

COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

June 27, 2008

Appearances:

- Bernard Coffey, Q.C. Commission Co-counsel
- Sandra Chaytor, Q.C. Commission Co-counsel

- Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL

- Peter Browne/Jane Hennebury Doctors Kara Laing et al

- Daniel Simmons Eastern Regional Integrated
. Health Authority

- Ches Crosbie, Q.C. Members of the Breast Cancer
. Testing Class Action
- Mark Pike NL Medical Association
- Jennifer Newbury Canadian Cancer Society (NL Division)
- David Eaton, Q.C.. . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities
- Simon Clements . . Drs. O'Malley, Pritzker, Wegrynowski & Mullen

LIST OF EXHIBITS

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Certificate

1 COMMISSIONER:
2 Q. Please be seated. Mr. Coffey.
3 DR. BRENDAN MULLEN, EXAMINATION BY BERNARD COFFEY, Q.C.
4 COFFEY, Q.C.:
5 Q. Thank you, Commissioner. Commissioner,
6 yesterday when we left off, I had just shown,
7 I had the Registrar show the--Dr. Mullen
8 Exhibit P-1840. But before we actually delve
9 into that, because there are certain terms
10 that are used in it, words or terms used,
11 there is a PowerPoint presentation, that short
12 one that Dr. Mullen has prepared, it's Exhibit
13 P-1839.
14 COMMISSIONER:
15 Q. All right, then.
16 COFFEY, Q.C.:
17 Q. And I'm going to ask Dr. Mullen to take us
18 through it, and provide some commentary upon
19 it and to bring, you know, certain aspects of
20 what's depicted in the screen to your
21 attention, you know, elaborate upon them,
22 okay.
23 COMMISSIONER:
24 Q. Okay.
25 COFFEY, Q.C.:

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1 Q. Go ahead, Doctor.
 2 DR. MULLEN:
 3 A. As Mr. Coffey mentioned, I thought in
 4 preparation for appearing before the council,
 5 some of the terms I use are quite technical
 6 and I thought a visual presentation might
 7 help.
 8 COMMISSIONER:
 9 Q. Um-hm.
 10 DR. MULLEN:
 11 A. This is not intended to be pathology 101 or
 12 complete pathology, it's very, very basic.
 13 And if I'm using terms that you don't
 14 understand, anyone doesn't understand, please
 15 interrupt and I'll try to be--explain as well
 16 as I can. What--yesterday when I was
 17 referring to the, once the specimen is removed
 18 from the patient and prior to its arrival in
 19 the pathology department, then handling has to
 20 be extremely standardized and meticulous.
 21 Once it arrives in the pathology department,
 22 we immediately section it. And when I talk
 23 about sectioning, I mean, it's--let me just--
 24 we make--oops, sorry. We make cuts in the
 25 specimen and these, by and large, are about

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1 one centimetre, 1.5 centimetres in width. And
 2 we cut right through the specimen, we leave
 3 them adherent to the back. This is to allow
 4 the formalin to penetrate. Formalin is the
 5 fixative which cross links proteins, and it
 6 has a penetration rate of one millimetre per
 7 hour. And I'll show you a cross section and
 8 what the implication of that is. And here you
 9 can see the specimen here, five centimetres
 10 long here. So this specimen would probably be
 11 15 to 20 centimetres in this diameter,
 12 probably the same int hat diameter and eight
 13 or ten centimetres in thickness. So that
 14 would be, for formalin to penetrate the
 15 maximum would be if we divided in half would
 16 take 40, basically take 40 hours and by the
 17 time the formalin penetrated the centre
 18 portion of the specimen it would be autolyzed.
 19 COFFEY, Q.C.:
 20 Q. And that, I take it, Doctor, would be if there
 21 were no cuts made?
 22 DR. MULLEN:
 23 A. No cuts, yes. If we're--now, let's go back to
 24 my peach yesterday. So if I have my peach and
 25 I throw it in the formalin, the peach would

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1 probably be four centimetres, so for it to
 2 penetrate would take two centimetres or 20
 3 hours for it to meet from both sides, a
 4 minimum of 20 hours. And while that's
 5 occurring the centre of the tissue is, because
 6 of the lack of blood supply, enzymatic
 7 processes would start to deteriorate. Now, we
 8 then place paper towels, these are what we
 9 call wicks, paper towels between the slices
 10 partly to keep the slices apart and partly to
 11 allow the formalin to be drawn into the
 12 specimen and it's placed in a volume of
 13 formalin that's anywhere from 15 to 20 times
 14 the volume of the specimen. We're limited
 15 because our containers are about four litres,
 16 but we try to--we maximize the fixative to the
 17 formalin. The formalin is very cheap, it's
 18 about \$13 or \$14 for 20 litres, so it's the
 19 most inexpensive product we have in our
 20 laboratory. Now, this is a--this is not from
 21 the original breast that I've showed you.
 22 This is a cross section of a, what we call a
 23 lumpectomy. The previous specimen is what
 24 would have been a mastectomy. And as you can
 25 see, let's see, the outside of the specimen

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1 and then this is the tumor. Now, this is a
 2 fresh specimen, it hasn't been fixed in
 3 formalin. So and here we have the ruler, so
 4 depending on the maximum diameter here, it
 5 would be probably about a centimetre to the
 6 edge of the tumor, probably a centimetre and a
 7 half to the tumor, so that's 15 hours before
 8 the formalin penetrates. And if you haven't
 9 made a cut in the specimen, the fixation, it
 10 would take 15 hours and -
 11 COFFEY, Q.C.:
 12 Q. I take it, Doctor, there's been no cut here,
 13 from the outside in it would take -
 14 DR. MULLEN:
 15 A. Yes, sorry, if it were intact and you hadn't
 16 made the--basically if you had the peach
 17 without cuts, it would take probably 15 hours
 18 to fix this specimen. And fat is very poor in
 19 fixing. So it's imperative that the specimen
 20 be handled properly. The minute it's removed
 21 from the patient, it has to be placed in a
 22 refrigerator, formalin in a refrigerator and
 23 then transported to the laboratory as quickly
 24 as possible, because it's the laboratory's
 25 responsibility to process the specimen

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<p>1 properly to make these cuts, to allow the 2 fixative to penetrate, to put in the paper 3 towel. So that's the imperative of the 4 laboratory. So it's in collaboration with 5 nursing, the porter system and the laboratory 6 we have the proper handling of the specimen. 7 Now, the next, I'm going to take you through a 8 series of slides. On the left-hand side will 9 be examples of the specimens that I will 10 referring--or the cases that I will be 11 referring to today in the review of the 12 original material. In preparation for my 13 visit here, just before I sent the slides 14 back, so that would be the end of April, I 15 believe, somewhere around then, I had a few 16 breast cases from the Sinai, so these are not 17 selected, this is not selected the best I can 18 do, this is what happened to arrive on my desk 19 that day. So basically what I'm going to show 20 you is the differences in proper fixation, 21 handling, fixation and processing from what I 22 consider acceptable on the right-hand side, 23 which is the Sinai case and on the left-hand 24 side, a compilation of cases from the 25 Newfoundland material that I reviewed. The</p>	<p>1 lack of a complete section. So you're not 2 sure if you are getting the complete section, 3 so you may have tumor, you may not have tumor, 4 you may have portions of the tumor. Now, when 5 I'm doing my--I referred to yesterday, when 6 I'm looking for benign ductal epithelium, I 7 scan the slide looking for benign ducts, so 8 when I go on to my estrogen and/or 9 progesterone receptor slides, I'll have some 10 indication where to look on the slide. And I 11 also want to know where the tumor is because 12 you'll see as we go through the Newfoundland 13 cases, I have to visualize where on the slide 14 I should be looking. Now, these are--this is 15 now the exploding slide issue or the exploding 16 specimen issue. These are estrogen receptor 17 stained specimens. This is the same slide 18 that I had from the Sinai, so this is the 19 tumor area. And you can see at this power, 20 it's staining brown and you see the complete 21 section, although it's an outline, you can 22 still see the complete section. On this slide 23 you have large, large gaps, as we go through 24 here, and folds here, so whatever tumor was 25 there in this area has dropped out. And so</p>
<p style="text-align: right;">Page 10</p> <p>1 original - 2 COFFEY, Q.C.: 3 Q. The slide, what we will be--later on what we 4 will be in the morning referring to a slide 5 review. 6 DR. MULLEN: 7 A. Yes. These are not slides that were restrained 8 at the Sinai, these are the slides that were 9 processed, stained in Newfoundland and then 10 referred to me to review, okay. So basically 11 here we have, this is the--on the right-hand 12 side, this would be a breast cancer and the 13 adjacent tissue would have fat and fibre 14 connective tissue and benign ducts. These 15 spaces are fat. On this side, this is a, the 16 section from Newfoundland, and here where we 17 have fat and--it's a complete section. Here 18 we have large, large gaps of the specimen that 19 aren't on the slide, so when the--this was 20 improperly fixed or processed or fixed and 21 processed and when they were cutting, these 22 parts dropped out, they weren't able to adhere 23 to the slide. So one of the difficulties in 24 assessing unfixed, unprocessed or improperly 25 fixed, improperly processed material is the</p>	<p style="text-align: right;">Page 12</p> <p>1 what's left there to assess is very limited 2 and it may not be representative of the entire 3 tumor. I have no guarantee that what's 4 present and what drops out are equivalent. 5 And this is another example, this is even 6 worse, this is the same section that I showed 7 earlier and - 8 COFFEY, Q.C.: 9 Q. And on the right is from Mount Sinai? 10 DR. MULLEN: 11 A. Yes, Mount Sinai. And here - 12 COFFEY, Q.C.: 13 Q. It's Mount Sinai's own produced - 14 DR. MULLEN: 15 A. Yes. This is a case - 16 COFFEY, Q.C.: 17 Q. - specimen and slide? 18 DR. MULLEN: 19 A. - this is in-house case stained with estrogen 20 receptor. The difference here, if I go back 21 to the--this is a hematoxylin and eosin, it's 22 pink and blue, the standard. Pick is the 23 cytoplasm, blue are the nuclei. Here the 24 brown is the ER stain and we only use a 25 counter stain, so you don't see the same</p>

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1 detail. It's not as though my--it's over
 2 exposed. It's a--this is the type of specimen
 3 we look at. And you can see these large,
 4 large gaps even worse that then--oh, no,
 5 that's the same one. Here, I mean, it's
 6 basically you throw something at a wall and
 7 hope something sticks, that's what it is.
 8 Large, large areas missing, just--and other
 9 areas where it's folded over. Now, I'm going
 10 to take you through some hematoxylin and eosin
 11 slides, these are microscopic, there'll be a
 12 low power, a high power and then we'll do the
 13 estrogen receptor and progesterone receptor.
 14 On the right-hand side we have the Sinai
 15 again. This is the histology of the slide I
 16 showed earlier. And this is an example of a
 17 case from Newfoundland. So if you look, here
 18 we have, this is tumor in this area and these
 19 are benign ductal epithelium. This is what
 20 I'm always looking for when I assess the slide
 21 at low--to see do I have tumor, do I have
 22 benign ductal epithelium. And then so I can
 23 then go on when I do my estrogen, progesterone
 24 receptor to look at those areas. And here, so
 25 we'll see the slightly higher power. In this

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1 area we have some residual epithelial cells,
 2 but the majority of the tumor I have here is
 3 dictotic, and at a higher power I'll tell you
 4 what those features are. Basically I'm seeing
 5 amorphous blob like material. I don't see the
 6 distinct outlines of cells. At a higher power
 7 you can see benign ductal epithelium and the
 8 tumor. And here you can see some residual
 9 cells; there is some staining blue. But these
 10 are what I'm referring to in the report as
 11 hollow nuclei. And basically what happens is
 12 as the cell dies or--and starts to autolyse,
 13 the chromatin, which is basically nuclear
 14 substance, starts to leach out and, drop out,
 15 and you have nothing, you have basically an
 16 empty space. And the idea when one stains for
 17 estrogen and progesterone receptor is to stain
 18 the nuclear substance for the protein, so if
 19 you have nothing left in the nucleus, you
 20 wouldn't be able to stain or if it's markedly
 21 decreased, the intensity of the stain will be
 22 almost nil. And I'll show you that as we go--
 23 okay. Now, this is an estrogen stain, again,
 24 of the same case from the Sinai. This is a
 25 low power. And a case from the Newfoundland

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1 material. It's not--doesn't--it's not the
 2 same as the exploding slides. Excuse me.
 3 Now, this is an example of a positive estrogen
 4 receptor. You can see the--I won't give you
 5 why they--these are malignant glands and the
 6 cells are staining strongly. You can see
 7 strong intensity here, variable intensity but
 8 almost, I would say, here probably 90 percent
 9 of the cells are staining. And here what I'm
 10 always looking for, what I keep referring to
 11 as the internal control, I'm looking at the
 12 benign ductal epithelium and checking to make
 13 sure that the specimen worked--specimen
 14 stained. So you can see--oops, oh, there it
 15 is. You can see in the benign ductal
 16 epithelium the cell is staining almost as
 17 intensely as that one. Here's one that's
 18 staining almost as intensely as that one. And
 19 if you recall yesterday I mentioned that in
 20 postmenopausal about 90 percent and in
 21 premenopausal 80 percent of women will have
 22 benign ductal epithelium that stains with
 23 estrogen, progesterone receptors, so that's my
 24 built-in standard. It's not 100 percent, but
 25 it's what I can use. Now, this is an example

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1 of Newfoundland's case material. Here we have
 2 some benign epithelium and here we have tumor.
 3 And you can see the difference in intensity,
 4 you can--if you squint and use your
 5 imagination, you can see a faint brown blush
 6 in the tumor cells. And here you can see,
 7 this is the internal control, and when I--the
 8 external control probably stained a little
 9 stronger than this, but this is what I used as
 10 my baseline. If these cells stained and this
 11 was the strong intensity, then I would accept
 12 these as staining positive. And if we look at
 13 a higher power, you can see, again, the benign
 14 ductal epithelium staining and then the tumor
 15 staining. And here you can see there's a
 16 faint brown blush, but the majority of the
 17 nucleus, as you can see, is gone, so there's
 18 nothing there in the majority of these cells
 19 to allow the protein--or the antibody to stick
 20 to the protein. But there is a brown blush in
 21 these cells. Unfortunately, I don't have a
 22 benign epithelium in this field. So that's--
 23 so yesterday when I was--when I have a breast
 24 case and I'm ordering in-house, so something
 25 that's done at the Sinai, I can choose the

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1 block that includes benign ductal epithelium
 2 so I'll have that internal control as a check
 3 in addition to the external control. And if
 4 we go back here, this is the difference
 5 between a pathologist knowing that that this
 6 is a good peach and that's a bad peach, that
 7 you really look at it and you know there's
 8 something wrong. Something's got to be in
 9 your fixation processing that, specimen
 10 handling, fixation and processing, that caused
 11 this artifact or this abnormality, okay. So
 12 I've covered the concept of fixation
 13 processing, the need for slicing, the formalin
 14 penetration, the rate and so why we do that
 15 fixation rate. I covered the presence of
 16 benign ductal epithelium ideally within the
 17 tumor but adjacent to is not bad, but
 18 hopefully on the slide. And then the
 19 artifacts that I'm referring to, the hollow
 20 nuclei and the exploding specimens. Is there
 21 any other that -
 22 COFFEY, Q.C.:
 23 Q. Doctor--sorry, go ahead.
 24 COMMISSIONER:
 25 Q. Sorry. No, you mentioned the intensity of the

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1 staining?
 2 DR. MULLEN:
 3 A. Yes. That -
 4 COMMISSIONER:
 5 Q. How important is that?
 6 DR. MULLEN:
 7 A. Well, that's usually a function of the amount
 8 of protein.
 9 COMMISSIONER:
 10 Q. u
 11 DR. MULLEN:
 12 A. But the studies have found that the intensity
 13 is graded as zero is absent, one for weak, two
 14 for moderate, three for strong, that the
 15 intensity is not as important as the
 16 percentage.
 17 COMMISSIONER:
 18 Q. Okay.
 19 DR. MULLEN:
 20 A. So as long as you have some, that's adequate.
 21 And I think Dr. O'Malley would have taken you
 22 through Allred scores -
 23 COMMISSIONER:
 24 Q. Yes, she did.
 25 DR. MULLEN:

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1 A. That would be--and I think she indicated
 2 originally we were looking at the combination
 3 of the two, but now the more important is the
 4 percentage.
 5 COMMISSIONER:
 6 Q. Okay.
 7 COFFEY, Q.C.:
 8 Q. Doctor, the slides that we've--or the
 9 photographic images of the slides from
 10 Newfoundland that you were asked to look at
 11 during the slide review in 2008 -
 12 DR. MULLEN:
 13 A. This is the -
 14 COFFEY, Q.C.:
 15 Q. You've had them up there on the screen. This
 16 is some of those slides.
 17 DR. MULLEN:
 18 A. Yes, yes, these are representative.
 19 COFFEY, Q.C.:
 20 Q. Sure.
 21 DR. MULLEN:
 22 A. This was--when I say representative, the boxes
 23 were ready to go back, and to grab a slide. I
 24 think I'd better have some example that--
 25 because using terms that people aren't

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1 familiar with.
 2 COFFEY, Q.C.:
 3 Q. If possible, it's useful to have them
 4 visualized.
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Doctor, those sorts of artifacts, as you
 9 referred to them, depicted on these slides, in
 10 your view, should they have been apparent to
 11 any pathologist who looked at those?
 12 DR. MULLEN:
 13 A. Yes. Yes, they should.
 14 COFFEY, Q.C.:
 15 Q. And I appreciate they weren't originally your
 16 cases, but if you, in your experience, had
 17 come across such slides in the past, you know,
 18 and being asked to interpret them, what, if
 19 anything, would you do?
 20 DR. MULLEN:
 21 A. Well, I think, as I graphically said
 22 yesterday, one I would think about. One I
 23 might let go. Two, umph, and then three,
 24 excuse the expression, and I continued on. We
 25 would immediately go back to--well, I would

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1 start with the path assistants, the people who
 2 actually gross the--when I say gross, people
 3 who actually accession the specimen and
 4 section it and fix it. Was there something
 5 wrong? When was this removed from the
 6 operating room? What did we do wrong? Why is
 7 this specimen not fixed? And then, if
 8 everything were fine there, I would then go on
 9 to the histology lab. Is there something
 10 wrong with our processor? Again, the
 11 processor is the machine that takes the fixed
 12 specimen and makes a paraffin block of it,
 13 that process. Is there something wrong there?
 14 And then if not, if neither of those, then we
 15 go back to was there a delay--those are easy
 16 to do because they're in house and they're
 17 very close to me.
 18 The next is if those two are correct,
 19 then we go to the operating room and what time
 20 was it removed? Was it left in the operating
 21 room or was it immediately brought to the
 22 histology area and put in the fridge in
 23 formalin? Was there some difference? Did we
 24 have a new nurse? Did we have a new porter?
 25 What caused this abnormality? So that would

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1 be the basic process.
 2 So the artifacts that I'm showing here
 3 are not immunohistochemistry artifacts. These
 4 are artifacts or abnormalities, to use a
 5 different term, that are caused between the
 6 time the specimen is removed from the patient
 7 to the time it is put in--a paraffin block is
 8 removed--sorry, paraffin block is prepared.
 9 COFFEY, Q.C.:
 10 Q. Now Doctor, could you describe for the
 11 Commissioner, please, what process, physical
 12 and mental process you go through in a case,
 13 for example, an in-house case at Mount Sinai
 14 from the perspective of you've ordered an ER
 15 and PR and I gather HER2/neu has been ordered
 16 for a particular patient, and you ordered the
 17 ER slide, the PR slide, I gather and H & E
 18 slide would show up and you've described how
 19 you would pick a particular block to do this.
 20 Perhaps you could just take us through, all
 21 the way from what you're--all the way
 22 including looking down through the microscope,
 23 as to what you're looking for.
 24 DR. MULLEN:
 25 A. All right. So the first--so step through, and

Page 23

1 stay on the right-hand side. This is a low
 2 power, this would be about a ten power
 3 magnification, so the actual is about a
 4 hundred of the original. I would examine the
 5 slide to make sure, before I order my--to
 6 order my ER and PR, I would look at the tumor,
 7 decide what type of tumor it was and do all
 8 the--for the synoptic reporting for the basic
 9 tumor. I would look to select the block for
 10 the ER/PR and HER2, I would look, not so much
 11 for the HER2, but for the ER and PR, look to
 12 find the presence of benign ductal epithelium,
 13 ideally as I said, within the tumor, but
 14 closely adjacent to the tumor. I mean, it's
 15 fine if I have to say I have benign ductal
 16 epithelium on the surface, but if this
 17 specimen wasn't processed properly--oops, I've
 18 lost my pointer--wasn't processed properly,
 19 the ductal epithelium out here may react but
 20 it wouldn't react in there. I've tried to
 21 make sure that it's as close to, if not within
 22 the tumor. So that, I would order my ER/PR
 23 and HER2.
 24 COFFEY, Q.C.:
 25 Q. On that particular block?

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1 DR. MULLEN:
 2 A. That block, and then, so I'd receive the
 3 slides. This would be a--I would look at it
 4 at low power, so basically I hold it up, see
 5 if there's any tumor, anything staining brown,
 6 then I'd go to a--put it under my microscope
 7 at a low power, scan the slide to basically
 8 follow that visual path as we go across, to
 9 yes, I have tumor. Then yes, I have ductal
 10 epithelium. Yes, the tumor is stained. Yes,
 11 the ductal epithelium is stained. Or no, the
 12 tumor has not stained and the ductal
 13 epithelium has stained or no, no. So those
 14 three combinations. The yes, yes, fine. No,
 15 yes, fine. No, no, neither, then I have to
 16 stop and think. Is there something in our
 17 technical? Is there some--so then I would
 18 look at the external control and I would look
 19 at the next--usually I get more than one case
 20 a day. I would look at the next case before I
 21 reported that one to make sure that the stains
 22 had worked, the internal control on the next
 23 case.
 24 So the two extremes are very easy. If
 25 there's no staining in this tumor, it's zero.

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1 If there is staining and it's almost every
 2 cell, I report it either as 95, because
 3 there's always one or two that aren't
 4 staining, or occasionally I would report it as
 5 100. Then, the next--so it's not those two
 6 extremes, I then look--step across the slide
 7 with my microscope, and when I say "step
 8 across" I move it sequentially across looking
 9 at each field. Field is my field of view.
 10 And assessing the proportion of cells that are
 11 staining. So I get the numerator, what--so
 12 the numerator are those cells staining brown
 13 and the denominator is the tumor cell. So
 14 it's numerator over denominator, and ideally,
 15 those of you who want to quibble about
 16 mathematics, ideally we would have the same
 17 amount of tumor in each field. So I can then
 18 do the average of the average. But if I
 19 don't, then I have to do some slight
 20 mathematical calculations. So it's numerator,
 21 number of brown, over brown plus tumor cells
 22 that don't stain for each field, and I go
 23 across it sequentially. Some of--I mean, and
 24 then I derive my percentage and I would then
 25 enter it in the synoptic report, which we saw

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1 yesterday. Then I would repeat the process
 2 for PR and -
 3 COFFEY, Q.C.:
 4 Q. For the PR slide?
 5 DR. MULLEN:
 6 A. Yes, PR slides. So that same process, look,
 7 did it stain, did it not stain, the controls,
 8 the tumor, and then go the same and step
 9 across. And then I think the--then, and then,
 10 so that's the actual physical. Then I--the
 11 thought process going through, all right, so
 12 if this is a well differentiated tumor or if
 13 it's a lobular type or tubular type or a
 14 mucinous colloid and this didn't stain, I
 15 mean, if they're anomalies that don't fit what
 16 the literature is, then I would--even though
 17 it didn't stain, I'd think again and I might
 18 have it repeated. So if I'm expecting a
 19 lobular carcinoma, a well differentiated
 20 carcinoma to be positive and it's not positive
 21 or it's not staining, even though the internal
 22 control, I may have it repeated because it's
 23 not fitting my preconceived idea of what the
 24 result should be. Even though everything
 25 technically looks fine, biologically it's not

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1 fine and let's repeat it before we go out. So
 2 these are--lobular carcinomas are about, what,
 3 90 percent positive, if not almost 100 percent
 4 positive. So if one of those turns out as
 5 being negative, alarm bells are going off.
 6 Let's go back and repeat. I mean, these are--
 7 the delay would be a day at most in reporting,
 8 but I think it's more important that we get
 9 the biology right before we report it.
 10 COFFEY, Q.C.:
 11 Q. Commissioner, you haven't intervened. Are you
 12 -
 13 THE COMMISSIONER:
 14 Q. I'm following so far.
 15 COFFEY, Q.C.:
 16 Q. Good, okay. I'll be relying upon you to
 17 intervene.
 18 THE COMMISSIONER:
 19 Q. I'm with you.
 20 COFFEY, Q.C.:
 21 Q. You haven't shown any reluctance in the past,
 22 so I do, in terms of that, just -
 23 THE COMMISSIONER:
 24 Q. Yes.
 25 DR. MULLEN:

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1 A. This is pathology 101, so the most basic.
 2 COFFEY, Q.C.:
 3 Q. So Doctor -
 4 THE COMMISSIONER:
 5 Q. Basically, all the latter part was just your
 6 way of saying that you're not just looking to
 7 do a mathematical exercise. You are thinking
 8 about what it is you're looking at and what
 9 one should see?
 10 DR. MULLEN:
 11 A. Yes.
 12 THE COMMISSIONER:
 13 Q. And using that to make a determination as to
 14 whether or not this is a slide on which you
 15 are prepared to give your opinion?
 16 DR. MULLEN:
 17 A. Yes, that is correct.
 18 THE COMMISSIONER:
 19 Q. Okay.
 20 DR. MULLEN:
 21 A. If you look--I mean, I believe Dr. O'Malley
 22 would have talked about the percentages that
 23 are positive.
 24 THE COMMISSIONER:
 25 Q. Um-hm.

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1 DR. MULLEN:
 2 A. You know, you can--I mean, any one slide can
 3 vary from what they expected. I mean, you
 4 know, we keep track of our statistics or I
 5 keep track of my statistics, what are
 6 positive, what are, you know, ER/PR positive,
 7 ER positive/PR negative, ER negative/PR
 8 positive and neg and negative, but you know,
 9 if I wait until I get a deviation from what
 10 the expected percentage is, and I'm not quite
 11 sure what deviation I would expect to trigger
 12 something, we trigger investigation based on
 13 each case. If there's something that doesn't
 14 fit, we then--we meaning myself and my
 15 colleagues and the technical staff, go and try
 16 to explain the abnormality or the deviation.
 17 I mean, that's not to say that you won't have
 18 a lobular that's negative, but you'd better
 19 make sure that you're happy it's--or that
 20 you're satisfied that all the technical, all
 21 the processing, and your interpretation are
 22 correct before you issue a negative report.
 23 COFFEY, Q.C.:
 24 Q. Doctor, if we could, please, if we could bring
 25 up, please, Exhibit P-1771? Now Doctor, we

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1 have heard references here from other
 2 witnesses from Mount Sinai to a form called a
 3 client satisfaction form or client
 4 satisfaction record.
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. That's correct?
 9 DR. MULLEN:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. What is a client satisfaction record? What's
 13 the purpose of it and what's it used for?
 14 DR. MULLEN:
 15 A. Well, the client is me. The client is the
 16 pathologist. It's used for communication
 17 between the tech--and documentation between
 18 the immunohistopathology lab. We also have it
 19 in our other labs. It would just have a
 20 different title. It's to explain or to flag
 21 technical issues to explain the quality of the
 22 slide. If the quality is not up to our usual
 23 standard, if there's any deviation from the
 24 quality, I will get this slide and the
 25 technologist will attempt to explain why the

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1 slide is not up to our standards. And in this
 2 case, the surgical case number has been
 3 redacted, outside number, I'm not sure. It's
 4 06124. It's from the submitting hospital,
 5 sometimes I don't have the submitting
 6 hospital. It's case number and then these
 7 are--since they're all St. Clare's Mercy, they
 8 haven't put my name here, and then the MLT
 9 comments, poorly preserved, and then the
 10 initials. So each technologist -
 11 COFFEY, Q.C.:
 12 Q. Is that pro, poorly preserved or -
 13 DR. MULLEN:
 14 A. Poorly processed, sorry. Poorly processed.
 15 COFFEY, Q.C.:
 16 Q. In that world, what does that mean, in your
 17 world?
 18 DR. MULLEN:
 19 A. That would have been either the fixation
 20 and/or processing that we cannot--once we have
 21 the block, so this is material that's been
 22 processed outside, fixed--removed, fixed,
 23 processed and a paraffin block prepared
 24 outside the hospital. So we use the term
 25 processed, fixed, whichever, I mean, almost

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1 interchangeably. We cannot tell which of the
 2 two or if either of the two or both of the
 3 processes were unsatisfactory. So basically,
 4 what we have is a block that we have
 5 difficulty making a slide of, and this would--
 6 if you go back to my--if you remember my first
 7 H & E slide, we would end up with holes
 8 possibly, and then when we're doing the
 9 immunohistochemistry, because we do antigen
 10 retrieval as part of the standard ER and PR
 11 staining which requires heating in an acid, it
 12 would most likely explode.
 13 COFFEY, Q.C.:
 14 Q. If we could -
 15 DR. MULLEN:
 16 A. And then -
 17 COFFEY, Q.C.:
 18 Q. Go ahead, sir.
 19 DR. MULLEN:
 20 A. So we go, and that's for me to fill in,
 21 whether it--and then corrective action. Here,
 22 there's not much corrective action we can do,
 23 and then I would sign it.
 24 COFFEY, Q.C.:
 25 Q. Doctor, here, on page two of the exhibit, this

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1 is just another case.
 2 DR. MULLEN:
 3 A. Yeah.
 4 COFFEY, Q.C.:
 5 Q. And the date request received, March 7th '06,
 6 and date slides completed, March 8th '06, and
 7 it's written here "tissue lifted from the
 8 slides in immunostain. If needs to be
 9 repeated, please let us know." So I take it
 10 this is something that comes to yourself?
 11 DR. MULLEN:
 12 A. Yes. So this would be--I can't speak to the
 13 specific case, but reading what they're
 14 saying, this would be the issue of the
 15 exploding slide or lifting and parts had
 16 fallen off, and the question they're asking me
 17 is "do you feel that there is enough
 18 identifiable tumor present to render an
 19 interpretation?" and that would be the--this
 20 would be the immunostains so it'd be ER/PR,
 21 either the ER, PR or both.
 22 COFFEY, Q.C.:
 23 Q. And here, go on to page three of the exhibit,
 24 there's again an outside case number. The
 25 pathologist is indicated to be yourself. The

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1 date is April 6th, 2006, and under the comment
 2 there's "Fatty tissue received. Unable to cut
 3 sections due to unprocessed tissue. Tried to
 4 cut at 5 -
 5 DR. MULLEN:
 6 A. At 5 and 6 microns.
 7 COFFEY, Q.C.:
 8 Q. - and 6 microns. Not possible" and the TW?
 9 DR. MULLEN:
 10 A. That's Trish.
 11 COFFEY, Q.C.:
 12 Q. Trish Wegrynowski. So this would communicate
 13 what to yourself, what sort of -
 14 DR. MULLEN:
 15 A. That we'd have to ask for another block. They
 16 can't get a section. This is not one of the
 17 issues of being able to get a section and then
 18 doing our little trick of putting it in--I
 19 don't know if she explained the issue of
 20 putting it in alcohol, floating it in alcohol.
 21 Usually when we cut--when we, the
 22 technologists cut a section, it floats in
 23 water and then they put it on the slide. If
 24 they're having difficulty cutting the section
 25 or it's starting to break up as they're

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1 cutting it, they have a little trick, some of
 2 them have a little trick where they put some
 3 alcohol, it doesn't really matter what the
 4 dilution is, some alcohol in the water. It
 5 doesn't have to be in the bath, it can be on a
 6 slide, and they float it out that way, and
 7 it's a technical trick to get the slide a
 8 complete section. Now that will allow me to
 9 look at an H & E, but again, because of the
 10 issue, it's poorly processed, when we go into
 11 antigen retrieval, there's no guarantee that
 12 I'll have anything left. We'll end up with
 13 those exploding slides or sections.
 14 COFFEY, Q.C.:
 15 Q. And -
 16 DR. MULLEN:
 17 A. And this one, I would probably say it's
 18 unacceptable and get something else.
 19 COFFEY, Q.C.:
 20 Q. If we could, and that particular outside case
 21 number is 06916-3, I believe. Here, the next
 22 page of the exhibit, page four, again the
 23 outside case number is S91606 -
 24 DR. MULLEN:
 25 A. Dash 12.

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1 COFFEY, Q.C.:
 2 Q. Dash 12. It's April 24th '06, which is about
 3 18 days later, and there's a note here, "the
 4 tissue is not well processed."
 5 DR. MULLEN:
 6 A. So this would be after I've said "can't
 7 diagnose. Please send another block." They
 8 would have sent another block and this would
 9 be our comment on the block, and here it's not
 10 well processed, a different technology, and
 11 unless I actually see the report, I'm not sure
 12 whether I would have gone forward or not.
 13 COFFEY, Q.C.:
 14 Q. And just going to go ahead and these are just--
 15 these are not at all--what is here,
 16 Commissioner, is not at all exhaustive. These
 17 are just kind of representative samples of a
 18 client satisfaction record, I understand.
 19 Page six, Doctor, this particular matter under
 20 the comment is "scant tissue in block. Did
 21 not trim." What does that refer to?
 22 DR. MULLEN:
 23 A. Sorry, when we receive a block, it's placed in
 24 a microtome to basically a razor--equivalent
 25 to a razor blade is used or a very sharp

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1 instrument is used to take a section at about
 2 four to five microns to make the section, and
 3 here, the technologist assesses visually the
 4 amount of material in the block. If there's
 5 only a few cells or a few, a little bit of
 6 tissue, they will not try to get a perfect
 7 section. They'll make the cut and get
 8 whatever they can, because if they trim to
 9 make a complete section, they may throw away
 10 all that tissue. Trimming is done at a much
 11 thicker cut than the final section. It could
 12 be done at 10 microns, 20 microns, but the
 13 final block or the final section should be
 14 about four microns. So they'll try at four
 15 microns to get a section. It's to preserve
 16 the--or maximize the amount of tissue
 17 available for analysis. If this--this may be
 18 the only tissue that is available and here, if
 19 you look at the outside case number, there is
 20 no other block, this was probably a biopsy of
 21 some sort. That's the only tissue available.
 22 We can't ask for another block. We maximize
 23 what we can on this.
 24 COFFEY, Q.C.:
 25 Q. Next page, Commissioner, page seven of the

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1 exhibit. This is another client satisfaction
 2 record and the reproduction here, make an
 3 effort at reading what appears to be there.
 4 "The tissue is not well processed. The
 5 section explodes upon contact with -
 6 DR. MULLEN:
 7 A. Water.
 8 COFFEY, Q.C.:
 9 Q. Water?
 10 DR. MULLEN:
 11 A. Water, yes.
 12 COFFEY, Q.C.:
 13 Q. So again, this would be the technologist
 14 informing you -
 15 DR. MULLEN:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. - of the problem with this?
 19 DR. MULLEN:
 20 A. This would be to tell me that I'm going to get
 21 an exploding section with the ER and PR.
 22 COFFEY, Q.C.:
 23 Q. Page eight of the exhibit, and again, this is
 24 another outside case number. You might be
 25 able to -

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1 DR. MULLEN:
 2 A. Okay. The block is re-embedded. The block
 3 something is--something missing on the--it's -
 4 COFFEY, Q.C.:
 5 Q. It's very difficult to read what's there.
 6 DR. MULLEN:
 7 A. Yes. Can I see the original? Is that any
 8 better than the pdf?
 9 COFFEY, Q.C.:
 10 Q. I will check on that.
 11 DR. MULLEN:
 12 A. Oh, so you just have the reproduction. Okay.
 13 COFFEY, Q.C.:
 14 Q. See if it's available.
 15 DR. MULLEN:
 16 A. The block is re-embedded. The block,
 17 something not possible remaining and the block
 18 is--I really can't.
 19 COFFEY, Q.C.:
 20 Q. So again -
 21 DR. MULLEN:
 22 A. Something is something in the middle.
 23 MR. BROWNE:
 24 Q. Block came out while trimming.
 25 COFFEY, Q.C.:

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1 Q. Yes.
 2 DR. MULLEN:
 3 A. Oh, good.
 4 COFFEY, Q.C.:
 5 Q. Good.
 6 DR. MULLEN:
 7 A. Oh, the block--oh so, trimming and the block
 8 is something in the--missing? No.
 9 COFFEY, Q.C.:
 10 Q. Something in the middle.
 11 DR. MULLEN:
 12 A. Something is in the middle. So basically, the
 13 preparation of the block was so poor that -
 14 COFFEY, Q.C.:
 15 Q. Would that be hollow in the middle, the word
 16 "hollow"?
 17 DR. MULLEN:
 18 A. Could be. Could have popped out, because of
 19 poor processing. I wouldn't want to -
 20 COFFEY, Q.C.:
 21 Q. Without seeing the original it would be
 22 difficult to say?
 23 DR. MULLEN:
 24 A. The original, yes.
 25 COFFEY, Q.C.:

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1 Q. And I appreciate that. Again, I'm just going
 2 through these for the Commissioner to get some
 3 sense of what sorts of communications would go
 4 to yourself as the pathologist from the
 5 technologist in respect to--I take it these--
 6 do these relate to Newfoundland, these--or
 7 would you be able to tell?
 8 DR. MULLEN:
 9 A. Did Trish selected them as Newfoundland cases?
 10 If she selected them as Newfoundland, they're
 11 Newfoundland, yes.
 12 COFFEY, Q.C.:
 13 Q. And page nine, I'm just going to go to. This
 14 is--here, the comment is what?
 15 DR. MULLEN:
 16 A. "Tissue is not well processed, leaving it very
 17 difficult to cut. Tried to obtain as much
 18 tumor on the slides as possible." That again
 19 is the--would be the poorly processed. We'd
 20 have holes in the H & E sections and possibly
 21 the exploding in the--on the ER and PR slides.
 22 COFFEY, Q.C.:
 23 Q. So I'm going--there are others there. If
 24 others want to ask you about them, the other
 25 lawyers can. I'm just--that's enough for my

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1 purposes here, Commissioner. So this sort of
 2 form, Doctor, has been used in your laboratory
 3 for how long?
 4 DR. MULLEN:
 5 A. As long as I can remember, but let me see at
 6 the bottom if it was--this particular form was
 7 in 2005. This was updated in 2005.
 8 COFFEY, Q.C.:
 9 Q. It says version four.
 10 DR. MULLEN:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. So I take it that there are earlier versions?
 14 DR. MULLEN:
 15 A. Yes. So this is my document. This is our
 16 document management immunohistochemistry
 17 manual 2005, standard operating procedure 11,
 18 document control.doc and version four. So for
 19 our accreditation, we have to document all of
 20 our operating procedures and all of our forms
 21 and then we also have to document this type of
 22 quality assurance or quality control program.
 23 COFFEY, Q.C.:
 24 Q. So this sort of form has been used in one form
 25 or another -

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1 DR. MULLEN:
 2 A. Oh yes.
 3 COFFEY, Q.C.:
 4 Q. - for a while, quite a while?
 5 DR. MULLEN:
 6 A. Yes. As I mentioned, it's used both in the
 7 routine histology, as well as in the special
 8 areas, special histology areas.
 9 COFFEY, Q.C.:
 10 Q. If we could, please, Registrar, take you now,
 11 Doctor, to Exhibit 18--P-1840. Now Doctor,
 12 this is a letter you wrote April 14th, 2008,
 13 up on the screen there yesterday. It's signed
 14 by yourself. Could you tell the Commissioner,
 15 please, how you came--and I'm going to refer
 16 to this as a slide review.
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Shorthand. How you came to do this slide
 21 review?
 22 DR. MULLEN:
 23 A. When co-counsel were in Toronto, they
 24 indicated in December to review the results of
 25 my findings on the retrospective study. In

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1 other words, the blocks, the 1106 blocks--11--
 2 yeah, 1106 blocks that were referred to
 3 Toronto for restaining and interpretation.
 4 They indicated they had an interest in
 5 reviewing--have someone review the original
 6 material. So those, when I talk about the--
 7 speak about the original material, I'm
 8 referring to the H & E sections and the ER/PR
 9 and external controls of the material that was
 10 stained in St. John's over that time period,
 11 from '07 to--sorry, '97 to '05, if I remember
 12 correctly. At that time, they indicated they
 13 were thinking of like 3,000 slides, so all of
 14 the original material.
 15 COFFEY, Q.C.:
 16 Q. And you were then subsequently asked to do
 17 what?
 18 DR. MULLEN:
 19 A. To review a selection of these slides, which
 20 turned out to be 550--approximately 540, well,
 21 547, something, somewhere around there. 500
 22 some odd slides, which were the--oh, sorry,
 23 539 cases and I think there were 547 slides.
 24 I was asked to review the H & E, the ER, PR,
 25 external controls when available, and the

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1 pathology report when available, and to
 2 comment on the--basically, to repeat my--the
 3 process of diagnosis of the tumor, the
 4 percentage ER positive, the percentage PR
 5 positive, presence/absence of internal
 6 controls, whether they stained, if they were
 7 present, or stained weakly, the presence--my
 8 assessment of the adequacy, and then to
 9 comment on the external controls, when
 10 available, whether they stained or didn't
 11 stain. Then to look at the pathology report
 12 and if I could glean from the original
 13 pathology report, a numeric value or a
 14 qualitative value for ER/PR, to enter that,
 15 and then I looked at the pathology report that
 16 I was presented with. If it had some
 17 reference to my reinterpretation and a
 18 proportion had a reference to my
 19 reinterpretation of the material, it would say
 20 something to the effect that the slides were
 21 stained in Mount Sinai hospital and Dr. Mullen
 22 reported this and this, I would enter them. I
 23 would make a comment whether they were
 24 concordant with the original interpretation in
 25 Newfoundland and then I would make some--or

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1 discordant and I'd make some comment, if they
 2 were discordant, whether--about the internal
 3 control presence or absence. So it's--once we
 4 see the spreadsheet, it'll become more obvious
 5 or clearer than what I'm saying now. So 539
 6 cases, basically the same process, extended to
 7 commenting where I could on discordance and
 8 concordance. I did not go back to my original
 9 material, the spreadsheet that I presented,
 10 and actually check what I had said. It was
 11 only if it was there.
 12 COFFEY, Q.C.:
 13 Q. Now just on that point, and I'll be exploring
 14 this a bit more with you as we go ahead, that
 15 in determining concordance or discordance as
 16 you've referred to it -
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. - you were utilizing whatever information was
 21 on the pathology report that you had received
 22 from Newfoundland in 2008.
 23 DR. MULLEN:
 24 A. That is correct.
 25 COFFEY, Q.C.:

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1 Q. And if the pathology report from Newfoundland
 2 that you received did refer to Mount Sinai's
 3 retrospective results, and they were included
 4 there, you would read what was written there
 5 and compare it to what you were seeing--what
 6 was written there with what you were seeing?
 7 DR. MULLEN:
 8 A. What the--yes.
 9 COFFEY, Q.C.:
 10 Q. In the original report?
 11 DR. MULLEN:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Pathology report, back in 1998, '99, 2000 or
 15 whatever.
 16 DR. MULLEN:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. On the same--because it would be in the same
 20 pathology report?
 21 DR. MULLEN:
 22 A. Yes, yes, the original would be--the original
 23 values--well, when we see the spreadsheet--I
 24 can't--I didn't--don't recall the percentage,
 25 but a vast majority of the--I should say, a

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1 large number of the cases had just
 2 qualitative, whether it was negative,
 3 completely negative or mostly negative type
 4 comments. I wasn't quite sure what those
 5 meant.
 6 COFFEY, Q.C.:
 7 Q. Yes.
 8 DR. MULLEN:
 9 A. Because having learnt in December that there
 10 were different cut points used for what was
 11 considered negative, I really couldn't comment
 12 on that.
 13 COFFEY, Q.C.:
 14 Q. So -
 15 DR. MULLEN:
 16 A. And when I talk about cut points, I'm talking
 17 about greater than 30 for ER, then greater
 18 than 10.
 19 COFFEY, Q.C.:
 20 Q. Now, what I'm going to do, and I'll approach
 21 it this way, I'm going to take you through the
 22 two-page report.
 23 DR. MULLEN:
 24 A. Okay.
 25 COFFEY, Q.C.:

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1 Q. And then go to the spreadsheet of the results
 2 you prepared from the slide review and then
 3 perhaps, as necessary, return to the report.
 4 Just to look at the first page of the April
 5 14th, 2008, Doctor. So you report here that
 6 you completed your review of five banker boxes
 7 containing in total 24 individual slide boxes
 8 and related original pathology reports were
 9 available. And you indicate that in mid April
 10 that was being returned to the Commission of
 11 Inquiry offices. Doctor, you refer to 539
 12 cases. Would that be 539--what do you mean by
 13 a case in this context?
 14 DR. MULLEN:
 15 A. Oh, 539 patient specimens.
 16 COFFEY, Q.C.:
 17 Q. So for any one patient specimen, how many
 18 slides would there be, generally?
 19 DR. MULLEN:
 20 A. Okay. Anywhere from two, ER/PR, to one, two,
 21 three, four, I'd say some had nine, I think up
 22 to nine, but the vast majority would have an
 23 H&E, an ER and PR, so there would be three.
 24 Some would have an external control of either
 25 ER and/or PR or both. And some cases I would

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1 have two sets of stains for, one H&E, two sets
 2 of stains for ER/PR and two sets of stains for
 3 the external controls for the ER/PR, so that
 4 would be one, four, five, seven, nine, so,
 5 yes, nine.
 6 COFFEY, Q.C.:
 7 Q. In some. I take it there weren't many that -
 8 DR. MULLEN:
 9 A. No, there were very few. And when see the
 10 spreadsheet it will become obvious. And some
 11 I would have the ERs control, external
 12 control, some I'd have the PR and some I said
 13 both.
 14 COFFEY, Q.C.:
 15 Q. Now, Doctor, here then you indicate that the
 16 results of your review are enclosed on a
 17 compact disc. And if you could just then take
 18 us, you say here that the disc contains an
 19 Excel spreadsheet labelled "Mount Sinai review
 20 by year."
 21 DR. MULLEN:
 22 A. Um-hm.
 23 COFFEY, Q.C.:
 24 Q. With sheet one labelled "NLCOIHR" and sheet
 25 two labelled "MSH data." And "NLCOIHR

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1 contains your original data forwarded to me
 2 for review," okay, so that's a spreadsheet the
 3 Commission had sent you. "MSH data contains
 4 the results of my" that would be your review?
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. "With additions and corrections as required.
 9 The patients are arranged alphabetically by
 10 year. The additions are indicated by either
 11 an asterisk after the number or the term Zymed
 12 or DAKO. The asterisk additions were
 13 necessitated by additional slides submitted
 14 with a separate block number. Zymed and DAKO
 15 additions were required because of the
 16 presence of duplicate slides on the same block
 17 with different immunohistochemical staining.
 18 The corrections involve year and block
 19 numbers. I've also enclosed a copy of the MSH
 20 data spreadsheet code which explains the terms
 21 used in the results section of the MSH data
 22 spreadsheet." So now if I could, having taken
 23 you through that, I just read it out to you,
 24 if we could, please, bring up, please, Exhibit
 25 P-1837? Just this is page 1 of the exhibit.

