi* mentioned earlier at a rate of 1 ml of each pathogen per 25 g of meat sample. This approach resulted in concentrations of 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat for *E. coli* O157:H7, and 1.67×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat for *S. typhi*. Samples were then subjected to a stomacher for 30 s. Standard and dry enrichment samples received 225 ml and 50 ml of pre-warmed (42 °C) *E. coli* O157 Bax[®] System media (Dupont), respectively. Samples were again stomached for 30 s. All enrichment bags were placed in an incubator shaker at 42 °C with household (ice) packs between bags. Ice packs were pre-warmed by placing them in a 42 °C incubator two days prior to the experiment.

At 6, 7, 8, and 24 h of incubation, 1 ml of broth of each enrichment bag was taken and placed in 1.5 ml centrifuge tubes. Samples were concentrated by centrifugation for 5 min at low speed. Supernatant was aspirated and pellet was resuspended in 1 ml phosphate buffer saline with 0.05% Tween (PBST).

5 Prior to *E. coli* O157:H7 detection by PCR method, an aliquot of sample suspension was concentrated with anti-*E. coli* O157 Dynabeads[®] (Dynal Biotech ASA, Oslo, Norway). All sample suspension with and without Dynabeads[®] were detected by PCR.

Background microflora of non-inoculated meat sample was analyzed. Ten grams of meat sample was placed in a stomacher bag and 90 ml of 0.1% peptone water was added to the bag.

10 The meat was subjected to a stomacher for 30 s. Serial dilution was made in 0.1% peptone water and 1 ml was plated on Petrifilm[™] Aerobic Count Plates (3M[™]). Plates were incubated at 37 °C for up to 48 h.

PCR. Multiplex PCR method was used for the detection of *E. coli* O157:H7 and *Salmonella* spp. A reaction mixture containing specific regions of the pathogens of interest was used as a positive control. Negative control was distilled water.

15 *E. coli* O157: Samples were subjected to a 55 µl mixture of lysis buffer containing MgCl₂ IGEPAL CA-630 detergent, primers, achromopeptidase and Tris buffer. The primer pairs amplified specific fragments of *E. coli* O157:H7 encoding for O157 antigen (*rfb*, 985 bp), intimin (*eae*, 309 bp), and shiga-like toxin 2 (*stx* 2, 255 bp) and 1 (*stx* 1, 180 bp) genes. Pure *Taq* Ready-To-Go beads (Amersham Biosciences, Piscataway, NJ) were used. *Taq* beads contained *Taq* polymerase, dNTPs, BSA, and detergent. The reaction conditions were 4 °C for 2 min, 95 °C for 2 min, 95 °C for 2 sec, 65 °C for 30 sec, 72 °C for 20 sec, 33 cycles of 95 °C for 10 sec, followed by 4 °C cooling period.

25 *Salmonella* spp.: Samples were subjected to a 55 µl mixture of lysis buffer containing MgCl₂ IGEPAL CA-630 detergent, primers, achromopeptidase and Tris buffer. The primer pairs amplified specific fragments of *Salmonella* spp. encoding for plasmid DNA (524 bp), *Salmonella* spp. fragment (300 bp), and chromosome (197 bp) genes. Pure *Taq* Ready-To-Go beads

(Amersham Biosciences) were used. *Taq* beads contained *Taq* polymerase, dNTPs, BSA, and detergent. The reaction conditions were 4°C for 2 min, 95°C for 2 min, 95°C for 2 sec, 65 °C for 30 sec, 72 °C for 20 sec, 33 cycles of 95 °C for 10 sec, followed by 4°C cooling period.

Electrophoresis was performed on 2% (w/v) agarose gel (Fisher Scientific, Fair Lawn, NJ), stained with ethidium bromide solution and viewed under a UV light source.

Results

Pre-packed meat trim had an average of 3.8 logs CFU/ml of aerobic plate counts. The four (*rfb*, *eae*, *stx 1*, and *stx 2*) target genes for *E. coli* O157 were detected by PCR methods with Dynabeads® (Figures 1 through 6) and without Dynabeads® (Figures 7 through 14) from samples incubated with dry and standard enrichment procedures for 6, 7, 8, and 24 h incubation. Likewise, the three (*spvc*, *sal 2*, and *inva*) target genes for *Salmonella* spp. were detected by PCR methods (Figures 14 through 22) from samples incubated with dry and standard enrichment procedures after 6, 7, 8, and 24 h incubation.

Figures 1 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard dilution method (1:10) for 6 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 2 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with a representative dry method (1:0.5) for 6 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 3 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 7 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 4 show amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 7 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 5 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 8 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 6 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 8 h and concentrated by Dynabeads®. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 7 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 6 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 8 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 6 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 9 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 7 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 10 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 7 h. Numbers 1, 2, 3 were

inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 11 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 8 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 12 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 8 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 13 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with standard method (1:10) for 24 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 14 shows amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings incubated with dry method (1:0.5) for 24 h. Numbers 1, 2, 3 were inoculation levels at 2.4×10^1 , 0.36×10^1 , and 0.036×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 15 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with standard method (1:10) for 6 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 16 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with dry method (1:0.5) for 6 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 17 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with standard method (1:10) or 7 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 18 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with dry method (1:0.5) for 7 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 19 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with standard method (1:10) for 8 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 20 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with dry method (1:0.5) for 8 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 21 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with standard method (1:10) for 24 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Figure 22 shows amplification products obtained by multiplex PCR of *Salmonella* spp. inoculated on meat trimmings incubated with dry method (1:0.5) for 24 h. Numbers 1, 2, 3 were inoculation levels at 1.6×10^1 , 0.24×10^1 , 0.042×10^1 CFU/g of meat, respectively. A and B were duplicate samples.

