

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 *****

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 *****

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6
7 GENEOSCOPY, INC.,

8 Petitioner

9 v.

10 EXACT SCIENCES CORPORATION,

11 Patent Owner

12
13 _____
Case IPR2024-01339

14 U.S. Patent No. 11,970,746

15
16 DEPOSITION OF DUNCAN H. WHITNEY, PhD,
17 called as a witness by and on behalf of Patent
18 Owner Exact Sciences Corporation, pursuant to 37
19 C.F.R., 42.53, of the United States Patent Trial
20 and Appeal Board, before Patricia Jodi Ohnemus,
21 RPR, RMR, CRR, CA-CSR #13192, NH-LSR #91, MA-CSR
22 #123193, and Notary Public within and for the
23 Commonwealth of Massachusetts, at Foley Hoag, 155
24 Seaport Avenue, Boston, Massachusetts, on Friday,
25 September 26, 2025, commencing at 10:00 a.m. EDT

Page 1

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I N D E X

TESTIMONY OF:	PAGE
DUNCAN H. WHITNEY, PhD.	
(By Ms. Fernands)	5

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E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
exhibit 1002	previously marked	6
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Exhibit 2054	press release: Geneoscopy New FDA-Approved Stool Collection Method Simplifies At-Home Colorectal Cancer Screening	29
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1 DUNCAN H. WHITNEY, PhD, having
2 satisfactorily been identified by
3 the production of a driver's license,
4 and being first duly sworn by the Notary
5 Public, was examined and testified as
6 follows to interrogatories
7 BY MS. FERNANDS:
8 Q. Good morning, Doctor Whitney.
9 A. Good morning.
10 Q. Could you please state your full name for
11 the record.
12 A. Duncan H. Whitney.
13 Q. Okay. You are at Foley Hoag today;
14 correct?
15 A. Yes.
16 Q. Is there anyone in the room with you?
17 A. Yes, Brendan Jones, counsel.
18 Q. All right. And is it just Brendan Jones?
19 A. Yes.
20 Q. And you are on a laptop for this remote
21 deposition today; correct?
22 A. I'm actually not on a laptop --
23 Q. Oh?
24 A. -- per se, but there's two screens here.
25 Q. So you are --

1 A. Oh, I guess I -- yeah. Yeah. Yeah. I
2 guess I am.

3 Q. You are on a computer for today's
4 deposition; is that right?

5 A. I'm on a computer, yes.

6 Q. Okay. Thank you.

7 And do you have any programs open on that
8 computer other than the Zoom meeting and the
9 Exhibit Share for the deposition?

10 A. I do not.

11 (Court Reporter comment.)

12 (Discussion off the record.)

13 (Question read back.)

14 A. That's correct. I do not.

15 Q. Okay. And in the Exhibit Share do you see
16 two exhibits right now, Exhibit 1002 and Exhibit
17 1086?

18 (Exhibit 1002, previously marked.)

19 (Exhibit 1086, previously marked.)

20 A. Yes, I see those.

21 Q. Do you also have any -- do you have any
22 hard copy documents there in the room with you?

23 A. I do. I have hard copies of both of those
24 exhibits.

25 Q. Okay. So you have a hard copy of Exhibit

1 1002, which was your declaration in this matter
2 that is -- and that was dated in August 20, 2024;
3 correct?

4 A. I don't believe I have a date on the
5 printed copy.

6 Q. Is there a signature page, page 20?

7 A. Oh, I'm sorry. Yup. Okay. (Witness
8 reviews document.)

9 Yes, so the signature is dated August
10 20th, 2024.

11 Q. Okay. And so the record is clear, that
12 one of the hard copy documents that you have in the
13 room with you is your declaration in IPR2024-10 --
14 1330, dated August 20, 2024?

15 A. That's correct.

16 Q. Okay. And then you also have in the room
17 with you in hard copy document called "Second
18 Declaration of Duncan Whitney in IPR2024-1330"
19 [verbatim]; is that correct?

20 A. That's correct.

21 Q. And that second declaration of Duncan
22 Whitney, that is dated August 21, 2025; is that
23 correct?

24 A. That's correct.

25 Q. And if you go to page 101 of that second

1 declaration --

2 A. Yes.

3 Q. -- and at page 101 of that second
4 declaration, is that your signature?

5 A. That is my signature, yes.

6 Q. Okay. If you could turn to the heading on
7 page 42 of your second declaration, Exhibit 1086.

8 MR. JONES: Anastasia, are you going to be
9 using -- there are two numbers, page numbers, on
10 this declaration.

11 MS. FERNANDS: Okay.

12 MR. JONES: One's Bates stamped and the
13 other --

14 MS. FERNANDS: That's an excellent --

15 MR. JONES: Can you tell me which one
16 you're going to use?

17 MS. FERNANDS: That's a good point. I was
18 actually looking at the -- not the Bates stamped
19 one but the actual page of the original
20 declaration, page 42. Thank you.

21 MR. JONES: Sorry for interrupting.

22 MS. FERNANDS: No need to apologize.

23 Q. So the question is clear, Doctor Whitney,
24 if you could go to page 42 as it is marked on the
25 declaration itself, a page that has a heading "B"

1 at the top of it.

2 Are you there?

3 A. Yes.

4 Q. Okay. And do you see on page 42, heading
5 B, the heading is "As of the Priority Date, at Home
6 Sample Separation was Routine"?

7 Do you see that?

8 A. Yes, I do.

9 Q. Okay. And then in paragraph 67 on the
10 next page, do you see in the second paragraph --
11 I'm sorry, the second sentence of paragraph 67 you
12 state (as read):

13 "For example, by the priority date,
14 at-home sample separation was a standard feature of
15 FIT tests like the one disclosed in Vilkin which
16 required a patient to separate a small portion of
17 the fecal portion that was to be shipped to the
18 diagnostic laboratory for testing from the rest of
19 the specimen which was discarded."

20 Do you see that?

21 A. Yes.

22 Q. And it's your opinion that, as of the
23 priority date for the '746 patent, sample
24 separation at home was routine; is that correct?

25 A. That's correct. Yes.

1 Q. And what do you mean by "routine" in that?

2 A. What I mean is that that was a common --
3 it was commonly done, is, to separate out a portion
4 of a stool sample for -- at home for sending in a
5 sample for testing for colorectal cancer testing.

6 Q. And when you refer to at-home sample
7 separation, what do you mean by that?

8 A. Meaning that a subject who was being
9 tested for colorectal cancer would produce a sample
10 at home and take a sample of that particular fecal
11 sample to be sent in to a lab.

12 Q. That's a lot of use of the word sample in
13 there.

14 When you say "take a sample of that
15 particular fecal sample," could you describe what
16 that entailed?

17 A. In that context, the context of taking a
18 sample, in this case specifically in reference to a
19 FIT test, would be to abide by the instructions
20 typically accompanying the -- the device or the
21 test itself, which would involve using a spatula or
22 some type of device to take a small portion of the
23 total stool sample to then be put into another
24 tube, typically that contained a preservative or a
25 stabilizing buffer.

1 Q. And after a spatula or other device is
2 used to take a small portion of the stool sample to
3 put into another container, what is done with the
4 remainder of the stool sample in this example with
5 the FIT test?

6 A. With a FIT test, typically the remainder
7 of that sample would be discarded if one were only
8 testing -- if one were only looking at using a FIT
9 test as the colorectal cancer screening, then that
10 portion that was taken and split out at home
11 obviously would be put into that device and the
12 remainder of that sample would be discarded.

13 Q. So -- and so you distinguished there in
14 connection -- with respect to the FIT test.

15 With respect to the claims of the '746
16 patent you're addressing in this, what is done with
17 the portion from which the -- what is done with the
18 remainder of the sample after a portion is taken
19 out using a spatula?

20 A. I'm not sure what you're asking. You're
21 asking me what is done in the context of the '746
22 patent itself?

23 Q. Yes. If you have an understanding. Yeah,
24 you distinguish between FIT test and other
25 instances. So let me ask a cleaner question:

1 Why did you distinguish between -- in this
2 instance of the FIT test -- or other types of
3 tests?

4 A. I'm not sure I intended to make a
5 distinction between different FIT tests.

6 Q. When I asked what is done with the
7 remainder of the sample after a spatula is used to
8 remove some of it, you said that in the FIT -- FIT
9 test circumstance that is discarded; is that
10 correct?

11 A. If one were only running a FIT test --
12 what I meant to say is that if one were only
13 running a FIT test, a portion which is required to
14 run that test is relatively small. So one would
15 take that portion, put it into the -- the
16 stabilization buffer which comes with the device,
17 and remainder of the sample would be discarded.

18 Q. Okay. And if one were running a FIT test
19 and a nucleic acid test on the sample -- on a
20 sample, what -- what would happen to the portion
21 from which the FIT test sample is taken?

22 A. I think it depends on the specific example
23 that you're referring to of a combination.

24 Q. So looking again at the sentence in
25 paragraph 67, that -- the second sentence that I

1 read earlier, when you say that "Vilkin required a
2 patient to separate a small portion of the fecal
3 portion that was shipped -- was to be shipped to
4 the diagnostic laboratory for testing," is that
5 referring to the small portion being shipped to the
6 diagnostic laboratory for testing; correct?

7 A. Let me read that.

8 (Witness reviews document.) Yes. In this
9 case what that's referring to is that the -- the
10 portion which was taken for the FIT test is a small
11 portion.

12 Q. And that small portion gets removed from
13 the sample with a spatula, is then inserted into
14 some form of container to be sent to the lab; is
15 that right?

16 A. That's correct.

17 Q. Now, in paragraph 68 on the next page, you
18 see your statement, you -- you state (as read):

19 "...I disagree with Doctor Backman's
20 assertion that a POSA in 2009 would not use
21 separate buffers to stabilize fecal DNA and fecal
22 blood proteins when performing a combined assay
23 that tests for both biomarker types."

24 Do you see that?

25 A. I see it, yes.

1 Q. Yeah. And is it your opinion that as of
2 2009 two different stabilizing buffers would have
3 been necessary to stabilize both nucleic acid and
4 hemoglobin?

5 MR. JONES: Objection.

6 A. I think -- well, first of all, I think it
7 depends, again, on -- on which is the specific test
8 that we're talking about, and so we can get into
9 that details, perhaps, but I think that in terms of
10 the -- the other side of that is that I am not
11 aware of any buffer that was available that could
12 be used to stabilize both hemoglobin and DNA in an
13 optimized sort of way in order to be able to run
14 both of those tests in a clinically effective
15 manner.

16 Q. You said that you are not aware of any
17 buffer.

18 Is it your opinion that there was no
19 buffer as of 2009 that would have stabilized both
20 DNA and hemoglobin in a stool sample?