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1 The reference to DAKO and Zymed.
 2 DR. MULLEN:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. You see that?
 6 DR. MULLEN:
 7 A. Case 1236, it's one, two, three, four, five
 8 and six down and then--I should have said Kit,
 9 as well, I missed that one.
 10 COFFEY, Q.C.:
 11 Q. Yes.
 12 DR. MULLEN:
 13 A. I had slides that were ER/PR labelled and they
 14 also had DAKO and Zymed and then DAKO and Kit.
 15 I wasn't quite sure what they meant, so I--and
 16 these were from '97, so I--to separate the
 17 reports, I put, I duplicated the demographics,
 18 the name, MCP number, date of birth and the
 19 block number, specimen number and block, year
 20 number, and then interpret them on different
 21 lines. Every time I had a slide, I would give
 22 an interpretation. I didn't average them, I
 23 didn't take the higher, didn't take the lower,
 24 whatever I had, there's a number.
 25 COFFEY, Q.C.:

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1 Q. Okay. Now, just go back then, please, to
 2 Exhibit P-1840? Now here, Doctor, beginning
 3 at the bottom of the first page you say "To
 4 summarize my observations, the overwhelming
 5 majority of cases had one or more of the
 6 following problems: Poor fixation or
 7 processing resulting in incomplete tissue
 8 sections; loss of the internal structure of
 9 the nucleus and staining restricted to the
 10 periphery of the slide. In our previous
 11 conversation I take that's you're referring to
 12 the interview that -
 13 DR. MULLEN:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. That occurred involving yourself and Ms.
 17 Chaytor and I in December of '07. The
 18 incomplete tissue section issue was referred
 19 to as, in quote, "exploding", sections. The
 20 exploding term is your term, I take it?
 21 DR. MULLEN:
 22 A. Yes, yes. There is a proper term, but the--
 23 you don't use that in literature, but.
 24 COFFEY, Q.C.:
 25 Q. You wouldn't have used the word "exploding".

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1 What would that be referred to as, Doctor, in
 2 the proper term, do you know?
 3 DR. MULLEN:
 4 A. Poor adherence.
 5 COFFEY, Q.C.:
 6 Q. Poor adherence.
 7 DR. MULLEN:
 8 A. Poor adherence.
 9 COFFEY, Q.C.:
 10 Q. That would be sections with poor adherence?
 11 DR. MULLEN:
 12 A. Yes, a section would not stain the slide. I
 13 like the exploding, it's more graphic.
 14 COFFEY, Q.C.:
 15 Q. In some of the material I reviewed, the
 16 exploding sections resulted in a loss of the
 17 invasion tumor on the ER/PR slides although it
 18 was present in the initial H&E section. I
 19 take it you referred to that -
 20 DR. MULLEN:
 21 A. Yes, if you recall when I was going through
 22 the pathology 101, because of antigen
 23 retrieval for ER and PR, it requires heating
 24 in an acid solution, the material doesn't
 25 adhere to the slide. It falls off. So,

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1 although you can get a section, an adequate or
 2 semi-adequate or section for a--the routine
 3 H&E, once you require any pre-treatment or
 4 before you stain any of the antigen retrieval
 5 processes, your chance of losing the section
 6 is quite high. And it results in that
 7 portions of the slide falling off, portions of
 8 the slide adhering to each other, rendering
 9 interpretation either not--you're unable to
 10 interpret or it's very difficult to interpret.
 11 COFFEY, Q.C.:
 12 Q. You go on to say here then that the second
 13 issue, "loss of the internal structure of the
 14 nucleus, we discussed as 'hollow' nuclei" and
 15 I take it that's it the same context, the "we"
 16 is, the -
 17 DR. MULLEN:
 18 A. Yes, you and Ms. Chaytor and Mr. Simmons.
 19 COFFEY, Q.C.:
 20 Q. Yes, Mr. Simmons was there for Eastern Health
 21 as well during the interview.
 22 DR. MULLEN:
 23 A. And my lawyer, Mr. Clements.
 24 COFFEY, Q.C.:

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1 Q. Yes.
 2 DR. MULLEN:
 3 A. I have to acknowledge my lawyer.
 4 COFFEY, Q.C.:
 5 Q. Mr. Clements was certainly also present. We
 6 discussed as "hollow" and I believe the word
 7 "hollow" was your term?
 8 DR. MULLEN:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. And what is that?
 12 DR. MULLEN:
 13 A. That's the hollow nuclei. That's the leaching
 14 out or the loss of the nuclear structure, the
 15 contents of the nucleoplasm which is
 16 chromatin, the DNA and all the proteins within
 17 the nucleus. So -
 18 COFFEY, Q.C.:
 19 Q. And that is caused by, generally -
 20 DR. MULLEN:
 21 A. Poor fixation processing. It's what we call
 22 autolysis, the tissue is actually digesting
 23 itself.
 24 COFFEY, Q.C.:
 25 Q. You continue by saying, "because of poor

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1 fixation, the nuclear substance is lost and
 2 markedly decreases the chance of staining for
 3 ER/PR". And I take it here, poor fixation
 4 includes potentially processing as well.
 5 DR. MULLEN:
 6 A. Yes, sorry, yes.
 7 COFFEY, Q.C.:
 8 Q. The third issue -
 9 DR. MULLEN:
 10 A. No, sorry, that would be a fixation only, for
 11 the hollow nuclei because if you have it, if
 12 it's fixed, it's there. The processing, you
 13 wouldn't get that part of the section. Sorry,
 14 to clarify, yes, this one I could tell would
 15 be fixation.
 16 COFFEY, Q.C.:
 17 Q. Where you're seeing a situation involving
 18 hollow nuclei.
 19 DR. MULLEN:
 20 A. Hollow nuclei, yes.
 21 COFFEY, Q.C.:
 22 Q. It's a fixation issue or problem.
 23 DR. MULLEN:
 24 A. Yes. It would be aggravated by poor
 25 processing, but it's mainly a fixation.

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1 COFFEY, Q.C.:
 2 Q. You go on to say then, "the third issue,
 3 staining restricted to the periphery of the
 4 slide refers to staining of the periphery of
 5 the section with absence of staining
 6 centrally".
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. And you continue by saying, "it is difficult
 11 to interpret the results of these cases as the
 12 peripheral staining results may not reflect
 13 the results of the entire tumor". What does
 14 that -
 15 DR. MULLEN:
 16 A. Again, if you go back to my peach analogy and
 17 the third section where I had the complete
 18 section of the tumor. Depending on how the
 19 specimen was grossed, in other words, how it
 20 was cut or if it wasn't cut or how thick the
 21 sections were or whether it was sectioned at
 22 all, it reflects the fact that the formalin
 23 has fixed the outside, but not the inside of
 24 the tumor. So, if I took a section through
 25 the middle of my--can I pull up the

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1 PowerPoint, sorry, I apologize. It's just
 2 easier to show it graphically. Okay. So, if
 3 this is sectioned, I would take a section
 4 through or the pathologist assistant would
 5 select this block--now when I say this block,
 6 this is what would be put through the
 7 processor to make a block. Now -
 8 COFFEY, Q.C.:
 9 Q. That little portion of this you just outlined
 10 -
 11 DR. MULLEN:
 12 A. Yes, that would be the tumor and some adjacent
 13 normal tissue. In this case, it's mostly fat.
 14 If this were, I mean, you have to use your
 15 imagination, if this were the closest distance
 16 or any--the fixative, if this were the
 17 complete peach, the closest distance is to
 18 here. So, depending on the time of fixation,
 19 I might end up with basically a rim of
 20 fixation here and nothing in the centre.
 21 COFFEY, Q.C.:
 22 Q. No proper fixation.
 23 DR. MULLEN:
 24 A. No proper fixation. So, we would end up with
 25 this type of this centrally and a little bit

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1 of viable tumor at the periphery. So, this
 2 part would be necrotic and the outside would
 3 be fixed properly. And if you recall
 4 yesterday, there was the exchange of e-mails.
 5 In one case I explained that in one section I
 6 really only had staining at the periphery and
 7 the other section where I changed the value,
 8 it was a little higher, I also had some
 9 identifiable, better preserved tumor.
 10 So, if you think of a sphere, if you're
 11 coming in from the outside, the margin--if I
 12 only take a section of the margin, cut off the
 13 tip of it, that will, theoretically, be
 14 uniformly fixed, but as I move towards the
 15 centre as the formalin moves in, I will have
 16 unfixed tissue centrally. And I need fixed
 17 tissue, well processed tissue for the stain.
 18 COFFEY, Q.C.:
 19 Q. And would you go back, please, Exhibit P-1840,
 20 thank you.
 21 DR. MULLEN:
 22 A. And the last line, "it's difficult to
 23 interpret results and peripheral staining may
 24 not reflect". And that was in the back and
 25 forth e-mails with, I believe it was Doctor

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1 Cook. And that would be, I take it, that
 2 exchange of e-mails would be representative of
 3 the sort of phenomenon you're talking about
 4 here?
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. In terms of the overall retrospective study,
 9 would it be limited to that one case or would
 10 -
 11 DR. MULLEN:
 12 A. Oh, no, no, no. This whole series were
 13 present in upwards of 90 percent. I mean, it
 14 was across the board. I mean, not each case
 15 had all three, the poor fixation processing
 16 with the explosion or the hollow or the
 17 doughnut issue for the peripheral staining,
 18 but the majority had the fixation processing
 19 with the hollow. A large proportion had the
 20 exploding and small proportion had the
 21 doughnut or absence the central staining.
 22 COFFEY, Q.C.:
 23 Q. And if we could then, Doctor, you go on then
 24 to, in paragraph 2, you say--and this is in
 25 the slide review, you're looking at now.

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1 DR. MULLEN:
 2 A. Yes, of the original stained slides.
 3 COFFEY, Q.C.:
 4 Q. Yes, the original stained slides, originally
 5 stained in Newfoundland, at least, you
 6 understood.
 7 DR. MULLEN:
 8 A. Yes, um-hm.
 9 COFFEY, Q.C.:
 10 Q. You write here, paragraph two, page two of the
 11 exhibit, "absence of the internal controls,
 12 many of the cases had no normally duct
 13 epithelium to use as an internal control on
 14 the initial H&E section. Additionally, in
 15 many cases where the original H&E section had
 16 normal duct epithelium, it was not present on
 17 the ER/PR slides as a result of the exploding
 18 section issue".
 19 DR. MULLEN:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. So, would you expand upon that a little bit
 23 for the Commissioner.
 24 DR. MULLEN:
 25 A. Okay. Registrar, can I have the PowerPoint

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1 popped up again, please. So, if this is the
 2 type of section that I'd see on an H&E, I
 3 would be able to identify tumor. I would be
 4 able to identify the normal duct epithelium,
 5 if it were present. Then when I went to match
 6 that to this, this is--I apologize, this is
 7 not the concordance slide with--this is not
 8 the ER that goes with that H&E, but if I were
 9 trying to match, I would be looking here for
 10 the invasive tumor. I'd be looking here for
 11 the normal duct epithelium and there would be
 12 large areas of the section that were missing.
 13 So, normal duct epithelium isn't that
 14 prevalent. I would lose it. And here it
 15 would be virtually impossible to find any.
 16 You might have a few residual, either tumor or
 17 duct epithelium up here, but the vast majority
 18 of this, there's nothing there to interpret.
 19 COFFEY, Q.C.:
 20 Q. So, if we can go back then, please, to Exhibit
 21 P-1840. Thank you. So, here under the
 22 "absence of the external controls", many of
 23 the cases you note had no normal duct
 24 epithelium to use as an internal control on
 25 the initial H&E section. I take it then that

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1 that particular block which was used to grade
 2 the H&E section that you were looking at, the
 3 slide that had been prepared two or perhaps
 4 five years or whatever before in Newfoundland.
 5 Looking at the H&E section slide, there just
 6 wasn't any, that you could see, normal duct
 7 epithelium there.
 8 DR. MULLEN:
 9 A. Um-hm.
 10 COFFEY, Q.C.:
 11 Q. And then in cases where there was, on the H&E
 12 slide, at times when you looked at the
 13 matching ER and PR slides, ER and PR slide did
 14 not have the tissue that had originally on the
 15 H&E slide had contained normal duct epithelium
 16 was missing -
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. - on the ER and PR slides.
 21 DR. MULLEN:
 22 A. A portion you can explain by--we talk about
 23 our white swan, the section that--you're
 24 getting another section. It may not be in
 25 that. And in rare cases where I didn't find

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1 normal duct epithelium in the H&E section, I
 2 might have found it in the ER or PR. So, I
 3 assess the three slides for the presence of
 4 normal duct epithelium.
 5 COFFEY, Q.C.:
 6 Q. Okay. Overall, many of the cases just--as you
 7 note, either had none on the H&E section that
 8 you could see or by the time it made it to the
 9 ER/PR slides, you couldn't see any normal duct
 10 epithelium on the original slides.
 11 DR. MULLEN:
 12 A. That is correct.
 13 COFFEY, Q.C.:
 14 Q. Paragraph three is, written here, "negative
 15 internal controls, in many cases, the internal
 16 control either did not stain or stain very
 17 weakly. Also with the exception of a small
 18 minority of cases, the ER internal control was
 19 significantly weaker than the PR internal
 20 control". Now, I take it again, to remind the
 21 Commissioner and those present here that
 22 you're looking at the original Newfoundland
 23 slides?
 24 DR. MULLEN:
 25 A. Yes, that is correct.

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1 COFFEY, Q.C.:
 2 Q. In saying this.
 3 DR. MULLEN:
 4 A. Yes. And the PowerPoint or not, is it worth
 5 it, Commissioner?
 6 THE COMMISSIONER:
 7 Q. Yes.
 8 COFFEY, Q.C.:
 9 Q. Yes.
 10 DR. MULLEN:
 11 A. Okay, back we go. So, again, I would look,
 12 the H&E, looking for an internal control which
 13 we have here, the Sinai case, the tumor here,
 14 I think that's malignant epithelium. I don't
 15 think I have benign internal control in this
 16 section. That wasn't what I was doing.
 17 Again, malignant. Here malignant staining,
 18 looking at the internal control and here, I am
 19 happy with the case from Newfoundland that
 20 there was benign epithelium and it did stain.
 21 So, this is what I'm referring to, looking at
 22 that benign epithelium, that it did stain and
 23 then I would assess the tumor. But
 24 unfortunately, I don't have a side-by-side
 25 comparison of ER and PR, but uniformly PR was

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1 stronger than ER. The ER stain was quite
 2 weak.
 3 COFFEY, Q.C.:
 4 Q. And that's in the internal controls.
 5 DR. MULLEN:
 6 A. Yes, internal and in the external controls.
 7 COFFEY, Q.C.:
 8 Q. Okay. What, if any significance in looking at
 9 that, did that have? Did that mean anything
 10 to you at the time?
 11 DR. MULLEN:
 12 A. Well, I would be worried that the stains
 13 hadn't been optimized and the validation
 14 hadn't been carried out properly, that I would
 15 be--the staining might not reflect the
 16 biology, to put it in as broad a context as
 17 possible, that if the ER stain hadn't been
 18 optimized and validated properly, we weren't
 19 staining appropriately.
 20 COFFEY, Q.C.:
 21 Q. "We" in the sense -
 22 DR. MULLEN:
 23 A. "We" meaning Newfoundland.
 24 COFFEY, Q.C.:
 25 Q. Back, historically.

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1 DR. MULLEN:
 2 A. Yeah, the historical.
 3 COFFEY, Q.C.:
 4 Q. And Doctor, under optimized conditions
 5 generally what you would expect to find in
 6 terms of staining of internal controls for ER
 7 and staining of internal controls for PR in
 8 terms of their intensity levels?
 9 DR. MULLEN:
 10 A. I would expect them to be--if I'd optimized
 11 them approximately equal, you might accept
 12 slight variabilities; one being stronger, one
 13 being slighter weaker. But you would want to
 14 optimize to the same level or as close to the
 15 level as possible.
 16 COFFEY, Q.C.:
 17 Q. And here in the slide review that you were
 18 conducting, you did make a point of noting
 19 that -
 20 DR. MULLEN:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. - or looking at multiplicity of slides, well
 24 over 500 ER slides and well over 500 PR
 25 slides, that--where there were internal

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1 controls and where the internal controls did
 2 stain, you noted that the ER internal control
 3 tended to be significantly weaker than the PR.
 4 DR. MULLEN:
 5 A. That's correct.
 6 COFFEY, Q.C.:
 7 Q. Doctor, looking at, and the fact that there
 8 were some, apparently, based on your
 9 observations, you refer, many of the cases had
 10 no--paragraph two, if I could, P-1840, thank
 11 you. "Many of the cases had no normal duct
 12 epithelium to use as an internal control on
 13 the initial H&E section".
 14 DR. MULLEN:
 15 A. Um-Hm.
 16 COFFEY, Q.C.:
 17 Q. Doctor, were you surprised by that? Was that
 18 expected?
 19 DR. MULLEN:
 20 A. No, no. The breast as well as for, I mean,
 21 the object in immunohistochemistry is to have
 22 controls. External controls are fine, they're
 23 mandatory, but the internal control really
 24 reflects the tissue from the time it has been
 25 removed from the patient to the time the slide

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1 arrives on your desk. They go hand in hand or
 2 they're through the same slide, same
 3 processing. Now, what do we use internal
 4 controls--skin, if I'm looking at--there are
 5 certain things that have built in internal
 6 controls If I'm doing controls for nerves, if
 7 I'm looking at a tumor and trying to see if
 8 there are nerves in it, it has neural
 9 differentiation, there may be benign nerves.
 10 If I'm looking at a keratin which marks for
 11 basically skin or derivatives of skin, if I
 12 have an internal control that has skin in it,
 13 that sort thing, you try to maximize your
 14 section by having both a built in internal
 15 control as well as the tumor. In many cases
 16 you can't have that control, but in breast, a
 17 large proportion of cases, especially in the
 18 pre-menopausal or the early post menopausal
 19 phase, it's only when we get quite, after the
 20 post menopausal phase, when there's lots of
 21 atrophy of the normal duct epithelium or loss
 22 of the normal duct epithelium, that you may
 23 not have the internal control. But you try to
 24 maximize, you try to select your slide to have
 25 the internal control. As they go along, the

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1 benign and the malignant are processed, are
 2 handled, fixed, processed, stained the same
 3 way and then the interpretation. It helps me
 4 establish my confidence in the interpretation.
 5 COFFEY, Q.C.:
 6 Q. Doctor, looking at paragraph three, were or
 7 was on the original slides, on the original ER
 8 slides and original PR slides that you looked
 9 at in the slide review, were there was
 10 internal control tissue, normal duct
 11 epithelium there, present, and you noted,
 12 looking at the original slides that it did not
 13 stain, the internal control tissue did not
 14 stain. As a pathologist doing an ER
 15 examination and a PR examination and seeing
 16 the internal control tissue present, but not
 17 staining, what, if anything, in your view,
 18 would that cause or should that cause a
 19 pathologist to do?
 20 DR. MULLEN:
 21 A. Again, it's not an absolute.
 22 COFFEY, Q.C.:
 23 Q. Yes.
 24 DR. MULLEN:
 25 A. But as I mentioned, post menopausal,

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1 approximately 90 percent, 88.8 or 9 percent,
 2 basically 90 and the pre-menopausal about 80
 3 percent have at least one percent of the
 4 epithelium stain. Again, one case acceptable,
 5 but I would have to look at sort of, a
 6 sequence. If they're always turning up
 7 negative, then I'd be very worried. Now, a
 8 sequence could be as short as three or as long
 9 as ten, that type of thing, but it's something
 10 I would keep in mind, my internal controls
 11 aren't working. I would comment on the--if
 12 you remember the synoptic reports we have,
 13 there is a comment that basically the--I mean,
 14 it's so obvious, not obvious, it's so
 15 consistent that our default is normal breast
 16 tissue was present to assess the internal or
 17 normal breast tissue reacted with the ER and
 18 PR stains. It's very rare that I actually go
 19 in and say, normal breast, except for
 20 metastatic carcinoma, I say, normal breast
 21 tissues are present. It's very rare that I
 22 say normal duct epithelium is not present and
 23 then it's even rarer that the breast tissue
 24 did not react with. So, it's an outlier or
 25 it's an infrequent finding and therefore,

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1 would alert me to be very careful.
 2 COFFEY, Q.C.:
 3 Q. And in a situation where you are seeing what
 4 you interpreted as fixation and/or processing
 5 artifacts -
 6 DR. MULLEN:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. - combined with an internal control that
 10 hadn't stained, what if anything -
 11 DR. MULLEN:
 12 A. You're asking for trouble. You really are
 13 asking for trouble trying to interpret that
 14 type of tissue. I mean, that would--going
 15 back to my one, two, three from yesterday,
 16 that would trigger, "whop", back we go; what
 17 are we doing wrong? What is going wrong?
 18 COFFEY, Q.C.:
 19 Q. Paragraph four, you've written, "stained
 20 deposit obscuring morphology. In many cases,
 21 excess stain was present either on the surface
 22 or beneath this section, both artifacts
 23 preclude assessment of the ER/PR staining in
 24 the areas affected". First of all, tell the
 25 Commissioner, what morphology is, first of

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1 all.
 2 DR. MULLEN:
 3 A. Morphology refers to the histology, the actual
 4 substance of the slide. If you recall, my
 5 PowerPoint again, okay, so when I talk about
 6 morphology, I'm talking about the histology.
 7 I can see ducts here. I can see cancer here.
 8 I can see normal here. If I threw brown stain
 9 on top that non-specifically adhered to the
 10 surface or somehow or other was--because the
 11 slide wasn't even, was underneath the section,
 12 I would have--basically, if I threw paint on
 13 the floor, you can't see the texture of the
 14 carpet. That's the issue that you have, brown
 15 on top of brown and you're not sure, is it
 16 restricted to the nucleus or is it a non-
 17 specific. So, that whole area you have to
 18 throw out from an interpretation and that can
 19 either because a slide was uneven and stain is
 20 present underneath or it wasn't properly
 21 washed from the slide. And that's another--
 22 that wasn't that common, but it did occur.
 23 And it's -
 24 COFFEY, Q.C.:
 25 Q. And I take it that it makes those particular

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1 portions of the slide, where that occurs
 2 unreadable.
 3 DR. MULLEN:
 4 A. Uninterpretable.
 5 COFFEY, Q.C.:
 6 Q. Uninterpretable.
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Paragraph 5 in P-1840, page two reads,
 11 "external controls, the external controls
 12 were inconsistent both between slides and
 13 within slides. In some cases the positive
 14 cells were barely stained. In occasional
 15 cases from 2005, the control stained both the
 16 nucleus and the cytoplasm, reflecting
 17 inadequate or incorrect validation." Could
 18 you elaborate upon that for the Commissioner,
 19 please?
 20 DR. MULLEN:
 21 A. Yes, the external controls are run, I'm not
 22 sure of the protocols, but the external
 23 controls are run with each batch of slides.
 24 And I believe in all of the cases from St.
 25 John's, it was a tumor that was used as an

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1 external control, it was a tumor that was
 2 positive for ER and PR. There were various--I
 3 don't know if it was the same tumor or various
 4 tumors, but it was the control, and
 5 interestingly it wasn't an uniformed staining,
 6 either with the ER or the PR and the intensity
 7 and the positivity rate or positivity--the
 8 number of cells that were positive varied, it
 9 wasn't uniform across the slide, it varied
 10 from area to area and in some cases, not that
 11 many, very few of the tumor cells were
 12 positive. In one or two, I believe, I was
 13 questioned whether they were even positive,
 14 whether the external control was positive. So
 15 it would not be the type of external control I
 16 would like. We use benign, we use endometrium
 17 or endocervix that the nuclei and the--well
 18 the endometrium, rather, the nuclei are
 19 positive in the endometrial cells, as well as
 20 the smooth muscle cells are positive and those
 21 are the type of control. It's not dependent
 22 on a tumor, so that was variability, some--
 23 questionable whether they're actually
 24 positive.
 25 COFFEY, Q.C.:

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1 Q. Okay.

2 DR. MULLEN:

3 A. And in occasional cases from 2005 -

4 COFFEY, Q.C.:

5 Q. If I could, Doctor, before you go on to that

6 last sentence, so the second sentence here,

7 the external controls were inconsistent both

8 between slides and within slides.

9 DR. MULLEN:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. That is between the control slides?

13 DR. MULLEN:

14 A. Yes, so if I had--when we see the spreadsheet

15 again, if I have a control slide with case one

16 from '97 and I had a control slide from case

17 five of '97, they were not equivalent.

18 COFFEY, Q.C.:

19 Q. The external controls.

20 DR. MULLEN:

21 A. The external controls were not equivalent, the

22 staining was not equivalent and then within

23 case one, the stain from area to area was not

24 equivalent -

25 COFFEY, Q.C.:

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1 Q. Within the external control slides.

2 DR. MULLEN:

3 A. Within the external control slides. In some

4 areas it was total absence of it; in other

5 areas it would be strong; in other areas it

6 would be questionable. And so both between

7 and within the individual slides, there was

8 variability.

9 COFFEY, Q.C.:

10 Q. And that's the individual control slides in

11 this context?

12 DR. MULLEN:

13 A. Yes, that's correct.

14 COFFEY, Q.C.:

15 Q. I'm sorry, Doctor, the last sentence,

16 paragraph five?

17 DR. MULLEN:

18 A. The occasional case from 2005, now I didn't

19 have an indication that they had changed--

20 "they" meaning St. John's, had changed their

21 processing, but these slides were labelled

22 with bar codes, so I, from experience from

23 other hospitals, we use the DAKO, as I

24 mentioned earlier, I thought these were

25 probably the Ventana stains and both the

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1 major--well, there weren't that many cases,

2 but some of the cases, both the nucleus and

3 the cytoplasm stained, so that would have

4 reflected either inadequate or incorrect

5 validation. When we validate--or when we

6 optimize and validate our immunohistochemistry

7 stains, we want to have sensitivity and

8 specificity. Here we had staining of both the

9 nucleus which is appropriate, but staining of

10 the cytoplasm, which is inappropriate.

11 COFFEY, Q.C.:

12 Q. And this is in respect of the controls?

13 DR. MULLEN:

14 A. Yes, the controls. So if you don't have an

15 adequately stained control, then you cannot

16 interpret the material.

17 COFFEY, Q.C.:

18 Q. This variability in the staining of the

19 external controls as between the external

20 controls or even within a particular external

21 control slide, what, if anything, as a

22 pathologist, you know, if you came across

23 that, you know, in your own daily work, what,

24 if anything, would that cause you to do? If

25 you saw the equivalent slide, for example, at

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1 Mount Sinai?

2 DR. MULLEN:

3 A. The Sinai, I don't know if Ms. Wegrynowski

4 mentioned that the technologists evaluate the

5 external controls, so we would not see the

6 external controls unless we had some reason to

7 ask to see them. It's the responsibility of

8 the technologist to review the external

9 controls, to be satisfied that they meet the

10 standards that have been established in

11 conjunction with the pathologist. So the

12 technologist and pathologist have established

13 guidelines and if they don't meet them, they

14 won't give me the slide. I would not have

15 seen this case until the external control had

16 stained appropriately and they were satisfied.

17 Now that's doesn't preclude me from

18 looking at the slide when I received it,

19 asking to--not being satisfied, asking to see

20 the external control and sending it back to

21 have repeated. But the first gatekeeper and

22 the most important gatekeeper is the

23 technologist who reviews the controls, both

24 internal and external.

25 COFFEY, Q.C.:

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1 Q. And the external controls -
 2 DR. MULLEN:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. - if one such external control slide, you did
 6 for some reason go and ask to see an external
 7 control slide and it was brought to you and
 8 you saw this sort of variability in staining
 9 of an external control slide which you did
 10 witness in some of the Newfoundland slides,
 11 what, if anything, would that cause you to do?
 12 DR. MULLEN:
 13 A. Just to go back to the Sinai, the external
 14 controls are benign tissue, the endometrium.
 15 So I know that everything should be staining.
 16 It should be uniform across the slide. If I
 17 have a section, the epithelia cells, the
 18 muscle cells should stain. If I have large
 19 areas of the slide which I saw equivalent in
 20 Newfoundland, I would be worried that the
 21 machine wasn't dispensing correctly, that only
 22 areas of the slide were being covered or some-
 23 -there was some biological or not biological,
 24 some--it would be a technical issue with the
 25 dispensing of the machine or the preparation

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1 of the slide that was causing the stain. But
 2 because they were using tumor slides, I--it's
 3 difficult to interpret properly. So the
 4 selection of the external control is very
 5 important. It has to allow you to assess the
 6 staining, both the reactivity as well as the
 7 extent of the staining.
 8 COFFEY, Q.C.:
 9 Q. Paragraph six, you say there was a--you go on
 10 to say here, "discrepancy between internal and
 11 external controls in only one or two of the
 12 539 cases I reviewed was the staining in the
 13 internal control as strong as the
 14 corresponding external control." And what are
 15 you referring to there, Doctor?
 16 DR. MULLEN:
 17 A. That if you recall, the internal controls were
 18 never as strong as the external controls. I
 19 would like to see my internal controls, if you
 20 recall from my cases, the internal and the
 21 tumor were the same.
 22 COFFEY, Q.C.:
 23 Q. Yes, that is the Mount Sinai slide you showed
 24 us?
 25 DR. MULLEN:

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1 A. Yes, yes. So if--let's separate these two.
 2 This we'll say will have--rather than having
 3 one slide, I'll divide it here as two slides.
 4 This would be the equivalent of an external
 5 control. I would like to see my external
 6 control, the staining and the internal control
 7 of the internal--sorry, the internal control
 8 of (unintelligible) epithelium be equivalent
 9 intensity, just to show that the processing
 10 and reactivity were the same. It doesn't
 11 necessarily have to be exact, but it should be
 12 in the same ballpark. But I was getting at
 13 the--from Newfoundland, using this slide as an
 14 example, that this, the external control--the
 15 internal control, if we use the tumor here,
 16 would be less than the external control. So
 17 it was always significantly less, questioning
 18 whether the processing fixation handling were
 19 equivalent.
 20 COFFEY, Q.C.:
 21 Q. Of the -
 22 DR. MULLEN:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. - the external control tissue and then -

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1 DR. MULLEN:
 2 A. And the internal control. I know that the
 3 internal and the tumor are handled essentially
 4 the same because they're on the same slide,
 5 but the external control, the slide was not
 6 stained at the same time because it wasn't--
 7 they weren't--the internal control, or sorry,
 8 the external control was not on the same slide
 9 so it wasn't stained the same time and the
 10 processing obviously, the fixation and
 11 processing were different because the tumor
 12 would have been removed before and a block,
 13 sort of a control block was kept and would be
 14 sliced as needed.
 15 COFFEY, Q.C.:
 16 Q. Now Doctor, you go on--if we go back, please,
 17 to 1840, page two, thank you. You go on to
 18 conclude by saying "there were very few cases
 19 in which there was a significant difference in
 20 my observation compared to that recorded on
 21 the original report. Some of my observations
 22 were higher than those recorded and some
 23 lower." Now again, I'll be referring to the
 24 report to put this paragraph in context, but
 25 you indicate that "there were very few cases,"

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1 that would be of the 539?
 2 DR. MULLEN:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. "in which there was a significant difference
 6 in my observation," that would be your
 7 observation of what?
 8 DR. MULLEN:
 9 A. Of the original H & E, ER and PR stained
 10 slides from Newfoundland.
 11 COFFEY, Q.C.:
 12 Q. Okay, what are you're looking at through the
 13 scope?
 14 DR. MULLEN:
 15 A. Yes, and -
 16 COFFEY, Q.C.:
 17 Q. Your interpretation, very few cases in which
 18 there was any significant difference in your
 19 observation of what you saw and observed of
 20 the Newfoundland, original Newfoundland
 21 slides, compared to what was recorded on the
 22 original report?
 23 DR. MULLEN:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. And this refers to, I take it, percentages and
 2 things like that?
 3 DR. MULLEN:
 4 A. Yes. I was a--I had great difficulty--I
 5 certainly couldn't do statistics because I'd
 6 learnt my lesson from preparing the statistics
 7 from your first visit, but I didn't know what--
 8 Newfoundland was more qualitative rather than
 9 quantitative. When we see the spreadsheet--I
 10 can't--off the top of my head, I can't
 11 remember the exact percentages, but they use
 12 terms "negative" and I didn't know what a
 13 negative meant. Was it 30, 10 or less than
 14 one? So that was--so I sort of tried to
 15 guesstimate whether it was that sort of thing,
 16 but when I say significant difference, I'm
 17 saying that I said it was zero and they said
 18 it was like 100, that type of thing, or zero.
 19 It would be one category greater zero, and
 20 they'd say 20 or 30 or 40, or I would say 20
 21 and they'd say zero. So that, it--you would
 22 need a statistician. You would need what the
 23 original cut offs were to qualify that
 24 statement. But it's just sort of ballpark.
 25 The interpretation didn't appear to be an

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1 issue.
 2 COFFEY, Q.C.:
 3 Q. Interpretation in the sense of -
 4 DR. MULLEN:
 5 A. Of the pathologists -
 6 COFFEY, Q.C.:
 7 Q. - arriving at a percentage?
 8 DR. MULLEN:
 9 A. Yes, the pathologist interpreting that slide
 10 and coming up with a number. We seemed to be
 11 fairly good correlation.
 12 COFFEY, Q.C.:
 13 Q. Now whether or not the slide should have been
 14 interpreted at all, I take it -
 15 DR. MULLEN:
 16 A. That's a different matter.
 17 COFFEY, Q.C.:
 18 Q. - that's a different issue?
 19 DR. MULLEN:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Okay, and I say, that's the original slides.
 23 DR. MULLEN:
 24 A. Yes, these are the original slides.
 25 COFFEY, Q.C.:

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1 Q. Commissioner, I'm going to ask now if we could
 2 go, please, bring up page three of this
 3 exhibit please? Thank you. This, I take it,
 4 is the MSH data spreadsheet code?
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And Doctor, I'm going to be asking you,
 9 Registrar, to switch back and forth then
 10 between this and Exhibit P-1837. Now, here,
 11 Doctor -
 12 THE COMMISSIONER:
 13 Q. Mr. Coffey, it's about 11, so I'll leave it to
 14 you to decide whether you want to launch into
 15 this exhibit before the break and interrupt or
 16 -
 17 COFFEY, Q.C.:
 18 Q. If I could -
 19 THE COMMISSIONER:
 20 Q. - whether you would prefer to -
 21 COFFEY, Q.C.:
 22 Q. - one heading and then we'll have a break,
 23 Commissioner.
 24 THE COMMISSIONER:
 25 Q. Okay.

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1 COFFEY, Q.C.:

2 Q. And the heading of this is "Dr. Brendan

3 Mullen, review of the five banker boxes

4 containing 24 individual slide boxes and

5 related original pathology reports, where

6 available."

7 DR. MULLEN:

8 A. Yeah.

9 COFFEY, Q.C.:

10 Q. "From Eastern Health. Received by the

11 Commission of Inquiry on hormone receptor

12 testing on April -

13 DR. MULLEN:

14 A. April 14th.

15 COFFEY, Q.C.:

16 Q. - April 14th, I'm sorry, 2008. So this is--

17 these spreadsheets. This is a spreadsheet.

18 If we could--there's a bunch of--and at page

19 16 of the exhibit, then it goes on through

20 page 30, there is--beginning at page 16,

21 there's a heading "Newfoundland and Labrador

22 pathology review of original slides provided

23 by Eastern Health to Dr. Brendan Mullen, Mount

24 Sinai Hospital." So I take it there was a

25 spreadsheet that accompanied the material, the

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1 slides, and what pathology reports were sent

2 to you?

3 DR. MULLEN:

4 A. Yes, that is correct.

5 COFFEY, Q.C.:

6 Q. Original pathology reports were sent to you,

7 and you prepared then your own spreadsheet?

8 DR. MULLEN:

9 A. Yeah, to facilitate reporting, I--the cases by

10 and large were divided by years, but to

11 facilitate reporting, they were not in any

12 order. I put them alphabetically, so I would

13 see the name. This has all been redacted.

14 I'd see the name and then--so it was just

15 easier for me to enter the data. This was a

16 labour of--should be something called love,

17 but it was a lot of work.

18 COFFEY, Q.C.:

19 Q. Commissioner, if we could break then?

20 THE COMMISSIONER:

21 Q. All right then, we'll take the morning break.

22 (RECESS)

23 THE COMMISSIONER:

24 Q. Please be seated. Mr. Coffey.

25 COFFEY, Q.C.:

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1 Q. Thank you, Commissioner. Now Doctor, here on

2 this spreadsheet, at page one of Exhibit P-

3 1837, there is--I'm going to go across the

4 headings at the top of the first page.

5 There's an ID number. Do you know what that

6 ID number is?

7 DR. MULLEN:

8 A. This was provided to me on the original

9 spreadsheet.

10 COFFEY, Q.C.:

11 Q. Okay, and that's the one coming out of

12 Newfoundland?

13 DR. MULLEN:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. The copy, the original slides.

17 DR. MULLEN:

18 A. NL, sorry.

19 COFFEY, Q.C.:

20 Q. Sure.

21 DR. MULLEN:

22 A. I had seen the copy of my letter, it was -

23 COFFEY, Q.C.:

24 Q. 1840, page one, Registrar, please? There you

25 are.

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1 DR. MULLEN:

2 A. Yes, sorry. It was provided to me on NLCI

3 Newfoundland Commission of Inquiry Hormone

4 Receptor.

5 COFFEY, Q.C.:

6 Q. Okay, and if we could go back then, Registrar,

7 please, to Exhibit 1837? Then of course, the

8 name, I take it, would be the patient's name -

9 DR. MULLEN:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. - as reported to you. The MCP number and the

13 date of birth is reported to you?

14 DR. MULLEN:

15 A. Yes, provided to me, yes.

16 COFFEY, Q.C.:

17 Q. Provided to you. And then the specimen number

18 is listed here in a column. I take it this

19 would be a specimen number which was provided

20 to you?

21 DR. MULLEN:

22 A. Yes, it would be either on the--it would be on

23 the pathology report, if the pathology report

24 was forwarded, and it would be on the block

25 that I received--sorry, not on the block,

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1 sorry, referring now to the slide, the slides
 2 that I received. So it would have the
 3 specimen number and it would also, in some
 4 cases, have the block number dash A, and the
 5 N/A if there was not--if there was no
 6 identifying block number.
 7 COFFEY, Q.C.:
 8 Q. No identifying block number on the slide
 9 itself?
 10 DR. MULLEN:
 11 A. Yes, that's correct.
 12 COFFEY, Q.C.:
 13 Q. Okay, so here then, the year specimen is--
 14 these are the '97 which would correspond, I
 15 take it, to the '97 as part of the specimen
 16 number?
 17 DR. MULLEN:
 18 A. Yes, that's correct.
 19 COFFEY, Q.C.:
 20 Q. The referral number, what is that, do you
 21 know?
 22 DR. MULLEN:
 23 A. That would be an internal number from St.
 24 John's. I don't know what that refers to.
 25 COFFEY, Q.C.:

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1 Q. And this is just--again, this was on the
 2 spreadsheet that accompanied the slides on
 3 their way to you?
 4 DR. MULLEN:
 5 A. Yes, that's correct.
 6 COFFEY, Q.C.:
 7 Q. Then the blocks, a heading blocks, which is, I
 8 take it, the block number associated with the
 9 particular specimen number and the slide?
 10 DR. MULLEN:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. Okay, then this heading here, if I could--
 14 sorry, about that.
 15 DR. MULLEN:
 16 A. No, that's fine.
 17 COFFEY, Q.C.:
 18 Q. So we go across the page here, there's MSH
 19 review, and then there's a heading HE, ER, PR,
 20 IC, F/P and EC. Could you take us through
 21 each of those?
 22 DR. MULLEN:
 23 A. The MSH review refers to my, Mount Sinai
 24 Hospital review, which is basically Mullen's
 25 review. The HE should actually be H & E.

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1 That was the original stained slide, and I
 2 would make a--and then the D, DTD, etcetera,
 3 refers to the code that was provided. It's
 4 basically the same as the code that we used
 5 for the retrospective review. I mean, there
 6 were one or two additions and one or two
 7 subtractions because we didn't have the same
 8 spread of tumors.
 9 COFFEY, Q.C.:
 10 Q. If I could, please, while we're on this, so
 11 this HE is referring, in effect, and in fact,
 12 to H & E?
 13 DR. MULLEN:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. And what is entered here, under the overall
 17 column heading of MSH review, which as you
 18 point out is really Dr. Mullen review -
 19 DR. MULLEN:
 20 A. Um-hm.
 21 COFFEY, Q.C.:
 22 Q. - particularized to yourself, and there are
 23 entries here. I'm just looking down through
 24 it. It's D, DT, DDL, DDD and so on, and some
 25 of them are blank. Where there are blanks,

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1 what would that signify, do you know?
 2 DR. MULLEN:
 3 A. That I did--if I recall, I did not receive the
 4 slide for that case.
 5 COFFEY, Q.C.:
 6 Q. Okay, and I'll be--yes, because there are some
 7 here that, as we go further out through the
 8 MSH review, there are just, the row is blank.
 9 DR. MULLEN:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. And I'll be taking you to that. So although
 13 there is a reference in, for example, in a
 14 specimen number -
 15 DR. MULLEN:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. - for that particular patient, you, at least,
 19 in your review of the slides, couldn't find
 20 corresponding slides?
 21 DR. MULLEN:
 22 A. That's correct. So did you want me to
 23 continue across?
 24 COFFEY, Q.C.:
 25 Q. Yes, if you could, please?