Collectively, the results show that enrichment of meat trimmings with the inventive 'dry' method (e.g., 1:0.5 wt./vol. dilution) gave results comparable to those obtained using standard (USDA) methods employing the art-recognized 1:10 dilution factor. This experiment showed

that enrichment of meat trimming with 'dry' method (1:0.5 dilution) showed similar results to the standard FDA (1:10 dilution) method. This experiment also showed that the dry enrichment method on samples inoculated with the highest (0.021×10^1 CFU/g) dilution of bacteria was able to produce sufficient signals as shown in the PCR results.

EXAMPLE II

(Novel minimal dilution methods were shown to be cost effective)

Costs comparisons of the inventive methods with those of the prior art are as follows:

TSB medium comparison:

TSB 1 lb (453.59 g) => \$25-27 (depending on quantity ordered);

Working dilution: 30 g/L;

From 453.59 g, make ± 15.11 L;

Price per Liter = $\pm$ \$1.65 to \$1.78;

Prior art price per sample (225 ml) = $(225/1000) \times 1.65 = \pm$ \$ 0.37 to \$0.40; and

Inventive method price per sample (50 ml) = $(50/1000) \times 1.65 = \pm$ \$ 0.082 to 0.089.

Bax® medium comparison:

E. coli O157 Bax® System media (Dupont Qualicon by Oxoid Ltd., Hampshire, England);

2.5 Kg (2500g) => about \$300.00;

Working dilution: 36.6 g/L;

From 2,500 g, make ± 68.3 L;

Price per liter = $\pm$ \$4.39;

Prior art price per sample (225 ml) = $(225/1000) \times 4.39 = \pm$ \$ 0.98; and

Inventive method price per sample (50 ml) = $(50/1000) \times 4.39 = \pm$ \$0.21.

CLAIMS

1. A method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising:

- obtaining a test sample at a first location, the sample being solid, semi-solid or liquid;
- diluting, at the *first* location, the sample with enrichment medium at a ratio between about 1:0.1 to about 1:2 (wt./vol.), or greater;
- incubating the diluted sample at an optimal temperature in an incubator during transit of the diluted sample to a *second* location that is a remote test location; and
- determining, at the remote test location, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

2. The method of claim 1, wherein diluting is at a ratio of 1:2 (wt./vol.) or greater.

3. The method of claim 1, wherein diluting is at a ratio of 1:0.5 (wt./vol.) or greater.

4. The method of claim 1, wherein diluting is at a ratio of 1:0.1 (wt./vol.) or greater.

5. The method of claim 1, wherein the optimal temperature is within, or substantially within, the optimal growth temperature range of the pathogen or other microbe in the particular enrichment medium.

6. The method of claim 1, wherein the optimal temperature is within, or substantially within, a temperature range that affords an optimal competitive growth advantage, relative to other microbes present in the sample.

7. The method of claim 5, wherein the optimal temperature range is from about 25 to about 45 °C.

8. The method of claim 6, wherein the optimal competitive temperature range is from about 35 to about 45 °C.

9. The method of claim 1, wherein the assay suitable for detection of pathogenic or microbial contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, bacteriophage-detection-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular target organisms or groups of target organisms, and combinations thereof.

10. The method of claim 1, wherein the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

11. The method of claim 10, wherein the pathogen or microbe is *Escherichia coli* O157:H7 (*E. coli* O157:H7, or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*..

12. The method of claim 1, wherein obtaining a sample is obtaining a standard Lot-unit sample.

13. The method of claim 1, wherein the sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples,

industrial samples, pharmaceutical samples, water samples, wastewater samples, bio-solid samples, air samples, samples taken by spore traps, settled dust, impingers, or filtration), and combinations thereof.

14. A method for remote detection of a pathogen or other microbe in a liquid sample comprising:

- obtaining a liquid sample at a first location;
- incubating the sample at an optimal temperature in an incubator during transit of the diluted sample to a *second* location that is a remote test location; and
- determining, at the remote test location, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

15. The method of claim 14, wherein the optimal temperature is within, or substantially within, the optimal growth temperature range of the pathogen or other microbe in the particular enrichment medium.

16. The method of claim 14, wherein the optimal temperature is within, or substantially within, a temperature range that affords an optimal competitive growth advantage, relative to other microbes present in the sample.

17. The method of claim 15, wherein the optimal temperature range is from about 25 to about 45 °C.

18. The method of claim 16, wherein the optimal competitive temperature range is from about 30 to about 45 °C.

19. The method of claim 14, wherein the assay suitable for detection of pathogenic or microbial contamination is selected from the assay group consisting of immunoassays, nucleic acid amplification-based assays, PCR-based assays, nucleic acid hybridization-based assays, bio-

sensor assays, immunostaining-microscopy-based assays, nucleic acid-array-based assays, DNA chip-based assays, bacteriophage-detection-based assays, classical microbiology-based assays, and chemical or biochemical assays based on the detection of compounds associated with particular target organisms or groups of target organisms, and combinations thereof.

20. The method of claim 14, wherein the microbe or pathogen is selected from the group consisting of *Escherichia coli* O157:H7 (*E. coli* O157:H7), enterohemorrhagic *Escherichia coli* (EHEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC), enteropathogenic *Escherichia coli* (EPEC), *Salmonella*, *Listeria*, *Yersinis*, *Campylobacter*, *Clostridial species*, *Staphylococcus spp.*; frank and opportunistic bacterial, fungal, viral, parasitic pathogens; indicator organisms including heterotrophes, generic *E. coli*, total and fecal coliforms and enterococcus; spoilage organisms including *Pseudomonas*; and combinations thereof.