21 A. No, I'm not sure that I'm saying that --
22 well, maybe I am saying that.

23 I -- what I am saying is that in order to
24 be able to run both a hemoglobin-based test as well
25 as a DNA-based test for use in colorectal cancer

1 screening from fecal samples, that it's imperative
2 that both of those analytes are properly preserved.
3 I believe that there very well may have been
4 buffers that were available and perhaps have been
5 described as potentially providing some
6 stabilization, but not necessarily optimized buffer
7 solutions that could be used for both of those
8 analytes.

9 Q. So, in your opinion, there may have been
10 buffers that could have stabilized both nucleic
11 acid and hemoglobin in stool in 2009; correct?

12 A. What I'm saying is that I'm allowing for
13 the realm of possibilities, but I'm also saying
14 that in order for a test to be effective as a
15 screening test, it's imperative that both of those
16 types of analytes are properly preserved. I'm not
17 aware of any data that shows that there is a single
18 buffer that could stabilize both of those types of
19 analytes in a way that's been demonstrated to be
20 useful in colorectal cancer screening.

21 Q. And, in your opinion, is it imperative
22 that a buffer be shown to stabilize the analyte in
23 a way that is effective in colorectal cancer
24 screening?

25 A. My opinion -- and I think most people --

1 experts in this field would -- would say that
2 the -- it's imperative that there's some data to
3 provide for a reasonable expectation that there
4 would be stabilization of both of these types of --
5 of analytes and that, if that data did not exist,
6 then I would think that a -- someone skilled in the
7 art would want to try to generate that data; but I
8 also think that, if there were data which had been
9 described in the literature, that that may in fact
10 provide sufficient expectations for success.

11 Q. And when you say it's imperative --
12 imperative that there be some data, in your
13 opinion, must there be some data for each analyte?

14 A. I think that's a very broad question.
15 Maybe you could break that down a little more?

16 Q. Okay. You said that, in your opinion,
17 it's imperative that there be some data to provide
18 reasonable expectation that the buffer would
19 stabilize the analyte; correct?

20 A. What -- what I'm saying is that if one --
21 I'm putting this into the -- the hype- -- the
22 hypothetical situation that we're talking about.

23 If -- if one were seeking to be able to
24 rely on DNA and hemoglobin biomarkers for the sake
25 of CRC detection or screening, that it's

1 imperative -- it's very important that both of
2 those types of analytes are optimally stabilized so
3 that we would not incur a particularly high number
4 of false negatives.

5 Q. For purposes of a person of ordinary skill
6 in the art seeking to develop a CRC test in 2009,
7 is it your opinion that that person of ordinary
8 skill in the art would require some data concerning
9 any particular analyte before being able --
10 motivated to use that analyte?

11 MR. JONES: Objection.

12 A. I'm not sure I understand the question.

13 Q. I'm sorry.

14 So it is your opinion that it would be
15 imperative that there be some data concerning the
16 ability of a buffer to stabilize the analyte of
17 interest; correct?

18 A. Yes, if one were relying on those analytes
19 for detection of cancer.

20 Q. And is it your position that -- is it your
21 opinion that, as of 2009, the person of ordinary
22 skill in the art seeking to develop a CRC screening
23 test would not be motivated to use a buffer unless
24 there was already some data for that buffer being
25 used with that analyte in stool samples?

1 MR. JONES: Objection.

2 A. I -- I think -- what I'm -- what I'm
3 saying is that, in order to be able to rely on the
4 detectability of both of these types of analytes so
5 that they could be used clinically to detect those
6 as a way of measuring colorectal cancer, that it's
7 a -- necessarily means that they should not be so
8 degraded that we can't detect them. So therefore
9 they need to be stabilized.

10 Q. Is it your opinion that a person in
11 2009 -- strike that.

12 Is it your opinion that a person of skill
13 in the art in 2009 would not be motivated to use a
14 buffer for CR -- for preservation of an analyte for
15 CRC cancer screening unless data already existed
16 for that particular buffer in combination with the
17 analyte of interest?

18 MR. JONES: Objection.

19 A. I think that in order to have a reasonable
20 expectation of success, a person of skill in the
21 art would want to have some predictability as to
22 whether or not a particular buffer would be
23 effective or not for a particular analyte.

24 Q. And, in your opinion, would the person of
25 ordinary skill in the art required -- require data

1 for the specific buffer, in combination with the
2 specific analyte, to have that predictability?

3 MR. JONES: Objection.

4 A. I -- I think that a person of skill in the
5 art would typically rely on data. The data would
6 not necessarily need to come from that
7 particular -- it wouldn't need to come from that
8 particular person. You know, person of -- skilled
9 in the art would typically be expected and be able
10 to interpret published data and, in some cases, be
11 able to convince themselves that there's -- based
12 on experiments that other people have done, that
13 there is a reasonable expectation that there would
14 be a successful outcome to -- to trying something.

15 If -- if that data did not already exist
16 in -- in the literature, then that person may want
17 to design experiments to test it themselves and
18 generate their own data.

19 Q. Is it your opinion, though, that a person
20 of ordinary skill in the art in 2009 would require
21 data, regardless of the source of the data,
22 concerning the specific buffer and the analyte of
23 interest in order to have a reasonable expectation
24 of success in preserving that analyte?

25 MR. JONES: Objection.

1 A. It depends on how we're defining data.
2 That's a very broad term. But there would need to
3 be some information available to provide convincing
4 evidence that a particular buffer would be
5 effective.

6 Q. In your opinion, what type of information
7 is necessary to provide convincing evidence that a
8 buffer is effective?

9 MR. JONES: Objection.

10 A. Again, that's a very broad question, but
11 in a very broad sense, I would say that a person
12 would want -- a -- a skilled person would want to
13 see either some type of large study -- actually,
14 the size of the study doesn't really matter.

15 They would want to see a study which
16 deploys the -- the buffers in question in some way
17 and that there is some evidence that the buffer is
18 doing what it's supposed to do.

19 Q. You say deploys the buffer in question in
20 some way. Would the study require, in your
21 opinion, that the buffer be used with the analyte
22 of interest?

23 MR. JONES: Objection.

24 Go ahead.

25 A. I -- yeah, the -- the question is -- is

1 difficult for me to answer only because we're
2 talking in very broad, general ways.

3 I think, you know, to get a little bit
4 down to -- a little bit more granular level, if one
5 wanted to look at the stability of DNA in human
6 fecal samples, one would be interested in knowing
7 which buffers would be effective at preserving that
8 DNA and perhaps furthermore showing that the buffer
9 was -- had been analyzed in a way that you could
10 actually characterize the DNA which is coming out
11 of that fecal sample, as an example.

12 Q. If you'd turn to paragraph 73 of your
13 declaration. It is Exhibit 1086.

14 A. Yes.

15 I'm sorry. Paragraph 73?

16 Q. Paragraph 73, yes.

17 A. Okay.

18 Q. Do you see the last sentence of the
19 paragraph 73 you state (as read):

20 "Indeed, it is telling that, even today,
21 Exact uses separate DNA on hemoglobin stabilizing
22 buffers in its Cologuard test despite the purported
23 advantages of using a single buffer."

24 Do you see that?

25 A. Yes.

1 Q. Now, you refer to -- all right.

2 So the Exact test, as it exists today,
3 that's Cologuard; correct?

4 A. Yes.

5 Q. And the Cologuard test, as it exists
6 today, requires the at-home separation of the stool
7 sample into two separate containers.

8 Is that your understanding?

9 A. That's my understanding.

10 Q. Okay. Why do you point out in your
11 declaration that is Exhibit 1086 that "Exact still
12 today uses separate DNA and hemoglobin in
13 stabilizing buffers"?

14 A. This statement is meant to reflect the
15 fact that, you know, there -- there is a -- an
16 argument which has been put forth to say that one
17 might be able to readily use a single buffer to
18 stabilize DNA and protein in a fecal sample for CRC
19 detection and that it -- it's pointing out, if we
20 look all the way up to -- and this is referring to
21 what was available as far as information back in
22 the priority date time frame, but just pointing out
23 that, even today, if it were that simple, then one
24 would think that Exact would have deployed that
25 type of approach, particularly since there are

1 other arguments that have been put forth that,
2 without doing -- or with doing that separation,
3 that it adds cost and complexities to the test.

4 Q. Do you disagree that having the at-home
5 user separate the fecal sample adds costs and
6 complexity to the test?

7 A. Do I disagree?

8 I -- I believe that the step of separating
9 a sample was -- has been routine since the
10 development of noninvasive colorectal cancer
11 screening tests from pretty much day one and that
12 what we're talking about here is -- in the case of
13 Cologuard -- is a test which admittedly improves on
14 the accuracy of a FIT test alone or an FOBT test
15 alone, but I don't regard that as adding cost and
16 complexity compared to what people have been doing
17 for decades.

18 Q. Would you agree that at-home separation is
19 an undesirable step if it can be avoided?

20 MR. JONES: Objection.

21 A. No, not necessarily.

22 Q. You think that it's desirable to require
23 the at-home user to use a spatula to separate a
24 portion of their stool sample?

25 MR. JONES: Objection.

1 A. What I think is most important is that
2 tests are developed that provide for the best
3 accuracy. If those tests require an at-home
4 separation and it's a relatively minimal added
5 step, I -- I don't believe that that's a
6 disincentive.

7 Q. And you think that the at-home separation
8 of the stool sample is a relatively minimal added
9 step?

10 A. Are we still talking about Cologuard?

11 Q. We're talking about any at-home test where
12 the user is asked to separate their stool sample.

13 In your opinion, is that a relatively
14 minimal added step?

15 MR. JONES: Objection.

16 A. I think it depends entirely on the
17 specific test that I'm talking about. I'm -- if I
18 gave you the impression that I was talking
19 generally, then that's my mistake.

20 What I was -- what I thought we were
21 referring to, since we had brought up this point in
22 the declaration, was the reference to Cologuard
23 specifically.

24 Q. So in reference to Cologuard specifically,
25 you think that the separation of the stool sample

1 is a relatively minimal added step; is that
2 correct?

3 A. That's correct.

4 Q. In other circumstances you think that the
5 separation of the stool sample would not be a
6 relatively minimal added step; is that correct?

7 MR. JONES: Objection.

8 A. Again, I think it depends on exactly what
9 the situation is that we're talking about. It's
10 nearly impossible to answer that question without
11 knowing those details.

12 Q. Knowing the detail of the type of test is
13 important to knowing whether or not it's a
14 relatively minimal added step to require separation
15 of the stool sample?

16 A. Yes. I would agree with that.

17 Q. In paragraph 43 -- I'm sorry. In
18 paragraph 73, that sentence we're looking at, you
19 refer to the "purported advantages of using a
20 single buffer."

21 Do you say -- see that?

22 The last sentence.

23 A. (Witness reviews document.) Yes.

24 Q. Why do you say "purported advantages"?

25 A. What I mean by that is that I'm not

1 aware -- I think we talked about this a little bit
2 earlier -- I'm not aware of a single buffer which
3 is used -- used to stabilize DNA and protein, if
4 I'm reading that correctly.