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1 DR. MULLEN:
 2 A. The ER, again refers to the estrogen receptor
 3 and that is the percentage of cells that were
 4 positive.
 5 COFFEY, Q.C.:
 6 Q. Okay, and that, I take it, is you looking -
 7 DR. MULLEN:
 8 A. Me looking at the original material.
 9 COFFEY, Q.C.:
 10 Q. The original slide?
 11 DR. MULLEN:
 12 A. Yes, the original slide. Now if you look down
 13 000, 1-2-3-4-5-6-7-8-9-10-11-12, you can see
 14 the twelfth one, so the first blank and then
 15 two more, three more rather, you can see 0/0.
 16 There, I would have had two slides and so I
 17 was getting independent interpretation of both
 18 slides. So they were both submitted with the
 19 same specimen number and the same block
 20 number, but 0/0 referred to separate
 21 interpretations.
 22 COFFEY, Q.C.:
 23 Q. So that would be actually two separate slides?
 24 DR. MULLEN:
 25 A. Yes, and then the next--well, when we go to

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1 PR, you notice I didn't receive a PR slide.
 2 COFFEY, Q.C.:
 3 Q. A corresponding PR slide
 4 DR. MULLEN:
 5 A. PR slide was not--okay, and then if you move
 6 down to this line where the RE425, is that
 7 showing as I go across?
 8 COFFEY, Q.C.:
 9 Q. Okay, just a second now. Yes, RE425 is there
 10 on the screen, yes.
 11 DR. MULLEN:
 12 A. Yes, here, we would have two slides, 10/--the
 13 first one interpreted as 10, second is two,
 14 and then the PR, the first, I believe it would
 15 be the--I'm not sure if I could tell in each
 16 case whether it was 10 and 70 and two and 30
 17 or would have been 10 and 30, if they're
 18 matching. But anyways, one would be 70, the
 19 second would be 30. The assessment of
 20 internal controls, again, independently for
 21 one slide, second slide and then the fixation
 22 process independently for that pair of slides.
 23 COFFEY, Q.C.:
 24 Q. Okay.
 25 DR. MULLEN:

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1 A. So that's that, I think that was the majority
 2 of--I don't think there was any that I had
 3 more--or even if I had three, it would be
 4 10/2/whatever, okay. Then the PR column
 5 refers to my interpretation of the original
 6 material, the progesterone receptor percentage
 7 positivity.
 8 COFFEY, Q.C.:
 9 Q. On the original PR slide?
 10 DR. MULLEN:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. Created in Newfoundland?
 14 DR. MULLEN:
 15 A. Yes, provided by Newfoundland to me. The IC
 16 refers to the presence or absence of an
 17 internal control, again on the slide provided
 18 to me that was prepared in Newfoundland. So
 19 here, the first would be present and stained,
 20 absent, present stained, present, the same and
 21 then present stained weakly. So those were
 22 the three--sorry, the four present, absent,
 23 present and stained, present stained weakly,
 24 the four options that I had before.
 25 COFFEY, Q.C.:

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1 Q. Now in terms of that, would this be the
 2 internal control for the ER slide, the
 3 internal control for the PR slide or both or
 4 how would that -
 5 DR. MULLEN:
 6 A. I would--for the internal control, my default
 7 was always to the estrogen receptor. If it
 8 were present, it refers to that. If it wasn't
 9 present, I would make--and the PR were
 10 positive, I would say the--if you look over in
 11 the comment, the ER internal control was
 12 negative.
 13 COFFEY, Q.C.:
 14 Q. Okay.
 15 DR. MULLEN:
 16 A. In this case, the present stain weakly, that
 17 was referring to the PR column.
 18 COFFEY, Q.C.:
 19 Q. Okay. Here is an example here, just looking
 20 at this, we'll look at the first row on the
 21 first page. In terms of that you've got ER
 22 zero, PR 70, IC, internal control, PS, which
 23 would be present and stained, F/P, which is A
 24 which I take is adequate?
 25 DR. MULLEN:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And then if you come out further, we still
 4 have to--I'll do those in a minute, but in the
 5 comments column you've got "MSH discordant."
 6 You've noted here "ER IC."
 7 DR. MULLEN:
 8 A. There should be a negative there.
 9 COFFEY, Q.C.:
 10 Q. Okay.
 11 DR. MULLEN:
 12 A. I'm sorry, my apologies.
 13 COFFEY, Q.C.:
 14 Q. Okay. ER IC negative. And, in fact, looking
 15 at these sometimes these can be stretched out
 16 or narrow, can't they?
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. And something gets cut off as you go. So we'd
 21 actually have to have the electronic
 22 spreadsheet in front of us to actually see the
 23 words?
 24 DR. MULLEN:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Because it's written all the way out. Okay,
 3 I'm sorry, Doctor, you were about to go into--
 4 you had gotten as far as the IC column.
 5 DR. MULLEN:
 6 A. Okay. The fixation and processing, again,
 7 adequate or poor. Again, the criteria were
 8 set very low, was there tissue on the slide
 9 that I could interpret, that would be
 10 considered adequate unless it was, like, one
 11 or two cells and then it would be poor or very
 12 low.
 13 COFFEY, Q.C.:
 14 Q. Very low?
 15 DR. MULLEN:
 16 A. Low standard to accept as adequate. Again, I
 17 -
 18 COFFEY, Q.C.:
 19 Q. You were setting in this context a low
 20 standard?
 21 DR. MULLEN:
 22 A. Yes, extremely low standard for both the
 23 retrospective review that we discussed
 24 yesterday and this review. It's a standard
 25 that, very--as I mentioned yesterday, it was

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1 basically, is there anything there that I can
 2 interpret with comfort, and that's a moving
 3 target but given the size of the original
 4 section of the H&E section, given what I
 5 perceived to be the tumor, given what I
 6 perceived to be the internal control, is there
 7 enough there on the ER slide and the PR slide
 8 that, as we discussed yesterday, we prepared
 9 and that we're discussing today that were
 10 prepared in Newfoundland, is there enough
 11 there that gives me reasonable comfort that I
 12 can make an interpretation. Again, this is
 13 all material that was--that I can't go back, I
 14 can't change anything after case one. It's
 15 not something, it's not a prospective, it's
 16 all retrospective, so.
 17 COFFEY, Q.C.:
 18 Q. And -
 19 DR. MULLEN:
 20 A. Then the next, the external control -
 21 COFFEY, Q.C.:
 22 Q. In C column, yes.
 23 DR. MULLEN:
 24 A. Okay. If you look, as we go down -
 25 COFFEY, Q.C.:

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1 Q. There's an awful lot of blanks.
 2 DR. MULLEN:
 3 A. Yes. A lot--external controls are, I believe--
 4 -well, we run them once, basically, with each
 5 batch of the stain, so we wouldn't have them
 6 necessarily tagged to each case. And they
 7 may--if Newfoundland were doing cases for the
 8 other--I should say, not Newfoundland, St.
 9 John's were doing cases for Clarenville or
 10 Carbonear or Corner Brook, etcetera, they
 11 would--they may have sent the external control
 12 to them for their interpretation or their
 13 comfort. But when they were available, again,
 14 P was poor. Let's see, what do we have? I'm
 15 sorry. Can I check my -
 16 COFFEY, Q.C.:
 17 Q. Yes, you can. Bring up, please, Exhibit 1840,
 18 please?
 19 DR. MULLEN:
 20 A. I got too many Ps and As.
 21 COFFEY, Q.C.:
 22 Q. Page 3, please. Here you go.
 23 DR. MULLEN:
 24 A. What did I say?
 25 COFFEY, Q.C.:

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<p>1 Q. And EC is further down.</p> <p>2 DR. MULLEN:</p> <p>3 A. Oh, sorry, okay.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. External control slides when available -</p> <p>6 DR. MULLEN:</p> <p>7 A. P for positive, query P for questionable,</p> <p>8 okay, all right.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And I'll be taking you through those, so that</p> <p>11 was just to remind yourself there?</p> <p>12 DR. MULLEN:</p> <p>13 A. Yes, positive--yes. I've got a lot of--P for</p> <p>14 positive, then query P for questionable.</p> <p>15 Theoretically there should be no negative, so.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And then we go on further, we go back then to</p> <p>18 NL--I'm sorry, 1837, go back up to the top of</p> <p>19 the page there, we see "NL original."</p> <p>20 DR. MULLEN:</p> <p>21 A. Okay.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Newfoundland and Labrador original. And a</p> <p>24 column entitled "ER" and a column entitled</p> <p>25 "PR." Now, in some instances there are</p>	<p>1 report there was no key or grid to what a</p> <p>2 negative meant, what a positive was. And in</p> <p>3 some cases, as in this one, the PR report--</p> <p>4 sorry, the PR value was given numerically. In</p> <p>5 this case in '97 it was zero and zero, here we</p> <p>6 have an ER less than five but we had no PR</p> <p>7 report. And this--sorry. So we're going -</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. So if we could just go up to the top again?</p> <p>10 DR. MULLEN:</p> <p>11 A. y</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. So the first one, first row, the particular</p> <p>14 patient was ER, it was reported in the</p> <p>15 original Newfoundland report as a negative?</p> <p>16 DR. MULLEN:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Which you recorded here as an N?</p> <p>20 DR. MULLEN:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. But as well the PR was reported as a 90?</p> <p>24 DR. MULLEN:</p> <p>25 A. Yes.</p>
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<p>1 letters or symbols or numbers?</p> <p>2 DR. MULLEN:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. There. Where did the info come from and what</p> <p>6 does it mean?</p> <p>7 DR. MULLEN:</p> <p>8 A. In a certain proportion of cases I was</p> <p>9 provided with the surgical pathology report.</p> <p>10 These tended to be cases from the St. John's</p> <p>11 area. And on the--on some of the pathology</p> <p>12 reports I was able to, able to review what the</p> <p>13 original report for the estrogen receptor and</p> <p>14 progesterone receptor status was. In some</p> <p>15 cases, for example, use the first one, ER was</p> <p>16 reported as negative. Now, this was 1997, so</p> <p>17 I'm not sure what a negative is, whether it</p> <p>18 was less than 30, less than ten or less than</p> <p>19 one, so I put it in as an N. If there was a--</p> <p>20 so that would be a qualitative result, and</p> <p>21 that's up to you to correlate with what the</p> <p>22 status was at that time. I didn't have any--</p> <p>23 there was no saying--there was no--if you</p> <p>24 recall from our synoptic reports, we say what</p> <p>25 we interpret as a positive. So for each</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Which would be 90 -</p> <p>3 DR. MULLEN:</p> <p>4 A. So that would, whichever threshold they were</p> <p>5 using, that would have been considered</p> <p>6 positive.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Yes.</p> <p>9 DR. MULLEN:</p> <p>10 A. And then the next--sorry, if we go down, this</p> <p>11 one was an oddity. This was a biochemical</p> <p>12 assay, so it would be negative and equivocal.</p> <p>13 This would be the Ligand binding assay. There</p> <p>14 would have been a hangover--not a hangover,</p> <p>15 whatever you want to call it, a hold over from</p> <p>16 the original testing.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And in terms of this, you, in referring to the</p> <p>19 biochemical assay results here, okay, you'd be</p> <p>20 doing so based upon the original pathology</p> <p>21 report in Newfoundland -</p> <p>22 DR. MULLEN:</p> <p>23 A. Yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. - which had been provided to you?</p>

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1 DR. MULLEN:
 2 A. Yes, that's correct.
 3 COFFEY, Q.C.:
 4 Q. Okay.
 5 DR. MULLEN:
 6 A. And then if we go down, Newfoundland, the
 7 result was from the Mayo Clinic, I'd make note
 8 of that. This one had little tissue on slide.
 9 And then my--so those are -
 10 COFFEY, Q.C.:
 11 Q. The sort of comments as we go down through the
 12 comments column, I'm not going to take you
 13 through every comment here in the comments
 14 column.
 15 DR. MULLEN:
 16 A. No, but -
 17 COFFEY, Q.C.:
 18 Q. But you would note in the comments column
 19 something, any pertinent observation, I take
 20 it?
 21 DR. MULLEN:
 22 A. Yes. Now, the MSH discordant, if the
 23 original--I shouldn't say the original
 24 pathology report. If the pathology report
 25 that was provided to me had my interpretation

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1 of the retro review, so those are the blocks
 2 that were sent to Toronto to the Mount Sinai
 3 that we stained and I interpreted, if they had
 4 reported the result to the clinician and
 5 provided it on the report, I would look at
 6 that report and say whether it was discordant
 7 or concordant. So discordant, so basically,
 8 and I don't have, I don't have the exact
 9 results here, this one if PR was 70 and ER was
 10 zero, and ER, the original was negative, the--
 11 I would say, I would think that we can check
 12 the--we'd have to go to check the two
 13 spreadsheets, that my ER that I reported in
 14 Toronto would probably be positive. And based
 15 on the fact that I have a very strong PR,
 16 chances are that ER would probably also be
 17 positive. And the discordant would be if it
 18 changed, basically if it changed categories.
 19 If it were zero or less than one and I changed
 20 it to anything greater than one, one to ten or
 21 ten or above, that I would call discordant,
 22 anything basically that I thought would
 23 indicate a change that might indicate a change
 24 in therapy.
 25 COFFEY, Q.C.:

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1 Q. And that would be you, in terms of recording
 2 something as discordant in the comments
 3 column, it was based upon the pathology report
 4 from Newfoundland that you received in 2008,
 5 you would read it?
 6 DR. MULLEN:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. If there was some reference to the
 10 retrospective results done by Mount Sinai
 11 recorded there, you'd look at that, the
 12 figures there, and compare that to the
 13 original pathology numbers or commentary,
 14 whatever it was, and make a determination
 15 yourself as to whether you thought your
 16 results, if they were reflected in the
 17 pathology report, were discordant with the
 18 original pathology report?
 19 DR. MULLEN:
 20 A. Yes, that is correct. And again, when I used
 21 my categories, they were based on the current
 22 practice at the Mount Sinai for therapy.
 23 COFFEY, Q.C.:
 24 Q. For therapy.
 25 DR. MULLEN:

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1 A. I did not go back to the original spreadsheet
 2 to look, like the 500 cases, that was sort of
 3 out of the scope of this review.
 4 COFFEY, Q.C.:
 5 Q. To actually check to see?
 6 DR. MULLEN:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. For example, you didn't go back to check
 10 against your original spreadsheet reports to
 11 see if on the actual pathology report St.
 12 John's had actually recorded it correctly?
 13 DR. MULLEN:
 14 A. Correct.
 15 COFFEY, Q.C.:
 16 Q. You didn't cross reference that?
 17 DR. MULLEN:
 18 A. Yes. And the ones that I didn't have, I
 19 didn't fill in. That was--this was time
 20 limited and -
 21 COFFEY, Q.C.:
 22 Q. So if we could, Doctor, what I'd like to do,
 23 please, is look at Exhibit P-1840, page 3,
 24 please? Thank you. And just to run down
 25 through this, Doctor, the MSH data spreadsheet

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1 code, MSH review. If we could, just up there,
 2 the tumor type, these, again, this code for
 3 tumor type we've seen before in the
 4 retrospective?
 5 DR. MULLEN:
 6 A. Yes. And when I was looking at the, reviewing
 7 this last night, there's one that I didn't
 8 have in here, "NT" there should be an "NIT" no
 9 invasive tumor. So after the processing for
 10 the ER/PR I lost the invasive component or
 11 there was no invasive component left, there
 12 was only ductal carcinoma in situ or there was
 13 no tumor at all. And there's a new term here
 14 that we didn't have in the previous case, and
 15 that's called lymphangitic carcinoma, which is
 16 basically the presence of tumor in lymphatics
 17 rather than an invasive component.
 18 COFFEY, Q.C.:
 19 Q. And there's at least one such case?
 20 DR. MULLEN:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. In this, these 539 or so?
 24 DR. MULLEN:
 25 A. Yes. And then the -

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1 COFFEY, Q.C.:
 2 Q. The number here.
 3 DR. MULLEN:
 4 A. Which we didn't have before, no H&E, no
 5 routine slide to assess tumor, and there was
 6 no tumor present in the ER/PR slide, so.
 7 COFFEY, Q.C.:
 8 Q. And under "ER" you have percentage cells
 9 positive, that is looking at the original ER
 10 slide?
 11 DR. MULLEN:
 12 A. Yes, that is again my interpretation of the
 13 original slides provided by Newfoundland.
 14 COFFEY, Q.C.:
 15 Q. And PR, same thing?
 16 DR. MULLEN:
 17 A. Same, same.
 18 COFFEY, Q.C.:
 19 Q. The IC here you've written here, "Internal
 20 controls with P present but not stained. PS
 21 present and stained. PSW, present and stained
 22 weakly. A for absent. The value refers to
 23 the ER internal control. If the ER and
 24 internal control was not present within the--
 25 was not present within, the value refers to

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1 the PR internal control?
 2 DR. MULLEN:
 3 A. Yes. I think the "and" should be dropped.
 4 COFFEY, Q.C.:
 5 Q. Yes.
 6 DR. MULLEN:
 7 A. If the ER internal control was not present
 8 within that section the value refers to the
 9 PR.
 10 COFFEY, Q.C.:
 11 Q. Yes. So if the ER internal control, that word
 12 "and" shouldn't be there. "If the ER internal
 13 control was not present within," that's within
 14 the slide?
 15 DR. MULLEN:
 16 A. With that section, yes.
 17 COFFEY, Q.C.:
 18 Q. The value refers to the PR internal control,
 19 that is the value in the IC column?
 20 DR. MULLEN:
 21 A. Yes, that's correct.
 22 COFFEY, Q.C.:
 23 Q. The comment in the latter case will state "ER
 24 IC negative," in other words, estrogen
 25 receptor, internal control, negative?

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1 DR. MULLEN:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And that would be out in the comments column?
 5 DR. MULLEN:
 6 A. That was in the comments.
 7 COFFEY, Q.C.:
 8 Q. "F/P," fixation and processing with A for
 9 adequate and P for poor." "EC" under that
 10 column "External control slides, when
 11 available," with a P, indicating positive.
 12 Question mark P, questionable positive. If
 13 both ER and PR external control slides were
 14 present, they were reported as P/P. If only
 15 the ER control slide was present, it was
 16 reported as "P". If only the PR control slide
 17 was present, I'm sorry, it was reported as
 18 slash, P. And if two sets of control slides
 19 were present, they were reported as "P/P/P.P."
 20 No external control was negative. What
 21 internal controls--external controls were
 22 there?
 23 DR. MULLEN:
 24 A. Yes. The -
 25 COFFEY, Q.C.:

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1 Q. The slide review, they all -
 2 DR. MULLEN:
 3 A. Well -
 4 COFFEY, Q.C.:
 5 Q. - were positive to some extent?
 6 DR. MULLEN:
 7 A. Positive or -
 8 COFFEY, Q.C.:
 9 Q. Or questionable positive?
 10 DR. MULLEN:
 11 A. There were a few that were questionably
 12 positive. And under the heading "NL original"
 13 the column ER and, the columns ER and PR, the
 14 results present on the accompanying--"The
 15 results present, on the accompanying report,"
 16 that is the surgical pathology report, I take
 17 it?
 18 DR. MULLEN:
 19 A. Yes.
 20 COFFEY, Q.C.:
 21 Q. When provided to you, "If a numerical value
 22 was not reported, then the qualitative result
 23 was entered" N for negative, MP for moderately
 24 positive, WP for weakly positive, OP for
 25 occasionally positive, and rare, r-a-r-e, for

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1 rare positive. Now, these terms, I'll just
 2 ask you now, the idea of using the phraseology
 3 "rare positive" or "occasionally positive" I
 4 take it that's just what was in the -
 5 DR. MULLEN:
 6 A. That was in the report.
 7 COFFEY, Q.C.:
 8 Q. And if it was there, that's the code you used?
 9 DR. MULLEN:
 10 A. Yes, yeah. Basically what I was doing was
 11 trying to group the reports. If there was a
 12 quantitative value, that was put in; if there
 13 was a qualitative, these were the terms that
 14 were used, negative, moderately positive,
 15 weakly positive, occasionally positive and
 16 rare, rare positive. I'm not sure, again,
 17 what the cut offs were, what they mean.
 18 COFFEY, Q.C.:
 19 Q. Here you conclude in that particular category
 20 here by saying "One PR result measured by
 21 biochemical means was reported as E for
 22 equivocal"?
 23 DR. MULLEN:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. Which is you just referred the Commissioner to
 2 that, that -
 3 DR. MULLEN:
 4 A. That's the Ligand binding assay.
 5 COFFEY, Q.C.:
 6 Q. Yeah.
 7 DR. MULLEN:
 8 A. I believe it was Ligand binding assay.
 9 COFFEY, Q.C.:
 10 Q. Here then under the heading, or the column
 11 entitled "Comment" you've written "When a
 12 surgical pathology report was provided which
 13 included the results of the MSH retrospective
 14 review, I compared the NL results to the MSH
 15 results. The results were categorized as
 16 concordant if the two results were in the same
 17 ER group and discordant if they were in
 18 different ER groups." And it's "(Negative
 19 being less than one percent, low positive
 20 being one to ten percent and positive being
 21 greater than ten percent)."
 22 DR. MULLEN:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. And, doctor, just to--without having all of

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1 these, what original--I'm sorry, what
 2 pathology reports, surgical pathology reports
 3 you did receive from Newfoundland in the
 4 course of the slide review, the slides
 5 themselves and the pathology reports were sent
 6 back to Newfoundland?
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Okay.
 11 DR. MULLEN:
 12 A. Everything, if you remember the cover letter,
 13 everything was returned to you. Sorry,
 14 returned to the Commission of Inquiry.
 15 COFFEY, Q.C.:
 16 Q. If we could, and this may--and I've just, I've
 17 picked two examples of something. If we could
 18 look, please, at, on this exhibit, 1837, look
 19 at, please, page 7? I'm just going to, if we
 20 could, come down toward the bottom of the page
 21 and--across here. And look at what is
 22 identified as number in the left-hand column,
 23 659? Thank you. Go back a bit further. 659,
 24 come across, and it's surgical number SS4 -
 25 DR. MULLEN:

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1 A. 4457.
 2 COFFEY, Q.C.:
 3 Q. - 547. The year is indicated to be 2000, the
 4 block is indicated to be A2. Just go across
 5 here now.
 6 COMMISSIONER:
 7 Q. So, seventh up from the bottom?
 8 COFFEY, Q.C.:
 9 Q. Yes, that's correct, Commissioner. Sorry.
 10 Look at the block there, it's A2. And coming
 11 across under the column H&E which would be D
 12 for ductal, as would -
 13 DR. MULLEN:
 14 A. Yes, using the code, yes.
 15 COFFEY, Q.C.:
 16 Q. The code. The ER under the column "MSH
 17 review" you categorized what you were seeing
 18 on the ER slide as a -
 19 DR. MULLEN:
 20 A. Five.
 21 COFFEY, Q.C.:
 22 Q. Five percent?
 23 DR. MULLEN:
 24 A. Um-hm.
 25 COFFEY, Q.C.:

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1 Q. And the PR slide as 20 percent?
 2 DR. MULLEN:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. Under the internal control you've indicated as
 6 A for absent?
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. At least on the slide, the original slide you
 11 were looking at. The F/P, in this context I
 12 believe is adequate?
 13 DR. MULLEN:
 14 A. Adequate, yes.
 15 COFFEY, Q.C.:
 16 Q. And -
 17 DR. MULLEN:
 18 A. That's the external controls present for both
 19 ER, present for both PR.
 20 COFFEY, Q.C.:
 21 Q. Yes. And then we come over -
 22 DR. MULLEN:
 23 A. That's right, sorry, yes, positive.
 24 COFFEY, Q.C.:
 25 Q. And under the Newfoundland original - in

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1 looking at the Newfoundland pathology report,
 2 the ER again reported, you know, here as five.
 3 DR. MUNDEN:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. And the PR as 30 to 35.
 7 DR. MUNDEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. And you've noted it to be Mount Sinai
 11 discordant.
 12 DR. MUNDEN:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. And in terms of that - and we'll just look at
 16 the five here and the five here.
 17 DR. MUNDEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Following the cursor - so, of course, they're
 21 the same figures.
 22 DR. MUNDEN:
 23 A. Yes, I agreed with their original
 24 interpretation.
 25 COFFEY, Q.C.:

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1 Q. The interpretation in the sense of the
 2 percentages.
 3 DR. MUNDEN:
 4 A. Yes. Yes.
 5 COFFEY, Q.C.:
 6 Q. For ER.
 7 DR. MUNDEN:
 8 A. Based on the material provided to me, I would
 9 have assessed that case as having five percent
 10 positive. The Newfoundland report had five
 11 percent positive. The PR, I said 20. It was
 12 reported as 30 to 35. For all intents and
 13 purposes, they are the same category. So ER
 14 is low positive in both cases. PR is positive
 15 in both cases.
 16 COFFEY, Q.C.:
 17 Q. Now if we could, please, bring up Exhibit P-
 18 1811. Now this we've looked at yesterday,
 19 doctor. This is your e-mail of January 20,
 20 2006, sending what is a spreadsheet of what
 21 was then thought to be the completed ER/PR
 22 results for the retrospective review conducted
 23 by Mount Sinai.
 24 DR. MUNDEN:
 25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. If we can go to page 3, and here we come down

3 the left-hand side and you will see - and I

4 haven't counted it up, Commissioner--if

5 somebody wants to, they're certainly welcome

6 to. Under the specimen number - and the

7 cursor is pointing--well, I had it pointed

8 there - it's SS4547. It's 00SS4547 and, if

9 anybody wants to, they can turn back to

10 Exhibit P-1837, Page 7, and they will see that

11 that's the same specimen number we were just

12 looking at. That's 7 from bottom on Page 7.

13 Okay, if we can go back then to - okay, P-

14 1811, thank you - and here 4547, we come

15 across -

16 DR. MUNDEN:

17 A. Block A2.

18 COFFEY, Q.C.:

19 Q. It's at Block A2. The comments - it came from

20 St. John's, identified as coming from St.

21 John's. The tumour is indicated in your

22 report of January 20th, the spreadsheet of

23 January 20, 2006. As the report said, the

24 tumour is a "D" for ductal. Here you've

25 reported the ER as 90, which would be 90

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1 percent?

2 DR. MUNDEN:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. And you've reported the PR as 80 percent.

6 DR. MUNDEN:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. And the internal control - that is the one -

10 DR. MUNDEN:

11 A. It would be -

12 COFFEY, Q.C.:

13 Q. - looking at the slides in Mount Sinai -

14 DR. MUNDEN:

15 A. Yes, a re-stain of the original block.

16 COFFEY, Q.C.:

17 Q. Yes.

18 DR. MUNDEN:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. Present and stained.

22 DR. MUNDEN:

23 A. Yes.

24 COFFEY, Q.C.:

25 Q. And F/P is adequate.

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1 DR. MUNDEN:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. So I take it then, doctor, that it's your view

5 that you're having reported - and I presume

6 that this 90 and 80 must have been reported

7 for this particular patient on their surgical

8 pathology report.

9 DR. MUNDEN:

10 A. Based on my key and based on the fact that I

11 said that they were discordant, it would be

12 logical to say that, yes, they were on the

13 report.

14 COFFEY, Q.C.:

15 Q. On the report.

16 DR. MUNDEN:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. Because you didn't actually go back to the

20 original spreadsheets -

21 DR. MUNDEN:

22 A. No. I had a time limit to have this done and

23 back because I believe there was some other

24 activity with these slides, so I didn't have

25 the time to do that.

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1 COFFEY, Q.C.:

2 Q. Now here, if indeed that 90 and 80 do appear -

3 DR. MUNDEN:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. - on the surgical pathology report related to

7 this particular patient, then the 90 and 80

8 would be discordant with a report of -

9 DR. MUNDEN:

10 A. Five and 30 - 5 and 20 or 5 and 30 -

11 COFFEY, Q.C.:

12 Q. Five and 30 to 35.

13 DR. MUNDEN:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. Okay.

17 DR. MUNDEN:

18 A. Discordant in the sense that low positive to a

19 very high positive.

20 COFFEY, Q.C.:

21 Q. Yes, and there's a big jump from 5 to 90, I

22 take it.

23 DR. MUNDEN:

24 A. Yes.

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1 COFFEY, Q.C.:

2 Q. In your world.

3 DR. MUNDEN:

4 A. Yes, that's a significant difference and the

5 response to therapy would be--the anticipated

6 response to therapy might be quite different.

7 COFFEY, Q.C.:

8 Q. Well, one other now while we have up this page

9 - if we could look at the specimen number in a

10 left-hand column on Page 3 of Exhibit of P-

11 1811, SS6349 - see that 6349 here?

12 DR. MUNDEN:

13 A. Yes.

14 COFFEY, Q.C.:

15 Q. Okay.

16 DR. MUNDEN:

17 A. Block D?

18 COFFEY, Q.C.:

19 Q. From across from Block, D it's ductal and it's

20 reported as here in January of 2006 in the

21 spreadsheet Mount Sinai has reported it as 90

22 for ER and zero for PR.

23 DR. MUNDEN:

24 A. Yeah.

25 COFFEY, Q.C.:

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1 Q. And the internal control is present and

2 stained and "A" for adequate

3 fixation/processing.

4 DR. MUNDEN:

5 A. Uh-hm.

6 COFFEY, Q.C.:

7 Q. And if we could, please, go to Exhibit P-1837,

8 Page 8, please, and if we come down -

9 DR. MUNDEN:

10 A. Six - oh yes, there we are.

11 COFFEY, Q.C.:

12 Q. The sixth row, we will see a specimen number

13 and the specimen number is 00SS6349.

14 DR. MUNDEN:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. And your specimen is 2000. It's Block D.

18 DR. MUNDEN:

19 A. It's coming across here.

20 COFFEY, Q.C.:

21 Q. The H&E in the MSH review of the slide review

22 conducted, reported in your view to H&E as "D"

23 for ductal. The ER is zero. The PR is zero.

24 The internal control is present - "P" meaning

25 present.

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1 DR. MUNDEN:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. But it's not stained - at least that's

5 correct.

6 DR. MUNDEN:

7 A. That's correct.

8 COFFEY, Q.C.:

9 Q. And looking back at your key, that would mean

10 the ER internal control was present but not

11 stained.

12 DR. MUNDEN:

13 A. That's correct.

14 COFFEY, Q.C.:

15 Q. F/P is marked with an "A" for adequate and, in

16 looking at the Newfoundland report, you had

17 noted there that--in reading it, the original

18 pathology report indicated--recorded as "N"

19 for negative.

20 DR. MUNDEN:

21 A. Yes.

22 COFFEY, Q.C.:

23 Q. For ER, and "N", a negative for PR.

24 DR. MUNDEN:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And you've noted this to be Mount Sinai

3 discordant.

4 DR. MUNDEN:

5 A. Yes.

6 COFFEY, Q.C.:

7 Q. So I take it, doctor, that here if indeed the

8 pathology report, when you looked at it,

9 contained the Mount Sinai results.

10 DR. MUNDEN:

11 A. Yes, there's a significant difference between

12 -

13 COFFEY, Q.C.:

14 Q. Well, negative, I take it, and 90.

15 DR. MUNDEN:

16 A. Ninety, yes - there is a significant

17 difference and with implications for therapy.

18 COFFEY, Q.C.:

19 Q. Because though Mount Sinai had said here - and

20 we look back at P-1811, please, Page 3 - yes,

21 so we have it. Thank you, Registrar. Even

22 though here looking at this, the ER is 90 and

23 the PR is zero.

24 DR. MUNDEN:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And the original pathology report had

3 indicated it was "N" for negative for PR which

4 would be concurrent with your review.

5 DR. MUNDEN:

6 A. Negative for both, I believe, yes.

7 COFFEY, Q.C.:

8 Q. Yes, but -

9 DR. MUNDEN:

10 A. Oh sorry, the PR, yes. Yes, I -

11 COFFEY, Q.C.:

12 Q. The PR was fine, I take it, in terms of

13 concordance.

14 DR. MUNDEN:

15 A. Yes, in the sense that whatever I was

16 interpreting it as zero - zero can be

17 negative.

18 COFFEY, Q.C.:

19 Q. Yes.

20 DR. MUNDEN:

21 A. Less than 10 or less than 30, depending on

22 their cut points at that time, but I was -

23 COFFEY, Q.C.:

24 Q. but if "N" meant negative -

25 DR. MUNDEN:

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. And was negative recorded there, and you had

4 recorded it as zero and zero would certainly

5 be negative.

6 DR. MUNDEN:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. But in terms of the ER for this particular

10 patient, St. John's you've noted here - in its

11 original pathology report, it's recorded this

12 particular patient's sample as "N" for

13 negative for ER.

14 DR. MUNDEN:

15 A. That is correct.

16 COFFEY, Q.C.:

17 Q. And 2006, certainly, you had reported as 90

18 percent positive for ER.

19 DR. MUNDEN:

20 A. That is correct.

21 COFFEY, Q.C.:

22 Q. If we could look, please - and I guess this is

23 another topic. It's something I did want to

24 visit though before concluding with you,

25 doctor, although I'm not quite there yet.

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1 Exhibit P-1838 - this, doctor, is labelled

2 Newfoundland ER/PR flow-chart. Have you seen

3 this before?

4 DR. MUNDEN:

5 A. Can I see when it was - sorry, the date, I'll

6 go to the bottom.

7 COFFEY, Q.C.:

8 Q. Sure.

9 DR. MUNDEN:

10 A. No, there is no date on it. Okay, this would

11 have been prepared some time after the

12 beginning of--in at least April of 2007

13 because Newfoundland had repatriated the ER/PR

14 and we were just doing QA's after March--I

15 think it was March 17th? Sorry, I don't have

16 it.

17 COFFEY, Q.C.:

18 Q. So the flow-chart, I take it is--

19 DR. MULLEN:

20 A. It's for the technical--it's for the handling

21 of the specimen.

22 COFFEY, Q.C.:

23 Q. To kind of keep track of how things should

24 flow, I take it.

25 DR. MUNDEN:

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. From Mount Sinai's perspective.

4 DR. MUNDEN:

5 A. Yes. Okay.

6 COFFEY, Q.C.:

7 Q. Okay, so that's -

8 DR. MUNDEN:

9 A. So do you want me to take you through it or -

10 COFFEY, Q.C.:

11 Q. If you would, please, yes.

12 DR. MULLEN:

13 A. Okay. So we have currently three types of

14 specimens that we are receiving at the Mount

15 Sinai Hospital, so all sites in Newfoundland.

16 There are the ER/PR retrospective cases.

17 These are the cases that are a follow-up to

18 the original review. So all of the blocks

19 from '97 to 2005 - these, I believe, are

20 blocks from patients that have requested a

21 repeat analysis. They may have been positive

22 called in Newfoundland or negative. I believe

23 they're mostly positives, and I'm repeating

24 them at the patient's request through the

25 clinician or the pathologist. So that would

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1 be that retrospective group. The ER/PR QA,
 2 that was active from--it would have been April
 3 2007 to probably - well, I think we'd probably
 4 have it on hold at the moment - to June 2008.
 5 These are cases that--really, they're actually
 6 blocks that are submitted to the Sinai for re-
 7 staining and interpretation and returned to
 8 Newfoundland on a spreadsheet, as are the
 9 first ones on a spreadsheet. This is quality
 10 assurance. They are having the staining
 11 repeated. They were having the staining
 12 repeated at the Mount Sinai Hospital and
 13 comparing it to the stains that were being
 14 done in Newfoundland. And then the third
 15 category, Newfoundland consults, these are
 16 cases, the prospective that we started in
 17 August of 2005. It's a continuation of that.
 18 So those would be the ER/PR and the HER2, any
 19 combination or permeation of that group. So
 20 either ER/PR and HER2 or ER/PR or HER2, so
 21 that's that group, and then this is basically
 22 how we fill out the form. The QA request
 23 comes and then the retrospective request form
 24 - they're put together. This is for
 25 Newfoundland and they're mailed to who

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1 receives them in the lab. So because these
 2 are not part of what we consider the service
 3 component and part of the research services
 4 area of the department, they're handled by
 5 Maria Mendes and Mona Reid, head of the
 6 Special Services and the technologist assigned
 7 to QA.
 8 On the other side, this is we're asking
 9 for--because they're consultations - if you
 10 recall the letter that we had to Dr. Dankwa as
 11 the template, it's basically a continuation of
 12 that form. We'd like a cover letter telling
 13 me what breast or the pathology report and
 14 they're mailed and they're handled as a
 15 consultation. So basically they're--and part
 16 of it is the type of form, I will issue a
 17 formal report that I then fax to the hospital.
 18 It expedites the reporting of the case. And
 19 the turn around time was like two or three
 20 days on most of these cases.
 21 COFFEY, Q.C.:
 22 Q. Okay.
 23 DR. MULLEN:
 24 A. Now, I believe there's another sheet with this
 25 or is that it? Okay. So the retrospective

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1 are the continuation. And if Newfoundland
 2 finds more cases that were initially missed,
 3 it's that group or the patients who have
 4 concerns and we're reconfirming their results.
 5 COFFEY, Q.C.:
 6 Q. Okay.
 7 COMMISSIONER:
 8 Q. So I take it the origin or the type of case
 9 which had been sent to you determines into
 10 which stream within Mount Sinai something
 11 flows?
 12 DR. MULLEN:
 13 A. Yes, that is correct. And the consequence of
 14 that is the type of report that is issued and
 15 the billing procedure.
 16 COMMISSIONER:
 17 Q. Billing.
 18 DR. MULLEN:
 19 A. One is billed to the heath, MCP and the other
 20 is billed to the hospital.
 21 COMMISSIONER:
 22 Q. All right.
 23 DR. MULLEN:
 24 A. The same, the same service is provided to

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1 both. They're both stained the same way and
 2 etcetera.
 3 COMMISSIONER:
 4 Q. Um-hm.
 5 DR. MULLEN:
 6 A. It's just the type of report. And the QA is
 7 an internal document for the department and
 8 the retro is for them to deal with.
 9 COMMISSIONER:
 10 Q. Okay.
 11 COFFEY, Q.C.:
 12 Q. Doctor, statistics, for example, positivity
 13 rates for ER and PR.
 14 DR. MULLEN:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. I'll just ask you do you, in your own
 18 practice, do you keep track of your own
 19 statistics?
 20 DR. MULLEN:
 21 A. Yes, rigorously.
 22 COFFEY, Q.C.:
 23 Q. Okay.
 24 DR. MULLEN:
 25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. Would it be fair if I was to ask you is that

3 something limited to yourself or peculiar to

4 yourself or is it universal or is there

5 something in between?

6 DR. MULLEN:

7 A. Something in between.

8 COFFEY, Q.C.:

9 Q. Okay. Perhaps you could elaborate on that?

10 DR. MULLEN:

11 A. Okay. As we were going through my CV you

12 notice I have a background in mathematics, so

13 I like playing with numbers or driving

14 numbers. So and I also I'm quite comfortable

15 using our lab information system. I'm also a

16 titch obsessive/compulsive so I report

17 everything the same way. I cut and paste. So

18 we have a fairly good lab information system,

19 but it has a few deficiencies. So it can only

20 search certain areas, it can search clinical

21 history and it can search diagnosis. So since

22 I've been doing Newfoundland and when I'm

23 doing Newfoundland and also the consultation

24 services in Ontario, I basically, to speed

25 things up, I cut and paste. I have templates,

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1 I cut the report and stick it in. So all of

2 my estrogen and progesterone--all of my breast

3 cases are signed out exactly the same way.

4 It'll be positive for estrogen receptor

5 protein, negative for estrogen receptor

6 protein, positive, open brackets, low,

7 whatever. And the same for progesterone and

8 then the HER2. So I do, I can do a search on

9 positive for estrogen and under my name

10 everything that I've signed out and I can do

11 it from any time frame, any time it's

12 accession, any source. So I run those every

13 six months or so. And I--and when you

14 presented to Toronto, I think I provided you

15 with--I don't know if I mentioned this

16 yesterday, my concern was not knowing what the

17 material was, what my positivity rate as

18 compared to the literature and I was quite off

19 on the retro review, which is the material

20 that was stained in Toronto. And to ground

21 myself and to convince myself that I actually

22 knew how to sign these things out, I had done

23 the--I compared it to the prospective material

24 from Newfoundland the same time, I compared it

25 to a series of regional hospitals that refer

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1 to us that I had signed out during the same

2 time frame, well, they started in '06 rather

3 than '05, and then I compared it to all my

4 material. So I had all of that, my ER

5 positivity rate, just--and then in preparation

6 for this appearance I've done my ER--I've done

7 the four categories, ER positive, PR positive,

8 ER positive, PR negative, sorry, ER negative,

9 PR positive, and ER negative, PR negative. So

10 I have all of that data from basically the

11 beginning of '05 to the beginning of--to the

12 beginning of June, I didn't--the first week in

13 June. The last cases from Monday I didn't

14 include into this. The other issue is that I

15 have done enough of these cases, and sorry,

16 the statistics I'm going to give you or

17 discuss, I have not included the retro review.

18 COFFEY, Q.C.:

19 Q. Yes.

20 DR. MULLEN:

21 A. That's -

22 COFFEY, Q.C.:

23 Q. Because I take it that was the -

24 DR. MULLEN:

25 A. That would skew everything.

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1 COFFEY, Q.C.:

2 Q. Because it was a very -

3 DR. MULLEN:

4 A. It was a selected group.

5 COFFEY, Q.C.:

6 Q. Selective group?

7 DR. MULLEN:

8 A. Yes. So they weren't in. But I did include

9 the prospective from Newfoundland because I

10 think those were legitimate to include. So I

11 have--I mean, to do statistics or to--if you

12 have ten cases, it's hard to say what your

13 positivity rate of, you know, seven, that 70

14 percent or six, is that a major deviation.

15 Once you start to get up into the thousands,

16 like I'm just trying to think--so basically

17 from the beginning of '05 to June of '08 I

18 have 1439 cases, so I think that gives me

19 robust enough numbers to do statistics on.