21. The method of claim 20, wherein the pathogen or microbe is *Escherichia coli* O157:H7 (*E. coli* O157: or H negative), *Salmonella*, *Listeria*, EHEC, and *Campylobacter*).

22. The method of claim 1, where in the sample is selected from the group consisting of beef, pork, sheep, bison, deer, elk, poultry, fish, produce, dairy products, dry goods, raw and processed foods, environmental samples, soil, sludge, surface samples, samples taken by impingers and filtration, pharmaceuticals, and samples analyzed using enrichment-detection protocols.

23. The method of claim 14, wherein the liquid sample is selected from the group consisting of fruit juice, vegetable juice, milk and dairy products, raw and processed liquid foods, environmental samples, water, wastewater, samples taken by impingers and filtration, botanical liquid, industrial liquids, pharmaceutical liquids, and other liquid samples analyzed using enrichment-detection protocols.

24. The method of claim 1, further comprising addition to the sample, prior to transit of the sample to the second location, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the target organism, and combinations thereof.

25. The method of claim 14, further comprising addition to the sample, prior to transit of the sample to the second location, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the target organism, and combinations thereof.

26. A method for remote detection of a pathogen or other microbe in a solid sample, semi-solid sample or liquid sample comprising:

- obtaining a test sample at a first location, the sample being solid, semi-solid or liquid;
- diluting, at the *first* location, the sample with enrichment medium at a range of ratio of about 1:0.1 to 1:2 (wt./vol.), or not diluting the sample;
- incubating the enriched sample at an optimal temperature in an incubator for testing in a second location that is an in-house or local lab; and
- determining, at the in-house or local lab, by assaying the diluted incubated test sample, or a portion thereof, with an assay suitable to detect the pathogen or other microbe, whether the sample is contaminated.

27. The method of claim 26, further comprising addition to the sample, prior to or during incubation, of a supplement selected from the group consisting of water, sugars, proteins, minerals, organics, vitamins and cofactors, antibiotics, dyes, indicators, buffers, agents to adjust the pH, water activity, nutritional contents, selective pressure to optimize the growth conditions for the target organism, and combinations thereof.

ABSTRACT OF THE DISCLOSURE

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 (wt./vol.) to 1:2 (wt./vol.), or greater, preferably at a ratio of about 1:0.1 (wt./vol.) or greater, or more preferably, at a ratio of about 1:2 (wt./vol.) 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 additions to adjust intrinsic deficiencies may be made, but the sample is nonetheless incubated during transit to the test location.

Electronic Acknowledgement Receipt

EFS ID:	31248912
Application Number:	15844407
International Application Number:	
Confirmation Number:	5392
Title of Invention:	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES
First Named Inventor/Applicant Name:	Mansour Samadpour
Customer Number:	22504
Filer:	Barry Davison/Janet Berdine
Filer Authorized By:	Barry Davison
Attorney Docket Number:	0066090-003US2
Receipt Date:	15-DEC-2017
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Application Type:	Utility under 35 USC 111(a)

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RAM confirmation Number	121817INTEFSW00006104040258
Deposit Account	040258
Authorized User	Janet Berdine

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

National Beef Ex. 1008

Page 217 of 239

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2017-12-15_0066090-003US2_ ADS.pdf	1823282	no	8
			7cd5c5312f1c87a44a998bc90a522a8238d73691		
Warnings:					
Information:					
2	Drawings-only black and white line drawings	2017-12-15_0066090-003US2_ Drawings.pdf	1599514	no	11
			e4f95ac0af3cc3a1e5f195a760e85c2c488f115f		
Warnings:					
Information:					
3	Power of Attorney	2017-12-15_0066090-003US2_ POA.pdf	2086045	no	2
			37d3633c87e67a0a208ccc6e7f592255c5978316		
Warnings:					
Information:					
4		2017-12-15_0066090-003US2_ Preliminary__Amendment.pdf	147851	yes	13
			2bd0929e1270915d0f322ca1170895829d33bec6		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Preliminary Amendment		1	1	
	Specification		2	2	
	Claims		3	9	
	Applicant Arguments/Remarks Made in an Amendment		10	12	
	Abstract		13	13	
Warnings:					
Information:					
National Beef Ex. 1008 Page 218 of 239					

5		2017-12-15_0066090-003US2_Application.pdf	333287	yes	39						
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	Multipart Description/PDF files in .zip description										
	Document Description		Start	End							
	Specification		1	33							
	Claims		34	38							
	Abstract		39	39							
Warnings:											
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6	Fee Worksheet (SB06)	fee-info.pdf	38364	no	2						
			9892b13bac09bc92ab318577f833edf2039fa67c								
Warnings:											
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Total Files Size (in bytes):			6028343								
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor Information:

Inventor	1				Remove	
Legal Name						
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Dr. ☐	Mansour		Samadpour	☐		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
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Postal Code	98155	Country	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button. Add						

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	22504		
Email Address	patentdocket@dwt.com	Add Email	Remove Email

Application Information:

Title of the Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		
Attorney Docket Number	0066090-003US2	Small Entity Status Claimed	☐
Application Type	Nonprovisional ☐		
Subject Matter	Utility ☐		
Total Number of Drawing Sheets (if any)	11	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	22504		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	12/360646	2009-01-27