5 (Witness reviews document.) Yeah. So
6 purported meaning that it's a hypothetical that, if
7 one could use a single buffer, perhaps that would
8 be easier. Again, in a relative sense, I don't
9 think that the separation in this case for
10 Cologuard is a -- is a major inconvenience, but if
11 one could come up with a single buffer that could
12 circumvent the need for that, that that would be a
13 purported advantage, but I'm not aware of any
14 buffers that have been described that allow that to
15 happen.

16 Q. Would you agree that the separation of the
17 stool sample to remove a portion of the sample for
18 use of the Cologuard test is the most confusing
19 step of Cologuard?

20 MR. JONES: Objection.

21 A. The most confusing?

22 Q. For the at-home user.

23 A. For the user.

24 I don't know that I have a strong opinion
25 about that one way or the other.

1 Q. Would you agree that having the at-home
2 user scrape the stool sample to remove a portion of
3 the sample is the most undesirable portion of the
4 at-home use of a test where -- such as in the
5 Cologuard configuration?

6 MR. JONES: Objection.

7 A. My -- my assessment of the science here --
8 what you're describing is trying to -- I think --
9 get some type of assessment from the users
10 themselves as to the desirability of using this
11 test. I've not talked to a lot of the users
12 firsthand other than family members who have used
13 the test successfully, and I'm not aware of how a
14 typical user might feel, other than what's been
15 published.

16 Q. You've been engaged by Geneoscopy in this
17 litigation -- in this IPR proceeding; correct?

18 A. Correct.

19 Q. When were you originally engaged by
20 Geneoscopy?

21 A. Oh, jeez. I -- I believe it was late
22 2023.

23 Q. And are you aware that Geneoscopy has a
24 CRC screening test that it calls ColoSense?

25 A. Yes, I'm aware.

1 Q. And are you aware that Geneoscopy
2 initially sought FDA approval of a ColoSense test
3 that required at-home separation of the stool
4 sample?

5 MR. JONES: Objection. Scope.

6 A. I'm sorry. Could you repeat the question?

7 Q. Are you aware that Geneoscopy sought FDA
8 approval of an at-home screening test that required
9 separation of the stool sample?

10 MR. JONES: Objection. Scope.

11 A. I'm aware that they had originally
12 developed a test for colorectal cancer screening
13 that required the separation of a sample at home.

14 Q. And in your declaration on -- that is
15 Exhibit 1086 on paragraph 143, you responded to
16 Doctor Backman's opinions concerning copying by
17 others; correct?

18 A. I'm sorry. Could you give me that page
19 number again.

20 Q. Paragraph 143 on page 96 as originally
21 numbered.

22 A. I did respond, yes.

23 Q. Okay. And in connection with that
24 response did you review Doctor Backman's analysis
25 of ColoSense practicing the '746 patent?

1 MR. JONES: Objection.

2 A. I believe I did. I have not -- I've not
3 reviewed that recently.

4 MS. FERNANDS: I'm going to put an exhibit
5 into the Exhibit Share.

6 Q. Other than reviewing Doctor Backman's
7 declaration, in connection with your opinions in
8 this matter did you review any other material
9 concerning Geneoscopy's ColoSense product?

10 A. I -- I had seen documents related to
11 ColoSense.

12 (Exhibit 2054, press release: Geneoscopy
13 New FDA-Approved Stool Collection Method
14 Simplifies At-Home Colorectal Cancer
15 Screening.)

16 Q. Do you recall what documents you have seen
17 related to ColoSense?

18 A. No. I don't recall specific documents
19 at -- at this moment as far as what I reviewed.

20 MS. FERNANDS: So I've added to the
21 Exhibit Share an exhibit we've marked as Exhibit
22 2054.

23 Q. Do you have that?

24 A. I see that, yes.

25 Q. Okay.

1 MR. JONES: I object to this exhibit for
2 relevance, hearsay, prejudice.

3 Go ahead.

4 Q. Doctor Whitney, have you seen this press
5 release before today?

6 A. I'm sorry. I've opened the wrong thing.
7 (Witness reviews document.)

8 MR. JONES: Objection. Relevance -- I
9 mean, objection. Scope.

10 A. Ah. Here we go. (Witness reviews
11 document.) Let me review it quickly.

12 To answer the question, I don't know if I
13 have seen this specific document, but I have -- I
14 have read documents that provide a similar message.

15 MS. FERNANDS: And for the record --

16 A. There may have been a -- sorry.

17 It may have been a web page. I'm not
18 sure.

19 MS. FERNANDS: For the record, Exhibit
20 2054 is a document downloaded from the Geneoscopy
21 website. And it is titled "Geneoscopy's New
22 FDA-Approved Stool Collection Method Simplifies
23 At-Home Colorectal Cancer Screening" and is dated
24 July 24, 2025.

25 MR. JONES: Objection to the scope.

1 Q. Doctor Whitney, when you testified that
2 you have seen documents with a similar message,
3 what similar message did you mean?

4 A. I -- I had seen announcements somewhere
5 indicating that they had FDA approval of a modified
6 method for collecting samples.

7 Q. And is it your understanding that that
8 modified method for collecting samples no longer
9 requires patients to separate their sample into
10 multiple containers at home?

11 MR. JONES: Objection. Scope.

12 A. For -- for this -- for the specific
13 application of the ColoSense test for colorectal
14 cancer screening, my understanding was that the
15 announcement was related to what you described; is
16 that, the at-home separation of a sample was not
17 required; that a single buffer could be used to
18 stabilize analytes used in the test.

19 Q. On what do you base your understanding
20 that a single buffer could be used to stabilize the
21 analytes?

22 COURT REPORTER: I think the end of your
23 question got cut off.

24 (Question read back.)

25 Q. Let me restate the question.

1 On what do you base your understanding
2 that a single buffer could be used in the new
3 redesigned ColoSense test?

4 MR. JONES: Objection. Scope.

5 And I caution the witness to the extent
6 that he -- not to reveal contents of conversations
7 with counsel. To the extent you can answer the
8 question without revealing contents of
9 conversations with counsel, to go ahead and answer.

10 A. My understanding was, in reading the press
11 releases or whatever it was that I had seen, was
12 that there was a new method for collecting samples;
13 that the data seemed to be quite positive and based
14 simply on the fact that using a single buffer one
15 could get high sensitivity and specificity for the
16 ColoSense test, that -- that that would be an
17 effective way of being able to collect samples.

18 I don't try to represent the data any
19 further than that.

20 Q. How did you become aware that the
21 redesigned ColoSense test used a single buffer?

22 MR. JONES: Objection.

23 MS. FERNANDS: I'm not asking for
24 privileged communications.

25 MR. JONES: Objection. Scope.

1 A. I believe I was informed by counsel at --
2 at the very first insistence.

3 Q. And you also referred to having
4 reviewed --

5 MR. JONES: Can I just object to the last
6 answer is that inadvert- -- he revealed the
7 contents of conversations with counsel.

8 Q. I believe in an earlier answer you
9 referred to having read either press releases or
10 other public information concerning the new
11 redesigned ColoSense test; correct?

12 A. I have.

13 Q. Do you recall when you read that public
14 information concerning the new redesigned ColoSense
15 test?

16 MR. JONES: Objection. Scope.

17 A. No, not exactly, no.

18 Q. Do you recall whether it was before you
19 submitted your second declaration which is dated
20 August 21, 2025?

21 MR. JONES: Objection. Scope.

22 A. I -- like I said, I don't recall exactly
23 when I read what I read.

24 Q. And in your declaration that's dated
25 August 21, 2025, as we discussed, you pointed out

1 in paragraph 73 that Exact still uses separate DNA
2 and hemoglobin stabilizing buffers; correct?

3 MR. JONES: Objection to form.

4 A. I think -- I think we've read that
5 sentence previously, and so as written, yes.

6 Q. You did not also point out that Geneoscopy
7 has now designed a test using the same buffer; is
8 that correct?

9 MR. JONES: Objection. Form.

10 A. I don't believe that's written anywhere in
11 this declaration.

12 Q. Do you know whether you were aware of that
13 fact before you submitted this declaration?

14 A. I do not, as I stated already.

15 Q. So turning to the document that we've
16 marked -- that I've marked as Exhibit 2054, the
17 press release from Geneoscopy dated July 24, 2025.

18 Do you see in the second sentence of the
19 press release it states (as read):

20 "The newly approved collection kit no
21 longer requires patients to separate their samples
22 into multiple containers"?

23 MR. JONES: Objection to scope.

24 A. I see the sentence, yes.

25 Q. Yeah. Do you see the next sentence, it

1 says (as read):

2 "This improves ease of use and reduces
3 barriers to at-home screening while maintaining
4 clinical performance"?

5 MR. JONES: Objection to scope.

6 A. I see that, yes.

7 Q. And would you agree that a collection kit
8 that does not require patients to separate their
9 samples into multiple -- multiple containers
10 improves ease of use?

11 A. I -- I think we've already talked about
12 this. I -- I think that the separation of a stool
13 sample in the context of either Cologuard or
14 ColoSense are relative statements and relative
15 degrees of inconvenience.

16 What I -- as -- as a person skilled in the
17 art, what I firmly believe is that the thing that
18 is of primary importance is diagnostic accuracy and
19 getting people to believe in a test result; and
20 although there may be some improvement, I wouldn't
21 say that I disagree with that statement, but I
22 don't believe that it's a very strong driver one
23 way or the other.

24 Q. You do not believe that whether a patient
25 has to separate their sample into multiple --

1 strike that.

2 You do not believe that whether a patient
3 has to separate their sample into multiple
4 containers is a strong driver?

5 A. I'll put it in my words.

6 What I'm saying is that diagnostic
7 accuracy, in my opinion, is perhaps the strongest
8 driver. It's the -- the most important thing is to
9 avoid false negatives. I believe that a test that
10 does or does not require a separation of a sample
11 at home depends on how that separation is done, but
12 assuming that we're talking about Cologuard and
13 ColoSense, I think that that added step is a
14 relatively minor inconvenience to a patient
15 relative to getting an accurate result.

16 Q. When you said that diagnostic accuracy is
17 the strongest driver, in your opinion, how are you
18 defining diagnostic accuracy?

19 A. Diagnostic accuracy, the way I would
20 describe that, is the sensitivity and specificity
21 of a test, among other things.

22 Q. What other things?

23 A. There's other ways that people could
24 interpret those inherent properties of a diagnostic
25 test, such as reporting out a negative predictive

1 value or a positive predictive value, likelihood
2 ratios, and a variety of other ways of interpreting
3 that same data.

4 Q. So looking back at the Geneoscopy press
5 release that was marked Exhibit 2054 from July of
6 2025, it also states that "this improves --"

7 It states that the fact that the
8 collection kit no longer requires patients to
9 separate their sample into multiple containers
10 reduces barriers to at-home screening.

11 Do you see that?

12 MR. JONES: Objection. Both to scope and
13 to form.

14 A. So you are talking about still the first
15 paragraph?

16 Q. Yeah. So if we go back to the first
17 paragraph, the second sentence of the first
18 paragraph points out that the (as read):

19 "The newly approved collection kit no
20 longer requires patients to separate their sample
21 into multiple containers."