20 And my category--my statistics, can I recall

21 the nurses' study for you? Did Frances

22 O'Malley speak about the nurses' study, the

23 expected positivities? Oh, she -

24 COFFEY, Q.C.:

25 Q. I think she may have in passing but -

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1 COMMISSIONER:
 2 Q. She didn't refer to it as the nurses' study.
 3 DR. MULLEN:
 4 A. Oh, sorry.
 5 COMMISSIONER:
 6 Q. I don't remember her referring to it as the
 7 nurses' study.
 8 COFFEY, Q.C.:
 9 Q. She may have used the actual service -
 10 DR. MULLEN:
 11 A. Yes, she may have the actually--I can pull out
 12 the report if you like. Sorry.
 13 COMMISSIONER:
 14 Q. Okay.
 15 DR. MULLEN:
 16 A. So the nurses' study, wish I had a blackboard,
 17 but anyways, ER positive, PR, it was the
 18 nurses' study of 2096 cases of breast cancer.
 19 The ER positive, PR positive, they had 1281,
 20 which is 61.2 percent were positive for both.
 21 ER positive, PR negative they had 318, which
 22 is 15.2 percent. ER negative, PR positive,
 23 they had 80 cases, which was 3.8 percent, and
 24 ER negative, PR negative, they had 19.9. So
 25 at the bottom--so to round things off, about

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1 76 percent should be, well, 76.4, to be exact,
 2 should be ER positive, another approximately
 3 3.8 percent should be PR positive, and then
 4 about 20 percent should be ER/PR negative. So
 5 I would be aiming for that ball park. So if I
 6 looked at the--when I presented my data in
 7 December, I just looked at the ER positivity,
 8 I didn't break it into the four groups at that
 9 time in December, so beginning of '05 to
 10 December, which includes the Mount Sinai
 11 internal cases, which proportionately would be
 12 very small compared to Newfoundland and my--
 13 the other consults I get, because I would be
 14 dividing that service. I do the majority of
 15 the ER/PR and consult work. I had 1133 cases
 16 and my PR--my ER positivity was 77.2 where the
 17 literature says I should be 76.4, so I didn't
 18 think that was too bad. And my, Greater
 19 Niagara, which is a, I believe three or four
 20 hospitals would be analogous to the
 21 Newfoundland situation where we have different
 22 hospitals processing the tissue, sending it,
 23 then they send it to the Mount Sinai, they
 24 don't do anything directly, send it to Mount
 25 Sinai, they were 79.4 percent positive. And

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1 Newfoundland, I had 236 cases that were--and
 2 79.2 percent. So the Newfoundland go forward
 3 or the Newfoundland perspective--prospective
 4 were in the right ball park. So to update -
 5 COFFEY, Q.C.:
 6 Q. The go forward current cases?
 7 DR. MULLEN:
 8 A. Yes, prospective from August, '05 to, that
 9 time is December, beginning of December, '07.
 10 COFFEY, Q.C.:
 11 Q. Okay.
 12 DR. MULLEN:
 13 A. So in preparation for this I did the '05 to
 14 basically the end of the first week of June.
 15 And I had done, by that time, 1439, so another
 16 basically 300 cases in five months or six
 17 months. I broke it down better here. My ER
 18 greater than ten and breaking it down were 78
 19 percent and my PR positivity rate was .5
 20 percent, so 78.5 percent. So that was--and my
 21 expected should be basically 80, so I'm in the
 22 70--sorry, 80 percent. So I'm in the--two
 23 percent off, which I don't think is too bad.
 24 COFFEY, Q.C.:
 25 Q. Doctor, when you say ER positive, the cut off

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1 for that positive is?
 2 DR. MULLEN:
 3 A. I added both, I added the greater than ten and
 4 greater than one.
 5 COFFEY, Q.C.:
 6 Q. Okay.
 7 DR. MULLEN:
 8 A. And greater than ten, if you remember the
 9 literature or you know the literature better
 10 than I do after discussing things with you,
 11 there's basically a dichotomist situation,
 12 you're either completely negative or greater
 13 than 70 in almost 90 percent of--over 90
 14 percent of cases. There are very few that are
 15 in the less than 70. So my ER that I had
 16 between one and ten were only 11 cases, which
 17 would be one one hundredth, one percent of my
 18 cases. So basically 78 percent were positive
 19 and the PR, this I have to look at, is only .5
 20 whereas the literature says about 3.8. So I
 21 might be slightly over calling the ER and
 22 under calling PR, but that's the--I am in the
 23 ball park.
 24 COFFEY, Q.C.:
 25 Q. Okay. And now in terms of the statistics

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1 themselves, though, I take it you utilized
 2 them just, I take it, like, as you say, about
 3 every six months or so you go and run your
 4 stats and have a look back. But I'm just
 5 going to ask you about the utility of
 6 statistics themselves. In the context,
 7 Doctor, of the day-to-day work of a
 8 pathologist in the sense that if you were
 9 relying solely upon statistics to determine
 10 from day to day whether or not you were
 11 diagnosing or reporting a case properly, I
 12 take it that you could go quite a period of
 13 time before the statistics would show you that
 14 you were over or under, over or under calling
 15 something?
 16 DR. MULLEN:
 17 A. Yes. I mean, statistics are great when you
 18 want to show how productive you are and how
 19 you fit into everything, but as I was trying
 20 to mention earlier, I don't know if I was
 21 clear enough, it is the individual case that
 22 triggers the alarm. The absence of internal
 23 controls, the lobulars, the tubulars, the
 24 mucinous that are negative, that is what
 25 triggers the alarm. I don't care what my

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1 stats are if I have 78.5 or whatever the
 2 exact, that has no bearing on my report. It's
 3 what the individual case is. And those, any
 4 deviation from what I expect and, you know,
 5 with the positive internal controls, the
 6 tumors being positive, any deviation triggers
 7 alarms, both myself, my colleagues and our
 8 staff. So if we don't fit what we expect, we
 9 act. We don't wait for my percentage to drop
 10 to, like, 75 or whatever it is. And when you
 11 get enough cases, you need a large deviation
 12 from normal practice to pick it up.
 13 COFFEY, Q.C.:
 14 Q. Doctor, how long has Mount Sinai been using
 15 the one percent figure?
 16 DR. MULLEN:
 17 A. I believe the beginning of 2000. I believe
 18 Dr. O'Malley may have spoken that she was a
 19 participant in the study that established the
 20 one percent cutoff. We started in 2000.
 21 COFFEY, Q.C.:
 22 Q. How about before that, what -
 23 DR. MULLEN:
 24 A. I believe it was ten percent. It's always
 25 been my policy and I believe most of my

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1 colleagues' policy to give a numerical value
 2 as well as an interpretation because as you
 3 know the literature changes, the clinicians'
 4 practices change, so it's much easier on a go-
 5 forward basis to give as much information as
 6 possible. It's very time consuming to pick up
 7 the slides, first of all, you have to find
 8 them, they may be--that sort of thing. You
 9 give as much information going forward so that
 10 they can deal with things.
 11 COFFEY, Q.C.:
 12 Q. And, Doctor, just something that arose
 13 yesterday and there's some topics I want to
 14 cover with you now. I apologize if I appear
 15 to be moving between different things, to
 16 yourself and the Commissioner. But you did
 17 reference yesterday a conversation you had
 18 with Dr. Carter in November of 2005 when she
 19 was in Toronto?
 20 DR. MULLEN:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. And you indicated to her, to us that you had
 24 spoken to her about concerns or problems you
 25 were observing, you know, in the Newfoundland

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1 material, the current Newfoundland material?
 2 DR. MULLEN:
 3 A. The prospective material, yes.
 4 COFFEY, Q.C.:
 5 Q. Prospective material. When you were speaking
 6 to Dr. Carter about that, do you recall if she
 7 said anything to you about--you know, did she
 8 make any observations in that regard?
 9 DR. MULLEN:
 10 A. Most of the--I mean, there were general--the
 11 conversation was general about I'm having
 12 issues, I'm doing a lot of, when I say extra
 13 work, it was referring to the HER2s that we
 14 had to go to FISH because of the--we didn't
 15 feel that the specimens were--it wasn't
 16 particular to the ER/PR, it was the general
 17 fixation processing issue. And then I, if I
 18 remember correctly, I mentioned yesterday a
 19 woman who had had bilateral breast surgery on
 20 the same day and one specimen was what I would
 21 consider adequate and the other specimen was
 22 almost uninterpretable, received the same
 23 time, removed within an hour or two of each
 24 other and path A was fairly acceptable, path
 25 B, and I asked her what conceivably could have

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1 happened. And she, if I remember correctly,
 2 mentioned that the--I don't think they had
 3 established a refrigerator in the operating--
 4 simple things like a refrigerator in the
 5 operating--not in the operating room, but in
 6 the receiving room, wherever, however they're
 7 set up there. And I'm not sure about their
 8 portering system and formalin. But the main
 9 thing that struck me was the absence of a
 10 fridge.
 11 COFFEY, Q.C.:
 12 Q. Did Dr. Carter at the time seem to you that
 13 she was aware of these sorts of issues
 14 already?
 15 DR. MULLEN:
 16 A. Yes, she seemed--it didn't come out in the
 17 testimony earlier, but I was--I had a few
 18 conversations with Dr. Carter over the fall
 19 and she was quite frustrated with, I don't
 20 want to put words in her mouth, but frustrated
 21 with the lack of response to her concerns, as
 22 well. I think my concerns mirrored her
 23 concerns. I believe when--I don't think
 24 there's anything that I've said that she would
 25 not have said.

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1 COFFEY, Q.C.:
 2 Q. I'm sorry, Doctor?
 3 DR. MULLEN:
 4 A. I'm sorry, I think my concerns mirrored her
 5 concerns. I don't want to put words in her
 6 mouth, but I don't think I've said anything
 7 that would contradict anything that she was
 8 saying.
 9 COFFEY, Q.C.:
 10 Q. And in terms of, because you've mentioned the
 11 refrigerator, Doctor, is there anything
 12 special about the sorts of fridge you're
 13 talking about or is it, you know, is it just a
 14 normal refrigerator?
 15 DR. MULLEN:
 16 A. It's a bar fridge, basically.
 17 COFFEY, Q.C.:
 18 Q. Pardon me?
 19 DR. MULLEN:
 20 A. Bar fridge. You go to Wal-Mart and you buy a
 21 Danby, like, "foom, foom".
 22 COFFEY, Q.C.:
 23 Q. Okay. So this is like the refrigerators -
 24 DR. MULLEN:
 25 A. It's \$300 at most.

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1 COFFEY, Q.C.:
 2 Q. Okay. So the refrigerator in this context
 3 would be just an ordinary refrigerator?
 4 DR. MULLEN:
 5 A. Yes, oh, yeah. There's nothing major about
 6 this. This doesn't have to be temperature
 7 controlled, it's just something to cool the
 8 specimen. I didn't--one of the issues when
 9 you're fixing something, formalin will
 10 penetrate faster if you heat the specimen.
 11 The problem is if you heat the specimen, it'll
 12 degrade much faster. So it's--so we do
 13 formalin before it arrives in the OR, we put--
 14 arrives in the department we put it in
 15 formalin in a fridge, like a--and because it's
 16 an under counter, it's basically what I would
 17 consider a bar fridge, like.
 18 COFFEY, Q.C.:
 19 Q. Yes.
 20 DR. MULLEN:
 21 A. I just bought one myself for sort of as a
 22 temporary thing, it's a Danby, it's less than
 23 \$300.
 24 COFFEY, Q.C.:
 25 Q. So, Doctor, in terms of that, and the whole

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1 point of it, I take it, in doing so, in
 2 storing the tissue in Formalin temporarily in
 3 a refrigerator is just to keep the Formalin
 4 and the tissue cool?
 5 DR. MULLEN:
 6 A. Yes, you're trying to cool the--cool the
 7 specimen to slow degradation. The ideal is
 8 the minute the specimen is removed, it's
 9 brought to pathology, it's serially sectioned
 10 and put in Formalin. If that's not available,
 11 then the next best thing is in Formalin, in a
 12 sufficient amount of Formalin in a
 13 refrigerator and then brought to pathology.
 14 And ideally breast surgery is not doing at
 15 6:00 on a Friday afternoon and sits in a
 16 fridge over the weekend, it's done, it's
 17 processed properly.
 18 COFFEY, Q.C.:
 19 Q. Doctor, the idea of false negatives, I'm
 20 sorry, false negatives, false positives, the
 21 concept of false positives for ER and PR, is
 22 there such a thing, a false positive?
 23 DR. MULLEN:
 24 A. Yes, they would be, if you have a properly
 25 validated antibody, it would be unlikely that

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1 you would get a false positive. False
 2 negatives would be much greater possibility.
 3 Basically what you're saying is that you're
 4 detecting something that's not there.
 5 COFFEY, Q.C.:
 6 Q. Yes.
 7 DR. MULLEN:
 8 A. So part of it might be your, well, your
 9 threshold value if you haven't--I believe Dr.
 10 O'Malley mentioned the TMAs that we do. When
 11 we validate an antibody, the estrogen,
 12 progesterone antibody we do tissue microray
 13 and these are specimens that have been
 14 correlated with Ligand binding assay, so we do
 15 a negative, so when it was negative, a low
 16 positive and a high positive. So we, when we
 17 do our antibodies, we match the reactivity to
 18 what's the biochemical assay, so that's
 19 basically the validation. And then we--so if
 20 you are getting, I don't know how you'd do it,
 21 but if you're getting a positive on a negative
 22 and you brought that into production, then,
 23 yes, you could have a false positive. But
 24 biologically, you know -
 25 COFFEY, Q.C.:

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1 Q. It would be rare?
 2 DR. MULLEN:
 3 A. Yes, very uncommon. Assuming you're using the
 4 right antibody.
 5 COFFEY, Q.C.:
 6 Q. Yes.
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Doctor, in terms of the prospective, is the
 11 term you use, or current cases from
 12 Newfoundland and Labrador, you've been
 13 reporting them, the current prospective cases
 14 since August of 2005 for all of Newfoundland
 15 and Labrador outside St. John's?
 16 DR. MULLEN:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. In particular. And up until March of,
 20 February/March of '07 for St. John's and you
 21 just started St. John's again?
 22 DR. MULLEN:
 23 A. Yes, that's correct.
 24 COFFEY, Q.C.:
 25 Q. Can you tell the Commissioner, please, I want

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1 to just explore with you two things, you did
 2 indicate in a January 20th, 2006 e-mail to Dr.
 3 Cook that there were some things you thought
 4 perhaps would be useful to discuss him, as
 5 well you had spoken to Dr. Carter back in
 6 November of '05. And your concerns were in
 7 relation to what you were seeing in the
 8 current cases then, what sorts of things?
 9 DR. MULLEN:
 10 A. The prospective. My concerns were basically
 11 that I was having the same sample preparation
 12 problems that existed in the retro. So
 13 whether it was--so the sample handling between
 14 the time it was removed from the patient to
 15 the time the block was prepared. So was it
 16 fixation issues or processing? And when we
 17 talk about fixation, we're talking, you know,
 18 that fridge issue would be part of the
 19 fixation issue, the transport to pathology,
 20 the serial--the sectioning of the specimen
 21 would all be part of the issues that should
 22 have been addressed. Basically the proper
 23 handling of the specimen between the time it's
 24 removed from the patient to the time I get a
 25 block, or the time the lab gets a block.

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1 Those are all the--there were all those
 2 issues.
 3 COFFEY, Q.C.:
 4 Q. Doctor, has that changed?
 5 DR. MULLEN:
 6 A. There has been a reduction in the issues, yes,
 7 there are still occasional cases, but over
 8 time the number has decreased.
 9 COFFEY, Q.C.:
 10 Q. I take it that the quality then, from your
 11 perspective, of the fixation process and the
 12 processing itself of the tissue into blocks
 13 has--what you're seeing under the microscope
 14 has improved?
 15 DR. MULLEN:
 16 A. Somewhat, yes.
 17 COFFEY, Q.C.:
 18 Q. Somewhat.
 19 DR. MULLEN:
 20 A. It's not, by no means is it 100 percent. I
 21 mean, we still have -
 22 COFFEY, Q.C.:
 23 Q. It's not as bad as it was?
 24 DR. MULLEN:
 25 A. No, but it's not 100 percent. It hasn't met

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1 the equivalent of either my Greater Niagara or
 2 my Humber River consult cases.
 3 COFFEY, Q.C.:
 4 Q. Okay. So, I'm sorry, could you just on that
 5 point?
 6 DR. MULLEN:
 7 A. That we can sit down, when we sit down to sign
 8 out the case, pick out which case, even before
 9 we look at the slides, this is Newfoundland,
 10 this is that sort of thing. They're still -
 11 COFFEY, Q.C.:
 12 Q. Even before you look at the slides?
 13 DR. MULLEN:
 14 A. Yes. I mean, as you look at--you don't pick
 15 up the requisition, you look at the slide, you
 16 see the artifacts of the tissue exploding.
 17 You know that this is going to be--there are
 18 certain places that we get that issue from.
 19 COFFEY, Q.C.:
 20 Q. And Newfoundland and Labrador -
 21 DR. MULLEN:
 22 A. There's more, there's more of them.
 23 COFFEY, Q.C.:
 24 Q. Yes. And you say -
 25 DR. MULLEN:

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1 A. But it's not 100 percent.
 2 COFFEY, Q.C.:
 3 Q. When you say you look at the slides, I take it
 4 you're looking at them just gross?
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Without a microscope.
 9 DR. MULLEN:
 10 A. Right, right.
 11 COFFEY, Q.C.:
 12 Q. You can even tell -
 13 DR. MULLEN:
 14 A. It doesn't take--you don't have to have a
 15 microscope to see that there's nothing on it.
 16 COFFEY, Q.C.:
 17 Q. Or there -
 18 DR. MULLEN:
 19 A. And pathology, remember, pathology is, from
 20 the naked eye through to--as most, the highest
 21 power you can get.
 22 COFFEY, Q.C.:
 23 Q. So, Doctor, in terms of that, I take it that
 24 dealing with that that there is a difference
 25 that you've--you could, if you had them here

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1 in front of you, different slides from
 2 different areas, different regions, not so
 3 much within Newfoundland as from different
 4 regions across the country where you're -
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. That you'd be able to say, well, this looks
 9 like a Newfoundland case even just looking at
 10 the -
 11 DR. MULLEN:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. - slide in a--without a microscope at all?
 15 DR. MULLEN:
 16 A. Right.
 17 COFFEY, Q.C.:
 18 Q. And you would attribute the shortcomings in
 19 that regard in respect of the product that you
 20 were seeing to fixation?
 21 DR. MULLEN:
 22 A. Slash, specimen handling, fixation/processing,
 23 if we include the pre placement in formalin
 24 serial section type, yes.
 25 COFFEY, Q.C.:

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1 Q. Okay.
 2 DR. MULLEN:
 3 A. I would--I think the vast majority of the
 4 problems that I am seeing in the prospective,
 5 because we handle all of our cases the same
 6 way, once we get the block, are the pre block
 7 preparation.
 8 COFFEY, Q.C.:
 9 Q. Now, doctor, in respect of the prospect of and
 10 current cases, okay, the current process and
 11 I'll refer to them, you've classed them as the
 12 prospective cases, you have been reporting
 13 them?
 14 DR. MULLEN:
 15 A. Oh, yes.
 16 COFFEY, Q.C.:
 17 Q. From Newfoundland and Labrador. How confident
 18 are you in relation to the accuracy of your
 19 reporting of ER and PR in respect of those
 20 cases?
 21 DR. MULLEN:
 22 A. I am as confident as the cases that I do in-
 23 house that are properly prepared because we
 24 work extremely---"we" meaning the
 25 technologists work extremely hard to get me a

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1 slide that's interpretable. And there are
 2 very rare cases that I will say
 3 "Uninterpretable. Please send another block."
 4 But the material we have is, before I
 5 diagnosis it, because again, remember, I
 6 discussed the philosophical, there is nothing
 7 you can do about the retro, but going forward,
 8 if I'm unsatisfied with the amount of material
 9 or the quality of the material, I'll ask for
 10 another block and then repeat it or we will
 11 work very diligently to get multiple sections
 12 to get interpretable material.
 13 COFFEY, Q.C.:
 14 Q. And that's for the current -
 15 DR. MULLEN:
 16 A. Yeah, that's current.
 17 COFFEY, Q.C.:
 18 Q. - prospective cases. From this province?
 19 DR. MULLEN:
 20 A. Yes.
 21 COMMISSIONER:
 22 Q. Sorry, Mr. Coffey, I'm just going to jump in
 23 here again. I'm just thinking in terms of
 24 organization of your lab, I'm just thinking in
 25 terms of lab organization.

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1 DR. MULLEN:
 2 A. Yes, um-hm.
 3 COMMISSIONER:
 4 Q. So then the business of proper fixation and
 5 processing is critical to the validity of your
 6 test but also it's not done properly, someone
 7 else down the line in your position, a
 8 pathologist, will have to either go back to
 9 the technicians and get further work done or
 10 perhaps if the lab is being properly run, the
 11 technicians themselves will recognize a
 12 problem and deal with it?
 13 DR. MULLEN:
 14 A. That's correct.
 15 COMMISSIONER:
 16 Q. But it seems to me that that means the cost
 17 per test of your operation would be much
 18 higher if your fixation, etcetera, were not
 19 done properly in the first place because the
 20 technicians and the pathologists have to take
 21 more time to get what they need to read the
 22 test. Is that -
 23 DR. MULLEN:
 24 A. In general, yes, yes. If your criteria--if
 25 your criteria for signing out are sufficiently

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1 high, you will send the material back to be
 2 repeated.
 3 COMMISSIONER:
 4 Q. Okay.
 5 DR. MULLEN:
 6 A. If you set your criteria low, that you'll
 7 accept anything, then it wouldn't make much
 8 difference. It would take longer for the
 9 technician to make a bad slide because they
 10 try to work at it, but if you're sending back
 11 for perfection, yes, it would take much longer
 12 and the cost would go up.
 13 COMMISSIONER:
 14 Q. Okay. Thank you.
 15 COFFEY, Q.C.:
 16 Q. Doctor, in respect of the retrospective cases,
 17 retrospective studies that you did.
 18 DR. MULLEN:
 19 A. Yes. So that -
 20 COFFEY, Q.C.:
 21 Q. The '97 to 2005, not the slide review but the
 22 retrospective study which the results of which
 23 you reported in a spreadsheet format?
 24 DR. MULLEN:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Okay. You've described for the Commissioner,
 3 you know, the artifacts and problematic
 4 aspects of what you were seeing?
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Okay. But in terms of the actual reporting
 9 itself, when you reported something as from
 10 your perspective positive in the sense of an
 11 ER and/or a PR result greater than one, okay,
 12 and in your world that's a positive?
 13 DR. MULLEN:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. If you reported it as positive, how confident
 17 are you in respect of the validity of that
 18 report? If you called it as a positive, are
 19 you satisfied that it was a positive aspect to
 20 the tumor cells?
 21 DR. MULLEN:
 22 A. Yes. Yes, I was confident that I would not
 23 report a positive unless I could justify in my
 24 own mind that it was positive. I think what I
 25 would like to clarify is some of the e-mail

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1 discussion we had, or discussions yesterday
 2 when we were--Dr. Cook and I were going back
 3 and forth as to whether something was, I think
 4 the one or two cases where I talked about the
 5 outside versus--so the percentage increased
 6 because the tissue is better fixed, but in
 7 those cases we were quibbling over, I
 8 shouldn't say quibbling, that minimizes the
 9 extent of the conversation. We were
 10 discussing the issue of basically what a
 11 positive is. In my world a positive is
 12 greater than one, it's low positive but it's
 13 positive. In his world I believe it's, after
 14 discussion with you, it's ten. So as far as I
 15 was concerned, it was positive, the patient
 16 was, in my world, the patient would be
 17 eligible for therapy. So whether I say it's a
 18 five or say it's a 12, it's not--it is a
 19 positive.
 20 COFFEY, Q.C.:
 21 Q. And in terms then of the--from your own
 22 perspective, you know, as a professional, when
 23 you reported in the retrospective spreadsheets
 24 that you called somebody an ER greater than
 25 one, whether it was two all the way up to 100,

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1 or a PR all the way from greater than one,
 2 two, up to 100, and that you were satisfied
 3 that a physician could -
 4 DR. MULLEN:
 5 A. Could act on that.
 6 COFFEY, Q.C.:
 7 Q. - could act upon that information.
 8 DR. MULLEN:
 9 A. The only reason we put it in a--well, I
 10 shouldn't say the only reason, one reason we
 11 put it in a spreadsheet was to facilitate
 12 reporting, and the other, I'm not sure of the
 13 legalities in Newfoundland, but in Ontario,
 14 the Public Hospital Act, if I issue a report,
 15 it has to become part of the patient's chart.
 16 So it was not my responsibility, or I
 17 shouldn't say not the responsibility, it's not
 18 my--it's not--I wished to have something put
 19 on the patient's chart until it had been
 20 reviewed by the Newfoundland pathology
 21 department. I mean, I was issuing reports and
 22 it was my understanding that they would look
 23 at my slides before they did anything, just to
 24 double check. I mean, out of a--there may
 25 have been a few maybe that they would

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1 interpret differently, which is legitimate, as
 2 I remember if I recall the discussion on the
 3 invasive carcinoma issue with Dr. Denic that I
 4 referred to yesterday, the three blocks from
 5 Western Memorial, two DCIS, one invasive, and
 6 I mean, pathology is not black and white.
 7 It's--as we've shown, it's various shades of
 8 brown, and pink and blue, and within and
 9 between sort of departments and pathologists,
 10 there are legitimate disagreements. I'm not
 11 saying they're misdiagnoses. They could be
 12 variant in interpretations and they are
 13 legitimate and no one, in my profession, takes
 14 exception to being asked to review something.
 15 It's not a personal slight. It's we are there
 16 to provide the correct diagnosis if somebody
 17 else has reviewed it and they don't agree or
 18 they want to question or they want further, it
 19 is entirely legitimate and we're happy to do
 20 it.
 21 COFFEY, Q.C.:
 22 Q. Doctor, the antibodies used for ER and PR -
 23 DR. MULLEN:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. I gather Mount Sinai uses two particular
 2 antibodies -
 3 DR. MULLEN:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. - one for ER and one for PR, and Ms.
 7 Wegrynowski and, I believe, Dr. O'Malley have
 8 referred to them, as have you. For example,
 9 for ER, are there other antibodies that can
 10 possibly be used?
 11 DR. MULLEN:
 12 A. Yes, there are multiple antibodies. Various
 13 companies, various clones within that can be
 14 used for both ER/PR. Did Dr. O'Malley and Dr.
 15 or Ms. Wegrynowski comment on why we use those
 16 specifics?
 17 COFFEY, Q.C.:
 18 Q. If they did, it won't hurt for you to remind
 19 us.
 20 DR. MULLEN:
 21 A. Okay.
 22 THE COMMISSIONER:
 23 Q. Work on that old preacher's principle. Tell
 24 me three times and I might -
 25 DR. MULLEN:

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1 A. I'm going to tell you what I'm going to tell
 2 you. I tell you what I tell you and then I
 3 told you what I told you. Okay. Good, that's
 4 what I teach my students. It also shortens
 5 the lectures. Just very quickly, Dr. O'Malley
 6 was involved in the study that basically
 7 established the one percent guideline, the
 8 basis of that, and she believes, and she's the
 9 lead in the ER/PR and HER2 area, that she
 10 believes that based on her literature review
 11 and personal experience that the best
 12 validated antibodies and the best cut-off
 13 points with clinical validation are by Allred,
 14 so he may not be the final author on the
 15 papers, but the two ER and the PR papers and I
 16 have the references if we need them. So
 17 anything greater than one percent for ER, I
 18 think she may have gone through. It was using
 19 an Allred score. There's the percentage and
 20 the intensity, so a score greater than three.
 21 MR. BROWNE:
 22 Q. Commissioner, excuse me, if the witness can be
 23 shown P-1728, page six, that's Dr. O'Malley's
 24 presentation and he may be able to tie it
 25 together.

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1 THE COMMISSIONER:
 2 Q. All right, sure.
 3 MR. BROWNE:
 4 Q. Yes, there's the reference to -
 5 DR. MULLEN:
 6 A. Okay.
 7 THE COMMISSIONER:
 8 Q. The Allred score, yes.
 9 MR. BROWNE:
 10 Q. Allred score.
 11 DR. MULLEN:
 12 A. Yes, all right.
 13 THE COMMISSIONER:
 14 Q. Thank you, Mr. Browne.
 15 DR. MULLEN:
 16 A. Don't like my locking it down.
 17 MR. BROWNE:
 18 Q. That would be page six.
 19 THE COMMISSIONER:
 20 Q. Page?
 21 MR. BROWNE:
 22 Q. (Inaudible).
 23 THE COMMISSIONER:
 24 Q. What page number are you talking about?
 25 MR. BROWNE:

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1 Q. (Inaudible).
 2 THE COMMISSIONER:
 3 Q. I do recall -
 4 DR. MULLEN:
 5 A. Do you want me to whip through and I can pick
 6 it up?
 7 THE COMMISSIONER:
 8 Q. Of course, easy.
 9 DR. MULLEN:
 10 A. Here we are. This would be the--sorry, do you
 11 have this? So the one in the lower left-hand
 12 corner, or the one on the left, so the Allred
 13 score was a combination of proportion or the
 14 percentage. So zero would be none. One would
 15 be less than 100, less than one percent. Two
 16 would be one to ten percent. Ten percent to
 17 33 percent, 33 percent to 66 percent, and then
 18 over 66 percent would be the score, and then
 19 the intensity would be zero--I think I alluded
 20 to this yesterday. Zero would be negative.
 21 One is weak. Two is intermediate and three is
 22 strong, intermediate or moderate. So the
 23 original score was anything greater than
 24 three. So that would be--sorry, anything
 25 greater than two, so three and above. So as

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1 few as one percent of cells that were weakly
 2 positive would respond to therapy, both
 3 chemotherapy--sorry, would respond to
 4 Tamoxifen, would respond to hormone
 5 manipulation, and for both the ER and PR, use
 6 in the term in one of the papers, they
 7 dichotomize the patients into two groups,
 8 those who responded and those who did not
 9 respond. So anybody less than one percent did
 10 not respond. There was a significant
 11 different rather in the response between less
 12 than one percent and one percent and greater.
 13 Now I'm not saying that somebody who--or the
 14 paper doesn't say that somebody who is two
 15 percent will respond to the same extent that
 16 somebody who is 95 percent, but there is a
 17 significant different in response at P less
 18 than--I think it was P less than .0014, if you
 19 do the manipulation, it's P less than .01, if
 20 you do the--take out the multiple variables.
 21 But at least a statistical significant
 22 difference in response, rate of response to
 23 hormone manipulation for both ER and PR
 24 greater than one percent. So that's why we
 25 use the one percent.

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1 COFFEY, Q.C.:

2 Q. That's your one percent. Doctor, in terms of

3 the various types of antibodies, okay, why

4 does Mount Sinai use the ones it does?

5 DR. MULLEN:

6 A. Because, as I was mentioning, Dr. O'Malley,

7 when we established these, these are the best

8 clinical and technically--best, the best

9 validated bodies, both--validated antibodies,

10 both clinically and technically.

11 COFFEY, Q.C.:

12 Q. Okay, clinically and technically?

13 DR. MULLEN:

14 A. Yes, so this criteria for scoring, plus--so

15 that would--plus how they were--we followed

16 the guidelines for staining.

17 COFFEY, Q.C.:

18 Q. I take it though, Doctor, as there are other

19 antibodies, I take it, that are perceived to

20 be acceptable by at least certain groups of

21 pathologists?

22 DR. MULLEN:

23 A. Yes, there are. That doesn't preclude other

24 hospitals from using other criteria, other

25 antibodies. I mean, this is what we've

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1 established, based on the literature, her

2 reading of the literature, and our clinicians

3 accept this practice.

4 COFFEY, Q.C.:

5 Q. Doctor, if St. John's was, for example, back

6 between 1997 and 2005, was using a different

7 antibody than Mount Sinai was, if it was,

8 during any of that, all or any of that period,

9 for ER or PR, would that have made any

10 difference to what we've talked about here, in

11 terms of your review, do you think?

12 DR. MULLEN:

13 A. It wouldn't have made a difference in the

14 sense of the reactivity. It might have made a

15 difference, depending on how those antibodies

16 had been validated clinically, whether one

17 percent or ten percent or 30 percent was the

18 valid cut off.

19 COFFEY, Q.C.:

20 Q. Okay.

21 DR. MULLEN:

22 A. It would be not the technical, but the

23 clinical -

24 COFFEY, Q.C.:

25 Q. Clinical end of that?

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1 DR. MULLEN:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. And you say you'd have to go talk to the

5 oncologist?

6 DR. MULLEN:

7 A. Yes, the oncologist.

8 COFFEY, Q.C.:

9 Q. And/or the pathologist who picked those

10 particular antibodies?

11 DR. MULLEN:

12 A. Yes. You have to be very careful. I'm a

13 pathologist, not a oncologist. So basically,

14 this is--I'm giving you the party line from

15 the pathology side. It's up to the Commission

16 to--they can totally ignore my reports, which

17 they do quite frequently. They have their own

18 ideas. Not so much on this, but on other

19 things I do.

20 COFFEY, Q.C.:

21 Q. Doctor, with respect to this, I noticed in the

22 reports that we've looked at, the actual

23 reports where you--the consults, or the

24 samples we looked at.

25 DR. MULLEN:

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1 A. Yes, prospective, yes.

2 COFFEY, Q.C.:

3 Q. You do note the actual antibodies used?

4 DR. MULLEN:

5 A. Yes, that's a -

6 COFFEY, Q.C.:

7 Q. And why is that?

8 DR. MULLEN:

9 A. The College of American Pathologists, the

10 requirement that we give the antibody and the

11 procedure. If I remember yesterday, we

12 mentioned it was 6--for estrogen receptor it's

13 6F11 LSAB, which is linked strepped avidin

14 procedure. There are other polymer

15 procedures, horseradish peroxidase procedures,

16 but that's the one we use for this one, and

17 PGR1294 for progesterone.

18 COFFEY, Q.C.:

19 Q. Okay, and the purpose in you so reporting that

20 is what? Because it's required?

21 DR. MULLEN:

22 A. Because it's a requirement for our

23 accreditation, plus I don't think it would

24 make any difference to the clinicians, as they

25 never even sort of--I don't think they read

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1 that line. They look at the number and then
 2 they look at our interpretation.
 3 COFFEY, Q.C.:
 4 Q. But someone, I take it, afterward going back -
 5 DR. MULLEN:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Looking at it, would be able to say, okay,
 9 three years ago or five years ago, Dr. Mullen
 10 reported these percentages, but he was
 11 utilizing these particular antibodies and this
 12 particular method?
 13 DR. MULLEN:
 14 A. Yes, yes.
 15 COFFEY, Q.C.:
 16 Q. Bearing that in mind, these are the numbers he
 17 got, okay.
 18 DR. MULLEN:
 19 A. And also, if you look at the recent reports,
 20 we reference everything.
 21 THE COMMISSIONER:
 22 Q. I'm sorry, you?
 23 DR. MULLEN:
 24 A. We reference what thresholds we use.
 25 THE COMMISSIONER:

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1 Q. Okay.
 2 DR. MULLEN:
 3 A. We give the threshold and we have a reference
 4 to the threshold.
 5 THE COMMISSIONER:
 6 Q. Yes.
 7 DR. MULLEN:
 8 A. Motion is the one paper and the other.
 9 COFFEY, Q.C.:
 10 Q. Doctor, could you tell the Commissioner,
 11 please, what, within Mount Sinai itself, in
 12 respect of, for example, IHC staining, in
 13 particular, ER and PR, what sorts of quality
 14 assurance measures are you, as a pathologist,
 15 involved in or are you aware of?
 16 DR. MULLEN:
 17 A. We have two, quality assurance and quality
 18 control. The quality assurance, we have four
 19 programs that we belong to. One is--let me
 20 just QMPILS, which is the Quality Management
 21 Program in Laboratory Services, which is from
 22 Ontario. There is the UK NEQAS, which is
 23 United Kingdom National External Quality
 24 Assurance Service. There is the College of
 25 American Pathologists, which is--and also,

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1 there's a new initiative in Canada through the
 2 College of--Canadian Association of
 3 Pathologists called CIQA, which is--I'm sorry,
 4 Immunohistochemistry Quality Assurance that
 5 has just started, which is looking at ER/PR
 6 and HER2 and if you read the Globe and Mail in
 7 the beginning of June, there was a large front
 8 page article on that, and those are the four
 9 that we--the external quality assurance, and
 10 then we have internal quality control in the
 11 laboratory and within the Department, Dr.
 12 O'Malley and I, since we are the major
 13 readers, have reviews. She'll look at mine,
 14 I'll look at hers, and she also--because she
 15 presents at tumor boards, which are review of
 16 all the cases, she'll review all of the--these
 17 are the in-hospital cases and compare. Now
 18 when we talk--and also, with all of these
 19 external, she and I will read separately and
 20 compare and contrast our results. Well, we
 21 should--we use the term "blinded". It's not a
 22 good term for pathologists. But I will
 23 interpret without knowledge of her results.
 24 She will interpret without knowledge of my
 25 results, and then "boomp, boomp, boomp", and

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1 then, you know, if she says 10 and I say 12,
 2 like minor. But if she says 100 and I say
 3 zero, then we have a discordance.
 4 COFFEY, Q.C.:
 5 Q. Or for example, if you said 10 and she says
 6 70, I take it that would be -
 7 DR. MULLEN:
 8 A. That'd be fine. Fine, I mean, we -
 9 COFFEY, Q.C.:
 10 Q. No, I'm sorry, 10 and 70.
 11 DR. MULLEN:
 12 A. Oh, sorry. No, that would be a major issue,
 13 major issue. Major issue, major, major,
 14 major.
 15 COFFEY, Q.C.:
 16 Q. And in terms -
 17 DR. MULLEN:
 18 A. But we had -
 19 COFFEY, Q.C.:
 20 Q. What would that--if that was to happen, I take
 21 it you'd both make inquiries then as to what
 22 had happened?
 23 DR. MULLEN:
 24 A. Yes. "Can't you see?" that sort of thing,
 25 yes.

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1 COFFEY, Q.C.:
 2 Q. Okay.
 3 DR. MULLEN:
 4 A. We would sit down and--we'd sit down and
 5 resolve the issues. I mean, it's not so much
 6 for the ER--ER and PR in our lab is robust,
 7 well established and we're quite happy with
 8 it, and it's--although it's sensitive to
 9 fixation and all the other things, within our
 10 laboratory, we've sort of accommodated for
 11 those things, especially for the in-house
 12 cases. The one we're having great difficulty
 13 with are the HER2's because they're very
 14 sensitive to proper fixation processing,
 15 etcetera, etcetera, etcetera, and it also has
 16 tremendous cost implications because if you
 17 have to move from the standard
 18 immunohistochemistry to resolve either
 19 discordant results or equivocal results, then
 20 it has a cost implication and a time
 21 implication, because you have to do what we
 22 mentioned yesterday as fluorescence in situ
 23 hybridization. So those are--and we are--we
 24 do, last year we did 1866 of those. I had to
 25 do that for a quality management program.