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		0066090-003US2	
		Application Number			
Title of Invention		ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES			
Prior Application Status		Patented		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12/360646	Continuation of	10/848253	2004-05-17	7531163	2009-05-12
Prior Application Status		Expired		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
10/848253	Claims benefit of provisional	60/470975	2003-05-16		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					Add

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This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

- ☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
- NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant	1	Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section. Clear		
Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
☐ Person to whom the inventor is obligated to assign.		☐ Person who shows sufficient proprietary interest
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		
Name of the Deceased or Legally Incapacitated Inventor:		
If the Applicant is an Organization check here. ☒		
Organization Name	Institute for Environmental Health, Inc.	
Mailing Address Information For Applicant:		
Address 1	15300 Bothell Way NE	
Address 2		
City	Lake Forest Park	State/Province WA
Country	US	Postal Code 98155
Phone Number		Fax Number
Email Address		
Additional Applicant Data may be generated within this form by selecting the Add button. Add		

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		

Assignee	1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.				
				Remove
If the Assignee or Non-Applicant Assignee is an Organization check here.				☐
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1				
Address 2				
City		State/Province		
Country ⁱ		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				Add

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Barry L. Davison/		Date (YYYY-MM-DD)	2017-12-15
First Name	Barry	Last Name	Davison, Ph.D., J.D.	Registration Number
				47,309
Additional Signature may be generated within this form by selecting the Add button.				Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	0066090-003US2
		Application Number	
Title of Invention	ENRICHMENT METHODS FOR THE DETECTION OF PATHOGENS AND OTHER MICROBES		

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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 records.
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.