22 Correct?

23 A. Correct.

24 Q. And would you agree that a collection kit
25 that does not require patients to separate their

1 samples into multiple containers would reduce
2 barriers to at-home screening?

3 MR. JONES: Objection to scope.

4 A. I think it's another way of asking the
5 same question which you have already asked, which
6 is do I believe that the -- this would impact the
7 at-home screening of the user; and, again, I think
8 it's a matter of relative importance.

9 So I think that there may be some people
10 that absolutely would not run this type of test if
11 they have to separate the sample at home.

12 (Jennifer Duke joined the Zoom.)

13 A. But I think that that's a relatively minor
14 barrier to -- to use of these kinds of tests and to
15 doing at-home screening relative to test accuracy.

16 Q. Do you see in the second paragraph of this
17 July 24, 2025, press release from Geneoscopy there
18 is a quote attributed to Dr. Erica Barnell?

19 MR. JONES: Objection as to scope.

20 A. I see two quotes.

21 Q. Do you see the first one?

22 A. Yes.

23 Q. And the first quote there states (as
24 read):

25 "We've taken a critical step toward

1 improving the at-home colorectal cancer screening
2 experience by removing one of the most burdensome
3 aspects for patients -- the scraping of stool."

4 Do you see that?

5 A. I see.

6 MR. JONES: Objection to scope.

7 A. Yes, I see that.

8 Q. And that point is attributed to Dr. Erica
9 Barnell; correct?

10 MR. JONES: Objection to scope.

11 A. Yes.

12 Q. Do you agree that the scraping of stool is
13 one of the most burdensome aspects for patients of
14 the at-home colorectal cancer screening experience?

15 MR. JONES: Objection to scope.

16 A. I -- I think this is a -- a very similar
17 kind of question. So my belief, as I think I --
18 I've tried to state very clearly, is that I think
19 the thing that is most important for an accurate
20 test -- or sorry -- for -- for a test to be adopted
21 is the -- is the accuracy of that test.

22 I think that, for people who are
23 interested in their health and screening for
24 colorectal cancer in the first place, that they're
25 willing to undergo certain inconveniences, not the

1 least of which is that -- I would say that still
2 the majority of people who get screened do that
3 through colonoscopy and not at-home tests.

4 And so I think that there's -- this may be
5 Dr. Barnell's opinion that this is one of the most
6 burdensome aspects for patients, but I don't know
7 that I share that opinion.

8 Q. Do you see in that same paragraph the last
9 sentence that states (as read):

10 "By eliminating the most confusing and
11 undesirable step, we believe ColoSense will drive
12 higher adherence and better outcomes"?

13 MR. JONES: Objection to scope.

14 A. I see that, yes.

15 Q. That is also attributed to Dr. Erica
16 Barnell?

17 MR. JONES: Objection to scope.

18 A. It would appear so, yes.

19 Q. Do you disagree that the scraping of stool
20 at home is the most confusing and undesirable step
21 of the at-home CRC screening experience?

22 MR. JONES: Objection to scope.

23 A. I think we talked about -- we touched on
24 this at least a little bit already. I don't intend
25 to represent what the user experience is for people

1 doing ColoSense. So I don't know what is most
2 confusing or undesirable for people; but, again, I
3 do believe that for people who are interested in
4 monitoring their health and are interested to
5 understand whether or not they have colorectal
6 cancer, which oftentimes appears without symptoms,
7 that they would be willing to take an at-home test
8 and follow the instructions; and -- and I think
9 that -- I -- again, I don't know what's most
10 confusing and undesirable to people using the test.

11 Q. And do you see the -- the second half of
12 that sentence states (as read):

13 "We believe ColoSense will drive higher
14 adherence and better outcomes."

15 Do you see that?

16 A. I see that.

17 Q. Would you agree that eliminating the
18 at-home scraping of stool is likely to drive higher
19 adherence and better outcomes from at-home
20 colorectal cancer screening?

21 MR. JONES: Objection to scope.

22 A. I -- I would give pretty much the same
23 answer I just gave, which is, that I don't -- I
24 don't -- you know, I haven't tried to represent
25 what is driving the -- the desirability of these

1 particular steps in running these tests.

2 What I do believe is that people who are
3 willing to do at-home testing for detection of
4 colorectal cancer, which oftentimes can appear
5 without symptoms, is that they're looking at having
6 a test which provides the -- the best accuracy.

7 If there are other things which may drive
8 adherence, then I think that's only a positive on
9 top of that. But I don't think that's a major
10 component of what we're talking about here.

11 Q. Do you agree the first step for any test
12 being successful is that the patient's will use it;
13 correct?

14 MR. JONES: Objection to form.

15 A. In order -- yeah, I -- in this context for
16 the sake of trying to get people to use at-home
17 tests, that, in order to be able to assess their
18 colorectal cancer risk, it is important that they
19 use the test.

20 MS. FERNANDS: We've been going about an
21 hour. Should we take a quick break?

22 MR. JONES: Sure.

23 (Recess was taken.)

24 (Exhibit 2055, article: Analytical
25 validation of a scrape-free multitarget

1 stool RNA test for colorectal cancer
2 screening.)

3 Q. So, Doctor Whitney, I've added to the
4 Exhibit Share an exhibit that I've marked as
5 Exhibit 2055.

6 Do you have that?

7 A. My computer is thinking.

8 Okay. Yes.

9 MR. JONES: I object to -- just for the
10 record, I object to the exhibit for materiality,
11 scope, and also for unfair prejudice.

12 Q. Doctor Whitney, the exhibit that I marked
13 as 2055 is an article published in Practical
14 Laboratory Medicine titled "Analytical validation
15 of a scrape-free multitarget stool RNA test for
16 colorectal cancer screening."

17 Do you see that?

18 MR. JONES: Objection to scope.

19 A. Yes.

20 Q. Have you -- have you seen this article
21 before today?

22 A. I have not.

23 Q. If you look at the authors of the article,
24 they include Erica Barnell and Andrew Barnell.

25 Do you see that?

1 A. Yes.

2 MR. JONES: Object to the scope.

3 Q. Do you know Erica Barnell or Andrew
4 Barnell?

5 MR. JONES: Objection. Scope.

6 A. I've spoken to each of them one time, I
7 believe.

8 Q. Are you aware that they are both employed
9 by Geneoscopy?

10 A. Yes.

11 Q. If you could look at the "Background" in
12 the -- "& Aims" in the abstract.

13 Do you see that?

14 MR. JONES: Objection. Scope.

15 A. Yes, I see it.

16 Q. Do you see the statement that (as read):

17 "Traditional stool-based colorectal cancer
18 (CRC) screening tests require patients to collect
19 and swab their own stool which can reduce adherence
20 due to aversion and introduce variability from user
21 error."

22 Do you see that?

23 MR. JONES: Objection. Scope.

24 A. Yes.

25 Q. Would you agree that traditional

1 stool-based CRC screening tests require patients to
2 collect and swab their own stool?

3 A. It's -- I'm not sure exactly what's
4 defined as traditional.

5 Q. Would you agree that FIT screening tests
6 available before 2009 required patients to collect
7 and swab their own stool?

8 MR. JONES: Objection.

9 A. I -- I would agree that FIT tests required
10 taking a small portion of a stool sample.

11 Q. Would you require that -- strike that.
12 Would you agree that requiring a patient
13 to take a small portion of a stool sample from a
14 larger portion of stool sample can reduce adherence
15 due to aversion?

16 MR. JONES: Objection.

17 A. I don't -- that's not something that I
18 have spent time forming an opinion about.

19 Q. Would you agree that requiring a patient
20 to remove a portion of a stool sample from a larger
21 portion using a FIT test can introduce variability
22 from user error?

23 MR. JONES: Objection to form.

24 A. I -- I'm -- I would not try to represent
25 what's written on this page. What I have done

1 research on and what I've -- I'm aware of as a
2 person of skill in the art is how FIT tests are
3 used, how some of the literature describes
4 stool-based tests, and things like that.

5 Q. Is it accurate to say you have no opinion
6 as to whether requiring the user to take a small
7 portion of stool sample from a larger portion
8 reduce -- reduces adherence due to aversion?

9 MR. JONES: Objection to form.

10 A. What was the first part of the question?

11 Q. Is it accurate that you have formed no
12 opinion as to whether requiring the user to
13 separate the stool sample by taking a small portion
14 from the larger portion reduces adherence due to
15 aversion?

16 MR. JONES: Objection to form.

17 A. I have an opinion about how tests are used
18 and, more importantly, the accuracy of -- of tests.
19 I -- as it relates in any way to adherence, that's
20 what my opinion would be about.

21 Q. Did you form an opinion concerning whether
22 the separation of the stool sample by the user
23 could produce adherence due to aversion?

24 MR. JONES: Objection to form.

25 A. What I -- what I have said already and

1 what I stand by is that the most important thing,
2 in my opinion, for people using tests to understand
3 their colorectal cancer risk is the accuracy of the
4 test.

5 Q. Would you turn to page 2 of Exhibit 2055.
6 Do you see the paragraph that begins "FIT for CRC
7 screening"?

8 MR. JONES: Objection to scope.

9 A. At -- the first full paragraph on the
10 second page? Is that what you're referring to?

11 Q. Yes.

12 A. Yes, I see it.

13 Q. Do you see that says (as read):

14 "FIT for CRC screening relies on at-home
15 sample collection."

16 Do you see that?

17 A. Yes.

18 Q. And FIT is the same thing as iFOBT;
19 correct?

20 A. Yes.

21 Q. And as of 2009 was it the case that iFOBT
22 for CRC screening relied on at-home sample
23 collection?

24 A. That's certainly my understanding, yes.

25 Q. The next sentence there it states (as

1 read):

2 "A patient passes a stool into the toilet,
3 uses a plastic wand to swab the stool surface at
4 several locations, and places the wand in a
5 buffered tube that stabilizes hemoglobin during
6 shipment to the laboratory (at-home FIT)."

7 Do you see that?

8 MR. JONES: Objection to scope.

9 A. Yes.

10 Q. And is it your understanding that that
11 sentence that describes at-home FIT by a patient
12 passing stool into the toilet using a plastic wand
13 to swab the stool surface at several locations and
14 placing the wand in the buffered tube accurately
15 describes how FIT was used as of 2009?

16 MR. JONES: Objection to scope.

17 A. I think that the FIT tests are -- that
18 people use the FIT test according to the kit
19 instructions. I would not attempt to represent
20 that that sentence represents how all FIT tests
21 were run.

22 Q. If you were to describe generally how FIT
23 tests were used in 2009, how would you describe
24 them?

25 A. I would say that a patient produces a

1 stool sample and takes a small portion of that
2 stool sample, using a part of the device, which
3 is -- we could call it a swab or a spatula or
4 something like that, and that that would then get
5 introduced to a container that has a stabilization
6 buffer in it.