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1 They wanted to know how many we reported.
 2 Those have--we have no control over the
 3 fixation. We have--there are guidelines which
 4 I mentioned earlier, the ASCO, College of
 5 American Pathology guidelines that tell
 6 fixation, etcetera, etcetera, and how to do,
 7 but we really have no control over it.
 8 COFFEY, Q.C.:
 9 Q. When you say control over it, I take it within
 10 Mount Sinai you would have control over -
 11 DR. MULLEN:
 12 A. Within, we have control, but it's the material
 13 coming from other institutions. I mean, there
 14 are very rigorous criteria for how to submit
 15 and how to analyze, but at the end of the day,
 16 what people decide to send to us, we can't
 17 deal much with.
 18 COFFEY, Q.C.:
 19 Q. Doctor, in terms of then, the idea that you
 20 would look at occasionally review in a blind,
 21 blinded way, Dr. -
 22 DR. MULLEN:
 23 A. (Unintelligible).
 24 COFFEY, Q.C.:
 25 Q. - something Dr. O'Malley had already looked at

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1 and vice versa. Does that occur for
 2 everything or does it occur on a percentage
 3 base, like so many every so many cases, or -
 4 DR. MULLEN:
 5 A. Which, the reviews?
 6 COFFEY, Q.C.:
 7 Q. The reviews, that sort of review.
 8 DR. MULLEN:
 9 A. It's 100 percent of the internals. She would
 10 review mine or whomever was presenting at
 11 tumor boards would review my cases and her
 12 cases, if she were not presenting, and that's
 13 100 percent. The ER/PR is not as rigorous.
 14 It's basically because HER2 is not reported
 15 the same time. She will have done the initial
 16 review and then I will do the HER2 and since
 17 I'm putting my name on the final report and
 18 vice versa, she's putting her name on my final
 19 report, I want to make sure that I agree with
 20 that result. So that's--that would be sort of
 21 we're on, we alternate. So it would be a
 22 small, but not insignificant number of cases.
 23 COFFEY, Q.C.:
 24 Q. And Commissioner, I'm going to ask we take
 25 break now for lunch. I'll come back, I have

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1 just a couple of other questions, but it may
 2 take the doctor some minutes to actually
 3 answer them.
 4 THE COMMISSIONER:
 5 Q. All right.
 6 COFFEY, Q.C.:
 7 Q. And then continue on with the other lawyers.
 8 THE COMMISSIONER:
 9 Q. All right then. We'll take the luncheon
 10 break, five after two.
 11 COFFEY, Q.C.:
 12 Q. Thank you, Commissioner.
 13 (LUNCH BREAK)
 14 THE COMMISSIONER:
 15 Q. Please be seated. Mr. Coffey.
 16 COFFEY, Q.C.:
 17 Q. Thank you, Commissioner. Dr. Mullen, in
 18 relation to the matter of the breast tissue
 19 of--breast tissue samples that you're seeing
 20 from Newfoundland on the prospective or
 21 current cases, you indicated that it's your
 22 view that they have--it has gotten better over
 23 time, but it still has a ways to go?
 24 DR. MULLEN:
 25 A. There are occasional cases that I'm not

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1 satisfied with the processing fixation issue,
 2 but overall, there's been a marked improvement
 3 over time.
 4 COFFEY, Q.C.:
 5 Q. And with respect to the cases, you know,
 6 individual particular blocks that you do have
 7 a concern about, how do you handle that?
 8 DR. MULLEN:
 9 A. Basically, two points, if I'm totally
 10 unsatisfied, don't feel I can render an
 11 accurate diagnosis, the tissue is un-
 12 interpretable or obviously if there's no tumor
 13 in the tissue, I'll ask for a second block.
 14 Otherwise, as I mentioned this morning, we
 15 will repeat our--if I don't feel comfortable
 16 on the original, we will repeat our staining,
 17 both the ER, PR and if we're doing the HER2
 18 obviously, and then if I'm satisfied that the
 19 second go is better, then I'll report it.
 20 Otherwise, I'll ask for a second block.
 21 COFFEY, Q.C.:
 22 Q. And Doctor, I take it overall then though, in
 23 respect of any one patient, I take it when you
 24 finally do issue a report in respect of ER and
 25 PR, HER2/neu, from your perspective, are you

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1 satisfied that you can do so?
 2 DR. MULLEN:
 3 A. Yes. When I put my name to the bottom of the
 4 report, I put my professional integrity on the
 5 line that it's correct. The technical work
 6 and the professional interpretation are
 7 correct and that the clinician can act on the
 8 results.
 9 COFFEY, Q.C.:
 10 Q. Doctor, you did also refer, before the lunch
 11 break, to the idea that matters involving
 12 fixation or processing of--and processing of
 13 tissue, and/or processing of tissue, that
 14 might affect breast tissue and ER/PR results
 15 and possibly HER2/neu results as well, any
 16 inadequacies in the fixation process for the
 17 processing of tissue process that might affect
 18 breast tissue, might also affect other tissue?
 19 DR. MULLEN:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. Is there anything about breast tissue and
 23 ER/PR and HER2/neu tests that make breast
 24 tissue particularly susceptible though to
 25 problems as a result of fixation or processing

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1 inadequacies?
 2 DR. MULLEN:
 3 A. Well, if you recall the slide show from this
 4 morning, or my peach analogy, breast specimens
 5 tend to--well, breast specimens, there are
 6 three types to surgical pathology. One is a
 7 core biopsy, essentially where a needle is
 8 placed in the breast and a small core, maybe
 9 one or two millimetres in diameter, three or
 10 four millimetres or maybe a centimetre or two
 11 in length, is extracted. That's put in
 12 formalin and then sent to the laboratory.
 13 There's immediate fixation and if they're
 14 using the proper amount of--or using the
 15 proper fixative, the ten percent neutral
 16 buffer formalin, I would not expect there to
 17 be an issue with the fixation. So that type
 18 of specimen is covered.
 19 The next type of specimen, and I'll put
 20 the two together, one is called a lumpectomy
 21 where a small amount of breast, the tumor and
 22 a rim of non-tumorous breast is removed, and a
 23 mastectomy where skin and breast are removed.
 24 Those require more extensive handling
 25 immediately. That's where I have the concern

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1 from where the specimen is removed from the OR
 2 that it be put in formalin, be placed in a
 3 refrigerator, if it's not immediately
 4 transported to the laboratory, and then
 5 serially sliced so that the fixative is
 6 through the slice and then whipped with the--
 7 we use paper towel, other materials can be
 8 used. Immediately fixed, so that the inherent
 9 deterioration that occurs in a specimen, a
 10 natural process, is inhibited as quickly as
 11 possible, so that we have preservation of the
 12 nuclear detail, the proteins, and essentially
 13 the antigens that the antibodies react to.
 14 COFFEY, Q.C.:
 15 Q. Doctor, and are there--in terms of the full--
 16 well, I gather the full spectrum of possible
 17 pathology tests, both special stain tests and
 18 IHC tests and so on, are there any particular
 19 tests that are prone to being more affected by
 20 inadequacies in fixation and processing than
 21 others?
 22 DR. MULLEN:
 23 A. Yes, there are three categories of stains,
 24 three categories, yes. There's routine H & E
 25 and then there are called the histochemical

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1 stains, where we'll stain for organisms or
 2 products within the cell, such as we do--I
 3 won't enumerate the types of stains, but
 4 anyways, stains for fungi, stains for micro
 5 bacteria. Those are fairly rigorous and you
 6 can do them on less than optimal tissue, but
 7 anything that requires preservation of an
 8 antigen, so with immunohistochemistry, we're
 9 trying to detect substances that are present
 10 on the outside of the cell, on the cell
 11 membrane, substances that are present in the
 12 cytoplasm, so the border between the cell and
 13 the nucleus and within the nucleus.
 14 So if you think of a cell, we'll go to
 15 another one of my food analogies, if you think
 16 of the cell as a fried egg. So we are trying
 17 to detect--if we're trying to do membrane,
 18 we're trying to detect the outskirts or the
 19 outside of the white. If we're trying to
 20 detect the cytoplasm, we're detecting the
 21 white. If we're doing the nucleus, we're
 22 trying to detect the yolk. Now think of a
 23 fried egg. Formalin basically is cross links
 24 proteins. It's the same as heat, heat for the
 25 egg, the same effect. So if you have

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1 something that's not fixed, so if you have
 2 your yolk that's not fixed -
 3 COFFEY, Q.C.:
 4 Q. Or optimally fixed, I take it.
 5 DR. MULLEN:
 6 A. Beg your pardon?
 7 COFFEY, Q.C.:
 8 Q. Fixed or at least, or optimally fixed, are you
 9 talking -
 10 DR. MULLEN:
 11 A. Not optimally fixed. So basically, if you
 12 take the egg out, the yolk runs. So you have
 13 nothing left. That's the analogy of the
 14 hollowed nucleus. So you want--those of you
 15 who like sort of hard eggs, but anyways,
 16 that's the optimum. You want a well fixed
 17 cytoplasm, so the white doesn't run and you
 18 want the yolk fixed and yellow so it doesn't
 19 run. So if it's the equivalent in a cell that
 20 it's not fixed, the yolk would flow out
 21 basically. So that's the analogy. Pathology
 22 uses a lot of food analogies.
 23 COFFEY, Q.C.:
 24 Q. And Doctor, in respect of that then, I take it
 25 these particular immunohistochemical stains

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1 and antibodies, I take it, they require, all
 2 things considered, a more careful attention to
 3 rigorous fixation or processing protocols?
 4 DR. MULLEN:
 5 A. Yes. The handling should--the handling has to
 6 be extremely rigorous, if you want to compare
 7 one to the other.
 8 COFFEY, Q.C.:
 9 Q. And Doctor, in respect to this entire matter,
 10 because you've been involved in the
 11 retrospective study, our analysis, you were
 12 involved in what I will refer to as the slide
 13 review in 1998 (sic.), and Doctor, from your
 14 perspective, the pathologists who originally
 15 reported these cases back in '97, '98, '99,
 16 2000 all the way up through 2005, in your
 17 view, should it have been apparent to them,
 18 one or more of them, that there was a problem?
 19 DR. MULLEN:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. And why is that?
 23 DR. MULLEN:
 24 A. The quality of the material was so inadequate
 25 that the interpretation, both of the H & E

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1 sections in some cases, as well as the
 2 interpretation--not just the interpretation,
 3 but the actual material that was present on
 4 the ER and PR specimens was less than
 5 certainly optimal and in some cases, almost
 6 less than would be required for analysis.
 7 COFFEY, Q.C.:
 8 Q. As an example, Doctor, there were two, I, in
 9 fact picked in particular when we were dealing
 10 with the discordant label that you'd put on,
 11 and I had referred then to 1998 slide review.
 12 It's actually 2008 slide review. That's my--
 13 misspoke then. You looked at the slides in
 14 2008. Doctor, where, for example, there was
 15 no internal control present on the original
 16 slide, original ER slide or original PR slide
 17 as created in Newfoundland, when a pathologist
 18 looked at that, would he or she, in your view,
 19 throughout the period '98, '97 through 2005,
 20 should he or she have noticed that there was
 21 no internal control tissue present?
 22 DR. MULLEN:
 23 A. Yes, oh yes. That would be one of the basics
 24 for assessment.
 25 COFFEY, Q.C.:

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1 Q. And if there was internal control tissue
 2 present, but it, at least in your view, had
 3 not stained, based upon the slide review,
 4 should that have caused him or her any
 5 concern?
 6 DR. MULLEN:
 7 A. It would cause concern. It would cause, not--
 8 maybe concern is too strong. It would cause
 9 pause, because as I have mentioned, it's not
 10 an all or none phenomenon. 90 percent in the
 11 post-menopausal patients with cancer versus 80
 12 percent in the pre-menopausal. But a caution,
 13 not a stop.
 14 COFFEY, Q.C.:
 15 Q. And in terms of, for example, you've referred
 16 to exploding areas of the slides.
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Should that have caused, in your view,
 21 pathologists who saw--any other pathologist
 22 who saw that concern, at least to at least
 23 make further inquiries?
 24 DR. MULLEN:
 25 A. Yes, I think yesterday I indicated that one

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1 maybe, two umph, and three, I'm not going to
 2 repeat the phrase, but three, major concern.
 3 Major, major, major concern.
 4 COFFEY, Q.C.:
 5 Q. And the phenomenon of the hollow nucleus,
 6 nuclei, I'm sorry, same thing, I take it?
 7 DR. MULLEN:
 8 A. Same thing, and to extend to the necrosis,
 9 yes. All of those, I mean, in any one case,
 10 one of those would be worrisome, but to have
 11 all of those in the same case or to have a
 12 sequence of these over a short period of time
 13 or even a long, extended to a longer period of
 14 time would cause great concern.
 15 COFFEY, Q.C.:
 16 Q. Doctor, we have seen here, if we could bring
 17 up Exhibit, please, P-1767? This is an
 18 article entitled "Recommendations for Improved
 19 Standardization of Immunohistochemistry."
 20 It's one, prepared by certain individuals and
 21 members of the ad-hoc committee on
 22 immunohistochemistry standardization. It was
 23 published in June of 2007. Dr. Pritzker has
 24 been referred to it, but I gather, Doctor,
 25 from what we have heard so far that these are

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1 recommendations by a group of pathologists
 2 setting out, from their perspective,
 3 recommendations for improved standardization
 4 of immunohistochemistry and they talk about
 5 here particular aspects of
 6 immunohistochemistry that can be problematic
 7 at times if not properly attended to.
 8 DR. MULLEN:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. I understand, Doctor, that you thought it
 12 might be helpful to go through at least some
 13 of this with the Commissioner, in terms of
 14 pointing out certain things.
 15 DR. MULLEN:
 16 A. Rather than taking you through the entire
 17 article, I thought the abstract.
 18 COFFEY, Q.C.:
 19 Q. Abstract, yes.
 20 DR. MULLEN:
 21 A. Those of you familiar with medical literature,
 22 I'm not sure what the legal--not familiar with
 23 legal literature, but medical literature, the
 24 abstract is basically quick synopsis and
 25 usually covers the points that are then in the

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1 article in greater detail.
 2 COFFEY, Q.C.:
 3 Q. Doctor, in our world, that's a headnote.
 4 DR. MULLEN:
 5 A. A which?
 6 COFFEY, Q.C.:
 7 Q. In our, the legal world, we call it a
 8 headnote.
 9 DR. MULLEN:
 10 A. Oh, headnote, okay. So I would--in this
 11 document, I would take your attention to the
 12 sentence that contributing factors. So -
 13 COFFEY, Q.C.:
 14 Q. That's about five or six lines down.
 15 DR. MULLEN:
 16 A. Yes, the third sentence.
 17 COFFEY, Q.C.:
 18 Q. Yes.
 19 DR. MULLEN:
 20 A. Now "the contributing factors were
 21 established"--this is what they, the ad-hoc
 22 committee felt to be major causative factors
 23 for the lack of reproducibility, consistency
 24 and if you go--if we go through it,
 25 "contributing factors were established to be

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1 under fixation and irregular fixation." This
 2 we've been harping on, both yourself and
 3 myself, for the last two days. "Use of non-
 4 formalin fixatives and ancillary fixation
 5 procedures divested from a deep and full
 6 understanding of the IHC assay parameters."
 7 That is not relevant in the--well, I shouldn't
 8 say it's not relevant. If they were using--if
 9 they being the--if the contributing
 10 laboratories were not using formalin
 11 fixatives, neutral ten percent buffered
 12 formalin, if they were making their own or
 13 they were storing it improperly or they
 14 weren't testing the pH, that could be an
 15 issue. But if they're buying the standard
 16 pre-made ten percent neutral buffer formalin,
 17 storing it properly, testing the pH on each
 18 package, then that would not be an issue. But
 19 then again, for size, the fixation would have--
 20 the specimen would have to be cut and wick'd,
 21 and if the laboratory did not have a deep and
 22 full understanding of the IHC assay
 23 parameters, then they would run into problems.
 24 "Minimal or absent IHC assay
 25 optimization," there again, when we were

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1 discussing, I believe it was this morning, the
 2 issue with the Ventana results where we had
 3 both nucleus and cytoplasm, that would have
 4 been an issue in this case. I'm not sure
 5 about the initial validation and optimization
 6 of the IHC assay in '97 and continuing
 7 through. I don't have any documentation on
 8 that and I really can't comment on it. And
 9 "lack of a standard system of interpretation
 10 and reporting," we saw in the review that I
 11 did of--that I reported in April of the cases
 12 from--that were selected and sent to me in
 13 March that we had reports that were negative,
 14 completely negative, moderately positive,
 15 rare, that sort of thing, and then some that
 16 gave a qualitative--sorry, quant--both
 17 qualitative and quantitative. So, and there
 18 was no documentation, not that I would expect
 19 necessarily documentation of their pattern of
 20 interpretation, but the reporting should be
 21 standardized.
 22 So then, the article, it goes through
 23 suggestions, but there's nothing here that
 24 either Trish on Tuesday or Wednesday, or
 25 myself and even Dr. O'Malley and Dr. Pritzker,

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1 there's nothing here that is new or not in
 2 practice in the majority of laboratories that
 3 I'm aware of.
 4 COFFEY, Q.C.:
 5 Q. Doctor, in terms of the retrospective study,
 6 there's one thing I wanted to ask you about,
 7 retrospective review that you conducted, there
 8 was, I take it, a particular format that you
 9 followed for--format in the sense of procedure
 10 followed, in terms of the controls being
 11 checked and so on over time. Did that ever
 12 change? Did the approach you took ever
 13 change?
 14 DR. MULLEN:
 15 A. Oh, yes. I don't have the exact date, but I--
 16 we get--we meaning the Mount Sinai, if you
 17 recall the e-mails, getting a lot of pressure
 18 to speed things up, and we made a decision, in
 19 conjunction with Eastern Health, we asked
 20 their agreement to this, that we would stop
 21 doing the negative controls with each
 22 specimen. The reason we did that was to
 23 increase the capacity on the machines to
 24 increase the throughput. We felt that we had
 25 established the negative control on, I

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1 believe, the first it may have been 200 or so
 2 cases, and we didn't--and we believed that it
 3 had no material impact to the results, and we
 4 had Eastern Health's concurrence or agreement
 5 to actually doing that. In retrospect,
 6 probably shouldn't have, but we should have
 7 stuck to our guns and gone through slowly, but
 8 it was an issue to get the results out as
 9 quickly as possible, and I don't--sorry.
 10 COFFEY, Q.C.:
 11 Q. These are external negative controls?
 12 DR. MULLEN:
 13 A. No, not the--yeah, external negative controls,
 14 not within a--had nothing to do with a
 15 specimen.
 16 COFFEY, Q.C.:
 17 Q. And they aren't the external positive
 18 controls?
 19 DR. MULLEN:
 20 A. No, the external positives were always run.
 21 Our policy in each case is to do a positive
 22 external control for each immunostain we do
 23 and a negative control with each specimen that
 24 we do. So we'd have one ER, one PR and one
 25 negative control. It's basically to eliminate

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1 the possibility of non-specific staining.
 2 Now, in my defence, we had established the
 3 protocol. There was no deviation from case to
 4 case. All of the reagents were the same. All
 5 of the procedures were the same, push the
 6 button and away it goes. So it was a
 7 calculated risk and as I said, we felt that it
 8 had no material impact on the results.
 9 COFFEY, Q.C.:
 10 Q. And when you say "no material impact" in this
 11 context, I take it that -
 12 DR. MULLEN:
 13 A. Would be -
 14 COFFEY, Q.C.:
 15 Q. - you were professionally comfortable and
 16 prepared to give the results?
 17 DR. MULLEN:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Despite the fact that for a certain period of
 21 time in respect of the retrospective cases
 22 only, I take it?
 23 DR. MULLEN:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. That the external negative controls were not
 2 being utilized?
 3 DR. MULLEN:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. Okay. And the purpose of such a negative
 7 external control is to eliminate or rule out
 8 the idea of non -
 9 DR. MULLEN:
 10 A. Non-specific binding. So basically you have--
 11 you prepare two solutions. One has the
 12 antibody, or in this case would have the 6F11
 13 or PTR1294, one substance, and the negative
 14 control would have everything except the
 15 antibody. And then the issue is a non-
 16 specific. When you're setting up--when you're
 17 validating, your negative control would be--
 18 would have the class of immunoglobulin but
 19 wouldn't have the specific antibodies. So
 20 there are two types of negative control, when
 21 you're validating or optimizing and validating
 22 and then when you're running.
 23 COFFEY, Q.C.:
 24 Q. And these related to the running, I take it?
 25 DR. MULLEN:

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1 A. Yes, this related to running. All of our
 2 optimization and validation had the negative
 3 control and some of these--the majority, I
 4 shouldn't say majority, large number of these
 5 cases had the negative control, as well. So
 6 as I said, it was a through put issue.
 7 COFFEY, Q.C.:
 8 Q. They're the questions I have, Commissioner,
 9 thank you.
 10 COMMISSIONER:
 11 Q. Thank you. Mr. Pritchard.
 12 MR. PRITCHARD:
 13 Q. Commissioner, I don't have any questions for
 14 this witness. Thank you.
 15 COMMISSIONER:
 16 Q. Mr. Simmons.
 17 DR. BRENDAN MULLEN, EXAMINATION BY MR. DANIEL SIMMONS
 18 MR. SIMMONS:
 19 Q. Thank you, Commissioner. Good afternoon, Dr.
 20 Mullen.
 21 DR. MULLEN:
 22 A. Mr. Simmons.
 23 MR. SIMMONS:
 24 Q. We've met before. I'm Dan Simmons, I'm the
 25 lawyer for Eastern Health. I do have a few

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1 questions for you. I'm going to start with
 2 something that you dealt with late this
 3 morning in your examination by Mr. Coffey. I
 4 just want to confirm some evidence that you've
 5 given. You've told us quite a bit about the
 6 retrospective review which you did which was
 7 the review of the slides produced at Mount
 8 Sinai from blocks that had been produced in
 9 Newfoundland from 1997 to 2005. You've told
 10 us of the issues that you identified
 11 concerning fixation and processing, and
 12 concerning internal controls?
 13 DR. MULLEN:
 14 A. Yes.
 15 MR. SIMMONS:
 16 Q. With those slides. But do I understand
 17 correctly that you've also told us that you
 18 were able to sign out and report a result on
 19 all those specimens, an ER and PR result for
 20 each of those specimens in the retrospective
 21 review?
 22 DR. MULLEN:
 23 A. That is correct.
 24 MR. SIMMONS:
 25 Q. Yes. And you are satisfied that you've

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1 reported an accurate result in accordance with
 2 the standards that you as a professional
 3 pathologist with expertise in the area apply
 4 to assessment of those tests?
 5 DR. MULLEN:
 6 A. Yes, that is correct.
 7 MR. SIMMONS:
 8 Q. Okay. So that we have every reason to be
 9 confident that the patients who had been
 10 relying on those retest results are able to
 11 rely on those?
 12 DR. MULLEN:
 13 A. Yes.
 14 MR. SIMMONS:
 15 Q. Okay. And in respect -
 16 DR. MULLEN:
 17 A. That, we're referring to the stained slides
 18 from Mount Sinai?
 19 MR. SIMMONS:
 20 Q. Yes.
 21 DR. MULLEN:
 22 A. Yes. So -
 23 MR. SIMMONS:
 24 Q. Exactly.
 25 DR. MULLEN:

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1 A. - the material that we actually stained, yes.
 2 MR. SIMMONS:
 3 Q. Yes, correct.
 4 DR. MULLEN:
 5 A. Yes.
 6 MR. SIMMONS:
 7 Q. And the other cases, the group, large group of
 8 cases you've spoke about are the what you've
 9 called the prospective cases which are the,
 10 I'll think of them as the new -
 11 DR. MULLEN:
 12 A. The go forward, yes.
 13 MR. SIMMONS:
 14 Q. The new cases, the go forward ones that you
 15 began to look at from August of 2005 and for
 16 three of the health authorities in
 17 Newfoundland you continue to review--have
 18 continued to review up until recently?
 19 DR. MULLEN:
 20 A. Yes. Yes, that's right. Central, Labrador,
 21 Grenfell and Western.
 22 MR. SIMMONS:
 23 Q. And Western?
 24 DR. MULLEN:
 25 A. Yes.

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1 MR. SIMMONS:
 2 Q. Right. And the same questions for those, we
 3 have no reason to, in any way, doubt any -
 4 DR. MULLEN:
 5 A. No.
 6 MR. SIMMONS:
 7 Q. - of those results that you've reported back
 8 from Mount Sinai?
 9 DR. MULLEN:
 10 A. No. I use the same standards that I would
 11 report to any other.
 12 MR. SIMMONS:
 13 Q. Right. So even though you've told us that at
 14 the beginning of this process in August '05
 15 you were seeing some issues with fixation and
 16 processing and you still see some occasional
 17 issues with it today, that should not cause us
 18 to doubt the reliability of those test reports
 19 in any way?
 20 DR. MULLEN:
 21 A. No.
 22 MR. SIMMONS:
 23 Q. Good. Okay. Eastern Health started retesting
 24 its own samples in about February, March of
 25 2007?

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1 DR. MULLEN:
 2 A. Yes.
 3 MR. SIMMONS:
 4 Q. So if I understand correctly, up until
 5 probably last week between that time,
 6 February, March of '07 and very recently the
 7 only ER/PR samples that you would have had
 8 stained at your laboratory and looked at
 9 yourself would be the quality assurance
 10 samples that were sent from Eastern Health?
 11 DR. MULLEN:
 12 A. From Eastern Health, yes.
 13 MR. SIMMONS:
 14 Q. Right. The other authorities continued to
 15 send their own samples?
 16 DR. MULLEN:
 17 A. Yes, that is correct.
 18 MR. SIMMONS:
 19 Q. Yes. And when looking at those quality
 20 assurance samples would you assess the quality
 21 of the fixation and processing -
 22 DR. MULLEN:
 23 A. Yes. If -
 24 MR. SIMMONS:
 25 Q. - as part of that process?

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1 DR. MULLEN:
 2 A. If you recall the spreadsheet that I use for
 3 my standard reporting, the ER--the tumor type
 4 ER/PR, internal control, fixation, processing,
 5 it was exactly the same.
 6 MR. SIMMONS:
 7 Q. Right. And if there were any problems with
 8 fixation and processing of those samples, you
 9 would report them back to Eastern Health?
 10 DR. MULLEN:
 11 A. Yes, that is correct.
 12 MR. SIMMONS:
 13 Q. And have you had to report back any issues in
 14 relation to those with the QA samples?
 15 DR. MULLEN:
 16 A. No. No, there were 39 samples and I don't
 17 believe I've reported.
 18 MR. SIMMONS:
 19 Q. Okay. And we've seen through some of the
 20 documentation that it was probably around May
 21 of '07 that you would have looked at the first
 22 of those, of those samples? I think we saw a
 23 reminder e-mail from May.
 24 DR. MULLEN:
 25 A. Yes, April. They started it in March, so I

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1 would say April, yes.
 2 MR. SIMMONS:
 3 Q. Right, okay. So from April of '07 until
 4 present those QA samples have been reviewed
 5 from Eastern Health and there have been no
 6 problems that you have found with fixation and
 7 processing of the samples?
 8 DR. MULLEN:
 9 A. The 39, I received 39 specimens and I was
 10 able, yes.
 11 MR. SIMMONS:
 12 Q. Yes. Mount Sinai participates in the UK NEQAS
 13 proficiency testing program?
 14 DR. MULLEN:
 15 A. Yes, that's correct.
 16 MR. SIMMONS:
 17 Q. Do you see the reports that come back from UK
 18 NEQAS on those for your laboratory?
 19 DR. MULLEN:
 20 A. No, I haven't seen them.
 21 MR. SIMMONS:
 22 Q. Do you know if that program also assesses the
 23 quality of fixation and processing of the
 24 samples?
 25 DR. MULLEN:

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1 A. I can't speak to the specifics. The only
 2 interaction I've had with the NEQAS for the
 3 ER/PR was doing the scoring.
 4 MR. SIMMONS:
 5 Q. Okay.
 6 DR. MULLEN:
 7 A. That would be Dr. O'Malley who would have
 8 dealt with that issue.
 9 MR. SIMMONS:
 10 Q. Right. I take, though, it wouldn't surprise
 11 you if that program also looked at that issue
 12 when they examine slides produced by their
 13 participating laboratories?
 14 DR. MULLEN:
 15 A. Yes.
 16 MR. SIMMONS:
 17 Q. Okay. I had some questions for you concerning
 18 the tracking of positivity rates.
 19 DR. MULLEN:
 20 A. Yes.
 21 MR. SIMMONS:
 22 Q. You've given us some evidence about some look-
 23 back work that you did on tests that you have
 24 reported on from 2005 to 2007?
 25 DR. MULLEN:

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1 A. Yes. 2008, yeah, or -
 2 MR. SIMMONS:
 3 Q. Yes, up to current?
 4 DR. MULLEN:
 5 A. Yes.
 6 MR. SIMMONS:
 7 Q. Up in 2008.
 8 DR. MULLEN:
 9 A. The beginning of June of 2008.
 10 MR. SIMMONS:
 11 Q. Right, yeah. But I'm curious in knowing a
 12 little bit more about the laboratory
 13 information system at Mount Sinai. I think
 14 we've heard from some other witnesses that
 15 there's been some change or upgrading to that
 16 system in about 2005 and a move to synoptic
 17 reporting?
 18 DR. MULLEN:
 19 A. Yes.
 20 MR. SIMMONS:
 21 Q. Right. And prior to 2005 were you
 22 participating or do you know if the laboratory
 23 or your laboratory service was doing any kind
 24 of annual gathering of positivity rates for ER
 25 and PR testing?

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1 DR. MULLEN:
 2 A. The laboratory I can't speak to.
 3 MR. SIMMONS:
 4 Q. No, okay. But yourself, you have been
 5 tracking your own, have you?
 6 DR. MULLEN:
 7 A. Yes, yes, because I use the same format, it's
 8 very easy for me to do that.
 9 MR. SIMMONS:
 10 Q. Right. And that's because you, as an
 11 individual pathologist, had chosen to put
 12 standardized language into the text of the
 13 pathology reports that you prepare?
 14 DR. MULLEN:
 15 A. Yes.
 16 MR. SIMMONS:
 17 Q. So you can search that text and know you can
 18 rely on finding all your positive tests and
 19 all your negative tests?
 20 DR. MULLEN:
 21 A. Yes.
 22 MR. SIMMONS:
 23 Q. Do you know if other pathologists at your
 24 institution reporting ER/PR tests had adopted
 25 the same practice?

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1 DR. MULLEN:
 2 A. No, they were not, they were putting--using--
 3 relying on the synoptic portions.
 4 MR. SIMMONS:
 5 Q. Okay.
 6 DR. MULLEN:
 7 A. For reporting.
 8 MR. SIMMONS:
 9 Q. Okay. Now, the synoptic portion has only been
 10 available since 2005?
 11 DR. MULLEN:
 12 A. Yes.
 13 MR. SIMMONS:
 14 Q. So prior to 2005 their reports would not
 15 necessarily have been searchable in the same
 16 way as yours?
 17 DR. MULLEN:
 18 A. No. They could be printed and searched that
 19 way, but automatic, no.
 20 MR. SIMMONS:
 21 Q. No. So you'd have to print them and go
 22 through them and manually identify the
 23 positives and the negatives?
 24 DR. MULLEN:
 25 A. Or we could--they could have prospectively

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1 just kept a log.
 2 MR. SIMMONS:
 3 Q. Okay. And do you know if anybody was doing
 4 it, taking -
 5 DR. MULLEN:
 6 A. I can't speak for other people.
 7 MR. SIMMONS:
 8 Q. Good, okay. And when you were interviewed in
 9 advance of this process, you were interviewed
 10 in December of '07?
 11 DR. MULLEN:
 12 A. Yes.
 13 MR. SIMMONS:
 14 Q. And you gave us the information that you
 15 talked about this morning where you had gone
 16 back and looked at your own ER/PR tests that
 17 you'd done for Mount Sinai, Niagara Region
 18 hospitals, Greater Niagara and Newfoundland
 19 from '05 forward?
 20 DR. MULLEN:
 21 A. I'd done the aggregate, everyone.
 22 MR. SIMMONS:
 23 Q. Yes.
 24 DR. MULLEN:
 25 A. And then because Newfoundland was a multi

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1 site, I looked at the Greater Niagara which is
 2 a multi site to see the comparison.
 3 MR. SIMMONS:
 4 Q. Right. And the comparison came out almost
 5 exactly the same, 79 -
 6 DR. MULLEN:
 7 A. 79.2 and 79.4, yes.
 8 MR. SIMMONS:
 9 Q. Right. And -
 10 DR. MULLEN:
 11 A. That was a prospective.
 12 MR. SIMMONS:
 13 Q. And at this point your view is that the
 14 literature suggests that it--the rate should
 15 be what?
 16 DR. MULLEN:
 17 A. Equivalent to that.
 18 MR. SIMMONS:
 19 Q. Equivalent to that?
 20 DR. MULLEN:
 21 A. Yeah.
 22 MR. SIMMONS:
 23 Q. So that review of the positivity rate for all
 24 samples coming from Newfoundland for 2005
 25 forward suggests that the rate of positivity

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1 is pretty well exactly what the literature
 2 says it should be?
 3 DR. MULLEN:
 4 A. Yes.
 5 MR. SIMMONS:
 6 Q. Which is a further reassurance that we can
 7 rely on the test results that have been
 8 reported, correct?
 9 DR. MULLEN:
 10 A. Yes.
 11 MR. SIMMONS:
 12 Q. Yes. I'm going to go back now to some of the
 13 early testimony that you gave for Mr. Coffey.
 14 You told us some about how you became
 15 involved, and what you knew of the
 16 arrangements that had been made for the
 17 retrospective review that you became involved
 18 in. And is my understanding correct that the
 19 arrangements about what Mount Sinai, the
 20 services Mount Sinai was going to provide to
 21 Eastern Health were really made with others
 22 and weren't made with you?
 23 DR. MULLEN:
 24 A. That's correct.
 25 MR. SIMMONS:

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1 Q. That's right. You didn't have any direct
 2 involvement in determining the scale or scope
 3 or number of tests that were going to have to
 4 be reviewed?
 5 DR. MULLEN:
 6 A. No. As I testified, I thought it was 50 to
 7 100.
 8 MR. SIMMONS:
 9 Q. Right. But the information you obtained about
 10 those things came internally from others
 11 within Mount Sinai and not directly from
 12 Eastern Health?
 13 DR. MULLEN:
 14 A. No, no.
 15 MR. SIMMONS:
 16 Q. Right. And your involvement in dealing
 17 directly with Dr. Cook was very limited?
 18 DR. MULLEN:
 19 A. A series of e-mails, yes.
 20 MR. SIMMONS:
 21 Q. Series of e-mails. So you would report test
 22 results to him by e-mail, by sending your
 23 spreadsheets to you and there was a series of
 24 inquiries over time that you responded to?
 25 DR. MULLEN:

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1 A. Yes.
 2 MR. SIMMONS:
 3 Q. Right.
 4 DR. MULLEN:
 5 A. That's correct.
 6 MR. SIMMONS:
 7 Q. And do you recall ever having any conversation
 8 with him to talk about things like the quality
 9 of the material you were seeing, any issues
 10 you were having, those sorts of things?
 11 DR. MULLEN:
 12 A. No. I recall two or three telephone
 13 conversations but I believe they were directed
 14 to speed.
 15 MR. SIMMONS:
 16 Q. Okay, so you did speak with Dr. Cook on a
 17 number of occasions on the telephone, then?
 18 DR. MULLEN:
 19 A. Yes.
 20 MR. SIMMONS:
 21 Q. Okay. And he was inquiring about getting the
 22 work done?
 23 DR. MULLEN:
 24 A. Yes.
 25 MR. SIMMONS:

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1 Q. You didn't take that opportunity to raise any
 2 of these issues of what you were observing
 3 with him at the time?
 4 DR. MULLEN:
 5 A. I'm trying to remember when the conversations
 6 were. Not at--no. It was the--the
 7 conversations on the quality were with Bev
 8 Carter in November.
 9 MR. SIMMONS:
 10 Q. Um-hm.
 11 DR. MULLEN:
 12 A. And then the e-mail in January.
 13 MR. SIMMONS:
 14 Q. Right. In which you suggested that some
 15 contact would be made?
 16 DR. MULLEN:
 17 A. Yes.
 18 MR. SIMMONS:
 19 Q. Okay. But aside from that there was no--and
 20 did you regard it as your mandate to assesses
 21 these sorts of issues and provide some kind of
 22 report to Eastern Health or did you view your
 23 role as more limited than that?
 24 DR. MULLEN:
 25 A. For which set of cases?

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1 MR. SIMMONS:
 2 Q. For the retrospective cases.
 3 DR. MULLEN:
 4 A. The retrospective, no, it wasn't my role to--
 5 nothing could be done with the retrospective
 6 cases.
 7 MR. SIMMONS:
 8 Q. Right.
 9 DR. MULLEN:
 10 A. The prospective cases because I was--this was
 11 material that was being removed at the time
 12 and we could intervene.
 13 MR. SIMMONS:
 14 Q. Yes.
 15 DR. MULLEN:
 16 A. Or they could intervene, it would--it might
 17 have been useful for them to.
 18 MR. SIMMONS:
 19 Q. Right, right. And the one occasion we know
 20 of when you passed some information on was
 21 when Dr. Carter was in Toronto?
 22 DR. MULLEN:
 23 A. Yes.
 24 MR. SIMMONS:
 25 Q. The prospective cases, the go-forward cases,

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1 were they all reported as consultations with a
 2 regular pathology report sent to Eastern
 3 Health and the other authorities?
 4 DR. MULLEN:
 5 A. Yes.
 6 MR. SIMMONS:
 7 Q. And on those reports you've given us some
 8 description of the type of information that's
 9 included. Would you, in those reports, report
 10 on any issues relating to the quality of the
 11 specimen itself, the fixation and processing?
 12 DR. MULLEN:
 13 A. Yes, there was a specimen adequacy, some cases
 14 I would put sub-optimal or borderline for
 15 interpretation.
 16 MR. SIMMONS:
 17 Q. Right.
 18 DR. MULLEN:
 19 A. And then in the fourth line, I think it's
 20 fourth line in the--I don't have it in front
 21 of me, but the comment about the internal
 22 control, whether it was present or absent and
 23 whether it stained.
 24 MR. SIMMONS:
 25 Q. Right, okay. Now, I'm going to be bouncing

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1 around a little bit, I'm not going to be
 2 following the sequence of questions as
 3 chronologically as Mr. Coffey was able to do
 4 with you and I apologize for that in advance.
 5 DR. MULLEN:
 6 A. No, that's fine.
 7 MR. SIMMONS:
 8 Q. Again, very early in your evidence you did
 9 mention that prior to 2005 you were doing or
 10 seeing far fewer ER/PR tests than following
 11 that. And I believe you said you saw maybe 50
 12 per year?
 13 DR. MULLEN:
 14 A. Yes.
 15 MR. SIMMONS:
 16 Q. Prior to that. And another point I understood
 17 you to say when you were talking about the
 18 HER2/neu test that there are guidelines from
 19 College of American Pathologists and ASCO
 20 recently put in place?
 21 DR. MULLEN:
 22 A. Yes.
 23 MR. SIMMONS:
 24 Q. That sent expectation of the minimum number of
 25 HER2 tests that a pathologist should see to

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1 maintain competency. Did I understand that
 2 correctly?
 3 DR. MULLEN:
 4 A. I believe it's the number the laboratory
 5 should do.
 6 MR. SIMMONS:
 7 Q. Oh, the number the laboratory should do.
 8 DR. MULLEN:
 9 A. The number the laboratory should do.
 10 MR. SIMMONS:
 11 Q. Right. And so it's not the number of
 12 pathologists, it's the -
 13 DR. MULLEN:
 14 A. No pathologists, no.
 15 MR. SIMMONS:
 16 Q. - number laboratories should do?
 17 DR. MULLEN:
 18 A. Sorry.
 19 MR. SIMMONS:
 20 Q. Okay, I misunderstood that. Are there any
 21 similar guidelines that you're aware of in
 22 relation to ER/PR testing?
 23 DR. MULLEN:
 24 A. Not that I'm aware of.
 25 MR. SIMMONS:

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1 Q. Okay. Do you know if there are any guidelines
 2 that suggests the number a pathologists should
 3 see to maintain sufficient competency to be
 4 reporting those tests?
 5 DR. MULLEN:
 6 A. No.
 7 MR. SIMMONS:
 8 Q. No. You've spoken a fair bit about the
 9 threshold for declaring a result positive and
 10 that the one that you use at Mount Sinai is
 11 one percent cells stained or greater?
 12 DR. MULLEN:
 13 A. Yes.
 14 MR. SIMMONS:
 15 Q. And we've heard some other evidence on that
 16 before. And am I correct in understanding
 17 that there are other institutions out there
 18 that don't adopt that standard and that have--
 19 may still use the ten percent threshold?
 20 DR. MULLEN:
 21 A. Yes, that is correct.
 22 MR. SIMMONS:
 23 Q. Yeah, okay. And is the determination of that
 24 strictly a matter for the pathology service or
 25 is it something that should be done in

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1 consultation with the treating physicians,
 2 whether they're oncologists or surgeons or
 3 others?
 4 DR. MULLEN:
 5 A. It's certainly, it is the role of the
 6 pathologist to report.
 7 MR. SIMMONS:
 8 Q. Yes.
 9 DR. MULLEN:
 10 A. It's the role of the clinician to interpret
 11 the report and act on it.
 12 MR. SIMMONS:
 13 Q. Right.
 14 DR. MULLEN:
 15 A. If the clinician wants to act on a one
 16 percent--that's why we're very particular in
 17 giving the percentage as well as what we've
 18 established as our threshold based on the
 19 literature.
 20 MR. SIMMONS:
 21 Q. Right.
 22 DR. MULLEN:
 23 A. But it's up to the--the clinician receives the
 24 report, it's incumbent upon them to act on the
 25 report based on their guidelines.

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1 MR. SIMMONS:
 2 Q. Right, on their assessment -
 3 DR. MULLEN:
 4 A. Yes.
 5 MR. SIMMONS:
 6 Q. - of whether the treatment is merited based on
 7 the test result?
 8 DR. MULLEN:
 9 A. Beg your pardon?
 10 MR. SIMMONS:
 11 Q. On their assessment of whether the treatment
 12 is warranted, based on factors including the
 13 percentage of positivity?
 14 DR. MULLEN:
 15 A. Yes, that is correct.
 16 MR. SIMMONS:
 17 Q. So if in another institution the pathologists
 18 and the oncologists consulting with each other
 19 determined that they would regard a ten
 20 percent positivity level as the threshold for
 21 what they would consider positive, would that
 22 be something that you would regard as being an
 23 unacceptable uncommon approach?
 24 DR. MULLEN:
 25 A. No, not at all.

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1 MR. SIMMONS:
 2 Q. Internal controls, you've told us that they
 3 will not always work, there are cases where
 4 you will have an internal control that stains
 5 negative, even though the test has been
 6 performed accurately and that the tumor has
 7 been properly stained and is interpretable.
 8 DR. MULLEN:
 9 A. That is correct.
 10 MR. SIMMONS:
 11 Q. There are some.
 12 DR. MULLEN:
 13 A. Yes.
 14 MR. SIMMONS:
 15 Q. So aside from the retrospective review and
 16 dealing with the cases that were part of this
 17 study, in your normal practice when you
 18 encounter a test result where there is an
 19 internal control tissue present but it has not
 20 stained, what's the first thing that you do?
 21 What's the next thing that you do then?
 22 DR. MULLEN:
 23 A. I look to see if the tumor stained. If the
 24 tumor stained, I'm happy to report that.
 25 MR. SIMMONS:

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1 Q. Uh-hm.
 2 DR. MULLEN:
 3 A. If the tumor hasn't stained and the internal
 4 control hasn't stained, if I have another
 5 block--if it's within the institution I have
 6 another block, I'll select that and I'll also
 7 repeat the original.
 8 MR. SIMMONS:
 9 Q. Okay. Do you ever go to the external control
 10 before repeating the test to determine whether
 11 the external control worked?
 12 DR. MULLEN:
 13 A. Well the external--I'm not--in our
 14 institution, I am not given any slides if the
 15 external control is negative. There is a
 16 gatekeep--I tried to explain yesterday, there
 17 is a gatekeeper function in the laboratory
 18 that if the external control and the internal
 19 control are questionable or not appropriate,
 20 then I don't see the case. If they're
 21 acceptable, the external control and the
 22 internal controls are acceptable to the
 23 technologist, then I receive the case and it's
 24 then my prerogative to either report the case
 25 or say it's unacceptable and send it back.

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1 MR. SIMMONS:
 2 Q. So there are not occasions when you would,
 3 yourself, then go to look at the external
 4 control slide?
 5 DR. MULLEN:
 6 A. Very, very rarely.
 7 MR. SIMMONS:
 8 Q. Okay. You also told us that apart from any
 9 problems that might exist with fixation,
 10 processing, quality issues and so on, there
 11 can be situations where you will get different
 12 results on an ER/PR test if the tissue that's
 13 being tested comes from different blocks in
 14 the same specimen or even from different--at
 15 different points in a block that has been
 16 repeatedly sliced.
 17 DR. MULLEN:
 18 A. That's correct.
 19 MR. SIMMONS:
 20 Q. How much variation can you see in the scoring
 21 of an ER and PR test from--because of those
 22 circumstances?
 23 DR. MULLEN:
 24 A. If it's well fixed -
 25 MR. SIMMONS:

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1 Q. Uh-hm.
 2 DR. MULLEN:
 3 A. - that unless there's a--there would not be a
 4 tremendous variability, maybe 20 percent from
 5 area to area.
 6 MR. SIMMONS:
 7 Q. Right. Okay.
 8 DR. MULLEN:
 9 A. And now the issue if it's not fixed, then
 10 there could be marked variability and that, I
 11 believe, we covered with Dr. Cook.
 12 MR. SIMMONS:
 13 Q. Sure, so even if there's no problem with the
 14 quality of the tissue, performance of the
 15 testing procedures, you could see up to 20
 16 percent variation, depending on where the
 17 tissue has come from, from within that
 18 specimen.
 19 DR. MULLEN:
 20 A. Now if you recall, I referenced a paper that
 21 mentioned its bi-modal distribution to be
 22 ER/PR -
 23 MR. SIMMONS:
 24 Q. Yes.
 25 DR. MULLEN:

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1 A. That 99 percent were 70 or above.
 2 MR. SIMMONS:
 3 Q. Uh-hm.
 4 DR. MULLEN:
 5 A. And the other--or zero, less than one, so
 6 there are very few that would be in the middle
 7 area.
 8 MR. SIMMONS:
 9 Q. Right.
 10 DR. MULLEN:
 11 A. So if you have a ninety which covers the 70,
 12 you certainly can't go to 110, but it would be
 13 that area.
 14 MR. SIMMONS:
 15 Q. Right, so if you're dealing with an
 16 institution where there has been an adoption
 17 of the ten percent cut off that we spoke of,
 18 it's conceivable then that this variation in
 19 testing from one block to another could
 20 produce test results that are either above or
 21 below that ten percent.
 22 DR. MULLEN:
 23 A. Yes.
 24 MR. SIMMONS:
 25 Q. Without there being anything that's

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1 identifiably done wrong with the tests -
 2 DR. MULLEN:
 3 A. No, that's correct.
 4 MR. SIMMONS:
 5 Q. Or the interpretation of it. And in fact,
 6 I'll just look at one example in relation to
 7 that, P-1811 please?
 8 DR. MULLEN:
 9 A. This is your January 20th, '06 e-mail with the
 10 large spreadsheet of test results and we'll go
 11 to page three and see if I'm lucky enough to
 12 find the one I was looking for. Probably
 13 about ten up from the bottom, there's a
 14 sample, a specimen number 99327788?
 15 DR. MULLEN:
 16 A. Uh-hm.
 17 MR. SIMMONS:
 18 Q. And it's one that there's two blocks there for
 19 it, there's a block 1B and a block 1C, do you
 20 see that?
 21 DR. MULLEN:
 22 A. Yes.
 23 MR. SIMMONS:
 24 Q. And if you look across at your reported
 25 results, they were both cases where the

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1 internal control stained positively.
 2 DR. MULLEN:
 3 A. Yes.
 4 MR. SIMMONS:
 5 Q. And they were both cases where the fixation
 6 and processing was adequate.
 7 DR. MULLEN:
 8 A. Yes.
 9 MR. SIMMONS:
 10 Q. And one of them is reported as an ER of less
 11 than one, which would be regarded as negative?
 12 DR. MULLEN:
 13 A. As negative, less than one.
 14 MR. SIMMONS:
 15 Q. And the other one is an ER of two, which in
 16 your institution would be regarded as
 17 positive.
 18 DR. MULLEN:
 19 A. As positive, that's correct.
 20 MR. SIMMONS:
 21 Q. Okay. Perhaps a question I should have asked
 22 Ms. Wegrynowski, but you may be able to help
 23 me, do you know what method your laboratories
 24 use for antigen retrieval for ER and PR tests,
 25 because I understand there's different ones

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1 available?
 2 DR. MULLEN:
 3 A. Yes, we use the trishydrochloride microwave.
 4 MR. SIMMONS:
 5 Q. Trishydrochloride?
 6 DR. MULLEN:
 7 A. Microwave.
 8 MR. SIMMONS:
 9 Q. And do you know how long that particular
 10 method has been in use?
 11 DR. MULLEN:
 12 A. That is a question for Ms. Wegrynowski.
 13 MR. SIMMONS:
 14 Q. Okay, you don't know if it's changed over time
 15 since you've been involved?
 16 DR. MULLEN:
 17 A. No. It certainly hasn't changed since she's
 18 been there.
 19 MR. SIMMONS:
 20 Q. Exhibit P-1837 please? Doctor Mullen, this is
 21 the spreadsheet that accompanied your report
 22 on the review of the original slides that were
 23 produced from 1997 to 2005 over an eight-year
 24 period, and you've reported the results of
 25 your observations on a case-by-case basis, but

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1 I gather you have not done any more
 2 sophisticated statistical analysis to
 3 recognize any trends over time or anything
 4 like that from this data?
 5 DR. MULLEN:
 6 A. No, I have not.
 7 MR. SIMMONS:
 8 Q. And I had just some questions to make sure I
 9 understand the portion of this table where you
 10 stated whether the results were discordant
 11 with the Mount Sinai retest results or not?
 12 DR. MULLEN:
 13 A. That is correct.
 14 MR. SIMMONS:
 15 Q. And you've explained, I think, fairly clearly
 16 to us that you didn't have the time available
 17 to go back and cross reference each of these
 18 specimens with the table that has the Mount
 19 Sinai retest results for those same specimens.
 20 DR. MULLEN:
 21 A. That is correct.
 22 MR. SIMMONS:
 23 Q. So you couldn't do a complete comparison?
 24 DR. MULLEN:
 25 A. No.