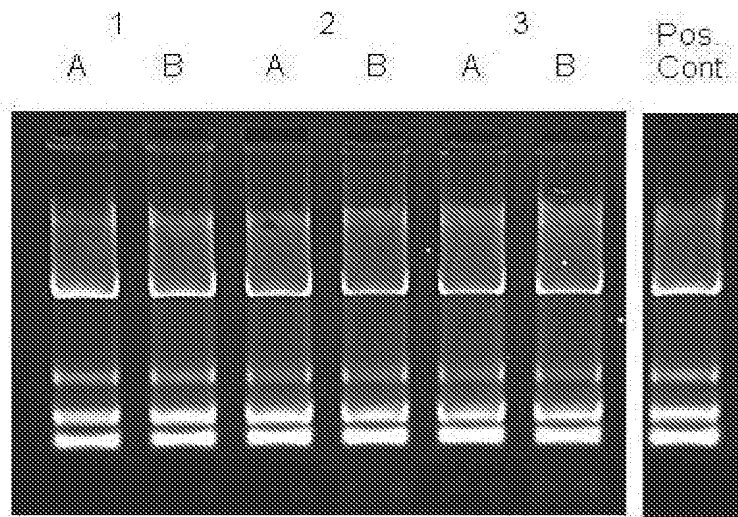


Figure 1

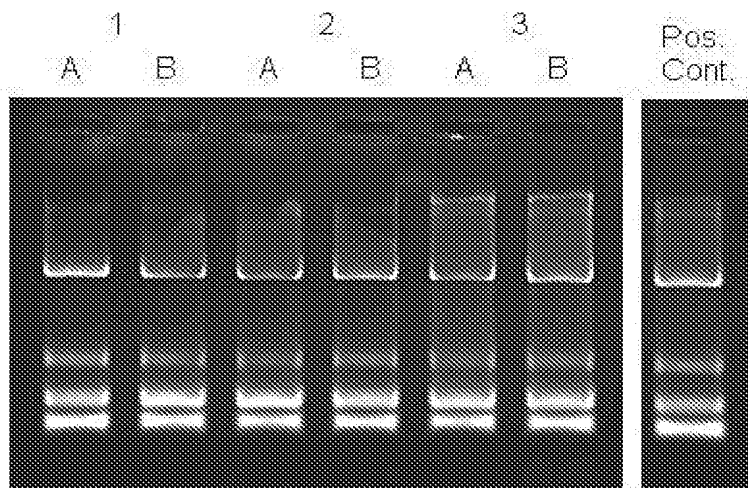


Figure 2

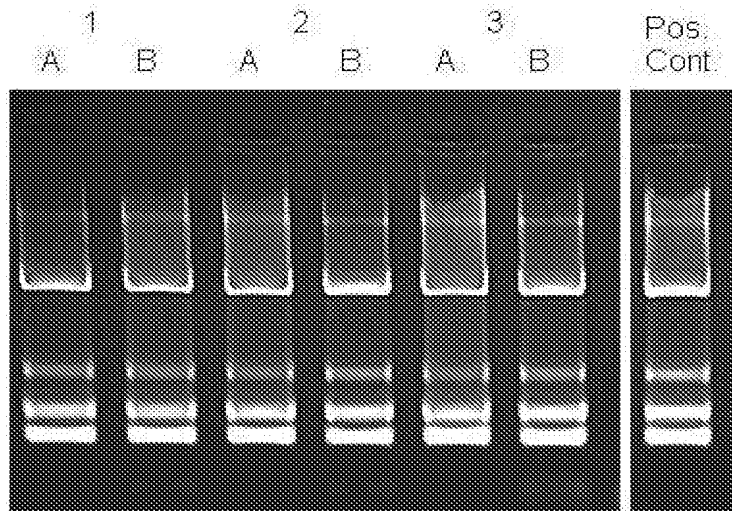


Figure 3

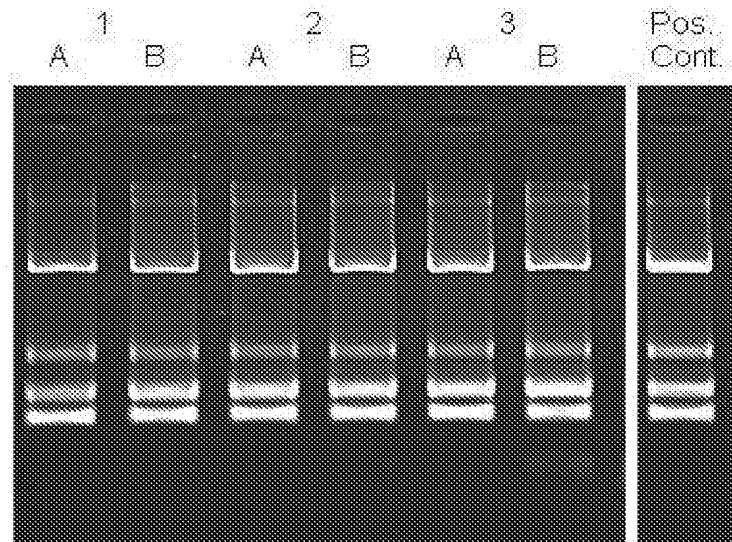


Figure 4

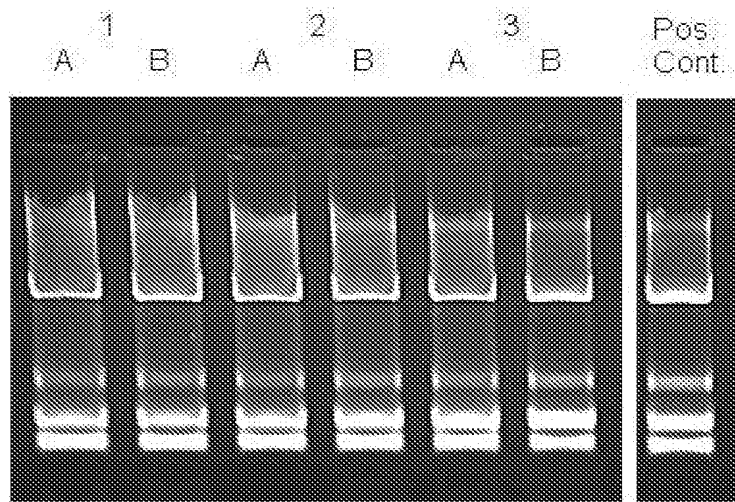


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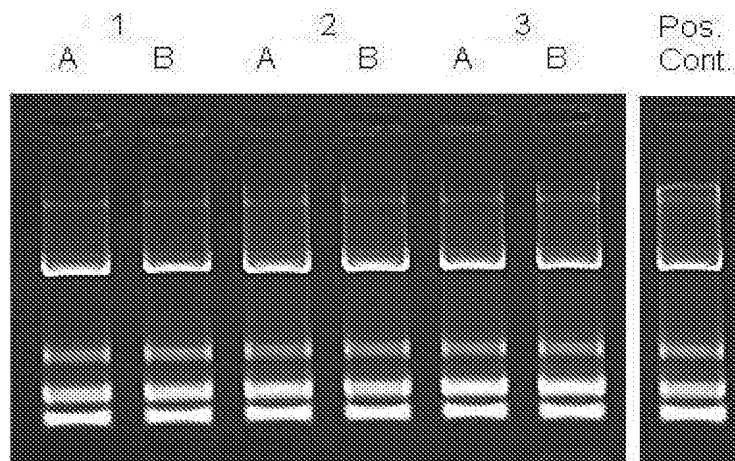


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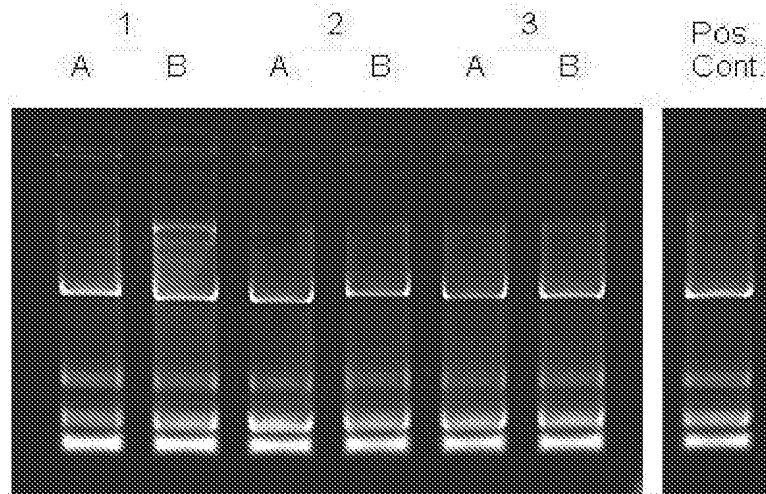


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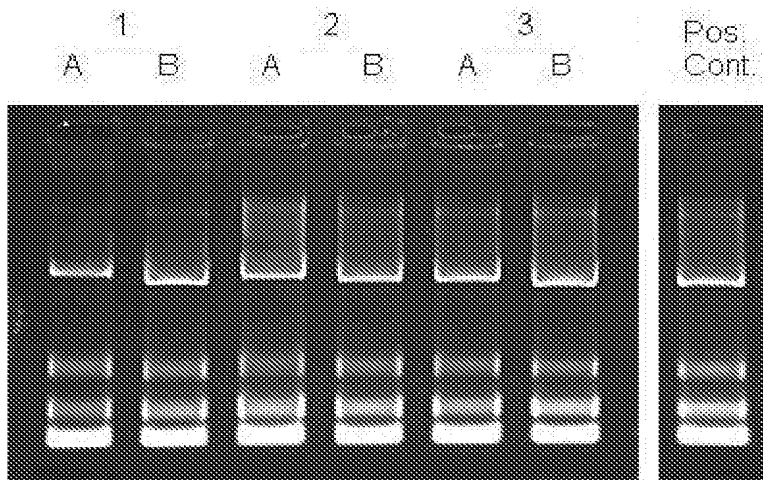