7 Q. Looking back at this Exhibit 2055, the
8 last paragraph of the introduction section begins
9 "Eliminating at-home."

10 Do you see that?

11 MR. JONES: Objection to scope.

12 A. Yes.

13 Q. That sentence reads (as read):

14 "Eliminating at-home stool scraping
15 represents a pragmatic opportunity to streamline
16 sample collection, enhance user acceptability, and
17 reduce analytical noise."

18 Do you see that?

19 MR. JONES: Objection to scope.

20 A. Yes.

21 Q. Would you agree that eliminating the
22 at-home scraping step of a CRC screening test
23 enhances user acceptability?

24 A. I -- I think we've addressed this question
25 a multiple of different ways, and I think that the

1 most important thing is the accuracy of the test in
2 terms of acceptability of that test for people who
3 are interested in understanding a colorectal cancer
4 risk.

5 Q. Do you disagree with the statement that
6 eliminating at-home stool scraping enhances user
7 acceptability?

8 MR. JONES: Objection. Scope.

9 A. I believe that at-home stool scraping
10 represents a small and relatively unimportant part
11 of the CRC screening process.

12 Q. Is it your opinion that in 2009 a person
13 of ordinary skill in the art would not have taken
14 into consideration user acceptability of the test?

15 MR. JONES: Objection to form.

16 A. I'm sorry. Could you repeat the question?

17 Q. Is it your opinion that a person of
18 ordinary skill in the art in 2009 seeking to
19 develop an improved CRC screening test would not
20 have taken into account user acceptability of the
21 test?

22 MR. JONES: Objection to form.

23 A. No, I think user acceptability is an
24 important part of a test which is going to be used
25 for CRC screening.

1 Q. And is it your opinion that a person of
2 skill in the art in 2009 would not have thought
3 that eliminating at-home stool scraping would
4 enhance user acceptability?

5 MR. JONES: Objection to form.

6 A. I believe that for CRC screening the user
7 acceptance is important for the adoption of the
8 test and that that's driven primarily by the
9 accuracy of the test and that other factors may
10 enter into user acceptability but they are
11 relatively minor compared to the overall accuracy.

12 Q. Could you turn to in Exhibit 2025
13 [verbatim] in the discussion.

14 A. Exhibit 2025?

15 Q. I'm sorry. 2055. The same exhibit we're
16 in. My apologies. Exhibit 2055 in the discussion?

17 MR. JONES: Just for clarity, you're
18 referring to page 6?

19 MS. FERNANDS: Yes, on page 6.

20 A. Okay.

21 Q. Are you there?

22 A. Yes.

23 Q. Do you see in that first sentence of the
24 discussion it states (as read):

25 "The multitarget stool RNA test (mt-sRNA,

1 ColoSense) is currently the only FDA-approved
2 stool-based CRC screening test that does not
3 require patients to perform a fecal swab."

4 Do you see that?

5 MR. JONES: Objection to scope.

6 A. Yes.

7 Q. Do you have an understanding of what it
8 means by "fecal swab," as used here?

9 MR. JONES: Objection to scope.

10 A. As I indicated previously, I've not read
11 this paper, but what I believe this is referring to
12 is the sampling of a portion of a stool sample.

13 Q. Do you see in the next sentence it says
14 "Eliminating at-home FIT swabbing."

15 Do you see that?

16 MR. JONES: Objection to scope.

17 A. Yes.

18 Q. So fecal swab appears to refer to the
19 at-home FIT separation.

20 Is that -- does that seem accurate?

21 MR. JONES: Objection to scope.

22 A. Again, I -- I don't know. If you're
23 pressing me on this point, I have not had a chance
24 to read this paper. So I don't know how they're
25 defining that necessarily.

1 Q. That sentence -- that next sentence in
2 "Discussion" states (as read):

3 "Eliminating at-home FIT swabbing
4 represents a transformative approach to CRC
5 screening by mitigating barriers to adherence while
6 maintaining diagnostic integrity through
7 standardized processing."

8 Do you see that?

9 MR. JONES: Objection to scope.

10 A. Yes.

11 Q. Okay. Do you disagree that eliminating
12 the at-home FIT swabbing represents a
13 transformative approach to CRC screening?

14 MR. JONES: Objection to scope.

15 A. Again, I've not read this paper. You're
16 pressing me on that particular term. What I will
17 reiterate is, if you're asking me about barriers to
18 adherence, my opinion is that the most important
19 thing for a CRC screening test is the accuracy of
20 that test; and that if people have confidence in
21 the test, it will be used and -- yeah, let me stop
22 there.

23 Q. Okay. Would you disagree that it would be
24 preferable to eliminate the need for patients to
25 separate their stool sample for patient adherence

1 with the CRC screening test?

2 MR. JONES: Objection to form.

3 A. I believe that the separation of a sample
4 at home by the subject is a secondary consideration
5 to the overall accuracy of the test.

6 Q. Okay. Would you agree that user would be
7 more willing to use a test that does not require
8 at-home separation?

9 MR. JONES: Objection to form.

10 A. I have not spoken to users. Again, I
11 think the most important thing is the accuracy of
12 the test.

13 Q. Okay. And so you disagree that the home
14 separation is a key adherence barrier?

15 MR. JONES: Objection to form.

16 A. I'm sorry. Re- -- re- -- repeat the
17 question?

18 Q. Would you agree that requiring at-home
19 separation of a stool sample is a key adherence
20 barrier for at-home CRC screening tests?

21 MR. JONES: Objection to form.

22 A. I think that the -- the separation of a
23 sample at home is not one of the most important
24 aspects of a CRC screening test.

25 Q. From a user adherence perspective, is

1 separation of the sample at home one of the key
2 adherence aspects?

3 MR. JONES: Objection to form.

4 A. I feel like I'm repeating myself over and
5 over, but I believe that the most important thing
6 for subjects to use a CRC screening test is the
7 accuracy of that test, which confers confidence in
8 the result they get from that.

9 Q. Would you agree that a person of ordinary
10 skill in the art in 2009 would also have considered
11 whether patients were willing to use the test?

12 MR. JONES: Objection to form.

13 A. Which test are we talking about in 2009?

14 Q. A person of ordinary skill in the art
15 seeking to develop an improved CRC screening test,
16 would that person of ordinary skill in the art
17 consider factors affecting patient adherence?

18 MR. JONES: Objection to form.

19 A. Anyone -- I would say that a person
20 skilled in the art developing a -- a CRC screening
21 test would certainly be interested in knowing that
22 the format for that test is acceptable enough that
23 people would use it.

24 Q. What do you mean "acceptable enough"?

25 A. Meaning that there are always going to be

1 tradeoffs in terms of how tests are being run, but
2 the most important thing is for a test to confer
3 high accuracy and confidence in that test; and so
4 if there are steps in the -- the test use that --
5 well, let me scratch that.

6 The -- I believe -- again, I believe that
7 the -- the accuracy of the test is the most
8 important thing. If there are steps that subjects
9 have to go through in order to provide a result,
10 people who are interested in their colorectal
11 cancer health risk are -- are -- want to be aware
12 that people are willing to go through those steps
13 in order to get to a result. And I would refer to
14 even colonoscopy as a good example of that.

15 Colonoscopy is not necessarily the most
16 desirable procedure to go through, but the vast
17 majority of people who are still screened today for
18 colorectal cancer risk undergo colonoscopy today.

19 Q. Would you agree that as of 2009 one of the
20 goals of at-home CRC screening was to expand the
21 number of people who screened?

22 A. In the 2009 time frame, my recollection
23 was that relatively few people were being screened
24 for colorectal cancer relative to all of the
25 asymptomatic people who could be screened.

1 So there were a variety of methods which
2 were being evaluated to try to get more people into
3 screening programs.

4 Q. So is it the case that one of the goals in
5 developing CRC screening tests as of 2009 was to
6 expand the -- the asymptomatic population that was
7 being screened?

8 A. I think to the extent that the goal in
9 2009 was to expand the number of people being
10 screened, that same goal exists today.

11 Q. That was a goal in 2009 and is still a
12 goal today.

13 Is that your understanding?

14 A. What I'm saying is that there -- the goal
15 is to get ideally 100 percent of people who are at
16 risk for developing colorectal cancer to be
17 screened.

18 Today that is less than 100 percent of
19 people. In 2009 it was less than 100 percent of
20 people.

21 Q. Turning back to your declaration, which is
22 Exhibit 1086, if you'd turn to paragraph 37.

23 A. Okay.

24 Q. And in paragraph 37 of Exhibit 1086 you're
25 discussing here certain calculations that Doctor

1 Backman provided; is that correct?

2 A. Yes, this is referring to some AUC values
3 that he calculated from some ROC curves.

4 Q. And those were AUC values that --

5 A. Can I -- can I change -- nah, never mind.

6 Q. Yeah, no. If you'd like to correct,
7 please, go ahead.

8 A. Yes. They -- there actually were no ROC
9 curves in -- in "Discussion" that we're talking
10 about here. The -- what I meant to say is the AUC
11 values which would correspond to a ROC curve is
12 what was being calculated by Doctor Backman, is my
13 understanding.

14 Q. Okay. And when you say ROC curve, what do
15 you mean?

16 A. So ROC curve is an acronym that stands for
17 receiver operator characteristic, and that
18 represents the full complement of sensitivity and
19 specificity values that a particular diagnostic
20 test would have.

21 Q. And when you refer to AUC values, what do
22 you mean?

23 A. That stands for area under the curve of
24 that particular ROC curve.

25 Q. How are AUC values used in assessing the

1 diagnostic accuracy of tests such as CRC screening
2 tests?

3 MR. JONES: Objection to form.

4 A. People use these in various ways, but the
5 AUC is similar to the accuracy, the overall
6 accuracy, of a particular test, but as I indicated,
7 it contemplates all combinations -- all potential
8 combinations of sensitivity and specificity and
9 therefore becomes a characteristic of that
10 particular test.

11 Q. And you state in this paragraph 37, the
12 second sentence.

13 Do you see the sentence beginning
14 "Furthermore"?

15 MR. JONES: Objection.

16 Q. Did I misstate?

17 A. I think you mean the third sentence?

18 Q. Yes. My apologies.

19 I missed the short sentence. Let's start
20 over.

21 You're in paragraph 37 of Exhibit 1086;
22 correct?

23 A. Yes.

24 Q. And the third sentence of paragraph 37
25 begins "Furthermore."

1 Do you see that?

2 A. Yes.

3 Q. And that states (as read):

4 "Furthermore, any calculation of an AUC
5 from a single pair of sensitivity and specificity
6 values, which was all the Lenhard study provided,
7 can provide only a rough estimation at best and
8 therefore is an inexact method for comparing test
9 performance."

10 Do you see that?

11 A. Yes.

12 Q. What do you mean when you say here "a
13 single pair of sensitivity and specificity values"?

14 A. What I mean is that the -- if you have a
15 single -- let's call it a decision threshold for,
16 you know, a test that may have -- well, scratch
17 that.