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1 MR. SIMMONS:
 2 Q. Between the two.
 3 DR. MULLEN:
 4 A. No.
 5 MR. SIMMONS:
 6 Q. This is just happens to be where you happen to
 7 have some information in the pathology report,
 8 you plugged it in?
 9 DR. MULLEN:
 10 A. Yes, that is correct.
 11 MR. SIMMONS:
 12 Q. So I take it from that then that we can't
 13 really use this particular table to draw any
 14 conclusions about the extent of the
 15 concordance or discordance overall?
 16 DR. MULLEN:
 17 A. No, it was not intended for that.
 18 MR. SIMMONS:
 19 Q. Right. And if we look even at the very first
 20 specimen there, the one's that ID No. 6 that
 21 you were referred to on this issue, this one
 22 here had a Mount Sinai review number of zero,
 23 for ER, which was your review of the original
 24 slide?
 25 DR. MULLEN:

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1 A. That is correct.
 2 MR. SIMMONS:
 3 Q. And we don't have on this table what the
 4 retest result was for the new slide prepared
 5 by Mount Sinai.
 6 DR. MULLEN:
 7 A. No.
 8 MR. SIMMONS:
 9 Q. And what we have on the NL original here is
 10 that you were able to gather from the original
 11 pathology report that it was reported as
 12 negative in 1997?
 13 DR. MULLEN:
 14 A. That is correct.
 15 MR. SIMMONS:
 16 Q. And we've heard, and I expect we will hear
 17 more, that in 1997, anything below 30 percent
 18 would have been reported as negative?
 19 DR. MULLEN:
 20 A. Yes, but there was no--in the report I had,
 21 there was no mention of what the negative cut
 22 off was, so I really -
 23 MR. SIMMONS:
 24 Q. Right.
 25 DR. MULLEN:

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1 A. - all I could do was put what the value was.
 2 MR. SIMMONS:
 3 Q. And we can look up this one and see what it
 4 is, but for the purposes of this particular
 5 report here, if you had a pathology report on
 6 this specimen that told you that Mount Sinai
 7 had retested it and it was 10 percent -
 8 DR. MULLEN:
 9 A. Yes.
 10 MR. SIMMONS:
 11 Q. You would have regarded that as discordant
 12 from an original report of negative?
 13 DR. MULLEN:
 14 A. I'm trying to remember. I can't--most likely,
 15 I'll just leave it at that.
 16 MR. SIMMONS:
 17 Q. Yes, right. The categorization here in the
 18 column "Fixation and Processing" where you've
 19 indicated either adequate or poor, do I
 20 understand correctly that in reviewing these
 21 slides, while you can identify if the end
 22 result of the whole fixation and processing
 23 sequence is adequate or not, you can't
 24 differentiate by looking at the slide as to
 25 whether the problem originated at the fixation

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1 stage or whether it was the processing stage
 2 to prepare the block?
 3 DR. MULLEN:
 4 A. You might be able to suggest that it was
 5 fixation if you have nuclear detail and you
 6 have nothing on the slide or it's falling off,
 7 but if you don't have nuclear detail, that
 8 would suggest that it was a fixation issue,
 9 but to -
 10 MR. SIMMONS:
 11 Q. In your review, though, you have not
 12 differentiated between the two?
 13 DR. MULLEN:
 14 A. No.
 15 MR. SIMMONS:
 16 Q. So the most we can say if you've got poor, the
 17 most we can say is that somewhere in that
 18 process from the operating room to where the
 19 block is prepared, something has gone wrong to
 20 affect the quality of the tissue?
 21 DR. MULLEN:
 22 A. Has gone wrong, yes.
 23 MR. SIMMONS:
 24 Q. Even though ultimately you were able to report
 25 it?

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1 DR. MULLEN:
 2 A. Yes.
 3 MR. SIMMONS:
 4 Q. If we look at that same page on exhibit P-
 5 1837, which is your table of the slide re-
 6 reads, you've pointed out already that there
 7 is one entry about two-thirds of the way down
 8 where you have NL Mayo Clinic results?
 9 DR. MULLEN:
 10 A. Yes.
 11 MR. SIMMONS:
 12 Q. And what I understand that that must have been
 13 an ER/PR test that had been sent out to the
 14 Mayo Clinic and reported back to St. John's,
 15 to Newfoundland from the Mayo Clinic?
 16 DR. MULLEN:
 17 A. Yes.
 18 MR. SIMMONS:
 19 Q. And I note that the ER and the PR are
 20 described in the column there as N and P for
 21 negative and positive, rather than with a
 22 percentage.
 23 DR. MULLEN:
 24 A. Yes.
 25 MR. SIMMONS:

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1 Q. Do I take it that if the Mayo Clinic had
 2 reported a percentage, that you would have
 3 included it in this table?
 4 DR. MULLEN:
 5 A. I didn't have the original Mayo Clinic report.
 6 MR. SIMMONS:
 7 Q. Okay.
 8 DR. MULLEN:
 9 A. All I had was the comment that these tests
 10 were done at the Mayo Clinic and negative,
 11 positive, so I really have no idea what the
 12 Mayo Clinic said.
 13 MR. SIMMONS:
 14 Q. Good, okay. Now I take it that this was a
 15 rather--the retrospective study here was a
 16 rather unusual exercise to take out such a
 17 large number of blocks from previous years and
 18 retest them and compare the results to the
 19 original--to the original testing.
 20 DR. MULLEN:
 21 A. Do you mean this study or the -
 22 MR. SIMMONS:
 23 Q. Yes. The retrospective study that you had to
 24 do in the sense of being asked -
 25 DR. MULLEN:

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1 A. '97 to '05, that study?
 2 MR. SIMMONS:
 3 Q. Yes.
 4 DR. MULLEN:
 5 A. In my experience, well, my limited experience,
 6 yes.
 7 MR. SIMMONS:
 8 Q. Have you, I mean, you've been a pathologist
 9 for quite some time and involved in this area
 10 and you're located at an institution which is
 11 well renown for its involvement in research
 12 and so on. Have you heard of anything like
 13 this being done anywhere before?
 14 DR. MULLEN:
 15 A. I've heard of it since we initiated this,
 16 there is a number of reviews going on across
 17 the country, but not specifically for ER/PR.
 18 MR. SIMMONS:
 19 Q. Uh-hm, right. But prior to this were you
 20 aware of any, even scientific study that
 21 anyone carried out to look back at ER/PR test
 22 results from previous years and retest them
 23 with current standards and technology and
 24 determine what the results would be?
 25 DR. MULLEN:

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1 A. I'm not.
 2 MR. SIMMONS:
 3 Q. Because if we look at the article that you
 4 were referred to a short time ago, P-1767
 5 please? This is the Goldstein article from
 6 2007.
 7 DR. MULLEN:
 8 A. Uh-hm.
 9 MR. SIMMONS:
 10 Q. And the beginning of the abstract says that
 11 "immunohistochemistry continues to suffer from
 12 variable consistency, poor reproducibility,
 13 quality assurance disparities and the lack of
 14 standardization resulting in poor concordance,
 15 validation and verification." Which seems to
 16 be a fairly blanket statement about these
 17 sorts of problems continuing to exist in the
 18 year 2007 in this field. And I wonder, I
 19 mean, you've read through the whole article,
 20 I'm sure, and reviewed it. What is your
 21 understanding of what the authors are
 22 suggesting here? Are they suggesting that
 23 these are problems narrowly confined or of
 24 more wide spread concern?
 25 DR. MULLEN:

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1 A. They're wide spread concern. Most of these
 2 refer to reproducibility between laboratories,
 3 quality assurance disparities, the--within a
 4 laboratory one would expect that the
 5 laboratory had established the criteria for
 6 performing both fixation, processing and
 7 staining.
 8 MR. SIMMONS:
 9 Q. But to state that there's a problem with
 10 reproducibility between laboratories, am I not
 11 correct that that suggests that the same
 12 specimen tested in two different laboratories
 13 could produce two different results?
 14 DR. MULLEN:
 15 A. Certainly.
 16 MR. SIMMONS:
 17 Q. And that that's, according to this article, a
 18 recognized problem in the field that still
 19 exists in 2007?
 20 DR. MULLEN:
 21 A. Yes, oh yes.
 22 MR. SIMMONS:
 23 Q. Thank you very much, Dr. Mullen, that's all
 24 the question I have for you.
 25 THE COMMISSIONER:

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1 Q. Mr. Browne?
 2 DR. BRENDAN MULLEN, EXAMINATION BY MR. PETER BROWNE
 3 MR. BROWNE:
 4 Q. Dr. Mullen, we met yesterday, I'm Peter
 5 Browne. Just a couple of questions, actually
 6 Mr. Simmons has covered a number of the areas
 7 that I was going to ask you about. Just
 8 toward the end of Mr. Coffey's questioning of
 9 you today, he asked you about in-house
 10 formalin and I think you, the preparation of
 11 in-house formalin, I thought I recalled some
 12 discussion about preparation or you referenced
 13 formalin preparation.
 14 DR. MULLEN:
 15 A. Yes, it was not uncommon in the 70's, 80's and
 16 90's for departments to prepare their own
 17 formalin.
 18 MR. BROWNE:
 19 Q. Yes.
 20 DR. MULLEN:
 21 A. So there were issues with standardization and
 22 all of those sorts of things. But I believe
 23 in the late 90's going forward, I can't speak
 24 for other laboratories, but the majority of
 25 laboratories buy commercially prepared

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1 formalin, 20 litre packages.
 2 MR. BROWNE:
 3 Q. Was it brought to your attention that in some
 4 of the labs here in Newfoundland that that
 5 practice may not have stopped until 2003?
 6 DR. MULLEN:
 7 A. I better explain, the only information I have
 8 about the Newfoundland practices--or I should
 9 say that I had with Newfoundland practices,
 10 was I had a block going forward, I had no
 11 information on the individual laboratories,
 12 that was not--I was not informed of that and I
 13 wasn't, as I mentioned, I wasn't privy to Ms.
 14 Wegrynowski's report until it was published.
 15 MR. BROWNE:
 16 Q. With regard to the issue of, and you said in
 17 the 90's, that's late 90's that that stopped
 18 or -
 19 DR. MULLEN:
 20 A. Certainly we stopped it, I can't give specific
 21 dates.
 22 MR. BROWNE:
 23 Q. And I guess the point you're making with
 24 regard to in-house formalin is that if no
 25 standards are in place for the preparation of

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1 that, that may affect fixation?
 2 DR. MULLEN:
 3 A. Certainly, certainly, that would be a major
 4 contributor.
 5 MR. BROWNE:
 6 Q. A major contributor?
 7 DR. MULLEN:
 8 A. That could be a major contributor if you have
 9 unstandardized formalin, if it's not ten
 10 percent neutral buffered, then that could be--
 11 that's the keystone to the fixation process
 12 and if you don't fix, then everything else is
 13 suspect.
 14 MR. BROWNE:
 15 Q. Okay. The term "low expresser" it's in
 16 relation to--I've read this in the literature
 17 about in relation to ER, is that a term that
 18 you're familiar with in pathology?
 19 DR. MULLEN:
 20 A. Expresser -
 21 MR. BROWNE:
 22 Q. Low expresser tumor.
 23 DR. MULLEN:
 24 A. That would probably have not--low expresser
 25 sounds like a person than a tumor, but -

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1 MR. BROWNE:
 2 Q. At least it's not a term that you're familiar
 3 with?
 4 DR. MULLEN:
 5 A. No, low positive and positive are the terms
 6 I've used.
 7 MR. BROWNE:
 8 Q. Okay, so that it may in fact, you may use
 9 different terminology with respect to
 10 positivity?
 11 DR. MULLEN:
 12 A. Yes.
 13 MR. BROWNE:
 14 Q. Okay, in terms of low, high -
 15 DR. MULLEN:
 16 A. Low positive or positive, yes. I mean,
 17 institutions vary with their terminology.
 18 MR. BROWNE:
 19 Q. And just moving from there into, you spoke
 20 about internal and external controls, if you
 21 used high expresser or high positive tumor as
 22 your external control, could that stain
 23 stronger than the internal control?
 24 DR. MULLEN:
 25 A. Yes.

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1 MR. BROWNE:
 2 Q. And I think you mentioned this morning and Ms.
 3 Wegrynowski when she testified the other day
 4 also mentioned about this instrument, the
 5 microtome and I think you were shown a number
 6 of client referral forms that you use in your
 7 institution about comments about, from the lab
 8 about -
 9 DR. MULLEN:
 10 A. The client satisfaction.
 11 MR. BROWNE:
 12 Q. Yes, and one of those referenced and I just
 13 want to, I think, point about trimming the
 14 tissue.
 15 DR. MULLEN:
 16 A. Yes.
 17 MR. BROWNE:
 18 Q. And because of the trimming there was a loss
 19 of tissue, did I understand?
 20 DR. MULLEN:
 21 A. No, they didn't trim because there was so
 22 little tissue, they didn't want to lose the
 23 tissue.
 24 MR. BROWNE:
 25 Q. Okay.

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1 DR. MULLEN:
 2 A. Do you want my graphic description with my
 3 Kleenex box?
 4 MR. BROWNE:
 5 Q. No, that's fine, you've explained that, so in
 6 terms of the layers--sure, I mean, if you
 7 wish, go ahead.
 8 DR. MULLEN:
 9 A. All right, this is essentially a block, it's
 10 paraffin wax with a tissue in it and put on
 11 plastic, a plastic container. It's put in a
 12 microtome which basically is the equivalent of
 13 a razor blade that moves sequentially, you can
 14 either have an automated or manual. Blocks,
 15 the paraffin wax is not necessarily--sorry,
 16 the paraffin wax is not necessarily flat and
 17 the embedding of the--or the position of the
 18 block is not always perpendicular to the
 19 microtome. So what happens is that if there's
 20 sufficient tissue there, the technologist will
 21 do a few cuts to get a flat face and then will
 22 do a--what you're basically trying to get at
 23 is a complete section of the tissue. But if
 24 there's very little tissue and they can see
 25 that through the depth of the tissue, they

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1 will not trim, they will just take whatever--
 2 they'll take sequential sections and use
 3 those. So that's what that's referring to.
 4 MR. BROWNE:
 5 Q. And again, staying with the issue of internal
 6 controls, are there instances where it is, I
 7 guess, not possible to get an internal
 8 control?
 9 DR. MULLEN:
 10 A. Certainly.
 11 MR. BROWNE:
 12 Q. Can you explain to the Commissioner those
 13 examples?
 14 DR. MULLEN:
 15 A. Well first of all the major group are patients
 16 who have metastatic carcinoma, that's breast
 17 carcinoma that has been removed, that's
 18 involved either a lymph node or other portions
 19 of the body that you would not expect to have
 20 breast tissue, obviously in a lymph node or
 21 breast tissue in a lung, so the absence of
 22 internal controls there would be certainly
 23 quite acceptable. And if you had internal
 24 control, you would worry. The next set of
 25 cases are, as I mentioned, in post menopausal

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1 patients, there's atrophy of the normal breast
 2 and you may, the likelihood of having an
 3 internal control would decrease with age.
 4 MR. BROWNE:
 5 Q. Okay.
 6 DR. MULLEN:
 7 A. So it's a selection issue.
 8 MR. BROWNE:
 9 Q. And is it sometimes difficult in core biopsies
 10 as well to obtain internal control?
 11 DR. MULLEN:
 12 A. Again, if it's pre menopausal verses
 13 postmenopausal.
 14 MR. BROWNE:
 15 Q. So it depends on pre and the post?
 16 DR. MULLEN:
 17 A. Yes, yes, that would be one of the major, plus
 18 if the core biopsy contains normal breast
 19 tissue or it contains tumor only.
 20 MR. BROWNE:
 21 Q. Okay, and then the issue about core biopsies
 22 that has been talked about a lot in the
 23 literature, in terms of results and problems
 24 with obtaining ER results, is that -
 25 DR. MULLEN:

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1 A. No, you can obtain ER results, one of the
 2 issues with the core biopsies is the
 3 representation of the tumor. Mr. Simmons
 4 alluded to the fact that there is variability
 5 from area to area, so if you get an area that
 6 is low, verses an area that is high, what we
 7 try to do is maximize the amount that we
 8 assess.
 9 MR. BROWNE:
 10 Q. And just moving now to your Mount Sinai in
 11 terms of the quality control, dealing with
 12 your in-house slides, do I understand from
 13 your evidence and Ms. Wegrynowski's evidence
 14 that if there's a concern with the quality of
 15 a slide, that there is a lead technician who a
 16 pathologist can go to and make complaints?
 17 DR. MULLEN:
 18 A. Yes, Ms. Wegrynowski is the -
 19 MR. BROWNE:
 20 Q. Is that person?
 21 DR. MULLEN:
 22 A. Yes, is that person. And there's also a
 23 medical head.
 24 MR. BROWNE:
 25 Q. And finally you mentioned this afternoon about

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1 the notion of bi-modal distribution and as a
 2 matter of fact, several preceding witnesses
 3 talked about that, that entity, was that just
 4 recently, a recent sort of recognition in
 5 literature? There was an article that was put
 6 in through one of the witnesses around, came
 7 out around 2005 that this wasn't really known
 8 before then?
 9 DR. MULLEN:
 10 A. I can't speak to that.
 11 MR. BROWNE:
 12 Q. That's all the questions I have, Commissioner.
 13 Thank you, Doctor.
 14 THE COMMISSIONER:
 15 Q. Mr. Eaton?
 16 EATON, Q.C.:
 17 Q. No questions, thank you.
 18 THE COMMISSIONER:
 19 Q. Now, do you have any questions, just looking
 20 at the clock in terms of taking the break and
 21 I'm wondering if it would be better if we took
 22 the break before you started questioning,
 23 assuming you have any.
 24 MS. NEWBURY:
 25 Q. I probably have about twenty or twenty-five

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1 minutes.
 2 THE COMMISSIONER:
 3 Q. Why don't we take the afternoon break.
 4 (RECESS)
 5 THE COMMISSIONER:
 6 Q. Please be seated. Ms. Newbury.
 7 DR. BRENDAN MULLEN, EXAMINATION BY MS. JENNIFER NEWBURY
 8 MS. NEWBURY:
 9 Q. Good afternoon, Dr. Mullen. Jennifer Newbury
 10 for the Canadian Cancer Society, Newfoundland
 11 and Labrador division. I have a few questions
 12 for you this morning (sic). First of all, I
 13 just wanted to ask you a little bit about the
 14 choice to use the research laboratory
 15 facilities at Mount Sinai, as opposed to your
 16 regular services, and do I understand it
 17 correctly that that was done for a couple of
 18 reasons: one being the capacity issues and
 19 second, it would also make it unnecessary for
 20 you to do a report in each case.
 21 DR. MULLEN:
 22 A. The capacity issue, yes. No, the report
 23 issue, I could have issued a report on the
 24 research services side, that was at the, I
 25 believe in discussions with Eastern Health,

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1 part of it was my understanding of the Public
 2 Hospital Act in Ontario, whether it was
 3 applicable or not in Newfoundland is--you can
 4 discuss with, well you're a lawyer here,
 5 obviously. Whether the report then would have
 6 to go to the patient's chart, well my
 7 understanding when I initiated this whole
 8 process, the 50 to 100 that I was doing, that
 9 it was a retrospective sort of, not a
 10 research, but a look back and it was time
 11 limited in a few cases and this would be the
 12 fastest and most effective way. And what my
 13 expectation was that the hospital would then
 14 review, the pathologist would then review my
 15 interpretation and deal with it that way.
 16 MS. NEWBURY:
 17 Q. Okay, so you were aware then that ultimately
 18 the work that you were doing would have been
 19 reflected in the patient's chart and that was
 20 being done for the purposes of patient care?
 21 DR. MULLEN:
 22 A. Not initially, but once we were into the
 23 process, then, yes.
 24 MS. NEWBURY:
 25 Q. Okay, at what stage did you understand that it

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1 was ultimately going to be for the purposes of
 2 patient care? Was it fairly early on in the
 3 process? When you realized that you were not
 4 just doing 50 to 100 cases, that you were -
 5 DR. MULLEN:
 6 A. When it started, yes, and especially when
 7 there was the request and I can't give you the
 8 exact dates, the request to pull things out to
 9 actually diagnose them for--and to issue a
 10 formal report.
 11 MS. NEWBURY:
 12 Q. Okay, so if you had any doubts before as to
 13 whether or not this was being done for patient
 14 care, that's what clinched it for you.
 15 DR. MULLEN:
 16 A. Yes, but from my point of view, other than the
 17 capacity issue, the interpretation would have
 18 been exactly the same, it's just a format of
 19 the report.
 20 MS. NEWBURY:
 21 Q. Sure, okay. And you are aware then that all
 22 of those reviews that you did for the
 23 retrospective review was ultimately for the
 24 purpose of patient care, even though you may
 25 not have known that from the very beginning.

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1 DR. MULLEN:
 2 A. Not initially, yes.
 3 MS. NEWBURY:
 4 Q. And were you ever told that any of the
 5 retrospective testing would be done for the
 6 purposes of peer review or quality review and
 7 therefore, subject to any sort of special
 8 privilege based on those categories?
 9 DR. MULLEN:
 10 A. No, you've seen the e-mails, those are fairly
 11 inclusive, certainly includes everything that
 12 I was aware of.
 13 MS. NEWBURY:
 14 Q. Okay.
 15 DR. MULLEN:
 16 A. And as I mentioned yesterday, I was always the
 17 last to know. We would commit to things and
 18 you have to do it.
 19 MS. NEWBURY:
 20 Q. Okay. And would you have expected that
 21 internal quality control procedures for a
 22 laboratory medicine program would have
 23 detected the types of fixation and processing
 24 problems that you were observing when you were
 25 doing the retesting?

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1 DR. MULLEN:
 2 A. Sorry, could you be--the beginning of your
 3 sentence, the laboratory internal quality?
 4 MS. NEWBURY:
 5 Q. Internal quality control procedures that you
 6 would--that you would have, for example, at
 7 Mount Sinai, would those have detected the
 8 types of fixation and processing problems that
 9 you were observing?
 10 DR. MULLEN:
 11 A. Yes, I would certainly expect that.
 12 MS. NEWBURY:
 13 Q. Okay. And would you have also -
 14 DR. MULLEN:
 15 A. I mean, you have to be very careful about
 16 using the term "quality control", I mean, when
 17 we talk about quality control and the
 18 statistics, I mean, those are fine, but it's
 19 each day, each case, each pathologist, that's
 20 the main quality check. Before they put their
 21 name on anything, they want to ensure that it
 22 is of the highest standard, so to say that you
 23 hide it under quality control, it's the
 24 individual pathologist who is ultimately
 25 responsible, so they should act at the time

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1 the specimen reaches their desk. So
 2 individual, yes, and then if you want to call
 3 the overall process of quality control, but
 4 case by case by case.
 5 MS. NEWBURY:
 6 Q. Right, but you do in fact have -
 7 DR. MULLEN:
 8 A. Yes.
 9 MS. NEWBURY:
 10 Q. Or you would expect to have on each and every
 11 case a quality control procedure that you're
 12 following for each individual case? And
 13 perhaps I'm not clear on the distinction
 14 between quality control and quality assurance.
 15 DR. MULLEN:
 16 A. Okay, well quality assurance is, in broad
 17 terms is a professional, that you're making
 18 sure that the interpretation is the same.
 19 Quality control is the, for the simple terms,
 20 is the technical, that each step is
 21 controlled. But if you're talking about a
 22 program, it's more that we compile figures and
 23 we take our client satisfaction sheets, that
 24 type of thing.
 25 MS. NEWBURY:

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1 Q. Right, looking at your statistics as an
 2 example.
 3 DR. MULLEN:
 4 A. Yes, but when I'm talking about the quality
 5 issue, it's the pathologist on that slide
 6 before they put their name on it, that
 7 everything has to be in place.
 8 MS. NEWBURY:
 9 Q. Okay. And if you had those internal
 10 procedures in place, they would detect it, in
 11 theory, on each and every slide as they're
 12 being reviewed?
 13 DR. MULLEN:
 14 A. Yes, because it's the individual pathologist,
 15 yes.
 16 MS. NEWBURY:
 17 Q. So contemporaneously really with reading of
 18 those initial slides, if you had the internal
 19 quality control procedures in place, that, in
 20 theory, ought to have detected each of these
 21 problems as they occurred or shortly after?
 22 DR. MULLEN:
 23 A. Yes, well going back to my lovely little
 24 comment yesterday, one, maybe, two, "umph",
 25 and three then -

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1 MS. NEWBURY:
 2 Q. Sure.
 3 DR. MULLEN:
 4 A. I mean, that's the key. I mean, you can have
 5 one-offs, we know that, one-offs, but if it's
 6 repeated, then it's time to act and in my
 7 institution, two is possible, three is we act.
 8 MS. NEWBURY:
 9 Q. And in addition to those internal quality
 10 controls, you would expect that external
 11 quality assurance programs, and I believe
 12 there are a variety of programs available -
 13 DR. MULLEN:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. You would have expected that those programs,
 17 had they been in place and utilized, that they
 18 would have detected the types of fixation and
 19 processing problems that you had seen?
 20 DR. MULLEN:
 21 A. No, the quality control or the quality
 22 assurance--well quality control yes, QMPLS we
 23 send our material. When I say QMPLS, Quality
 24 Management Program Laboratory Services in
 25 Ontario, yes, we send. The quality assurance

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1 programs, slides are sent to us, we stain an
 2 we interpret, no. So that would not pick up
 3 the fixation processing issue. QMPLS would.
 4 MS. NEWBURY:
 5 Q. Okay.
 6 DR. MULLEN:
 7 A. QMPLS is a technical, okay, so QMPLS they're
 8 basically, when we're talking about the
 9 pathology laboratory, there are patterns of
 10 practice which are essentially surveys and
 11 when I alluded to the 1866, the last QMPLS
 12 survey on HER2 was how many did you do, so ran
 13 my stats, 1866. There are, so that's pattern
 14 of practice, the other is interpret--well,
 15 it's not really interpretative, cytology
 16 slides we issue a diagnosis, they're more of,
 17 because of legal restrictions, they're not--we
 18 make a diagnosis but it's not attributed to
 19 any one person, it's laboratory. And then
 20 there are the technical, but they will send
 21 you a specimen, you stain it or you send
 22 slides that you've processed and stained and
 23 they evaluate them. So that's the technical
 24 side.
 25 MS. NEWBURY:

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1 Q. That's the distinction. So then you've got
 2 both external quality control and external
 3 quality assurance programs available.
 4 DR. MULLEN:
 5 A. Yes, yes, that's correct.
 6 MS. NEWBURY:
 7 Q. And QMPLS is considered to be an external
 8 quality control.
 9 DR. MULLEN:
 10 A. Yes, quality management, yes.
 11 MS. NEWBURY:
 12 Q. And you UK NEQAS program would be external
 13 quality assurance?
 14 DR. MULLEN:
 15 A. Both.
 16 MS. NEWBURY:
 17 Q. They have both programs.
 18 DR. MULLEN:
 19 A. Yes.
 20 MS. NEWBURY:
 21 Q. And do you sign up for one or both?
 22 DR. MULLEN:
 23 A. No, I think it's included, Mr. Simmons was
 24 saying they assess your staining, then that
 25 would be the quality control and the quality

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1 assurance is we make the diagnosis.
 2 MS. NEWBURY:
 3 Q. Okay.
 4 DR. MULLEN:
 5 A. But I stand to be corrected on that.
 6 MS. NEWBURY:
 7 Q. Okay, so you think then if you had external
 8 quality control programs in place, then that
 9 could have detected the types of fixation and
 10 processing problems that you were observing.
 11 DR. MULLEN:
 12 A. May have.
 13 MS. NEWBURY:
 14 Q. May have, okay, so really the key would be the
 15 internal quality controls.
 16 DR. MULLEN:
 17 A. Yes.
 18 MS. NEWBURY:
 19 Q. That's the first and foremost program that you
 20 look it.
 21 DR. MULLEN:
 22 A. Yes, everything is done--initial is your, I
 23 mean, it's a canary in the mind, you have
 24 something internal.
 25 MS. NEWBURY:

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1 Q. Sure. I wonder if I could have exhibit P-0144
 2 please? This is an e-mail that you weren't
 3 involved in, but I just wanted to refer you,
 4 it's an e-mail between George Tilley and
 5 Carolyn Chaplin, it's actually an exchange on
 6 October 19th, 2005. George Tilley was the CEO
 7 of Eastern Health at the time.
 8 DR. MULLEN:
 9 A. And Carolyn Chaplin -
 10 MS. NEWBURY:
 11 Q. And Carolyn Chaplin was in communications for
 12 the province at that time.
 13 DR. MULLEN:
 14 A. Okay, Government of Newfoundland, okay.
 15 MS. NEWBURY:
 16 Q. Yes, for the Government of Newfoundland, she
 17 was previously involved with the Department of
 18 Health, but had moved positions by this time
 19 and I'm not going to lead you through the
 20 details on that unless you want to look at it,
 21 of course. There's one comment here that I
 22 wanted to ask if you're familiar with and
 23 that's towards the bottom of the page and it's
 24 the, I guess technically it's the fourth last
 25 paragraph in the e-mail and it starts, "I have

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1 talked to the CEO of Mount Sinai to see if we
 2 can expedite the retesting process."
 3 DR. MULLEN:
 4 A. Sorry, can I see the date of this? Sorry, I'm
 5 just trying to put it in -
 6 MS. NEWBURY:
 7 Q. Yeah, they're October 19th. Put it in context,
 8 sure.
 9 DR. MULLEN:
 10 A. Yes, what pressures.
 11 MS. NEWBURY:
 12 Q. So those, the original e-mail and the response
 13 are both on the 19th of October, 2005. And
 14 here in the fourth last paragraph--and if you
 15 want to take your time and go through it, but
 16 I'll show you the key paragraph first -
 17 DR. MULLEN:
 18 A. No, that's fine.
 19 MS. NEWBURY:
 20 Q. "I have talked to the CEO of Mount Sinai to
 21 see if we can expedite the retesting process.
 22 I have also started investigating where we can
 23 put this issue nationally, since this appears
 24 to be more than a local problem. One of my
 25 CEO colleagues in Ontario, who is also an

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1 oncologist, told me earlier tonight it is gray
 2 test." And he's talking generally in this e-
 3 mail, as I understand it, about ER/PR testing,
 4 so I think that the reference to gray test is
 5 a reference to the ER/PR testing. And I just
 6 want to ask did anyone at Eastern Health ever
 7 discuss this concept with you about whether or
 8 not this is considered to be a gray test, that
 9 terminology?
 10 DR. MULLEN:
 11 A. No, I've never heard that term.
 12 MS. NEWBURY:
 13 Q. Okay, ever, not from anyone -
 14 DR. MULLEN:
 15 A. Not from anyone, no. I mean, it's a brown
 16 test, but it's not a gray test, yes.
 17 MS. NEWBURY:
 18 Q. And you mentioned earlier this morning that
 19 pathology isn't black and white.
 20 DR. MULLEN:
 21 A. No, and I flippantly said brown and white but
 22 there's an art to it and a science to it.
 23 MS. NEWBURY:
 24 Q. Right, okay. And had you been asked about
 25 this at the time, would you have agreed with

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1 the characterization there of ER/PR testing to
 2 be a gray test?
 3 DR. MULLEN:
 4 A. No, I would not.
 5 MS. NEWBURY:
 6 Q. And why not?
 7 DR. MULLEN:
 8 A. My understanding is--gray test--if we follow
 9 the recommendations that were in the, for
 10 standardization, I mean, internally you have
 11 the same fixation, if you optimize everything,
 12 then your reproducibility should be quite
 13 high.
 14 MS. NEWBURY:
 15 Q. Okay.
 16 DR. MULLEN:
 17 A. And I'm not sure if the gray test is, they're
 18 referring to reproducibility or whether the
 19 interpretation of it, so whether it's of value
 20 to anyone, I'm not sure.
 21 MS. NEWBURY:
 22 Q. Okay. But in any event that wasn't a concept
 23 discussed with you at anytime by anyone at
 24 Eastern Health.
 25 DR. MUNDEN:

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1 A. Low man on the totem pole, as I mentioned.
 2 MS. NEWBURY:
 3 Q. And did any of your colleagues at Mount Sinai
 4 who may have more direct contact with
 5 representatives of Eastern Health, did any of
 6 those individuals ever discuss this with you?
 7 DR. MUNDEN:
 8 A. I mean, the e-mail, I'm not sure whether it
 9 was--most of them - "Where are you on the
 10 status?" It's not "Hurry up." It's "Where
 11 are you on the status" type of thing.
 12 MS. NEWBURY:
 13 Q. Uh-hm. Okay. You're just updating.
 14 DR. MUNDEN:
 15 A. I mean, it's not as though we were holding
 16 them. At that time it was a capacity issue so
 17 then that may have been the impetus. I can't
 18 suggest it may have been the impetus to buy
 19 the machine, validate and go.
 20 MS. NEWBURY:
 21 Q. Uh-hm.
 22 DR. MUNDEN:
 23 A. Okay. CEO's have a unrealistic expectation of
 24 the turnaround time for material.
 25 MS. NEWBURY:

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1 Q. Okay.
 2 DR. MUNDEN:
 3 A. Snap their fingers and hope for the best, or
 4 expect--doesn't happen. There are physical
 5 constraints.
 6 MS. NEWBURY:
 7 Q. Okay, thank you. Could I have Exhibit P-0110,
 8 please? This is a transcript of a live news
 9 conference dated May 18, 2007, and Mr. Tilley
 10 is the person who's, for the most part, being
 11 recorded here in the transcript.
 12 DR. MUNDEN:
 13 A. Yes, okay.
 14 MS. NEWBURY:
 15 Q. I mean, you can feel free to read the whole
 16 thing if you want.
 17 DR. MUNDEN:
 18 A. No, no, I'm just reading what Nancy said,
 19 okay.
 20 MS. NEWBURY:
 21 Q. Okay, but I'll refer you to a paragraph on
 22 Page 3. You can see a lot of this is just a
 23 quote from Mr. Tilley, and again this is
 24 during the news conference. Mr. Tilley says
 25 here, and it's right there in the middle of

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1 the page. "We saw a change in results for 317
 2 patients and, as you point out, there is an
 3 element of uncertainty in this particular test
 4 and it's quite well known both nationally and
 5 internationally. When we first became of this
 6 and decided to suspend treatment, our
 7 physicians and technologists spent a great
 8 deal of time looking inside the organization
 9 looking at the procedure for that test. We
 10 also sought the input of a technologist and a
 11 physician more independent of the organization
 12 to come and give us an objective assessment as
 13 to what we do and how we do it. I recall that
 14 the comments of the physician were that he
 15 considered us to be in the middle of the pack
 16 in terms of laboratory services with regards
 17 to ER/PR." And my question is, were you ever
 18 asked by anyone at Eastern Health how its lab
 19 compared with other labs in Canada?
 20 DR. MUNDEN:
 21 A. Though may I suggest it might have been Dr.
 22 Banerjee.
 23 MS. NEWBURY:
 24 Q. I believe it was.
 25 DR. MUNDEN:

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1 A. Yes.
 2 MS. NEWBURY:
 3 Q. Yes, I'm fairly sure that's -
 4 DR. MUNDEN:
 5 A. No, I -
 6 MS. NEWBURY:
 7 Q. Yes, I should have said that.
 8 DR. MUNDEN:
 9 A. This is my second visit to Newfoundland.
 10 MS. NEWBURY:
 11 Q. Yes.
 12 DR. MUNDEN:
 13 A. I have not had the opportunity - and the other
 14 one was years ago - I've not had the
 15 opportunity to review the lab. I've not been
 16 asked to review the lab. That was out of the
 17 scope of my involvement in this project.
 18 MS. NEWBURY:
 19 Q. I appreciate that. You had a fairly defined
 20 scope of activity.
 21 DR. MUNDEN:
 22 A. Yes.
 23 MS. NEWBURY:
 24 Q. But I guess, you know, even though it may not
 25 have been to do a review of the lab itself,

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1 you do have some insight, I guess, into what
 2 the product or what the results were.
 3 DR. MUNDEN:
 4 A. But it's difficult to, as Mr. Simmons was
 5 pointing out through his line of questioning,
 6 it's very difficult for me at the end of the
 7 day to go back and say whether it was the
 8 operating room's issue, the fixation issue,
 9 the formalin issue. It's a compilation of all
 10 of those and, sitting in Toronto in my office,
 11 it's not my--I would certainly be beyond my
 12 ability to say it was this, this or this.
 13 MS. NEWBURY:
 14 Q. Right, and I do appreciate that but I guess
 15 I'm just curious whether or not anyone ever
 16 discussed with you -
 17 DR. MUNDEN:
 18 A. No.
 19 MS. NEWBURY:
 20 Q. Because you would have some insight in terms
 21 of what you did see in terms of your
 22 retesting.
 23 DR. MUNDEN:
 24 A. Other than my discussion with Dr. Carter and
 25 my e-mail to Dr. Cook, no.

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1 MS. NEWBURY:
 2 Q. Okay, and no one ever said from Eastern
 3 Health, you know, "We understand that we're in
 4 the middle of the pack in terms of laboratory
 5 services relating to ER/PR, do you agree or
 6 what do you think," you know -
 7 DR. MUNDEN:
 8 A. No, no, nobody asked me that question.
 9 MS. NEWBURY:
 10 Q. And if you had asked, would you have been able
 11 to give any comment - agree, disagree - just
 12 in terms of your role, what you saw with the
 13 testing?
 14 DR. MUNDEN:
 15 A. You're asking me to speculate on something I
 16 don't feel comfortable doing.
 17 MS. NEWBURY:
 18 Q. Okay.
 19 DR. MUNDEN:
 20 A. Because, I mean, my experience with the ER/PR,
 21 I mean, the middle of pack are two of us.
 22 There's Mount Sinai.
 23 MS. NEWBURY:
 24 Q. Right.
 25 DR. MUNDEN:

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1 A. And Eastern Health. I mean, I haven't gone
2 anywhere else to -

3 MS. NEWBURY:

4 Q. Okay.

5 DR. MUNDEN:

6 A. So I really - it's not relevant.

7 MS. NEWBURY:

8 Q. Okay.

9 DR. MUNDEN:

10 A. And I think it's--we're back to our
11 statistics.

12 MS. NEWBURY:

13 Q. Right.

14 DR. MUNDEN:

15 A. We're at the top, they're at the bottom, if
16 you have two, but it's--I don't really -

17 MS. NEWBURY:

18 Q. You don't have enough information about what
19 other labs are doing.

20 DR. MUNDEN:

21 A. I don't have anybody else, and I certainly
22 don't have anybody above us.

23 MS. NEWBURY:

24 Q. Yes.

25 DR. MUNDEN:

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1 A. I'm not suggesting we're the top, but of two
2 what's middle of the pack, I don't know.

3 MS. NEWBURY:

4 Q. Right. Okay. So you don't have another -

5 DR. MUNDEN:

6 A. No.

7 MS. NEWBURY:

8 Q. Enough information about the rest of the pack,
9 basically.

10 DR. MUNDEN:

11 A. No.

12 MS. NEWBURY:

13 Q. Okay.

14 DR. MUNDEN:

15 A. I mean, let's be honest.

16 MS. NEWBURY:

17 Q. Yes.

18 DR. MUNDEN:

19 A. You need three numbers for mean standard
20 deviation.

21 MS. NEWBURY:

22 Q. Sure.

23 DR. MUNDEN:

24 A. If numbers--average mean standard deviation -

25 MS. NEWBURY:

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1 Q. Okay.

2 DR. MUNDEN:

3 A. You can't do that on this. I'm not going to
4 be flippant, but I just don't know.

5 MS. NEWBURY:

6 Q. Yes. No, that's fine. If I could have
7 Exhibit P-0104, please? This is another
8 document that you're probably not familiar
9 with. This is an e-mail from a communications
10 person from Eastern Health to a communications
11 person with the Department of Health, and it
12 attaches materials for a technical briefing
13 that was held by Eastern Health in December of
14 2006, and I just wanted to refer you to a
15 couple of comments in that technical briefing.
16 Page 31, please, and what is set out here are
17 some questions and answers that Eastern Health
18 had prepared, and I understand would have been
19 referenced during the technical briefing, and
20 just scroll down to the bottom of the page.
21 Question number 12, right here in the middle,
22 it's asking, "Were there quality checks in
23 place when the error was discovered," and the
24 answer, 12, "All laboratory testing conducted
25 at Eastern Health use the standard controls."

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1 Were you asked by anyone at Eastern Health
2 whether or not that would be an appropriate
3 answer to that particular question?

4 DR. MUNDEN:

5 A. No.

6 MS. NEWBURY:

7 Q. Okay. And if you had been asked, would you
8 have been able to agree, as it relates to what
9 you saw with ER/PR testing? Obviously, you
10 can't talk about everything that happened at
11 Eastern Health.