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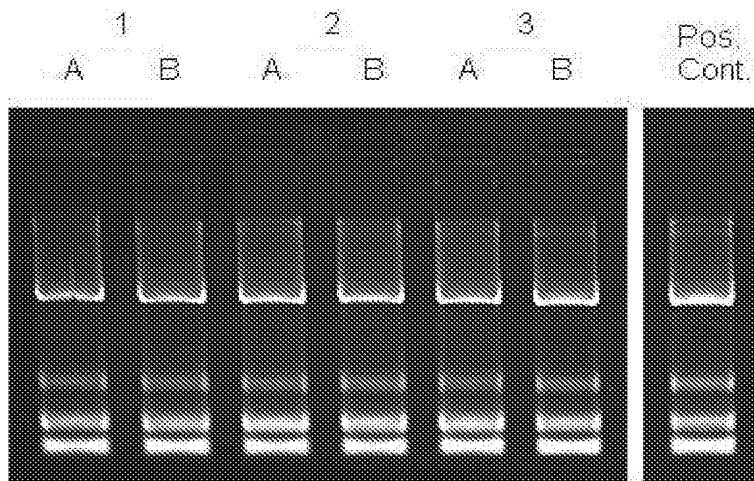


Figure 9

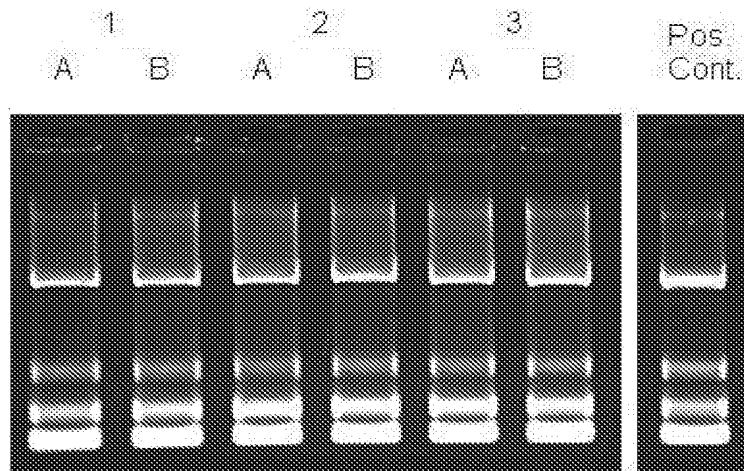


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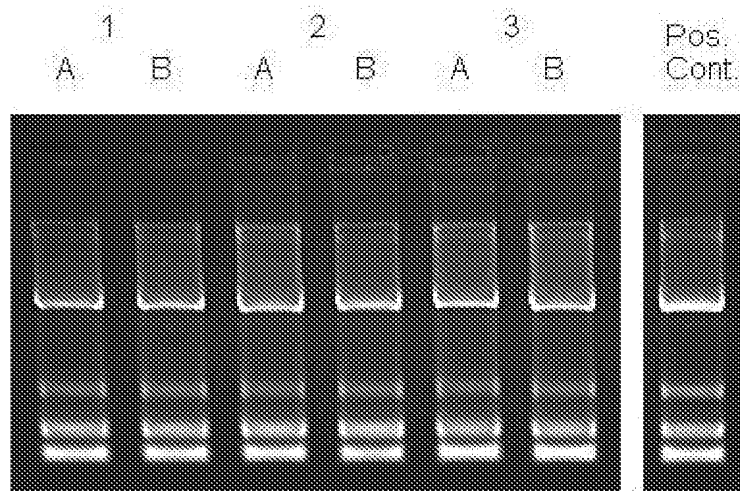


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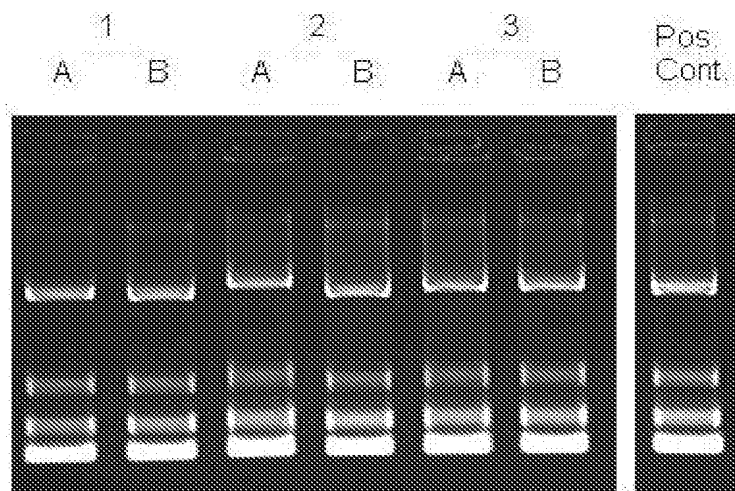