18 What I mean by that is that what was
19 provided in the paper was a sensitivity and
20 specificity for FOBT and the -- the HIC1 in this
21 case I think -- (witness reviews document) Yes.

22 And so what I mean by a single pair is
23 that for either one of those there is one set of
24 sensitivity and specificity numbers.

25 Q. Then you also state that this can provide,

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1 quote, "only a rough estimation as best."

2 Do you see that?

3 A. Yes.

4 Q. Why can this provide only a rough
5 estimation at best, in your opinion?

6 A. You just asked me a moment ago for a
7 definition of a ROC curve. My definition was that
8 it represents the full complement of potential
9 sensitivity and specificity values for a given
10 test.

11 That was not provided in this paper.
12 Neither was a -- a ROC curve provided in this
13 paper. It was only a single pair of sensitivity
14 and specificity values.

15 So it's not possible to calculate an area
16 under the curve for a ROC curve when you don't have
17 a ROC curve.

18 Q. Continuing that same sentence we were
19 looking at in paragraph 37, you state that, in your
20 opinion, "this is an inexact method for comparing
21 test performance."

22 Do you see that?

23 A. Yes.

24 Q. And what do you mean by "inexact method"
25 there?

1 A. It's not clear how Doctor Backman actually
2 calculated the AUC, but he does refer to it as an
3 AUC of a ROC curve. And as I just indicated, there
4 is no ROC curve that's provided in the -- in the
5 paper or in the data.

6 And so representing this as a measure of
7 an AUC, it's impossible that that could be an exact
8 measure of the ROC curve because it doesn't exist.
9 So that's why I say at best there is a methodology
10 that he presumably used but it could only provide
11 an estimate.

12 Q. So turn to paragraph 40 of your
13 declaration that is Exhibit 1086.

14 A. Yeah.

15 Q. And you state there in paragraph 40, the
16 first sentence is (as read):

17 "A more straightforward mathematical
18 method that does not require making estimates and
19 that was commonly used to -- to combining
20 sensitivity and specificity to arrive at a single
21 comparative metric is to calculate test accuracy."

22 Do you see that?

23 A. Yes.

24 Q. And you referred earlier to overall
25 accuracy. Is there a difference between overall

1 accuracy and test accuracy?

2 MR. JONES: Objection to form.

3 A. Where did I refer to that earlier?

4 Q. Sorry. In an answer earlier you used the
5 term "overall accuracy."

6 What do you mean by overall accuracy?

7 A. I -- I -- my use of the term is the same
8 as accuracy here.

9 Q. Your use of overall accuracy and test
10 accuracy is the same?

11 A. In this context, yes.

12 Q. And then the next sentence here in your
13 paragraph 40 concerning test accuracy, you state
14 that (as read):

15 "Test accuracy is calculated at the sum of
16 true positive and true negative samples divided by
17 the sum of the complete sample set."

18 Correct?

19 A. Yes.

20 Q. Prior to submitting the declaration that
21 is Exhibit 1086, have you used test accuracy to
22 compare diagnostic tests?

23 A. You're asking me in my career?

24 Q. In your work, yes. In your experience.

25 A. Yes.

1 Q. In what context have you used test
2 accuracy to compare diagnostic tests before?

3 A. I'm not sure I can answer that. I mean --

4 Q. Is it something --

5 A. Sorry. Yeah.

6 Go ahead.

7 Q. Is it something that you've commonly used,
8 this formula that is the second sentence of your
9 paragraph 40, the calculation of the sum of true
10 positive and true negative samples divided by the
11 sum of the complete sample set?

12 A. What I've --

13 MR. JONES: Form.

14 A. What I've typically done, quite honestly,
15 is to look at sensitivity and specificity of -- of
16 tests. But when looking at overall accuracy, I
17 would use a similar equation, I guess -- or similar
18 description.

19 Q. You say you would use a similar
20 description. Would you use this equation that is
21 the second sentence of your paragraph 40 or a
22 different equation?

23 A. Well, it's not actually an equation. It's
24 more of a description.

25 Q. Is it the sum of true positive and true

1 negative samples divided by the sum of the complete
2 sample set is not an equation?

3 A. It's not written as an equation, but I
4 think we're -- yes.

5 Q. Okay. That could be written as an
6 equation; right?

7 A. Yes.

8 Q. True positive plus true negative over sum
9 of sample set?

10 A. Yes.

11 Q. And when you said you used a similar
12 description, have you used the equation true
13 positive plus true negative over sum of sample set
14 or some different equation for assessing test
15 accuracy?

16 MR. JONES: Objection to form.

17 A. I've used -- I'm not aware of using a
18 different form.

19 Q. And is it your opinion that calculating
20 test accuracy is a better way to compare the
21 performance of the HIC1 alone, as recorded in
22 Lenhard, with the performance of HIC1 testing and
23 gFOBT together, as reported in Lenhard?

24 MR. JONES: Objection to form.

25 A. Better than what?

1 Q. Better than the AUC calculation done by
2 Doctor Backman.

3 A. Well, again, my declaration indicates that
4 the AUC calculation cannot be accurate if it's
5 based on a ROC curve that does not exist.

6 My point is that if one has all of the
7 data to enable calculation of an accuracy
8 statistic, that that would be a more accurate way
9 of representing the data.

10 Q. And, in your opinion, does Lenhard contain
11 all of the data necessary to calculate an accuracy
12 statistic?

13 A. What they look at is the sensitivity --
14 they provide a sensitivity and a specificity value
15 for each of the HIC1 -- I believe the FOBT, as well
16 as the combined. So based on those numbers, one
17 could calculate the accuracy numbers.

18 Q. Is that all of the data that is necessary
19 to calculate test accuracy, in your opinion?

20 MR. JONES: Objection to form.

21 A. The denominator in these equations
22 includes -- well, you're asking me about
23 sensitivity and specificity?

24 Q. I'm asking you whether the Lenhard data is
25 adequate, in your opinion, to calculate test

1 accuracy?

2 A. I believe that it is.

3 Q. In that paragraph 40 you state that (as
4 read):

5 "With respect to the Lenhard assays, the
6 HIC1 assay itself has a test accuracy of 80
7 percent."

8 Do you see that?

9 A. Yes.

10 Q. And you state that (as read):

11 "...the addition of the FOBT test improved
12 the test accuracy to 81.3 percent."

13 Correct?

14 A. Yes.

15 Q. In calculating the test accuracy for the
16 HIC1 assay, what did you use for the true positive
17 number?

18 MR. JONES: Objection to form.

19 A. For which one of those?

20 Q. In calculating the 80 percent test
21 accuracy for the HIC1 assay -- you do not show your
22 calculations here in your declaration; correct?

23 A. I provide these two numbers.

24 Q. Do you recall what you used as the true
25 positive number for HIC1?

1 A. I don't recall what the specific number
2 was. I would guess that it's -- we could take it
3 directly from the paper, however.

4 MS. FERNANDS: I've added to the Exhibit
5 Share Exhibit 1004, which is the Lenhard
6 publication.

7 (Exhibit 1004, previously marked.)

8 Q. Do you have Exhibit 1004, the Lenhard
9 publication?

10 A. Yes.

11 Q. And having that Exhibit 1004, are you able
12 to identify for me which value you used for the
13 true positive for the calculation of 80 percent
14 test accuracy for HIC1 alone?

15 A. For the HIC1, I believe -- I believe I
16 used -- yeah. So the -- I believe I used the
17 values that -- that went into the sensitivity of
18 the HIC1 assay. So...

19 Q. Which value is that?

20 A. It -- sorry. What was the original
21 question? What are you asking me for?

22 Q. In calculating 80 percent test accuracy
23 for the HIC1 assay alone, using the sum of true
24 positive and true negative samples divided by the
25 sum of the complete sample set, what was the

1 numeric value you used for true -- true positive?

2 A. For true positive, in this case it would
3 have been 11 out of the 26, I believe.

4 Q. And that 26 was known cancer patients;
5 correct?

6 A. Correct.

7 Q. Okay. Staying with just HIC1 assay alone,
8 in your calculation of test accuracy of 80 percent,
9 what did you use for the true negative?

10 A. Let's see. (Witness reviews document.)
11 I'm looking for the exact number -- if I -- if I
12 look at table 3, it looks like there were 50
13 controls, two of them were not used, and one was
14 positive for HIC1. So that would be, I believe, 47
15 out of -- sorry -- I believe it would be 47 out of
16 48.

17 Q. And those are a total of 48 controls;
18 correct?

19 A. Under the HIC1 it looks like there are 48
20 controls that were used.

21 (Court Reporter comment.)

22 Q. And then for the denominator of this --
23 the sum of the complete sample set, what did you
24 use for that?

25 A. So it would have been the 48 controls that

1 we were just talking about and the 26 cancers that
2 we were previously talking about.

3 Q. So if I'm doing my math right, that's 74?
4 48 plus 26?

5 A. Sure.

6 Q. And of those 74, more than a third were
7 known cancer; correct?

8 A. It would appear to be true, just -- just
9 barely more than a third.

10 Q. Now, turning then to the combination of
11 HIC1 with FOBT, what did you use for the true
12 positives for the combination?

13 A. So going back to table 4, I believe that I
14 used the 17 out of 26.

15 Q. And for the combination of HIC1 and FOBT,
16 what did you use for true negatives?

17 A. I believe that what I used -- out of the
18 whole set of controls in table 3, there were --
19 there were three total samples that -- sorry.
20 There was 47 samples that were used for both tests.

21 And in this case, of those 47, there
22 was -- looked like there was 44 that were true
23 negatives.

24 Q. So then the sum?

25 A. Oh, sorry, sorry. No, I missed one. No,

1 I missed a couple. Sorry.

2 (Witness reviews document.) I believe it
3 was probably 42.

4 Q. So there are five -- if I count them
5 correctly -- plus signs in the FOBT column; is that
6 right?

7 A. That's what I'm looking at as well, yes.

8 Q. Okay. And then in line 81, the only plus
9 sign in the HIC1 column is also a plus in the FOBT.
10 So five is the total number of --

11 A. I'm sorry. Say that again.

12 Q. Because -- because in line 81 there's a
13 plus sign in both HIC1 and FOBT, five is our total
14 number of plus signs; right?

15 A. Correct.

16 Q. So five is our total number of false
17 positives for the combination; is that right?

18 A. Correct.

19 Q. And then, as you said, there were three
20 that were not used as all; right?

21 A. Yes.

22 Q. So of the 47, we take out the five false
23 positives, and we get to 42 controls; correct?

24 A. Correct.

25 Q. So here we have 17 true positives of the

1 sample set of 26 and 42 true negatives.