12 DR. MUNDEN:

13 A. No.

14 MS. NEWBURY:

15 Q. But just from your perspective.

16 DR. MUNDEN:

17 A. Of course, I didn't get the negative controls
18 but we stopped doing negative controls.

19 MS. NEWBURY:

20 Q. Uh-hm.

21 DR. MUNDEN:

22 A. I mean, I had the external controls in the
23 cases that they were available. I can't go
24 beyond that.

25 MS. NEWBURY:

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<p>1 Q. Okay.</p> <p>2 DR. MUNDEN:</p> <p>3 A. Okay. I mean, again that would be something</p> <p>4 either Dr. Banerjee or Ms. Wegrynowski could</p> <p>5 speak to.</p> <p>6 MS. NEWBURY:</p> <p>7 Q. Okay.</p> <p>8 DR. MUNDEN:</p> <p>9 A. They actually did site visits.</p> <p>10 MS. NEWBURY:</p> <p>11 Q. Right, but in the materials that you saw</p> <p>12 you've pointed out a number of problems with</p> <p>13 internal controls - quality.</p> <p>14 DR. MUNDEN:</p> <p>15 A. Yes, yes.</p> <p>16 MS. NEWBURY:</p> <p>17 Q. And sometimes the complete absence of those</p> <p>18 controls.</p> <p>19 DR. MUNDEN:</p> <p>20 A. Yes.</p> <p>21 MS. NEWBURY:</p> <p>22 Q. And Page 32, which is the next page there,</p> <p>23 Question Number 14 - and, again, this is</p> <p>24 referring generally to the problems with the</p> <p>25 ER/PR testing, so that would include the</p>	<p>1 DR. MUNDEN:</p> <p>2 A. So this is eight or ten months later.</p> <p>3 MS. NEWBURY:</p> <p>4 Q. Yes, that's correct, almost a year later.</p> <p>5 DR. MUNDEN:</p> <p>6 A. Okay.</p> <p>7 MS. NEWBURY:</p> <p>8 Q. Okay. First of all, were you asked whether or</p> <p>9 not more could have been done to prevent this</p> <p>10 from happening?</p> <p>11 DR. MUNDEN:</p> <p>12 A. No.</p> <p>13 MS. NEWBURY:</p> <p>14 Q. By anyone at Eastern Health?</p> <p>15 DR. MUNDEN:</p> <p>16 A. No.</p> <p>17 MS. NEWBURY:</p> <p>18 Q. And would you have been able to agree with the</p> <p>19 answer, had you been asked?</p> <p>20 DR. MUNDEN:</p> <p>21 A. "Could more have been done to prevent this</p> <p>22 from happening" - and this is referring to</p> <p>23 everything -</p> <p>24 MS. NEWBURY:</p> <p>25 Q. The problems with the ER/PR testing.</p>
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<p>1 retrospective testing that you had been</p> <p>2 involved in. Question Number 14, "Could more</p> <p>3 have been done to prevent this from</p> <p>4 happening," and the answer, "This is</p> <p>5 impossible to answer at this point." And just</p> <p>6 to remind you, this is December of 2006 that</p> <p>7 this technical briefing is being held.</p> <p>8 DR. MUNDEN:</p> <p>9 A. 2006?</p> <p>10 MS. NEWBURY:</p> <p>11 Q. Yes, so that would be almost a year after you</p> <p>12 had completed the retrospective testing.</p> <p>13 DR. MUNDEN:</p> <p>14 A. Are you sure this is '06?</p> <p>15 MS. NEWBURY:</p> <p>16 Q. Yes.</p> <p>17 DR. MUNDEN:</p> <p>18 A. Because we reported everything in--was it</p> <p>19 April of '06?</p> <p>20 MS. NEWBURY:</p> <p>21 Q. January.</p> <p>22 DR. MUNDEN:</p> <p>23 A. January of '06.</p> <p>24 MS. NEWBURY:</p> <p>25 Q. January of 2006, you had the bulk of it done.</p>	<p>1 DR. MUNDEN:</p> <p>2 A. I would suggest if the proper--not proper - if</p> <p>3 standardized handling, fixation, processing</p> <p>4 had been in place - I can't speak to the</p> <p>5 immunohistochemistry. I think Ms. Wegrynowski</p> <p>6 did that report.</p> <p>7 MS. NEWBURY:</p> <p>8 Q. Uh-hm.</p> <p>9 DR. MUNDEN:</p> <p>10 A. But based on what I was receiving, if there</p> <p>11 were standard handling, fixation and</p> <p>12 processing, it might have helped to minimize.</p> <p>13 I can't speak to the rest.</p> <p>14 MS. NEWBURY:</p> <p>15 Q. Sure. I just wanted to ask you to explain</p> <p>16 something I was a little bit confused about</p> <p>17 yesterday, and I want to try to reconcile in</p> <p>18 my mind a couple of comments that you made.</p> <p>19 One of your comments, and you have indicated</p> <p>20 this a couple of times now - you had indicated</p> <p>21 that if there was material present--or if this</p> <p>22 material was present, the type of material</p> <p>23 that you were seeing in the retesting, the</p> <p>24 problems with the handling, fixation and</p> <p>25 processing -</p>

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1 DR. MUNDEN:
 2 A. Uh-hm.
 3 MS. NEWBURY:
 4 Q. Then you might be able to tolerate one, the
 5 second -
 6 DR. MUNDEN:
 7 A. That's the issue - would you wait for
 8 statistics?
 9 MS. NEWBURY:
 10 Q. Right.
 11 DR. MUNDEN:
 12 A. Or do you act on what the issues are?
 13 MS. NEWBURY:
 14 Q. Yes.
 15 DR. MUNDEN:
 16 A. Right?
 17 MS. NEWBURY:
 18 Q. And by case number three, you'd act.
 19 DR. MUNDEN:
 20 A. Yes.
 21 MS. NEWBURY:
 22 Q. Okay.
 23 DR. MUNDEN:
 24 A. As I expressed.
 25 MS. NEWBURY:

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1 Q. Yes. And you had also indicated when you were
 2 discussing this concept of not acting, not
 3 waiting for your states, but acting on case
 4 number three.
 5 DR. MUNDEN:
 6 A. Yes, we might act on two or even one but -
 7 MS. NEWBURY:
 8 Q. Right. Sure.
 9 DR. MUNDEN:
 10 A. Yeah.
 11 MS. NEWBURY:
 12 Q. But certainly by three the red flag is there
 13 and you're going to take action.
 14 DR. MUNDEN:
 15 A. Yes.
 16 MS. NEWBURY:
 17 Q. And you had also mentioned while you were
 18 discussing that that what's affecting the
 19 breast tissue is also affecting other
 20 specimens that are being received, so it's not
 21 something you would see in isolation.
 22 DR. MUNDEN:
 23 A. No.
 24 MS. NEWBURY:
 25 Q. Now I think you explained in further detail

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1 this morning that some other testing may not
 2 susceptible to the types of--you might be able
 3 to work better with problematic specimens.
 4 DR. MUNDEN:
 5 A. Yes.
 6 MS. NEWBURY:
 7 Q. In terms of fixation processing more so than
 8 with the breast specimens.
 9 DR. MUNDEN:
 10 A. Yes.
 11 MS. NEWBURY:
 12 Q. But you would be seeing these types of slides
 13 over and over in other specimens aside from
 14 breast tissue?
 15 DR. MUNDEN:
 16 A. That's correct. Okay.
 17 MS. NEWBURY:
 18 Q. So that's one comment that I wanted to just
 19 consider.
 20 DR. MUNDEN:
 21 A. To correct, oh yes.
 22 MS. NEWBURY:
 23 Q. And to compare it with another comment that
 24 you made that there are very few pathologists
 25 who had the opportunity to review the number

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1 of cases that you've reviewed, both
 2 prospective and retrospective, and what is
 3 inherently obvious to you if you're looking at
 4 something for the first time or if you see a
 5 case a month, it may not be as obvious to
 6 another pathologist. So if you were a
 7 pathologist in a routine service and you just
 8 see something sort of sporadically, you may
 9 not have the same level of alertness as to a
 10 potential problem.
 11 DR. MUNDEN:
 12 A. Yes.
 13 MS. NEWBURY:
 14 Q. And I guess what I'm trying to reconcile is if
 15 you have fixation and processing for specimens
 16 other than breast tissue, would you not expect
 17 the pathologist to see these types of things
 18 more often and be alert to the problems even
 19 though they're in a routine pathology service?
 20 DR. MUNDEN:
 21 A. Yes. It's particularly magnified in breast
 22 tissue or any tissue that has a lot of fat in
 23 it because fat is very difficult to fix and if
 24 you're not necessarily sectioning it.
 25 MS. NEWBURY:

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1 Q. Uh-hm.
 2 DR. MUNDEN:
 3 A. The other types of specimens - basically, it
 4 would be small specimens. Biopsies would go
 5 into formalin, would fix nicely. If there's a
 6 processing issue, then the pathologist may
 7 pick that up but, if it's mainly a handling
 8 and fixation, it's large specimens. So the
 9 large specimens that one routinely gets are
 10 bowels, and those hospitals routinely open.
 11 MS. NEWBURY:
 12 Q. Uh-hm.
 13 DR. MUNDEN:
 14 A. So they're not enclosed, so the formalin would
 15 penetrate quite nicely. The adipose tissue
 16 around the bowel may not fix well.
 17 MS. NEWBURY:
 18 Q. Uh-hm.
 19 DR. MUNDEN:
 20 A. Uteri, those are opened, standard opening, so
 21 the processing there--the protocols that are
 22 usually in place would tend to mitigate
 23 against the issue as obvious as you see in
 24 breast.
 25 MS. NEWBURY:

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1 Q. Okay.
 2 DR. MUNDEN:
 3 A. But the same sort of issue, the fixation.
 4 MS. NEWBURY:
 5 Q. Right. So even though the consequences may
 6 not be the same in terms of it interfering
 7 with your ability to stain and to read those
 8 results -
 9 DR. MUNDEN:
 10 A. Uh-hm.
 11 MS. NEWBURY:
 12 Q. Would it still give an opportunity for the
 13 pathologist to become familiar with the types
 14 of fixation and processing problems?
 15 DR. MUNDEN:
 16 A. Yes. Across the board, as I said, there's
 17 nothing special about the fixation and
 18 processing of breast. The only variation from
 19 other tissues is that--depending on age, tends
 20 to be more fat than other specimens.
 21 MS. NEWBURY:
 22 Q. Okay, thank you. Now you've explained in some
 23 detail about the monitoring that you do
 24 yourself in terms of the positivity rates of
 25 ER and PR. Do you do any other types of

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1 monitoring as detailed a fashion as you do
 2 with the positivity rates, and some of the
 3 other things that I'm thinking about are the
 4 positivity by type of cancer, by grade of
 5 cancer, anything else. Do you keep any stats
 6 on that?
 7 DR. MUNDEN:
 8 A. No. I mean, I can do it but it's not
 9 something I do routinely.
 10 MS. NEWBURY:
 11 Q. Okay. And does anyone at your laboratory do
 12 that?
 13 DR. MUNDEN:
 14 A. No. You mean, in breast? No, no.
 15 MS. NEWBURY:
 16 Q. Not the breast at all?
 17 DR. MUNDEN:
 18 A. No.
 19 MS. NEWBURY:
 20 Q. Okay. And is that something that the cancer
 21 registry is involved in, would you know? Do
 22 they keep that sort of information?
 23 DR. MUNDEN:
 24 A. In Ontario every cancer report is sent to the
 25 registry and it's done in real time, the

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1 minute it's signed it goes, and I don't know
 2 what they do with the data.
 3 MS. NEWBURY:
 4 Q. Okay.
 5 DR. MUNDEN:
 6 A. I mean, there are quality indicators in
 7 Ontario that are published, a completeness of
 8 reports.
 9 MS. NEWBURY:
 10 Q. Uh-hm.
 11 DR. MUNDEN:
 12 A. And it's basically filling in the synoptic
 13 report of what they actually do with that type
 14 of material, that may be research more than a
 15 diagnostic.
 16 MS. NEWBURY:
 17 Q. Okay, how they manipulate the material.
 18 DR. MUNDEN:
 19 A. Yes. I mean, we're in the infancy of quality
 20 management in Ontario for this sort of thing.
 21 MS. NEWBURY:
 22 Q. Okay. Do you know the types of information
 23 that will be included in the reports relating
 24 to ER/PR or breast specimens.
 25 DR. MUNDEN:

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1 A. Yes, well, breast specimen, if you're aware,
 2 the College of American Pathologists, their
 3 guidelines -
 4 MS. NEWBURY:
 5 Q. Uh-hm.
 6 DR. MUNDEN:
 7 A. The College of American Pathologists, a large
 8 organization with a lot - we are accredited by
 9 the College of American Pathologists. The
 10 Pathology Community of Ontario in
 11 collaboration with Cancer Care Ontario has
 12 entered into--or is in the process of entering
 13 into an agreement with the College of American
 14 Pathologists who use on a formal basis their
 15 checklist.
 16 MS. NEWBURY:
 17 Q. Uh-hm.
 18 DR. MUNDEN:
 19 A. As the gold - I won't call the gold standard -
 20 as a standard of reporting in Ontario. There
 21 are five sites that are mandatory at the
 22 moment and we're rolling them out, increasing
 23 the numbers. We in Ontario, because we have
 24 one cancer agency -
 25 MS. NEWBURY:

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1 Q. Uh-hm.
 2 DR. MUNDEN:
 3 A. Very different than the Americans, and so they
 4 will have access to cancer data on four
 5 million people, both diagnosis and treatment.
 6 So we have a system in Ontario in the major
 7 hospitals that are called PIMS, Pathology
 8 Information Management System, basically real
 9 time in our hospitals - sends the data to
 10 Cancer Care Ontario. Other hospitals,
 11 depending on their computer system, are
 12 batched at the end of the day, batched at the
 13 end of the month, and those four institutions
 14 that don't have a lab information system, I
 15 think most of us have now, send the reports
 16 manually.
 17 MS. NEWBURY:
 18 Q. Okay.
 19 DR. MUNDEN:
 20 A. And they're extracted, and so all of the
 21 mandatory spots on the cancer checklist are
 22 captured. And we are evaluated for our
 23 completeness. Now, just--quality management
 24 in pathology--can I deviate for just a second?
 25 MS. NEWBURY:

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1 Q. Sure.
 2 DR. MULLEN:
 3 A. Quality management in pathology in Ontario, we
 4 have--just before I came on Tuesday--I'm the
 5 chair of the section Laboratory Medicine of
 6 Ontario Medical Association. I'm also
 7 secretary of the Ontario Association of
 8 Pathologists. I wear multiple hats. So the
 9 OAP, the OMA has joined with Quality
 10 Management Program, Laboratory Services, and
 11 Cancer Care Ontario to devise a strategy to
 12 ensure quality management in Ontario, and
 13 we've--and we haven't officially adopted the
 14 term, but it's quality 4, F-O-U-R, or the
 15 number four for pathology because of the four
 16 organizations. We are in the process--we
 17 realize there is a--well, I won't say a crisis
 18 of confidence, but there is unsettled--the
 19 population in Canada and in Ontario, because
 20 of two incidents, has concerns about quality
 21 in laboratory medicine. So we are trying--we
 22 are in the infancy, these four organizations
 23 which represent the profession and Quality
 24 Management represents the--it's a joint
 25 Ministry of Health, OMA organization that

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1 accredits laboratories. We are trying to
 2 develop processes to ensure quality.
 3 Now when we talk--what we're referring to
 4 at the moment, when we're talking about--I'm
 5 just going to talk about surgical pathology
 6 quality management. There are completeness,
 7 the four issues in quality management for
 8 pathology reports: completeness of the report,
 9 so we're talking about the checklist, and that
 10 we can do through Cancer Care Ontario; the
 11 timeliness, basically a report three years
 12 after the fact is of no value, so it's the
 13 timeliness, the turnaround time; completeness,
 14 timeliness; the accuracy, we have no way at
 15 the moment of doing the accuracy, so if I
 16 diagnose grade one and it's grade two, that's
 17 type of thing, those will be under
 18 development; and the fourth issue is
 19 accessibility, in other words, if I have a
 20 report, but it goes in the mail and nobody can
 21 access it, it's not very useful to anyone. So
 22 that's--so the four key points for laboratory
 23 medicine in our quality management program are
 24 those four, timeliness, accuracy, completeness
 25 and accessibility, and we're doing--we're

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1 initially doing cancer because we have Cancer
 2 Care Ontario as a collaborator and once we've
 3 developed guidelines for that, we'll then move
 4 out from there.
 5 MS. NEWBURY:
 6 Q. Okay. So then in terms of the category number
 7 one, completeness -
 8 DR. MULLEN:
 9 A. Yes.
 10 MS. NEWBURY:
 11 Q. And having forms that have all of the
 12 recommended -
 13 DR. MULLEN:
 14 A. Required.
 15 MS. NEWBURY:
 16 Q. - required -
 17 DR. MULLEN:
 18 A. Required, they're mandatory and I'm not sure
 19 of the term, voluntary. Sorry, I can't--
 20 mandatory and optional.
 21 MS. NEWBURY:
 22 Q. Okay.
 23 DR. MULLEN:
 24 A. That go in. Part of the mandatory, when I was
 25 talking about the surgical pathology

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1 requisition is it's nice to know that it's a
 2 breast. It's nice to know which side, but one
 3 of the fields that they have, they being the
 4 College of American Pathologists, is quadrant,
 5 so upper, outer, lower and inner, the four of
 6 them, upper, outer, but anyway, it's
 7 quadrants, and those of you who--well, nobody
 8 here practices medicine, that is never
 9 complete. So our standard, we used to be
 10 tagged as, you know, deficiencies. Well, we
 11 now put in not specified, that type of thing.
 12 So pathology is a collaboration between the
 13 surgeon or the clinician and the pathologist.
 14 If they don't give us any information, it's
 15 very difficult to give them the appropriate
 16 report. So this is our attempt, infancy at
 17 the moment, to develop a quality management
 18 that deals with this.
 19 MS. NEWBURY:
 20 Q. And do you envision that all of this
 21 information, the mandatory information that
 22 will be included in the report, would be
 23 passed along to the Cancer Registries?
 24 DR. MULLEN:
 25 A. Oh, it's grabbed automatically. It has to be

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1 there or it shows the deficiencies and the
 2 CEOs, there's a Cancer Wait Time Strategy in
 3 Ontario and the funding for cancer, I mean,
 4 that we--has been given to hospitals and they
 5 have to sign accountability agreements and one
 6 of the accountabilities is that you will
 7 report synoptically. So that's the carrot and
 8 the stick, and supposedly, the money will come
 9 to pathology, but as you know, or those of you
 10 in administration, it never comes to
 11 pathology. It goes somewhere else.
 12 MS. NEWBURY:
 13 Q. Thank you. I just wanted to ask a little bit
 14 more about what's been called retroconverters
 15 and that's the--that's a term that's been used
 16 here for results that were -
 17 DR. MULLEN:
 18 A. For the seven cases?
 19 MS. NEWBURY:
 20 Q. - were positive that were converted to
 21 negative.
 22 DR. MULLEN:
 23 A. Yes.
 24 MS. NEWBURY:
 25 Q. And I'm just wondering if your retrospective

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1 review could have--and you'd mentioned this
 2 morning that there is a possibility for false
 3 positives, hypothetically -
 4 DR. MULLEN:
 5 A. Yes.
 6 MS. NEWBURY:
 7 Q. - to occur, and one of the things that you had
 8 identified as a possible contributor to that
 9 would be improper validation of antibodies?
 10 DR. MULLEN:
 11 A. Yes, that's correct.
 12 MS. NEWBURY:
 13 Q. Okay, and I'm just wondering if your
 14 retrospective review could have detected that
 15 type of a problem, if such a problem had
 16 existed?
 17 DR. MULLEN:
 18 A. No. It was--if I remember correctly, it was--
 19 well, I was--the cases that were selected to
 20 be sent to me were the negatives. So 30 or
 21 less and then ten and less. So I wouldn't
 22 have had anything that was called a positive.
 23 Those were not sent to me. So I couldn't do
 24 the retroconverters.
 25 MS. NEWBURY:

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1 Q. But if some had inadvertently been -
 2 DR. MULLEN:
 3 A. Yes.
 4 MS. NEWBURY:
 5 Q. - included in that group, would you have been
 6 able to identify if there was a problem with
 7 the validation of the antibodies or was that
 8 something outside the scope of what you're
 9 looking at?
 10 DR. MULLEN:
 11 A. That would be outside the scope of this
 12 review.
 13 MS. NEWBURY:
 14 Q. Okay.
 15 DR. MULLEN:
 16 A. Because, as I said, they were all negatives,
 17 and I wouldn't have known the--I didn't know
 18 the results to begin with. So that's some -
 19 MS. NEWBURY:
 20 Q. You didn't know the results, okay.
 21 DR. MULLEN:
 22 A. No, that was something that either the
 23 Newfoundland authority or whomever is going to
 24 analyze the data would be able to speak to.
 25 MS. NEWBURY:

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1 Q. Okay. Now I understand that there was a
 2 possibility that some ER positives might have
 3 been inadvertently included in the group and
 4 if that were the case, could you have detected
 5 the antibody validation problem or is that
 6 something -
 7 DR. MULLEN:
 8 A. Personally, no, because I didn't have the
 9 original slide to compare with. I didn't have
 10 the result to compare with.
 11 MS. NEWBURY:
 12 Q. Right.
 13 DR. MULLEN:
 14 A. No.
 15 MS. NEWBURY:
 16 Q. Because you were using your own antibodies on
 17 those slides?
 18 DR. MULLEN:
 19 A. Yes.
 20 MS. NEWBURY:
 21 Q. Okay. So in that case, you wouldn't have been
 22 able to give confirmation or assurances to
 23 Eastern Health that there are no issues with
 24 that?
 25 DR. MULLEN:

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1 A. No, no. Remember, the case selection were
 2 negatives, as I found out in December of '07,
 3 negatives less than 30 initially and then
 4 negatives less than 10.
 5 MS. NEWBURY:
 6 Q. And if you were to delve into that area, if
 7 you thought there was any reason to be
 8 concerned, you would actually have to look at
 9 the original slide?
 10 DR. MULLEN:
 11 A. All positive. No, I'd have to look at the
 12 positives.
 13 MS. NEWBURY:
 14 Q. The positives?
 15 DR. MULLEN:
 16 A. Yes.
 17 MS. NEWBURY:
 18 Q. And original slides of the positives or could
 19 you -
 20 DR. MULLEN:
 21 A. No, I'd have to do the same thing.
 22 MS. NEWBURY:
 23 Q. Okay, you would have to get blocks and look at
 24 -
 25 DR. MULLEN:

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1 A. Yes, and do the whole process again, and -
 2 MS. NEWBURY:
 3 Q. And then compare -
 4 DR. MULLEN:
 5 A. - because then I would--what had called a
 6 positive would then come out as a zero or less
 7 than one or whatever cut off we were using.
 8 They do--it would have to be a duplicate study
 9 of the positives.
 10 MS. NEWBURY:
 11 Q. Right, and then -
 12 DR. MULLEN:
 13 A. Of what had been positives.
 14 MS. NEWBURY:
 15 Q. And to compare the two results?
 16 DR. MULLEN:
 17 A. Yes, that's correct.
 18 MS. NEWBURY:
 19 Q. And the reason I'm asking you that is I had
 20 some information that there were some
 21 conversions from--and perhaps just for
 22 completeness sake, I can refer you to the
 23 Exhibit 0125, page 42. This is an analysis
 24 that was done, dated November 23rd, 2006.
 25 It's just a brief synopsis of the results of

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1 the retesting and there's a number of
 2 categories there.
 3 DR. MULLEN:
 4 A. So, sorry, total case, 97, okay, 2760. The
 5 2760 comes from?
 6 MS. NEWBURY:
 7 Q. That's my understanding of the total of the--
 8 they weren't reviewed, but that's the total
 9 number of cases that were subject to initial
 10 ER/PR testing between '97 and 2005.
 11 DR. MULLEN:
 12 A. Okay.
 13 MS. NEWBURY:
 14 Q. But I understand that -
 15 DR. MULLEN:
 16 A. Oh, okay, so that's -
 17 MS. NEWBURY:
 18 Q. - a small section--that's all of the initial
 19 ER/PR testing, so that would include positives
 20 and negatives.
 21 DR. MULLEN:
 22 A. Okay, so when we're talking about total cases
 23 reviewed, that would be a paper review?
 24 MS. NEWBURY:
 25 Q. Yeah, I'm not--yes.

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1 DR. MULLEN:
 2 A. Okay, yes.
 3 MS. NEWBURY:
 4 Q. So that's all of the initial -
 5 DR. MULLEN:
 6 A. So, okay.
 7 MS. NEWBURY:
 8 Q. I don't think Mount Sinai, as I understand it,
 9 was involved in that.
 10 DR. MULLEN:
 11 A. No, I think if you look at the next line, the
 12 total that were retested would be 939. I'm
 13 not sure of the date. Okay.
 14 MS. NEWBURY:
 15 Q. Okay, and I think those numbers might have
 16 been, you know, revised upwards, you know,
 17 somewhat after.
 18 DR. MULLEN:
 19 A. Results have changed. So basically, they're
 20 saying that I've done two-thirds of it, over
 21 two-thirds, probably three-quarters by that
 22 time, a little over three-quarters, probably
 23 80 percent. No change in results and
 24 subsequently no change in treatment, 433.
 25 Confirmed negative were 341. Confirmed

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1 negative from panel, I'm not sure what that
 2 refers to.
 3 MS. NEWBURY:
 4 Q. That would have nothing to do directly with
 5 Mount Sinai. There was a panel set up here.
 6 DR. MULLEN:
 7 A. Okay.
 8 MS. NEWBURY:
 9 Q. And I guess the next line is the one,
 10 confirmed positive results, and again, I know
 11 that it's kind of hard to show you this
 12 because the positive, negative definitions
 13 were changing over the course of time.
 14 DR. MULLEN:
 15 A. So am I to understand that it was the 12 that
 16 would have been less than ten that were
 17 greater than ten, is that--or less than 30,
 18 greater than 30. Is that what we're referring
 19 to?
 20 MS. NEWBURY:
 21 Q. I guess it's the definition of what--people
 22 that had been defined to be positive at the
 23 time that they were initially tested and it
 24 was confirmed as positive upon retesting.
 25 That's what I take from this. And then if you

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1 scroll down -
 2 DR. MULLEN:
 3 A. And then the DCIS, 52, okay. I'm just going
 4 to look at my little cheat sheet. Okay,
 5 sorry, I shouldn't use the word "cheat sheet"
 6 but my little card, okay.
 7 MS. NEWBURY:
 8 Q. And looking down towards the bottom of the
 9 page, next to the cursor here, it says
 10 "originally had a degree of ER positivity, but
 11 on retesting was negative" and they have four.
 12 DR. MULLEN:
 13 A. Okay.
 14 MS. NEWBURY:
 15 Q. So it appears that there were, if you add the
 16 four -
 17 DR. MULLEN:
 18 A. And the 12.
 19 MS. NEWBURY:
 20 Q. - with the 12, that you would have had 16--
 21 what had been defined, I guess by someone, has
 22 positive -
 23 DR. MULLEN:
 24 A. Yes.
 25 MS. NEWBURY:

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1 Q. - and of those 16, four had converted or were
 2 now considered to be negative, and I'm just
 3 wondering, can you shed any light on that?
 4 DR. MULLEN:
 5 A. No. There was an exhibit earlier in the day,
 6 the retroconverter. Does any--Mr. Browne, you
 7 seem to remember all of these exhibits. Do
 8 you -
 9 MR. BROWNE:
 10 Q. 1822.
 11 DR. MULLEN:
 12 A. Thank you. Can we see 1822? Sorry, I don't
 13 mean to run this, but it just--that was the
 14 one with seven, if I'm correct. Is that it?
 15 No.
 16 MR. SIMMONS:
 17 Q. Excuse me, Commissioner. Where does this
 18 document--these are numbers that Dr. Mullen
 19 hasn't seen before. Ms. Newbury has made
 20 assumptions about what they mean. I just
 21 wonder if there's much value in examining him
 22 on these numbers (inaudible).
 23 THE COMMISSIONER:
 24 Q. Well, he's going to tell me if he can't
 25 comment on them, I'm quite sure.

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1 DR. MULLEN:
 2 A. Okay, sorry, can I--sorry, if this is--okay,
 3 all right. That's--this is all I have, and I
 4 can't shed any more light on this. All I
 5 would know on the retro, and let's see, okay,
 6 this is the--and from Dr. Denic, "I would like
 7 to thank you"--okay, "seven patients who
 8 turned out to be retroconverters." That's--
 9 this is all I've been -
 10 MS. NEWBURY:
 11 Q. That's fine, and I'm not expecting you to be
 12 able to answer to the numbers there. I just
 13 wanted to -
 14 DR. MULLEN:
 15 A. No, this would -
 16 MS. NEWBURY:
 17 Q. - talk to you about the principles and if you
 18 had anything, you know, from what you've seen,
 19 that could shed any light on any issues that
 20 there may or may not be with the ER positive
 21 results.
 22 DR. MULLEN:
 23 A. No, all I can speak to is this e-mail and I
 24 really can't speak to the briefing note. I'm
 25 just not familiar with those numbers.

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1 MS. NEWBURY:
 2 Q. Okay, and you weren't involved with testing
 3 for ER/PR positive tests?
 4 DR. MULLEN:
 5 A. No.
 6 MS. NEWBURY:
 7 Q. And you can't comment whether or not there
 8 were any problems or that there weren't any
 9 problems with ER/PR positive tests? That
 10 wasn't within the scope of what you were
 11 doing?
 12 DR. MULLEN:
 13 A. No, it wasn't within the scope, but I'm not--
 14 these are--these were selected, correct me if
 15 I'm wrong, these were selected by Dr. Denic
 16 and I don't know what criteria they used for
 17 me to--I don't know why they thought they were
 18 retroconverters. I mean, it would be pure
 19 speculation on my part and I don't feel
 20 comfortable doing that.
 21 MS. NEWBURY:
 22 Q. No, that's fine. I just wanted to know--
 23 basically, I'm trying to find the scope of
 24 what you were involved in and what you can or
 25 cannot comment upon.

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1 DR. MULLEN:
 2 A. Can I just take a second to clarify?
 3 MS. NEWBURY:
 4 Q. Sure.
 5 DR. MULLEN:
 6 A. Okay, the--here we go with my four. Four
 7 things, the retrospective review of blocks
 8 that had been called negative, less than 30 or
 9 less than ten, time periods I'm not sure, 1106
 10 of those blocks. I can't do cases because I
 11 wasn't playing with my Excel. So 1106 of
 12 those blocks. At the same time, I was
 13 involved with the prospective review--I'm
 14 sorry, not prospective review, prospective
 15 from August 8th of 2005 to today from the
 16 three plus variable from St. John's. I was
 17 involved starting April of '07, in QA going
 18 forward, and also the Commission of Inquiry
 19 review of the cases that we discussed this
 20 morning, and then this group of seven, I'm not
 21 sure whether I included or not, so this would
 22 be a fourth category. So that was the scope
 23 of my activity. So for the retro review, yes,
 24 I knew it was a retroconverter review, because
 25 they started it. The going forward, I had no

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1 idea whether they were positive or negative,
 2 because that was my initial diagnosis. The
 3 QA, I had no idea whether they were positive
 4 or negative. That was initial diagnosis. And
 5 the retro, until I had the meeting with Mr.
 6 Simmons, Mr. Coffey, Ms. Chaytor, I had no
 7 idea what that was.
 8 MS. NEWBURY:
 9 Q. Okay.
 10 DR. MULLEN:
 11 A. So, and I had no communication with Eastern
 12 Health on the scope of these, other than the
 13 e-mails that you've seen, and one or two
 14 conversations, conversation with Bev Carter
 15 that I spoke about, and then the conversations
 16 just basically as "where are your slides?"
 17 from Dr. Cook. So that, if that clarifies?
 18 MS. NEWBURY:
 19 Q. Yes, it does, thank you.
 20 DR. MULLEN:
 21 A. Sorry.
 22 MS. NEWBURY:
 23 Q. Thank you, those are all the questions I have.
 24 THE COMMISSIONER:
 25 Q. Thank you. Mr. Crosbie?

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1 DR. BRENDAN MULLEN, EXAMINATION BY CHESLEY CROSBIE, Q.C.
 2 CROSBIE, Q.C.:
 3 Q. Thank you, Commissioner. Ches Crosbie, Dr.
 4 Mullen. I represent the members of the Breast
 5 Cancer Testing Class Action, and there's a
 6 term "optimizing" that's come up frequently
 7 during your testimony and before that. Just
 8 to explain that a little bit. Is optimizing
 9 something which is optimal--sorry, something
 10 which is optional or is it something that you
 11 have to do in order to turn out a reliable,
 12 acceptable quality of product when you're
 13 doing ER and PR stains?
 14 DR. MULLEN:
 15 A. It is mandatory.
 16 CROSBIE, Q.C.:
 17 Q. It is mandatory.
 18 DR. MULLEN:
 19 A. It's not optional.
 20 CROSBIE, Q.C.:
 21 Q. You didn't tell us, when you were speaking
 22 earlier, you mentioned that you kept the data
 23 to see what the percentages of the positivity
 24 percentages were.
 25 DR. MULLEN:

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1 A. Yes.
 2 CROSBIE, Q.C.:
 3 Q. On the retrospective cases that you did?
 4 DR. MULLEN:
 5 A. Yes.
 6 CROSBIE, Q.C.:
 7 Q. And you--I don't know if you said you were
 8 taken apart, but words more or less to that
 9 effect, and then you realized why you were
 10 getting the rate that you were getting. Were
 11 you able to tell us what the rate was?
 12 DR. MULLEN:
 13 A. Yes. Let me look at my cards. Okay, this is--
 14 refers to the 997 blocks that--no, sorry.
 15 997 blocks of--so ER negative--997 blocks, so
 16 this is blocks, the cases, some cases will
 17 have multiple blocks, so it may not be--it
 18 would be certainly less than 997 patients, and
 19 this was the data, I believe I presented to--I
 20 think it was the December data. So I had 444,
 21 which is 44.5 percent were ER negative. ER
 22 less or equal to one were 18, which was 1.8
 23 percent. ER -
 24 CROSBIE, Q.C.:
 25 Q. Sorry, give me that again.

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1 DR. MULLEN:
 2 A. ER less than or equal to one were 18 which was
 3 1.8 percent, rounding off, basically a
 4 thousand is the denominator. ER greater than
 5 one to ten, I had 69 cases which is 6.9 and ER
 6 greater than ten, I had 466, so 46.7 percent.
 7 So, in my classification, I would have ER
 8 negative of 46.3, ER positive of 53.7. Using
 9 the Eastern Health criteria, I would have 53.2
 10 percent negative and whoever wants to do the
 11 mathematics, forty some odd percent of
 12 positive. It's easy for me to add 6.9, but
 13 53.7 minus 6.9 is 46.8, I think 46.8?
 14 CROSBIE, Q.C.:
 15 Q. Depending on the criteria, you mean, depending
 16 on -
 17 DR. MULLEN:
 18 A. The cutoff point, yes.
 19 CROSBIE, Q.C.:
 20 Q. That's another point I wanted to raise with
 21 you for clarification because I think you
 22 explained to us that 70 percent of cases will
 23 be--I don't know if you were specific to ER or
 24 PR or both--I think you said 70 percent of
 25 cases will be--sorry, the cases will be 70

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1 percent staining, nuclear staining, or better
 2 in 90 of cases. Did I have that right?
 3 DR. MULLEN:
 4 A. Yes, that was bi-modal distribution, sorry, in
 5 the bi-modal distribution you would have
 6 either 0 or greater than 70 in about 99
 7 percent. It's the other one percent that are
 8 in between. That's not ER positivity. That's
 9 either greater than 70 or 0, less than one.
 10 So, that you cannot use to calculate ER/PR
 11 rates. The nurses study is the one that we
 12 use to calculate -
 13 CROSBIE, Q.C.:
 14 Q. No, but what I'm trying to understand and
 15 maybe I'm barking up the wrong tree, but I'm
 16 trying to understand the effect of shifting
 17 cutoff points from 30 percent to 10 percent to
 18 one percent -
 19 DR. MULLEN:
 20 A. That would not be -
 21 CROSBIE, Q.C.:
 22 Q. - on your positivity rate, will it have much
 23 affect or will it have really a fairly minor
 24 effect? If the distribution of positivity is
 25 in the higher ranges -

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1 DR. MULLEN:
 2 A. Yes, it shouldn't have much affect.
 3 CROSBIE, Q.C.:
 4 Q. It should not have much affect.
 5 DR. MULLEN:
 6 A. Now, if you read the paper, it is very
 7 particular about standardization, fixation,
 8 processing and everything has to be optimized.
 9 In our cases--I shouldn't say our cases--in
 10 the cases that I reviewed, I cannot say that
 11 they were optimized. Therefore that paper is
 12 the what one should aim for, but if you do the
 13 spread, I didn't do the spread in this,
 14 there's certainly a lot if you just scan down
 15 the list. There were a lot between one and
 16 70.
 17 CROSBIE, Q.C.:
 18 Q. Okay. With that caveat and it may be
 19 something to remember by the time I get to the
 20 last issue I want to bring up with you which
 21 is the actual, the false negative rates in the
 22 samples that in the period 1997 through 2005
 23 and also the positivity rates. There's a
 24 spreadsheet that I believe you've had a chance
 25 to look at, but the essential point here now

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1 is that there may be very little effect on the
 2 positivity rate, for example, when one
 3 considers the change in cutoff points.
 4 DR. MULLEN:
 5 A. You would have to plot the data and
 6 recalculate it and I didn't do that.
 7 CROSBIE, Q.C.:
 8 Q. Okay. Well, it may be late in the day for
 9 that, but we'll get to that now in a few
 10 minutes.
 11 DR. MULLEN:
 12 A. I don't have the sheet here to be able to
 13 manipulate the data, but that's something your
 14 statistician should do.
 15 CROSBIE, Q.C.:
 16 Q. Or somebody's statistician?
 17 DR. MULLEN:
 18 A. Well, my background is theoretical math, not
 19 statistics.
 20 CROSBIE, Q.C.:
 21 Q. Okay. So, anyway, the standard that I gather
 22 is being looked for for positivity is
 23 somewhere around 78 percent or the high 70s?
 24 DR. MULLEN:
 25 A. The ER/PR, the nurses study is 61.5, the ER

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1 positive/PR negative is 15.2. So that, for ER
 2 itself would be 76.4 and then ER negative/PR
 3 positive, 3.8 percent. So, basically 80
 4 percent, 79, 80 percent, that range.
 5 CROSBIE, Q.C.:
 6 Q. And what does that tell you? If you're
 7 looking at your statistics from time to time
 8 and you see that you're in that range
 9 somewhere or close to it, is that--it's not a
 10 guarantee a good quality outcome, it's just
 11 one check on it, is that it?
 12 DR. MULLEN:
 13 A. What I've tried to get across, the concept
 14 that statistics are nice, but it's the
 15 individual case that we live and die on. If
 16 my aggregate statistics are fine, but I
 17 misdiagnosed or the ER/PR it misinterpreted or
 18 on the individual case, that's 100 percent
 19 error rate for that patient.
 20 CROSBIE, Q.C.:
 21 Q. Yes, and I think you've done a good job of
 22 explaining that and I think I took that point
 23 myself. So, it may be useful to know your
 24 positivity rate, but it's only one take on
 25 whether your process is working well

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1 (phonetic).
 2 DR. MULLEN:
 3 A. Certainly, certainly.
 4 CROSBIE, Q.C.:
 5 Q. Did I get from you that you had the feeling
 6 that communications were less than optimal
 7 with St. John's while this process was going
 8 on?
 9 DR. MULLEN:
 10 A. With?
 11 CROSBIE, Q.C.:
 12 Q. Well, in terms of, for example, you being
 13 given an opportunity to state to someone in
 14 authority such as Doctor Cook the
 15 unsatisfactory nature of the materials you
 16 were continually receiving.
 17 DR. MULLEN:
 18 A. I had the conversation with Doctor Carter, I
 19 mean, we had a very open and frank
 20 conversation over a couple of days and
 21 reviewed cases together. So, I thought that--
 22 that was certainly one communication. And
 23 Doctor Cook, the communication was basically,
 24 other than my e-mail about the quality was
 25 where are the slides and here are the reports

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1 type, that was that -
 2 CROSBIE, Q.C.:
 3 Q. You didn't have the kind of conversation you
 4 had with Doctor Carter with him?
 5 DR. MULLEN:
 6 A. No, no.
 7 CROSBIE, Q.C.:
 8 Q. Or with anybody?
 9 DR. MULLEN:
 10 A. That's correct. Now, they were in
 11 communication--the lab director may have been
 12 in communication with Doctor Pritzker. And I
 13 just found out that the CEO to CEO issue--I
 14 hadn't heard about that one before.
 15 CROSBIE, Q.C.:
 16 Q. You actually don't know what happened in terms
 17 of communication between Doctor Carter, Doctor
 18 Cook or anybody else or how good their
 19 relations were, do you?
 20 DR. MULLEN:
 21 A. No, beyond the scope of my ability to answer.
 22 CROSBIE, Q.C.:
 23 Q. Also, I got the feeling that you had the
 24 feeling that when your reports and whatnot
 25 went back to St. John's, that they were just

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1 going to rubber stamp it and adopt it as their
 2 own, is that correct?
 3 DR. MULLEN:
 4 A. Well, that was my concern, that I would prefer
 5 that they actually look at the slides, confirm
 6 my opinion and then act.
 7 CROSBIE, Q.C.:
 8 Q. Do you know what they did
 9 DR. MULLEN:
 10 A. No, I don't.
 11 CROSBIE, Q.C.:
 12 Q. Can we bring up that exhibit P-1837
 13 spreadsheet, please. This is something I want
 14 to ask you because I just want to understand
 15 something here. Just looking right at the
 16 item number, it's ID'd number 6 right at the
 17 top of that, page -
 18 DR. MULLEN:
 19 A. Yes.
 20 CROSBIE, Q.C.:
 21 Q. - one.
 22 DR. MULLEN:
 23 A. Yes.
 24 CROSBIE, Q.C.:
 25 Q. You've described that as a discordant test.

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1 DR. MULLEN:
 2 A. Um-hm.
 3 CROSBIE, Q.C.:
 4 Q. And however, I'm just trying to understand,
 5 you got your PRs, 70 and then 90 and your ERS
 6 0 -
 7 DR. MULLEN:
 8 A. And negative.
 9 CROSBIE, Q.C.:
 10 Q. - and negative. Why is that described as
 11 discordant? I'm just trying to get a handle
 12 on it.
 13 DR. MULLEN:
 14 A. If you recall my--the discordant referred to
 15 my Mount Sinai review of the retrospective
 16 block. If the value that I reported was
 17 present on the pathology report and it varied
 18 by one degree, it wasn't in the same category,
 19 I would call it discordant.
 20 CROSBIE, Q.C.:
 21 Q. Yes.
 22 DR. MULLEN:
 23 A. So, this is--I agreed with their initial
 24 interpretation of the slide, but my review of
 25 their retrospective review where we re-stained

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1 the block, would of had a different result.
 2 CROSBIE, Q.C.:
 3 Q. Is that visible here?
 4 DR. MULLEN:
 5 A. No, I don't have it on there. What you have
 6 to do -
 7 CROSBIE, Q.C.:
 8 Q. Oh, I see, you're relating this information to
 9 something that's not on the spreadsheet?
 10 DR. MULLEN:
 11 A. Yes.
 12 CROSBIE, Q.C.:
 13 Q. I see.
 14 DR. MULLEN:
 15 A. My task--I don't have a copy of the letter--
 16 but I was tasked to do this and get them back
 17 before the end of April.
 18 CROSBIE, Q.C.:
 19 Q. So, to that, when re-stained, according to
 20 your lab standards turned out to be
 21 discordant?
 22 DR. MULLEN:
 23 A. Yes.
 24 CROSBIE, Q.C.:
 25 Q. I understand.

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1 THE COMMISSIONER:
 2 Q. If I understood your evidence this morning,
 3 what is NL original and what is MSH review
 4 here is that the latter being your opinion
 5 based on the same slide that was used in NL
 6 original?
 7 DR. MULLEN:
 8 A. Yes, that is correct.
 9 THE COMMISSIONER:
 10 Q. Whereas the comment refers to the slide that
 11 you used and produced from a block -
 12 DR. MULLEN:
 13 A. Yes, that is correct.
 14 THE COMMISSIONER:
 15 Q. - in Mount Sinai earlier in the process?
 16 DR. MULLEN:
 17 A. Yes.
 18 CROSBIE, Q.C.:
 19 Q. Just wondering, is there material here for
 20 publication or do you intend to publish on any
 21 of this?
 22 DR. MULLEN:
 23 A. I have no intention of publishing this. This
 24 is not an academic exercise.
 25 CROSBIE, Q.C.:

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1 Q. You're the expert, I'm just asking.
 2 DR. MULLEN:
 3 A. No, no.
 4 CROSBIE, Q.C.:
 5 Q. Okay. You touched on this again today in some
 6 of the questioning, but yesterday you made the
 7 point that--and none of us doubt it--you see a
 8 high volume of this material and a high volume
 9 of this test. And so you may be more apt to
 10 fairly quickly recognize problems where
 11 somebody who's only seeing one or two a month
 12 may not.
 13 DR. MULLEN:
 14 A. That's correct.
 15 CROSBIE, Q.C.:
 16 Q. But you may have clarified this and I'm trying
 17 to understand, if your material is as
 18 unsuitable as you've described, poorly fixed
 19 or it suffered in some other way through the
 20 process, is that not something an ordinary
 21 pathologist or an average pathologist who
 22 doesn't see a lot of this, the IHC kind of
 23 testing should be able to recognize?
 24 DR. MULLEN:
 25 A. That's correct.

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1 CROSBIE, Q.C.:
 2 Q. That would be a skill possessed by any
 3 pathologist or that you would expect them to
 4 possess.
 5 DR. MULLEN:
 6 A. That's correct.
 7 CROSBIE, Q.C.:
 8 Q. And furthermore, if the pathologist is working
 9 with good externals controls, would that help
 10 them to spot if there's a difficulty or
 11 problem or -
 12 DR. MULLEN:
 13 A. If I recall my testimony, I don't see the
 14 external controls--it's not our policy in our
 15 laboratory for pathologists to see the
 16 external control routinely. If there's a
 17 question -
 18 CROSBIE, Q.C.:
 19 Q. That's technologists in your -
 20 DR. MULLEN:
 21 A. Yes, yes.
 22 CROSBIE, Q.C.:
 23 Q. Here, if I understand it correctly, the
 24 pathologist was to look at the external
 25 controls and they were set out, is that how

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1 you understand it?
 2 DR. MULLEN:
 3 A. They were provided to, I don't know the policy
 4 in St. John's, but reading--I've forgotten
 5 where I read this, that some were not
 6 available because they had been sent to the
 7 pathologist in the other communities or they
 8 did multiple and were sent to the pathologist.
 9 CROSBIE, Q.C.:
 10 Q. Yes, some were sent out, not with controls.
 11 DR. MULLEN:
 12 A. Well, I can't state that.
 13 CROSBIE, Q.C.:
 14 Q. Well, I think we can from what we've seen
 15 because we may even have a look at it now in a
 16 second. So, pathologists generally should be
 17 able to notice the effect of poor fixation?
 18 DR. MULLEN:
 19 A. I would agree.
 20 CROSBIE, Q.C.:
 21 Q. By the way, is this kind of testing, IHC
 22 testing, testing where you're looking for
 23 antibodies, is this kind of a way of the
 24 future? Are we going to see a lot more of
 25 this?