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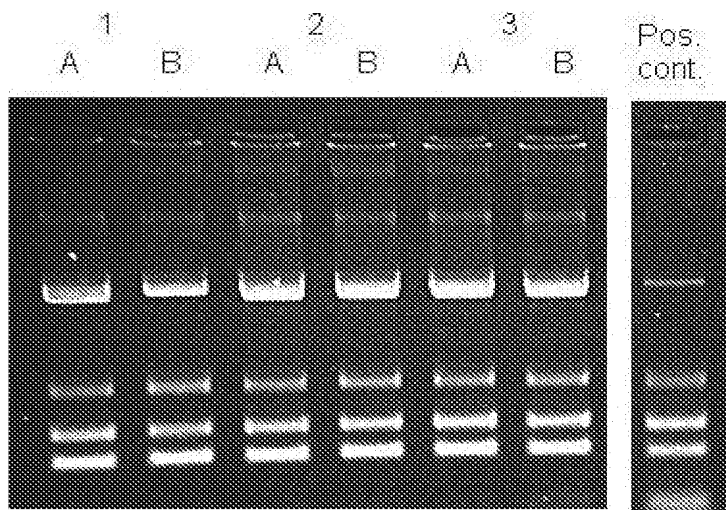


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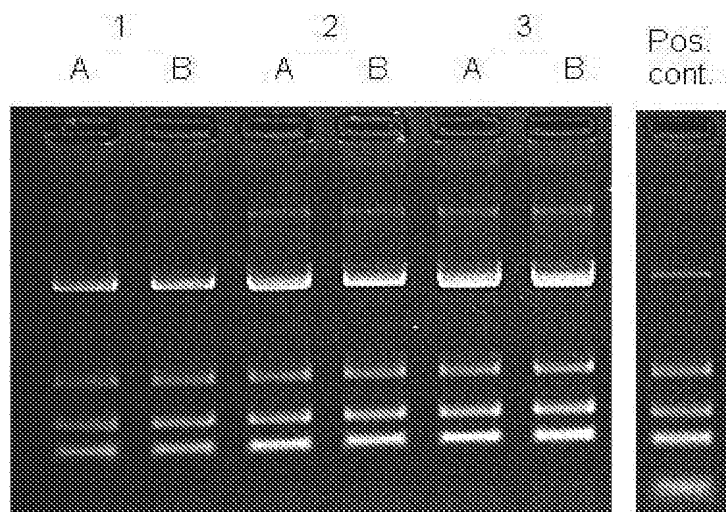


Figure 14

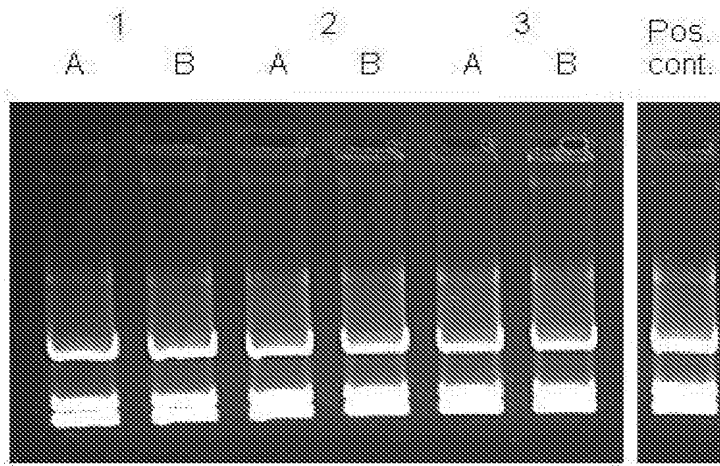


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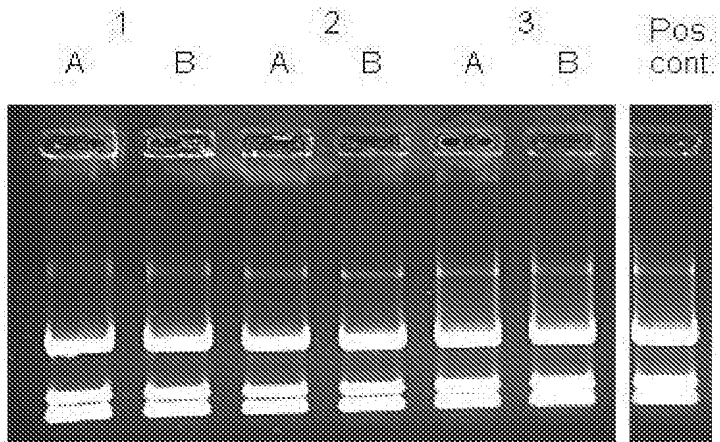


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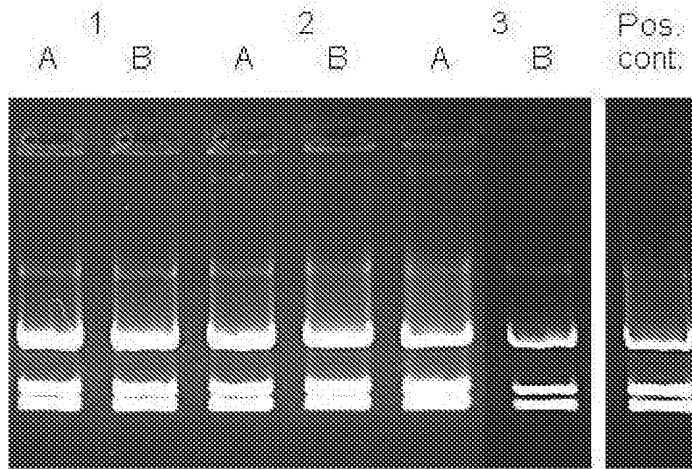