2 What was the sum of the complete sample
3 set that you used for the combination?

4 A. I would -- I would guess that it would be
5 the -- would be the 47 controls in total and the 26
6 cancers.

7 Q. So that's 73 for the complete sample set;
8 correct?

9 A. Correct.

10 Q. And so the 26 cancers, again, is a little
11 more than one-third of the complete sample set;
12 right?

13 A. Yes, I -- just barely.

14 Q. So would you agree that one-third positive
15 cancer diagnoses is not representative of the
16 prevalence of CRC in the general population?

17 A. The prevalence of CRC in an average risk
18 asymptomatic population is probably closer to 1
19 percent.

20 Q. Did you do anything to take prevalence
21 into account when you calculated test accuracy
22 in -- of the HIC1 and on the HIC1 plus FOBT
23 combination as reported in Lenhard?

24 A. The sensitivity and specificity of a test,
25 particularly as reported in this paper, is an

1 inherent value of a particular test. If one were
2 to take into account the prevalence of a disease,
3 one would want to do that for the sake of
4 calculating things like a negative predictive value
5 or a positive predictive value.

6 But the prevalence is not necessarily
7 taken into account in terms of calculating the
8 accuracy of the inherent properties of that test.

9 Q. Going back to paragraph 40 of your
10 declaration, the last -- the second-to-last
11 sentence there, you state that (as read):

12 "...the result is a slightly higher
13 estimated accuracy for the combined test than
14 either the HIC1 test alone or the gFOBT alone."

15 Do you see that?

16 A. Do you want to do this so I'm not toggling
17 back and forth?

18 Q. Do you have the -- do you have your --

19 THE WITNESS: I'm sorry. Could you repeat
20 the question.

21 Q. No problem. So I went quickly back to
22 your declaration; your declaration that is Exhibit
23 1086; correct?

24 A. Yes.

25 Q. In paragraph 40 that we were looking at.

1 A. Yes.

2 Q. Are you there?

3 In the second-to-last sentence of
4 paragraph 40 you state (as read):

5 "Thus, when test accuracy is calculated
6 from the Lenhard data, the result is also a
7 slightly higher estimated accuracy for the combined
8 test than either the HIC1 test alone or the gFOBT
9 alone."

10 Do you see that?

11 A. Yes.

12 Q. Did you calculate test accuracy for the
13 gFOBT alone?

14 A. I -- I believe I did. I don't -- I don't
15 know what those numbers were. I believe I must
16 have.

17 Q. Okay. Didn't include them here in this
18 paragraph of your declaration; correct?

19 A. I do not see them right here, no.

20 Q. Okay. When you say "this is a slightly
21 higher estimated accuracy," why do you say
22 estimated?

23 A. I'm not sure. (Witness reviews document.)
24 Yeah, I don't know why that word is here, but...

25 Q. And when you say it's slightly higher, the

1 81.3 percent versus the 80 percent, is that a
2 statistically significant difference?

3 A. I didn't look at statistical significance
4 in this case.

5 Q. You -- paragraph 40 of your declaration,
6 you do not have any citations to that paragraph;
7 correct?

8 A. I'm sorry. Repeat the question?

9 Q. In paragraph 40 of your declaration that
10 we're looking at concerning test accuracy, do you
11 cite to any references?

12 A. I don't -- I don't believe so, no.

13 Q. Okay. You don't cite any reference that
14 gives a formula for test accuracy; correct?

15 A. No, I think that's a pretty common method
16 that people use.

17 Q. You don't cite to any reference that
18 endorses the use of -- use of test accuracy as a
19 calculation to compare two different tests for the
20 same purpose; correct?

21 A. I -- I think comparing test accuracy is a
22 very common procedure that anyone would use.

23 Q. Okay. And you don't cite to anything that
24 does -- test accuracy, that calculating test
25 accuracy, as you did here, is an appropriate way to

1 compare the results of the tests as a -- as they
2 are reported in Lenhard; correct?

3 A. I don't believe it's required.

4 Q. Okay. Did you do any research in
5 connection with your declaration to identify any
6 references that endorse the use of test accuracy?

7 A. I think that people commonly calculate
8 test accuracy.

9 Q. In connection with preparing your
10 declaration, did you review any references
11 concerning the calculation of test accuracy?

12 A. I don't know that I did or did not.

13 Q. Do you recall whether you've reviewed
14 anything -- any references concerning the
15 calculation of test accuracy in connection with the
16 preparation of your declaration?

17 A. What I'm saying is I don't recall.

18 Q. If you did, you did not cite anything;
19 correct?

20 A. Correct.

21 MS. FERNANDS: I think we're at just about
22 another hour. Shall we take another quick break?

23 MR. JONES: Sure.

24 (Recess was taken.)

25 (Exhibit 2056, article: The Use of

1 "Overall Accuracy" to Evaluate The
2 Validity of Screening or Diagnostic
3 Tests.)

4 Q. Doctor Whitney, in the Exhibit Share I've
5 added another exhibit, and it's marked as Exhibit
6 2056.

7 Do you have that?

8 A. No. Let me refresh this. Okay.

9 MR. JONES: If you could just wait a
10 second so I could look at the exhibit.

11 MS. FERNANDS: Sure. Go ahead.

12 MR. JONES: Okay.

13 Q. Doctor Whitney, do you have Exhibit 2056
14 in the Exhibit Share?

15 A. Yes.

16 Q. And what we've marked as Exhibit 2056 is a
17 review article from the Journal of General Internal
18 Medicine dated 2004 and titled "The Use of 'Overall
19 Accuracy' to Evaluate the Validity of Screening or
20 Diagnostic Tests."

21 Do you see that title?

22 A. Yes.

23 Q. Have you ever read this article before?

24 A. I may have. I -- it doesn't -- I don't
25 have a recollection of reading this.

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1 Q. Are you familiar with the Journal of
2 General Internal Medicine?

3 A. I am.

4 Q. That's a peer-reviewed journal?

5 A. Yes.

6 Q. And you did not consider this article in
7 connection with offering your opinions concerning
8 test accuracy; correct?

9 A. I did not.

10 Q. If you turn to the second page of the
11 document, it's the page with page No. 461 of the
12 article in "Methods."

13 A. Okay.

14 Q. If you look to the fifth sentence -- let
15 me see if I'm counting right. Sorry. Fourth
16 sentence. Do you see the sentence that begins
17 "Overall accuracy"?

18 A. Yes.

19 Q. And it states (as read):

20 "Overall accuracy is the probability that
21 an individual will be correctly classified by a
22 test; that is, the sum of the true positives plus
23 true negatives divided by the total number of
24 individuals tested."

25 Do you see that?

1 A. I see that.

2 Q. And that's consistent with the formula
3 that you used in calculating test accuracy;
4 correct?

5 A. I believe it is, yes.

6 Q. Could you turn to the "Discussion," which
7 is on the page marked 464 of the article.

8 A. Okay.

9 Q. In the discussion do you see the third
10 paragraph that begins "These examples"?

11 A. Yes.

12 Q. And that sentence -- that first sentence
13 states (as read):

14 "These examples also point toward another
15 problem."

16 Do you see that?

17 A. I see the sentence, yes.

18 Q. Okay. And then there is a colon, and it
19 says (as read):

20 "Estimates of overall accuracy may be
21 particularly misleading when obtained from studies
22 where the disease prevalence in the study
23 population diverges considerably from a prevalence
24 in the actual clinical population where the test
25 will be applied (target population)."

1 Do you see that?

2 A. Yes.

3 Q. Okay. Would you agree that "Estimates of
4 overall accuracy may be particularly misleading
5 when obtained from studies where the disease
6 prevalence in the study population diverges
7 considerably from the prevalence in the actual
8 clinical population"?

9 MR. JONES: Objection to form.

10 A. You're asking me if that sentence in
11 general -- if I agree with that?

12 Q. Yes.

13 A. What -- what I believe is that the
14 sensitivity and specificity are an inherent value
15 of a diagnostic test, and it is always generated by
16 some set of data. The real question is whether or
17 not that data is representative of another
18 population in which that type of test might be
19 used.

20 And so this statement is -- I believe is
21 trying to say that, you know, a study, if it were,
22 let's say, relatively small study as in the -- the
23 Lenhard study, if that -- one -- one could still
24 calculate a sensitivity or specificity, an accuracy
25 number from that data, but if one were then asked a

1 question whether or not those exact values are
2 representative of what someone might see in a
3 different population, that I would agree that
4 that's not necessarily how someone would want to
5 look at that data.

6 Q. So do you disagree with the author's
7 statement that (as read):

8 "...estimates of overall accuracy may be
9 particularly misleading when obtained from studies
10 where the disease prevalence in the study
11 population diverges considerably from the
12 prevalence in the actual clinical population where
13 the test will be applied"?

14 MR. JONES: Objection to form.

15 A. What I'm saying is that the mis- -- any
16 misleading aspect to -- in order to agree with that
17 statement or disagree with that statement, one
18 would have to figure out what is the context in
19 which we're talking about this. It appears as
20 though this sentence is talking about a prevalence
21 in an actual clinical population.

22 And what I'm saying is that, if one had a
23 test that they were developing -- sorry -- that
24 they were trying to characterize the performance of
25 that particular test and it had something other

1 than what was represented in the clinical
2 population, that it may be -- it might not be
3 representative of the exact numbers that one would
4 expect in one population versus another.

5 Q. And do you see the next sentence here (as
6 read):

7 "Under such circumstances, the weights
8 applied to sensitivity and specificity in
9 estimating overall accuracy will differ from those
10 that would apply if prevalence estimates from the
11 target population were used"?

12 A. I see that.

13 Q. In calculating what you've called test
14 accuracy in your declaration, did you do anything
15 to account for the prevalence of CRC in the overall
16 population?

17 MR. JONES: Objection to form.

18 A. The objective of calculating the accuracy
19 in this declaration was in direct contrast to the
20 methodology that had been used by Doctor Backman to
21 get an overall assessment of the sensitivity and
22 specificity in Lenhard. Neither one of those
23 calculations is intending to represent the clinical
24 population. It's just a matter of trying to
25 provide an assessment of what is the accuracy of --

1 of the HIC1 test versus when you combine it with
2 FOBT.

3 But in all of this it's not the overall
4 accuracy calculation which is the main point here.
5 It's about looking at whether or not HIC1
6 complements the FOBT and vice versa; and if it
7 does, then the combination of those two is better
8 than either one of those individually.

9 Q. In the calculations that you used to
10 calculate test accuracy as reported in paragraph 40
11 of your declaration, the number of CRCs was more
12 than a third of the total number of subjects;
13 correct?

14 MR. JONES: Objection to form.

15 A. The population that was included in the
16 Lenhard study was not intended to be representative
17 of the clinical population in which any of these
18 tests would ultimately be used if successfully
19 validated in a clinical study.

20 And to answer your question directly,
21 yeah, just simple math, I would suggest that 26 is
22 more than a third of 76 or whatever the total
23 number was.

24 Q. Do you know, as you sit here today, how
25 the comparison of HIC1 alone to HIC1 combined with

1 gFOBT would change if the total number of subjects
2 were more representative of a complete population
3 such that the prevalence was closer to the 1
4 percent?