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1 DR. MULLEN:
 2 A. It's current practice, more, I'm not sure if
 3 more. The new trend now is to molecular
 4 diagnostics. That's where the research
 5 companies and research labs are putting their
 6 money because of potential payoffs, but the
 7 actual diagnosis, little or--I shouldn't say
 8 little--the shift is more to the molecular
 9 diagnostics.
 10 CROSBIE, Q.C.:
 11 Q. This is part of a trend towards
 12 individualizing treatments more and more to
 13 patients?
 14 DR. MULLEN:
 15 A. Yes, genomic medicine.
 16 CROSBIE, Q.C.:
 17 Q. Could be go to Exhibit P-1853, please? Just
 18 to explain, sir, this is a document taken out
 19 of parallel court proceedings which is the
 20 class action that I mentioned just a few
 21 minutes ago and these are answers to
 22 interrogatories provided by an official of the
 23 hospital. Interrogatories are simply written
 24 questions and these are written answers. And
 25 if we could go to the answer, answer No. 3,

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1 please, which -
 2 COMMISSIONER:
 3 Q. Answer No. 3 or page No. 3.
 4 CROSBIE, Q.C.:
 5 Q. Pardon me, Commissioner?
 6 COMMISSIONER:
 7 Q. Was it answer No. 3 or page No. 3?
 8 CROSBIE, Q.C.:
 9 Q. Answer 3, page 2.
 10 COMMISSIONER:
 11 Q. Thank you.
 12 CROSBIE, Q.C.:
 13 Q. I think I have, actually, I got my questions
 14 out of order. We should go to question--to
 15 answer No. 10, which will be on page 4.
 16 COMMISSIONER:
 17 Q. No. 10?
 18 DR. MULLEN:
 19 A. Do you have the right interrogatory?
 20 CROSBIE, Q.C.:
 21 Q. 1852.
 22 DR. MULLEN:
 23 A. We're on 1853.
 24 COMMISSIONER:
 25 Q. 1852.

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1 CROSBIE, Q.C.:
 2 Q. Did I say 1853? 1852, I want to do this in
 3 chronological order, so I'm sorry, we should
 4 start with 1852 and it's answer 10, page 4.
 5 Okay. I think we went through these,
 6 actually. Mr. Coffey is just raising whether
 7 they're technically entered. I believe we did
 8 enter them when Ms. Wegrynowski testified.
 9 COMMISSIONER:
 10 Q. Would you just check our list and make sure
 11 these are entered?
 12 CROSBIE, Q.C.:
 13 Q. I remember raising that with you,
 14 Commissioner, at the outset.
 15 COMMISSIONER:
 16 Q. There were four exhibits entered, I just
 17 don't, off the top of my head, remember what
 18 the numbers were.
 19 CROSBIE, Q.C.:
 20 Q. While they're checking that, Doctor, anyway,
 21 we should go to No. 10. I believe they were.
 22 COMMISSIONER:
 23 Q. Okay.
 24 CROSBIE, Q.C.:
 25 Q. So the question there, do you have paragraph

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1 10?

2 DR. MULLEN:

3 A. Yes.

4 CROSBIE, Q.C.:

5 Q. Is "What controls were run in all instances?"

6 Answer, "Technical controls were run in all

7 instances. Technical controls are the

8 inclusion of confirmed positive control

9 patient tissue samples." And then "What is

10 the hospital policy on documentation of

11 controls and on retention of the

12 documentation?" Answer, "There is no written

13 hospital or lab policy on the documentation of

14 controls and the retention of such

15 documentation." You can read the rest of the

16 answer, but that's the essential point I

17 wanted to bring out. Then moving down to 13,

18 "Does the documentation show the controls were

19 working in all documented cases?" And answer

20 there is "Not all pathologists referred to the

21 technical and internal controls in their

22 reports. I estimate that in 50 percent of all

23 cases the pathologist referred to the

24 technical controls in his or her report." So

25 can you explain for the Commission, please,

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1 what you understand to be going on there?

2 DR. MULLEN:

3 A. I just have to look, sorry, before I put my--I

4 want to look at one of my synoptic reports.

5 CROSBIE, Q.C.:

6 Q. Specifically what I'm getting at is should

7 this information be reported by the

8 pathologist, the presence of these controls?

9 DR. MULLEN:

10 A. Well, the new standards, yes, to be reported,

11 the standard line is put in most reports,

12 positive and negative.

13 CROSBIE, Q.C.:

14 Q. New standards as of when?

15 DR. MULLEN:

16 A. I can't tell you the exact date.

17 CROSBIE, Q.C.:

18 Q. Is it since 2005?

19 DR. MULLEN:

20 A. Well, we revised our reports in, I believe in

21 2005 when we went to synoptic reporting, so

22 since 2005 we've put it in.

23 CROSBIE, Q.C.:

24 Q. Would it be acceptable not to mention or, as

25 it's put here, not to refer to the technical

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1 and internal controls in reports even in 2005

2 or, for that matter, 1997?

3 DR. MULLEN:

4 A. Probably '97 it would have been standard

5 practice not to refer, but I -

6 CROSBIE, Q.C.:

7 Q. The last answer here is at 17, page 6, please?

8 And the question is, "Please provide a copy of

9 the bench procedure for antigen retrieval

10 during the use of the DAKO system." Answer

11 is, "Please see the bench procedures for

12 certain clones attached." And then can we go

13 to page 7? And, sir, why don't you scroll

14 through at your own pace and you can see what

15 was provided?

16 DR. MULLEN:

17 A. Yes. That's the standard hand out.

18 CROSBIE, Q.C.:

19 Q. That's the manufacturer's?

20 DR. MULLEN:

21 A. Manufacturer's. That's what we--you were

22 asking for the SOP or asking -

23 CROSBIE, Q.C.:

24 Q. Bench procedures, how do you understand that?

25 DR. MULLEN:

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1 A. I would provide the standard operating--the

2 SOP, not just that. What we do is this is a

3 reference would be referred to under standard

4 operating procedure. So it's taken -

5 CROSBIE, Q.C.:

6 Q. Is this a standard operating procedure?

7 DR. MULLEN:

8 A. No, not to my--not in our institution.

9 CROSBIE, Q.C.:

10 Q. Could we go then to 1853, please, page 2?

11 This is another interrogatory and answer a

12 little bit later.

13 DR. MULLEN:

14 A. Um-hm.

15 CROSBIE, Q.C.:

16 Q. And so at page 2, answer 3, we're trying

17 again, "Please attach a copy of the bench

18 manual for the DAKO system, specifically

19 written methodology in antigen retrieval,

20 controls negative and positive, etcetera."

21 Answer, "Please see attached Appendix A."

22 Could you take us there, please? That's page

23 5. And further on. And again, sir, you may

24 want to scroll through and see what we've been

25 given.

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1 DR. MULLEN:
 2 A. I'm not quite sure what all the scratch outs
 3 are, but. This would be closer to a SOP.
 4 But, I mean, I'd have to go through it point
 5 by point by point by point. This sounds--I
 6 shouldn't say sounds like, this appears to be
 7 something that is specific to the laboratory,
 8 and that's basically what a standard operating
 9 procedure is. Now, whether it's complete or
 10 not, I can't really speak to it. And also
 11 it's, this would be something that Ms.
 12 Wegrynowski and the technical people would
 13 prepare.
 14 CROSBIE, Q.C.:
 15 Q. If you go to page 9, can you do that, sir?
 16 DR. MULLEN:
 17 A. Nine. Okay, one second. Six. And this would
 18 be supporting documentation.
 19 CROSBIE, Q.C.:
 20 Q. Does this seem to be DAKO specification
 21 literature from the DAKO manufacturer?
 22 DR. MULLEN:
 23 A. Yes, this we would not include as part of our
 24 SOP. This would be kept in a manual with
 25 reference to the antibody. SOPs are actual

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1 procedures. This is supporting documentation.
 2 CROSBIE, Q.C.:
 3 Q. So then when Dr. O'Malley told us a few days
 4 ago that we include a statement about our
 5 positive and negative lab controls, that's
 6 something newer, is it?
 7 DR. MULLEN:
 8 A. Yes. I cannot tell you the specific day that
 9 it started, the guidelines. But we instituted
 10 it as a standard sort of in the canned message
 11 for the synoptic reports in 2005. Before that
 12 it may not have been included.
 13 CROSBIE, Q.C.:
 14 Q. P-1604, please? Can you go to page 2, please?
 15 We understand these to be handwritten notes of
 16 Dr. Cook.
 17 DR. MULLEN:
 18 A. Okay.
 19 CROSBIE, Q.C.:
 20 Q. And reading this note here, he spoke to Dr.
 21 Nagihily about why Clarenville discontinued ER
 22 and PR slides. Dr. Nagihily replied, "This
 23 was due to poor quality and to lack of
 24 external controls," plus the fact they were
 25 paying for this.

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1 DR. MULLEN:
 2 A. And as far as she knows they discontinued
 3 without notifying people in St. John's, okay.
 4 CROSBIE, Q.C.:
 5 Q. Is there any contents of that note there that
 6 surprises you?
 7 DR. MULLEN:
 8 A. I believe yesterday I answered that one of the
 9 first questions was on our, the Mount Sinai
 10 Hospital's first contact or first review--not
 11 review, first processing of tissue from
 12 Clarenville, I had the wrong spot, my
 13 apologies, Peninsulas Health Care, if this is-
 14 -if Clarenville is Peninsulas, we were
 15 approached in 1999, the first record I have
 16 was October 5th, 1999 that we performed ER and
 17 PR staining. In 2005 I had a conversation at
 18 the Ontario Association of Pathologists'
 19 meeting with Dr. Yassa, who I believe was a
 20 pathologist at the time in Clarenville or one
 21 of, I don't know if the only or one, and he
 22 relayed--I asked him why--this was after I had
 23 been approached to do the review, why--he told
 24 me he'd been in Newfoundland and he was in

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1 Clarenville, so I asked him why he had sent
 2 them to us and basically this is the reason,
 3 he wasn't provided external quality controls,
 4 he was not happy with the service or the
 5 quality of the service and therefore he sent
 6 them to us. And as I related, from October
 7 5th, '99 until September of 2005, we provided
 8 technical services. We cut the--they sent us
 9 a block, we cut and stained the slides, each
 10 controls and sent them to Newfoundland.
 11 CROSBIE, Q.C.:
 12 Q. So what you understood from other sources
 13 corroborates what's in that?
 14 DR. MULLEN:
 15 A. Yes, yes.
 16 CROSBIE, Q.C.:
 17 Q. Okay. Sir, perhaps you could assume that this
 18 is accurate information. Up to around 1999
 19 here we had an enzyme immune assay technique
 20 performed in the biochemistry division of the
 21 lab at Eastern Health and the Health Sciences,
 22 and then testing for IHC was switched to the
 23 anatomical pathology division. Anatomical
 24 pathology is used to doing ordinary histology,
 25 right?

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1 DR. MULLEN:
 2 A. Plus electron microscopy,
 3 immunohistochemistry, the whole cytopathology,
 4 the whole area.
 5 CROSBIE, Q.C.:
 6 Q. What would you do if you were in charge of the
 7 transition, as I just described it, to ensure
 8 good reliable IHC staining?
 9 DR. MULLEN:
 10 A. Basically I would establish the--I would
 11 optimize the antibodies. I would--looking at
 12 the biochemistry and basically I believe what
 13 probably Dr. O'Malley and Ms. Wegrynowski, we
 14 established tissue a tissue microray. We
 15 would go back to tissue, archival tissue, well
 16 fixed, well preserved, that was called
 17 positive, low positive, and I can't give you
 18 the actual thinamoles (phonetic), positive,
 19 low positive and negative and establish our
 20 antibody that would be--that would do the
 21 optimization to that. Then we would, once
 22 we've done that, then I'd run a concordance
 23 survey to see if we would go back to archival
 24 cases and look at stain and see what the
 25 positivity rate was compared to the Ligand

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1 binding assay or whatever the assay was at the
 2 time. That's basically -
 3 CROSBIE, Q.C.:
 4 Q. How large a number of cases would be included
 5 in a concordance if you were doing this
 6 transition?
 7 DR. MULLEN:
 8 A. Depends on the statistical results. You do
 9 enough to be statically robust, so I can't
 10 give you an--20, 40, 50, somewhere in that
 11 rage.
 12 CROSBIE, Q.C.:
 13 Q. Depending on what results you're getting?
 14 DR. MULLEN:
 15 A. Yes, if they weren't--you would keep--then
 16 you'd start over again. I mean, you'd have
 17 to--it'd be iteration, if it wasn't working,
 18 you would optimize again.
 19 CROSBIE, Q.C.:
 20 Q. Would you have to ask yourself some questions
 21 about training for staff who were going to be
 22 doing the procedure?
 23 DR. MULLEN:
 24 A. Certainly. I mean, that's all part of the
 25 validation of an antibody or introduction of

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1 an antibody.
 2 CROSBIE, Q.C.:
 3 Q. Okay. So you understand that to include
 4 training of staff?
 5 DR. MULLEN:
 6 A. Yes.
 7 DR. MULLEN:
 8 A. That's the way, okay, that's the way your mind
 9 works, okay.
 10 DR. MULLEN:
 11 A. Yeah, sorry.
 12 CROSBIE, Q.C.:
 13 Q. So personnel issues would have to be looked at
 14 and, I suppose, a budget would have to be
 15 drawn up for this, would it?
 16 DR. MULLEN:
 17 A. Well, we would hope there would be a transfer
 18 of the budget from biochemistry to pathology
 19 because stopping one test in one area,
 20 personnel, the personnel and reagent support,
 21 etcetera, would be hopefully transferred to
 22 pathology.
 23 CROSBIE, Q.C.:
 24 Q. You would expect this to be no extra cost?
 25 DR. MULLEN:

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1 A. I don't know what the Ligand binding assay
 2 cost.
 3 CROSBIE, Q.C.:
 4 Q. Okay. Can we bring up document 1850, please?
 5 This is a memorandum from Dr. Khalifa.
 6 DR. MULLEN:
 7 A. Yes.
 8 CROSBIE, Q.C.:
 9 Q. And it's addressed to all Newfoundland
 10 pathologists, February, 1998. It's about
 11 reporting of estrogen and progesterone
 12 receptor immunohistochemical results. I'm
 13 just going to give you an opportunity to scan
 14 through that, it's a few pages in length. On
 15 page 3 you'll notice "Positivity is defined by
 16 nuclear staining detected in any number of
 17 malignant cells," and it goes on to discuss
 18 the 30 percent -
 19 DR. MULLEN:
 20 A. The 30 percent, the cut off, the American
 21 (unintelligible) Surgical Pathology, yes.
 22 CROSBIE, Q.C.:
 23 Q. Which is a 1990 publication?
 24 DR. MULLEN:
 25 A. Yes, that's correct.

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1 CROSBIE, Q.C.:

2 Q. And it's repeated down below in example 2 in

3 that table there.

4 DR. MULLEN:

5 A. All right.

6 CROSBIE, Q.C.:

7 Q. And then you'll see a report of our experience

8 over a nine-month period. January '97 to

9 September, '97.

10 DR. MULLEN:

11 A. Um-hm.

12 CROSBIE, Q.C.:

13 Q. I take it this is the confirmation exercise?

14 DR. MULLEN:

15 A. Yes, yes. Okay.

16 CROSBIE, Q.C.:

17 Q. And you see from the tables on the page you're

18 on and also the comments that this was

19 performed on a total of 19 cases for estrogen

20 and 17 cases for progesterone?

21 DR. MULLEN:

22 A. Okay.

23 CROSBIE, Q.C.:

24 Q. Is that a small series for doing this kind of

25 exercise?

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1 DR. MULLEN:

2 A. Were the results statistically significant?

3 CROSBIE, Q.C.:

4 Q. You're the expert.

5 DR. MULLEN:

6 A. I can't do the stats, I can't do the chi

7 square off the top of my head, but -

8 CROSBIE, Q.C.:

9 Q. So why don't you explain what would have to be

10 performed to know that, to answer the question

11 you just asked me?

12 DR. MULLEN:

13 A. Basically you'd have to do statistics, are

14 these--is there a significant difference, and

15 if they are, fine, if they're not, fine.

16 CROSBIE, Q.C.:

17 Q. Okay. Do you see that analysis in the paper?

18 DR. MULLEN:

19 A. No, no.

20 CROSBIE, Q.C.:

21 Q. Is it likely -

22 DR. MULLEN:

23 A. I really would, I mean, to comment on this I'd

24 really have to sit down and go through and

25 review it. I mean, reading a six-page

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1 document at quarter to five after two days,

2 I'd have to--really going beyond what I feel

3 comfortable doing until I actually review it.

4 CROSBIE, Q.C.:

5 Q. I'm sure we can sympathize with you. So -

6 DR. MULLEN:

7 A. And I think -

8 CROSBIE, Q.C.:

9 Q. - thanks for helping us to that extent.

10 DR. MULLEN:

11 A. But I think the statistician who is going to

12 review the results might be a better person to

13 ask.

14 CROSBIE, Q.C.:

15 Q. Just quickly, can we go to 0067, which is a

16 letter from Dr. Cook to Dr. Robert Williams,

17 the Vice President Medical Services. And page

18 2 of that, please?

19 DR. MULLEN:

20 A. May 24th, okay.

21 CROSBIE, Q.C.:

22 Q. At the foot of that page 2 it's, Dr. Cook is

23 explaining to Dr. Williams what Dr. Ejeckam

24 did at the foot. Here we are. He says, "In

25 early 2003 Dr. Ejeckam, our point man,

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1 discontinued testing of the ER/PR receptors

2 with the manual method for a six-week period.

3 A memo was circulated to all pathologists

4 across the province stating this. The

5 technique was temporarily halted because of

6 erratic staining which required readjustments

7 of titration and staining times." So that's

8 essentially what Dr. Ejeckam adjusted or

9 tinkered with is the staining times and

10 titration.

11 DR. MULLEN:

12 A. Um-hm.

13 CROSBIE, Q.C.:

14 Q. "Once he felt confident of the reliability of

15 staining the test was reintroduced."

16 DR. MULLEN:

17 A. Okay.

18 CROSBIE, Q.C.:

19 Q. And now, sir, I'd like to take you to a table

20 which I guess we may have to enter, which I

21 think we all have a copy of. That's called P-

22 1841.

23 MR. SIMMONS:

24 Q. Excuse me, Commissioner, I know it's twice in

25 one afternoon, but this is the document we

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1 were just given on break and haven't had an
 2 opportunity to look at it beforehand, but it
 3 appears to be a collection of statistics and
 4 data for--compiled and prepared for Mr.
 5 Crosbie by Dr. Charles Hutton. And it doesn't
 6 have the appearance of being anything that Dr.
 7 Mullen has been involved in preparing or even
 8 with--before as far as I know, so I just
 9 wonder if this is a document which we should
 10 be being put in thorough this witness or if it
 11 should wait until when Dr. Hutton is called.

12 COMMISSIONER:
 13 Q. Mr. Browne, you're on your feet, as well.

14 MR. BROWNE:
 15 Q. Similarly, Commissioner, we've heard about
 16 reliability and producibility and I have some
 17 concerns about what's gone into this without
 18 having the witness who's prepared it under
 19 oath and examined, (inaudible) no reliability
 20 and this kind of thing.

21 COMMISSIONER:
 22 Q. Well, let's find out what the comfort of the
 23 witness is with what he's had -

24 CROSBIE, Q.C.:
 25 Q. Perhaps I could address that? The information

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1 -

2 COMMISSIONER:
 3 Q. Yes, why don't you do that.

4 CROSBIE, Q.C.:
 5 Q. - in the tables is taken directly out of the
 6 answers to interrogatories. In other words,
 7 it comes straight from Eastern Health. That's
 8 the information contained in, under "Total
 9 Tests" in that column there, as noted by
 10 footnote 2. And also in "Total Negatives", in
 11 that column there. And "False Negatives", in
 12 that column there is also taken from
 13 information supplied by Eastern Health. If we
 14 want to walk back to the answers, I can prove
 15 that, you know, step by step, I've done that
 16 for myself, or anyone can check that. The
 17 rest of these percentages are merely
 18 arithmetic calculations anyone can do by use
 19 of a calculator. It would be unfortunate if I
 20 couldn't ask this gentleman about his comments
 21 on these results.

22 COMMISSIONER:
 23 Q. Well, let's first find out if--are you aware
 24 that these are materials coming from your
 25 client?

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1 MR. SIMMONS:
 2 Q. I can only read the bottom that references
 3 these two exhibits, but I haven't had a chance
 4 to cross reference or to see if, in fact, the
 5 numbers here are taken directly out of those
 6 answers to interrogatories or if these
 7 calculated percentages are correct or if
 8 they're taken from the interrogatories at all.
 9 I mean, again, I wonder at the utility of -

10 COMMISSIONER:
 11 Q. Just a minute now, Mr. Simmons. In the event
 12 that--what would be your position in the event
 13 that Mr. Crosbie's statement is absolutely
 14 correct and that is that they came out of
 15 interrogatories produced by Eastern Health in
 16 another proceeding and there were mathematical
 17 calculations for the purpose of which this
 18 question, you can assume, were correct?

19 MR. SIMMONS:
 20 Q. I still question what point and purpose is of
 21 putting this to Dr. Mullen and inviting his
 22 comment on.

23 COMMISSIONER:
 24 Q. Mr. Browne, do you want to add in?
 25 MR. BROWNE:

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1 Q. Again, if I can go back to reliability and
 2 reproducibility and Dr. Mullen previous
 3 comment about statistical analysis. I mean,
 4 there are numbers here, percentages which I'm
 5 reading that Dr. Hutton has tabulated and we
 6 don't know how--whether he's gotten that
 7 corrected--correct or not and we can't examine
 8 him on it and that's the -

9 COMMISSIONER:
 10 Q. At the moment. That doesn't mean you can't in
 11 the future.

12 MR. BROWNE:
 13 Q. True, but I guess the question being, I mean,
 14 can this witness comment on it.

15 COMMISSIONER:
 16 Q. All right, thank you. Now, Mr. Crosbie, I
 17 take the point, but I do think we do have to
 18 resolve, and I'll leave it to you, ask the
 19 question of the witness of whether or not he's
 20 in a position to answer, he feels comfortable
 21 with answering questions related to these
 22 documents. For myself, if the witness is
 23 comfortable with them and if it can--we can
 24 deal with this as an exhibit taken in on the
 25 basis of the, noting the objections of these

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1 two parties with a view that confirmation of
 2 the information may have to be checked in the
 3 future.
 4 CROSBIE, Q.C.:
 5 Q. Sure.
 6 COMMISSIONER:
 7 Q. If this witness is comfortable with answering
 8 questions related to that kind of material.
 9 CROSBIE, Q.C.:
 10 Q. It's not hard to confirm the information, just
 11 by going back to the answers. But at this
 12 late point on Friday afternoon maybe we can
 13 skip that step -
 14 COMMISSIONER:
 15 Q. Well, yes, I'm sorry, Mr. Clements?
 16 MR. CLEMENTS:
 17 Q. Commissioner, I wonder if I could provide my
 18 client some advice on -
 19 COMMISSIONER:
 20 Q. You can, indeed.
 21 MR. CLEMENTS:
 22 Q. - how he might answer the questions and could
 23 we have a recess for one or two minutes for me
 24 to do that?
 25 COMMISSIONER:

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1 Q. Yes. Mr. Crosbie, would you--you realize that
 2 this is a witness from out of town, so
 3 whatever way we have to deal with this, we
 4 have to deal with it today.
 5 CROSBIE, Q.C.:
 6 Q. Yes, indeed.
 7 DR. MULLEN:
 8 A. I have an 8:00 flight, so, that's fine, it's
 9 not that far to go.
 10 COMMISSIONER:
 11 Q. Mr. -
 12 COFFEY, Q.C.:
 13 Q. If we could, Commissioner, it might facilitate
 14 things, too, certainly from Mr. Clement's
 15 perspective, if a question could just be
 16 phrased without being answered, at least we'd
 17 have some sense about -
 18 COMMISSIONER:
 19 Q. Of what the question is to be.
 20 DR. MULLEN:
 21 A. What you're asking me.
 22 COMMISSIONER:
 23 Q. Yes. Thank you, Mr. -
 24 CROSBIE, Q.C.:
 25 Q. Well, one question I would ask is assuming

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1 these figures to be accurate, or the table to
 2 be accurate, you can see there at a certain
 3 point in time the premise is that Dr. Ejeckam
 4 did an intervention and the rest of us have
 5 heard a lot of information about that. His
 6 intervention appeared to result in getting the
 7 positivity rates up, but if you look in the
 8 column under "False Negatives", the false
 9 negative rate appeared to remain high, if not
 10 go higher. And one question I wish to ask the
 11 witness was could he venture any explanation
 12 as to how that could be?
 13 COMMISSIONER:
 14 Q. All right. Well, why don't we take that five-
 15 minute break that's been asked for and you can
 16 consult with your client.
 17 (RECESS)
 18 COMMISSIONER:
 19 Q. Please be seated. Mr. Clements?
 20 MR. CLEMENTS:
 21 Q. Yes. Mr. Crosbie can ask his question. I
 22 don't know that the witness is going to be
 23 able to help him with the answer, but the
 24 witness can explain that.
 25 COMMISSIONER:

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1 Q. Oh, okay. Gets a little more complicated.
 2 CROSBIE, Q.C.:
 3 Q. I really didn't expect it to be simple.
 4 COMMISSIONER:
 5 Q. Okay. Now, are we all clear? What I'm
 6 allowing here is the asking of the question
 7 and we'll leave it to the witness to determine
 8 whether or not he feels that he's in a
 9 position to provide an answer given the
 10 circumstances and he will explain what those
 11 are. What use I may make of this you may
 12 argue in the future based on whether or not
 13 the underlying facts are or are not
 14 established. Now, do you want to put your
 15 question again, Mr. Crosbie, so we all know
 16 what it is?
 17 CROSBIE, Q.C.:
 18 Q. Yes, I believe my -
 19 THE COMMISSIONER:
 20 Q. Oh, and before you do that, I know--because
 21 the document itself, what was the number
 22 again? Could you give it to me?
 23 CROSBIE, Q.C.:
 24 Q. P-1841.
 25 THE COMMISSIONER:

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1 Q. P-1841 and that has not been put into
 2 evidence, as I understand it.
 3 REGISTRAR:
 4 Q. No, Commissioner.
 5 THE COMMISSIONER:
 6 Q. Okay. We'll make it an exhibit.
 7 EXHIBIT ENTERED AND MARKED P-1841.
 8 CROSBIE, Q.C.:
 9 Q. Thank you.
 10 THE COMMISSIONER:
 11 Q. Now, would you put your question please.
 12 CROSBIE, Q.C.:
 13 Q. Yes, I believe the question was you can see
 14 there are various percentages by year, which
 15 is I mentioned before, derived from data
 16 provided in sworn answers to interrogatories
 17 that we quickly looked at as we were passing
 18 along there about a half an hour ago. So the
 19 percentages give you false negative rates in
 20 the column on the right-hand side, and you can
 21 also see positivity rates in the column in the
 22 third from the left.
 23 DR. MULLEN:
 24 A. Uh-hm.
 25 CROSBIE, Q.C.:

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1 Q. And what I was going to ask you was with an
 2 improvement in the positivity rate for 2003 to
 3 the level of 76 percent, which I believe you,
 4 from information you gave us before would be
 5 an acceptable range, what you'd be looking
 6 for, yes?
 7 DR. MULLEN:
 8 A. That is correct.
 9 CROSBIE, Q.C.:
 10 Q. That's an improvement from the overall
 11 positivity rate of 58 percent in the period
 12 1997 to 2002, yes?
 13 DR. MULLEN:
 14 A. Yes, correct.
 15 CROSBIE, Q.C.:
 16 Q. Appears to follow the intervention by Dr.
 17 Ejeckam, as far as you can tell, yes?
 18 DR. MULLEN:
 19 A. Yes, that's correct.
 20 CROSBIE, Q.C.:
 21 Q. So it is, intervention seems to have a
 22 positive effect on the quality of the process
 23 to the extent that it raised the positivity
 24 rate.
 25 MR. CLEMENTS:

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1 Q. Excuse me, that's not the question that Mr.
 2 Crosbie previously put. He's now cross-
 3 examining the witness on -
 4 CROSBIE, Q.C.:
 5 Q. Well, I'm just bringing him, I'm just bringing
 6 everyone through it step by step. These are
 7 all factual things in it and my next question,
 8 if he agrees with that is can he explain why
 9 the overall false negativity rate or for that
 10 matter for 2003 remains stuck at 44 percent
 11 and over the entire period, 45 percent, that's
 12 the question.
 13 THE COMMISSIONER:
 14 Q. Is the witness in a position to assist?
 15 DR. MULLEN:
 16 A. I can't speak to this data and I don't feel
 17 comfortable speaking to it, but I think what's
 18 been explained both by Ms. Wegrynowski and
 19 myself and other witnesses, there are
 20 approximately 30, 40 steps that any one of
 21 those could account for the abnormalities,
 22 beyond that, I can't be more specific. I'm
 23 sorry, but I just can't analyze the data.
 24 CROSBIE, Q.C.:
 25 Q. Let me ask one more question.

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1 THE COMMISSIONER:
 2 Q. Well, let's find out what the question is and
 3 then we'll determine whether or not any
 4 doesn't object to -
 5 CROSBIE, Q.C.:
 6 Q. I want to know what the witness thinks or how
 7 he evaluates if it's true, a false negative
 8 rate of 45 percent?
 9 THE COMMISSIONER:
 10 Q. That's an abstract question as to what he--
 11 what his reaction is to a false negative rate
 12 of 44 percent?
 13 CROSBIE, Q.C.:
 14 Q. If that's an accurate number.
 15 THE COMMISSIONER:
 16 Q. If that is an accurate number.
 17 DR. MULLEN:
 18 A. And it doesn't appear on here, so it's not a
 19 specific column, so that would be a very high
 20 false negative rate.
 21 CROSBIE, Q.C.:
 22 Q. I'm sorry, it is there, under false negative
 23 grand total.
 24 DR. MULLEN:
 25 A. Oh grand total, my apologies.

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1 THE COMMISSIONER:
 2 Q. Date, 2003 on the -
 3 DR. MULLEN:
 4 A. I was looking at any of the specifics, you're
 5 adding year by year by year.
 6 CROSBIE, Q.C.:
 7 Q. Grand total for the period.
 8 DR. MULLEN:
 9 A. It would be a high rate.
 10 MR. SIMMONS:
 11 Q. Commissioner, if I might on that point, it
 12 depends too on what's intended by the term
 13 "false negative rates" and what that's a
 14 percentage of.
 15 DR. MULLEN:
 16 A. Yes, I mean, -
 17 THE COMMISSIONER:
 18 Q. Which goes back to the witness's earlier point
 19 in terms of knowledge of that underlying -
 20 DR. MULLEN:
 21 A. I don't know what this is, so 45 would be high
 22 if--it's best not to go speak to the specifics
 23 in this case.
 24 CROSBIE, Q.C.:
 25 Q. Thank you.

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1 THE COMMISSIONER:
 2 Q. Thank you, Mr. Crosbie. Mr. Pike?
 3 MR. PIKE:
 4 DR. BRENDAN MULLEN, EXAMINATION BY MR. MARK PIKE
 5 MR. PIKE:
 6 Q. Dr. Mullen, Mark Pike is my name. I'm the
 7 lawyer for the Newfoundland and Labrador
 8 Medical Association. Just a small point and
 9 maybe I missed it earlier, when you carried
 10 out this review for the Commission of some
 11 slides that were sent to you -
 12 DR. MULLEN:
 13 A. Are you referring to the data I spoke to this
 14 morning?
 15 THE COMMISSIONER:
 16 Q. The data sent by the--the slides sent by the
 17 Commission?
 18 MR. PIKE:
 19 Q. Yes, yes, I am.
 20 DR. MULLEN:
 21 A. So that's exhibit -
 22 THE COMMISSIONER:
 23 Q. Are we looking at P-1837?
 24 MR. PIKE:
 25 Q. Yes, P-1837. Just, I'm wondering whether you

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1 are aware of the criteria that was used to
 2 determine which slides you'd be reviewing,
 3 whether you participated in the selection
 4 criteria of those slides or whether you just
 5 reviewed what you were given?
 6 DR. MULLEN:
 7 A. I was reviewing what I was given. I have
 8 subsequently become aware of what the criteria
 9 were, but I didn't know the criteria until
 10 last night.
 11 MR. PIKE:
 12 Q. Okay, that's my question. Thank you very
 13 much.
 14 THE COMMISSIONER:
 15 Q. All right, Mr. Clements, did you have any
 16 questions today?
 17 MR. CLEMENTS:
 18 Q. Just one.
 19 DR. BRENDAN MULLEN, EXAMINATION BY MR. SIMON CLEMENTS
 20 MR. CLEMENTS:
 21 Q. Dr. Mullen, is there any information that you
 22 would like to give to the Commissioner on the
 23 training of pathologists, regarding IHC
 24 procedures and your comments generally on that
 25 topic?

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1 DR. MULLEN:
 2 A. This will be, I wanted an opportunity to speak
 3 on one of my major concerns, I mean, I think
 4 Ms. Wegrynowski spoke about her concerns about
 5 having adequately training medical
 6 technologists. I want to mirror that for the
 7 training of pathologists. At the moment
 8 pathologists are focused on, I should say
 9 pathology training programs are focused on the
 10 cutting edge, the molecular diagnostics.
 11 We've lost track of, as we can see from this
 12 material, the necessity to be able to analyze
 13 routine material and to do any of the special
 14 stains that include in immunohistochemistry.
 15 So if one of the recommendations or I don't
 16 want to prejudge what you're going to say, is
 17 that the training programs be very sensitive
 18 to the requirements for basic training, that
 19 the diagnosis, the processing of tissue, the
 20 interpretation of tissue be enhances, not at
 21 the expense of the cutting edge, but be
 22 preserved and enhanced, that's basically -
 23 THE COMMISSIONER:
 24 Q. So the point being that in our rush to the
 25 latest in technology, we should not forget

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1 that there are basics there that everybody
 2 should know.
 3 DR. MULLEN:
 4 A. Yes, that's correct. You have to walk before
 5 you can run.
 6 THE COMMISSIONER:
 7 Q. Thank you.
 8 DR. MULLEN:
 9 A. That was all, thank you.
 10 THE COMMISSIONER:
 11 Q. Was there anything arising, Mr. Coffey?
 12 DR. BRENDAN MULLEN, EXAMINATION BY BERNARD COFFEY, Q.C.
 13 COFFEY, Q.C.:
 14 Q. Yes, just one or two, Commissioner, if I
 15 could? Just Doctor, something that Mr.
 16 Simmons raised with you. I think he pointed--
 17 if we could, please, Registrar, Exhibit P-
 18 1811? And go to page three, please? I
 19 believe, if we could -
 20 DR. MULLEN:
 21 A. Which one was it?
 22 COFFEY, Q.C.:
 23 Q. There was here, down--I believe Mr. Simmons
 24 referred you to the -
 25 DR. MULLEN:

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1 A. 7788
 2 COFFEY, Q.C.:
 3 Q. Yes, 99SU7788, it was a block 1B and a block
 4 1C from that specimen, and he referred you to
 5 the fact that in the block 1B, your analysis,
 6 as reported in the retrospective review was
 7 less than one for ER and zero for PR, and then
 8 on block 1C, which is a different block, the
 9 slides from that you reported as two for ER
 10 and zero for PR.
 11 DR. MULLEN:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. That sort of--well, the zero for the PR are
 15 identical.
 16 DR. MULLEN:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. The difference between one block reporting at
 20 less than one and a block, that's block 1B,
 21 and block 1C reporting at two, is that sort of
 22 a difference, bearing in mind that, I take it,
 23 the two different blocks are two different
 24 pieces of tissue?
 25 DR. MULLEN:

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1 A. That is correct.
 2 COFFEY, Q.C.:
 3 Q. Is that expected or reasonable in the
 4 circumstances, do you believe?
 5 DR. MULLEN:
 6 A. Yes, yes. The implication here in our
 7 situation that one would trigger therapy, the
 8 other one wouldn't. That's -
 9 COFFEY, Q.C.:
 10 Q. Yes.
 11 DR. MULLEN:
 12 A. But, you know, the difference between a one
 13 and a two is--you know, there's a 50 percent
 14 difference, but it's -
 15 COFFEY, Q.C.:
 16 Q. It's one in 100 as opposed to two in 100?
 17 DR. MULLEN:
 18 A. Yes. Yes, you have to remember that.
 19 COFFEY, Q.C.:
 20 Q. And if we could, please, again something that
 21 Mr. Simmons asked you about a particular
 22 instance, Exhibit, Registrar, P-1837, page
 23 one? This is the April 2008 spreadsheet.
 24 DR. MULLEN:
 25 A. Yes, okay.

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1 COFFEY, Q.C.:
 2 Q. And Mr. Simmons, in fact, he referred you, I
 3 believe, to ID No.--the first row, ID No. 6.
 4 As it turns out, the specimen number is
 5 97SU6297. It's block A and as we come across
 6 here, he indicated to you, of course, that
 7 you--had you indicate that well, looking at
 8 the original Newfoundland report, Newfoundland
 9 and Labrador original pathology report, and if
 10 you could, and you have here, looking at the
 11 piece of paper you've reported here that you
 12 interpreted and recorded it with the ER was
 13 their reported as negative and PR as 90.
 14 DR. MULLEN:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. And that he had you indicate though that N in
 18 this context, you wouldn't know the cut off
 19 was one, 10 or 30?
 20 DR. MULLEN:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. And therefore it could be variable and
 24 therefore, in calling it as Mount Sinai
 25 Hospital discordant, it -

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1 DR. MULLEN:
 2 A. I may have taken liberties because my value is
 3 zero.
 4 COFFEY, Q.C.:
 5 Q. Yes.
 6 DR. MULLEN:
 7 A. So I would have -
 8 COFFEY, Q.C.:
 9 Q. That would be zero in the context of, I take
 10 it, your looking at an original Newfoundland
 11 slide?
 12 DR. MULLEN:
 13 A. Yes, this is the original of Newfoundland, so
 14 the negative -
 15 COFFEY, Q.C.:
 16 Q. And just to put this in context, if we could
 17 bring up, please, Exhibit P-1811, page 14,
 18 please, and I'm looking at that, if we could,
 19 just a moment please, Commissioner, if I
 20 could, and bearing in mind or recalling that
 21 the specimen number was 97SU6297.
 22 DR. MULLEN:
 23 A. Yes, okay, there it is.
 24 COFFEY, Q.C.:
 25 Q. And if we go down toward the bottom exactly

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1 there, Doctor, toward the bottom of the page,
 2 it's about the 1-2 -
 3 DR. MULLEN:
 4 A. 80/90.
 5 COFFEY, Q.C.:
 6 Q. - eighth from the bottom.
 7 DR. MULLEN:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. And we come across there, it's block A and in
 11 January or before that, but certainly by
 12 January of 2006, on block A, the slides
 13 prepared at Mount Sinai, you had reported the
 14 ER as 80 and the PR as 90?
 15 DR. MULLEN:
 16 A. That's correct.
 17 COFFEY, Q.C.:
 18 Q. So I gather that in terms of the issue of
 19 concordance or discordance, in fact -
 20 DR. MULLEN:
 21 A. Whether it was 30 -
 22 COFFEY, Q.C.:
 23 Q. The slide, the PR slide that you produced at
 24 Mount Sinai, you called as 90?
 25 DR. MULLEN:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And apparently, and looking at the original
 4 report from the pathology, who's unspecified,
 5 the report that was sent to you, and you
 6 looked at, you recorded or noted that that
 7 pathologist, back in apparently 1997, had
 8 recorded the PR as 90 as well?
 9 DR. MULLEN:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. But the pathologist back in '97 had recorded
 13 the ER as negative, N negative, whatever that
 14 might be.
 15 DR. MULLEN:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. However, you had -
 19 DR. MULLEN:
 20 A. Zero.
 21 COFFEY, Q.C.:
 22 Q. You had zero for what you saw -
 23 DR. MULLEN:
 24 A. On the original slide.
 25 COFFEY, Q.C.:

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1 Q. And therefore perhaps agreeing with what he
 2 was seeing there, but on the--but when on a
 3 retrospective slide, the one from Mount Sinai,
 4 the one processed at Mount Sinai, you had
 5 recorded it or reported it, the ER has 80?
 6 DR. MULLEN:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. And there would be, I take it, under any--
 10 would there be any circumstances under which
 11 80 and negative would not be discordant?
 12 DR. MULLEN:
 13 A. No, if I remember correctly, the cut off in
 14 '97, I don't know when you changed to ten, it
 15 was 30. Then it subsequently went to ten, and
 16 I'm not sure, through my analysis or through
 17 my data when it was called--when it changed to
 18 ten.
 19 COFFEY, Q.C.:
 20 Q. But even from 30 to 80, I take it, that would
 21 be discordant?
 22 DR. MULLEN:
 23 A. Yes, it would be discordant, yes.
 24 COFFEY, Q.C.:
 25 Q. Just wanted to--and again, they're the

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1 questions I have, Commissioner. I do want to
 2 thank you, Doctor.
 3 THE COMMISSIONER:
 4 Q. All right, thank you very much.
 5 DR. MULLEN:
 6 A. You're welcome.
 7 THE COMMISSIONER:
 8 Q. Thank you all. This comes--marks the end of a
 9 long week, and I'm sure for you, Dr. Mullen, I
 10 want to thank you very much for having come
 11 all this way, you and the many others from
 12 Mount Sinai who've helped us during this week.
 13 We are most grateful to you and wish you a
 14 safe journey home.
 15 DR. MULLEN:
 16 A. Thank you.
 17 THE COMMISSIONER:
 18 Q. Thank you, Mr. Clements, for your contribution
 19 as well, and we wish you, as well, a safe
 20 journey back. As far as I know, this is our
 21 last witness from Mount Sinai, so we're not
 22 likely to see Mr. Clements again in this
 23 process. Perhaps in another forum, Mr.
 24 Clements.
 25 COFFEY, Q.C.:

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1 Q. Well, I won't commit to that, but right now,
 2 it's not anticipated, but I'm not giving any
 3 commitment.
 4 THE COMMISSIONER:
 5 Q. All right.
 6 DR. MULLEN:
 7 A. I would prefer a commitment on the record.
 8 COFFEY, Q.C.:
 9 Q. Thank you, Doctor.
 10 THE COMMISSIONER:
 11 Q. Which I don't blame you.
 12 COFFEY, Q.C.:
 13 Q. You won't be back though.
 14 DR. MULLEN:
 15 A. Thank you.
 16 THE COMMISSIONER:
 17 Q. I remind everybody that we will begin sittings
 18 next week on Wednesday, so you can enjoy that
 19 holiday that you lost this week on Monday of
 20 this week. Yes, next week, sorry. The
 21 holiday that you lost on Monday, you'll get on
 22 this Monday, and we'll see you all on
 23 Wednesday at 9:30.
 24 COFFEY, Q.C.:
 25 Q. Thank you, Commissioner.

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1 THE COMMISSIONER:
 2 Q. Thank you.
 3 Upon conclusion.

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1 CERTIFICATE
 2 I, Judy Moss, hereby certify that the foregoing is
 3 a true and correct transcript in the matter of the
 4 Commission of Inquiry on Hormone Receptor Testing,
 5 heard on the 27th day of June, A.D., 2008 before
 6 the Honourable Justice Margaret A. Cameron,
 7 Commissioner, at the Commission of Inquiry, St.
 8 John's, Newfoundland and Labrador and was
 9 transcribed by me to the best of my ability by
 10 means of a sound apparatus.
 11 Dated at St. John's, Newfoundland and Labrador
 12 this 27th day of June, A.D., 2008
 13 Judy Moss

Inquiry on Hormone Receptor Testing

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Inquiry on Hormone Receptor Testing

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