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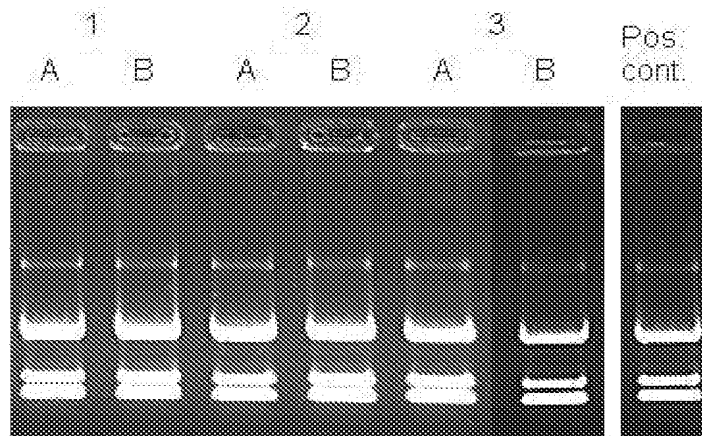


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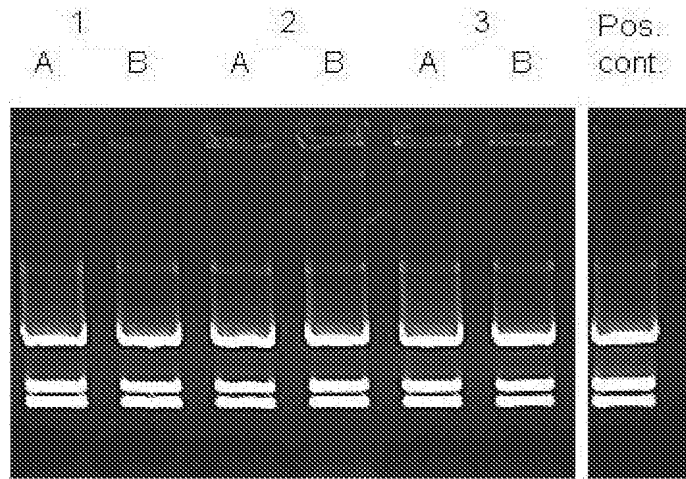


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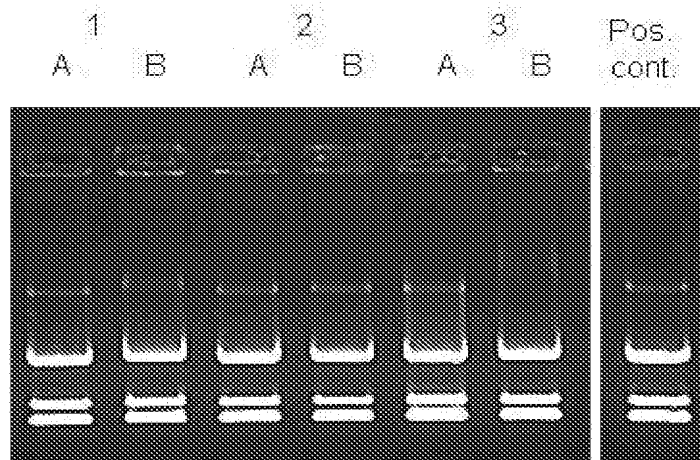


Figure 20

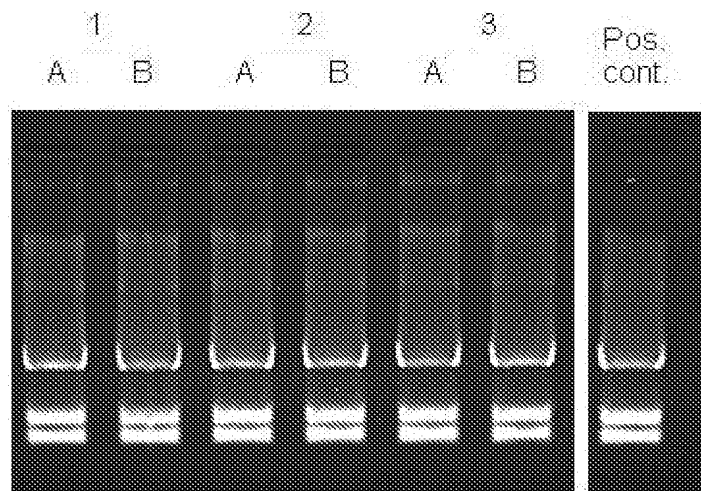


Figure 21

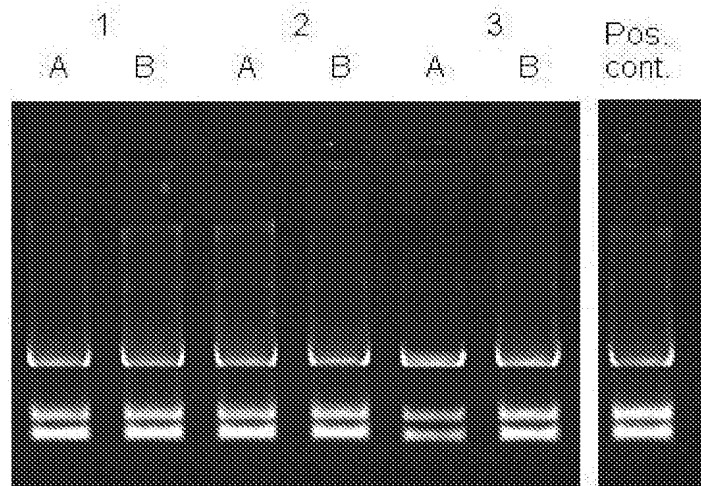


Figure 22

SCORE Placeholder Sheet for IFW Content

Application Number: 15844407

Document Date: 12/15/2017

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