5 MR. JONES: Objection to form.

6 A. I'm sorry. Can you -- could you ask that
7 question again?

8 Q. Sure. That was probably very badly
9 formed.

10 Do you know, as you sit here today, how
11 the calculations for the comparison of HIC1 to HIC1
12 combined with FOBT --

13 (Internet disruption.)

14 (Question read back.)

15 MS. FERNANDS: Okay. Let me re-ask a
16 question, then. I'm not...

17 Q. If -- do you know, as you sit here today,
18 how the comparison of HIC1 to the HIC1 combined
19 with FOBT results would differ if the prevalence
20 were the 1 percent that is more representative of
21 the general population?

22 A. I believe what my -- that was the
23 penultimate question, I think; right?

24 Q. I believe the court reporter had said she
25 missed the question. So I'm reasking so that she

1 can get the question and answer.

2 A. All right. So my -- my belief is that --
3 what I think the Lenhard paper demonstrates is that
4 the HIC1 assay detects cancers that the FOBT test
5 misses. And the FOBT test detects cancers that the
6 HIC1 test misses.

7 So I believe that that clearly
8 demonstrates that there is a complementary behavior
9 to the combination of those two assays for
10 improving sensitivity of a test overall by
11 combining those two, and that that would apply to
12 the population that was used in the Lenhard paper,
13 as well as in a screening population.

14 But I also would say that Lenhard was not
15 intending to try to represent a clinical population
16 in his study. He was merely looking for the
17 feasibility of combining those two types of assays.

18 Q. In your declaration, particularly if you
19 have it in hard copy there, still at paragraph 40,
20 you use the calculation of test accuracy; correct?

21 MR. JONES: Objection to form.

22 A. Paragraph 40 talks about test accuracy;
23 correct.

24 Q. And you, in your opinion, state that that
25 is (as read):

1 "A more straightforward mathematical
2 method that does not require making estimates and
3 it was commonly used to combine -- combining
4 sensitivity and specificity to arrive at a single
5 comparative metric."

6 Correct?

7 A. Correct. And in this context, that's a
8 statement relative to the Lenhard study. It's not
9 intended to extend that to another population that
10 has a very different prevalence in this case.

11 Q. In your opinion, would a person of skill
12 in the art in 2009 seeking to develop a CRC
13 screening test want to know how they compared in
14 the prevalence of the general population?

15 MR. JONES: Objection to form.

16 A. A person of skill in the art would
17 typically look at a result like the Lenhard result
18 and look for the primary learning from that study.
19 And the primary learnings of this study are that it
20 is not representative of a clinical population but
21 it does show that a fecal DNA test complements the
22 FOBT test and vice versa, and that if one wanted to
23 know how that test would perform in a clinical
24 population, someone skilled in the art would
25 recognize that that study would have to be run.

1 Q. The second declaration that we've
2 marked -- that is marked as Exhibit 1086, how much
3 time did you spend preparing that declaration?

4 A. Oh. Many, many hours.

5 Q. Can you estimate how many?

6 A. No. I -- I really can't.

7 Q. Do you know how many hours you spent
8 preparing declarations for Geneoscopy in this
9 IPR2024-01330 overall?

10 A. No, I'm not sure I could even estimate
11 that.

12 Q. Since you were deposed in May in
13 connection with this IPR, have you had any other
14 depositions?

15 A. I don't believe so. I mean, I -- I
16 haven't had any other depositions if May was the
17 date of when that last deposition was.

18 Q. When you and I sat in Boston --

19 A. Yes.

20 Q. -- with Brendan for the last deposition,
21 you have not been deposed in any matter since then?

22 A. I have not, no.

23 Q. Okay. What did you do to prepare for your
24 deposition today?

25 A. I certainly reviewed a number of different

1 documents.

2 Q. And did you do anything else?

3 A. Yes, I met with counsel earlier this week.

4 Q. Without revealing the substance of any
5 conversations, for how long did you meet with
6 counsel?

7 A. Two separate days. Probably about four
8 hours each day.

9 Q. Okay. And during the deposition here
10 today, did you -- this is a yes-or-no question:
11 During the deposition here today, did you discuss
12 your testimony with counsel during breaks?

13 A. No.

14 MS. FERNANDS: I have no further questions
15 for you today.

16 MR. JONES: Well, I have no questions.

17 MS. FERNANDS: Thank you for your time,
18 Doctor Whitney.

19 THE WITNESS: Thank you, Anastasia.

20 COURT REPORTER: Do you want a rough
21 transcript, Brendan?

22 MR. JONES: I mean, I don't want anything
23 unnecessarily charged to my client. So if getting
24 the rough transcript's also we'd also be charged,
25 then I certainly don't need it for any actual

1 purpose. I have no -- I have no more briefs in
2 this case.

3 MS. FERNANDS: Brendan doesn't have my
4 deadline. I have a deadline for Friday.

5 (Whereupon the deposition ended at
6 12:37 p.m.)

CERTIFICATE OF STENOGRAPHER

I, Patricia Jodi Ohnemus, Licensed Shorthand Reporter in and for the States of California and New Hampshire and Notary Public in and for the Commonwealth of Massachusetts, the officer before whom the proceedings were taken, do hereby certify that the foregoing transcript is a true and accurate record of these proceedings; that said proceedings were taken in stenotype note by me remotely on the 26th day of September, 2025, commencing at 9:59 a.m. (EDT) and ending at 12:37 p.m. (EDT).

I further certify that present on behalf of Geneoscopy, Inc., Attorney Brendan Jones of Foley Hoag, LLP, and on behalf of Party Exact Sciences, Attorney Anastasia Fernands of Quinn, Emanuel, Urquhart & Sullivan LLP.

I further certify that I am not related to, nor associated with any of the parties or their attorneys, nor do I have any disqualifying interest, personal or financial, in the actions within.

Dated this September 29, 2025.

A handwritten signature in cursive script that reads "Patricia Jodi Ohnemus". The signature is written in dark ink and is positioned above the printed name of the stenographer.

Patricia Jodi Ohnemus, CRR, RPR, RMR

DECLARATION UNDER PENALTY OF PERJURY

I, Duncan H. Whitney, PhD, do hereby
certify under penalty of perjury that I have read
the foregoing transcript of my remote deposition,
taken on September 26, 2025, that I have made such
corrections as appear noted herein in ink;
initialed by me; that my testimony contained
herein, as corrected, is true and correct.

Dated this _____ day of 2025 at
_____, Massachusetts

Duncan H. Whitney, PhD

JOB NO. 7598845

1 Duncan Whitney, Ph.D

2 duncanhwhitney@gmail.com

3 September 29, 2025

4 RE: Geneoscopy, Inc. v. Exact Sciences Corporation

5 9/26/2025, Duncan Whitney, Ph.D, (#7598845).

6 The above-referenced transcript has been
7 completed by Veritext Legal Solutions and
8 review of the transcript is being handled as follows:

9 ___ Per CA State Code (CCP 2025.520 (a)-(e)) - Contact Veritext
10 to schedule a time to review the original transcript at
11 a Veritext office.

12 _XX_ Per CA State Code (CCP 2025.520 (a)-(e)) - Locked .PDF
13 Transcript - The witness should review the transcript and
14 make any necessary corrections on the errata pages included
15 below, notating the page and line number of the corrections.
16 The witness should then sign and date the errata and penalty
17 of perjury pages and return the completed pages to all
18 appearing counsel within the period of time determined at
19 the deposition or provided by the Code of Civil Procedure.
20 Contact Veritext when the sealed original is required.

21 ___ Waiving the CA Code of Civil Procedure per Stipulation of
22 Counsel - Original transcript to be released for signature
23 as determined at the deposition.

24 ___ Signature Waived - Reading & Signature was waived at the
25 time of the deposition.

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1 ___ Federal R&S Requested (FRCP 30(e)(1)(B)) - Locked .PDF
2 Transcript - The witness should review the transcript and
3 make any necessary corrections on the errata pages included
4 below, notating the page and line number of the corrections.
5 The witness should then sign and date the errata and penalty
6 of perjury pages and return the completed pages to all
7 appearing counsel within the period of time determined at
8 the deposition or provided by the Federal Rules.
9 ___ Federal R&S Not Requested - Reading & Signature was not
10 requested before the completion of the deposition.

1 Geneoscopy, Inc. v. Exact Sciences Corporation
2 Duncan Whitney, Ph.D(#7598845)
3 E R R A T A S H E E T
4 PAGE_____ LINE_____ CHANGE_____
5 _____
6 REASON_____
7 PAGE_____ LINE_____ CHANGE_____
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19 PAGE_____ LINE_____ CHANGE_____
20 _____
21 REASON_____
22 _____
23 _____
24 (Duncan Whitney, Ph.D) Date
25

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[describes - driving]

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California Code of Civil Procedure

Article 5. Transcript or Recording

Section 2025.520

(a) If the deposition testimony is stenographically recorded, the deposition officer shall send written notice to the deponent and to all parties attending the deposition when the Original transcript of the testimony for each session of the deposition is available for reading, correcting, and signing, unless the deponent and the attending parties agree on the record that the reading, correcting, and signing of the transcript of the testimony will be waived or that the reading, correcting, and signing of a transcript of the testimony will take place after the entire deposition has been concluded or at some other specific time.

(b) For 30 days following each notice under subdivision (a), unless the attending parties and the deponent agree on the record or otherwise in writing to a longer or shorter time period, the deponent may change the form or the substance of the answer to a question, and may either approve the transcript of the deposition by signing it, or

refuse to approve the transcript by not signing it.

(c) Alternatively, within this same period, the deponent may change the form or the substance of the answer to any question and may approve or refuse to approve the transcript by means of a letter to the deposition officer signed by the deponent which is mailed by certified or registered mail with return receipt requested. A copy of that letter shall be sent by first-class mail to all parties attending the deposition.

(d) For good cause shown, the court may shorten the 30-day period for making changes, approving, or refusing to approve the transcript.

(e) The deposition officer shall indicate on the original of the transcript, if the deponent has not already done so at the office of the deposition officer, any action taken by the deponent and indicate on the original of the transcript, the deponent's approval of, or failure or refusal to approve, the transcript. The deposition officer shall also notify in writing the parties attending the deposition of any changes which the deponent timely made in person.

(f) If the deponent fails or refuses to approve the transcript within the allotted period, the

deposition shall be given the same effect as though it had been approved, subject to any changes timely made by the deponent.

(g) Notwithstanding subdivision (f), on a seasonable motion to suppress the deposition, accompanied by a meet and confer declaration under Section 2016.040, the court may determine that the reasons given for the failure or refusal to approve the transcript require rejection of the deposition in whole or in part.

(h) The court shall impose a monetary sanction under Chapter 7 (commencing with Section 2023.010) against any party, person, or attorney who unsuccessfully makes or opposes a motion to suppress a deposition under this section, unless the court finds that the one subject to the sanction acted with substantial justification or that other circumstances make the imposition of the sanction unjust.

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