

COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 15, 2008

Appearances:

- Bernard Coffey, Q.C. Commission Co-counsel
- Sandra Chaytor, Q.C./Mandy Woodland 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./Darlene Russell. Members of the Breast Cancer
. Testing Class Action

- Mark Pike NL Medical Association
- Jennifer Newbury Canadian Cancer Society (NL Division)
- Blair Pritchett. Central, Western and Labrador-Grenfell
. Regional Integrated Health Authorities

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Certificate

1 THE COMMISSIONER:

2 Q. Ms. Chaytor.

3 MR. KENNETH GREEN, RESUMES STAND, EXAMINATION BY SANDRA

4 CHAYTOR, Q.C. (CONT'D)

5 CHAYTOR, Q.C.:

6 Q. Good morning, Commissioner. Good morning, Mr.

7 Green.

8 MR. GREEN:

9 A. Good morning.

10 CHAYTOR, Q.C.:

11 Q. When we broke last time, I believe, Mr. Green,

12 we were looking at some continuing education

13 that you've done in the past couple of years.

14 MR. GREEN:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. If we could have, please, Registrar, P-2167?

18 And perhaps, Mr. Green, you could tell us what

19 this is, which course this was and when you

20 took this course?

21 MR. GREEN:

22 A. This is one of the NSH conferences that I

23 attended.

24 CHAYTOR, Q.C.:

Page 5

1 Q. Sorry, I'm just going to ask you to speak up
 2 because we're competing with the air
 3 conditioners today.
 4 MR. GREEN:
 5 A. Okay.
 6 CHAYTOR, Q.C.:
 7 Q. Thank you.
 8 MR. GREEN:
 9 A. These are workshops at the NSH conferences,
 10 which I attended. The first one is
 11 Fluorescence In Situ Hybridization. Second
 12 one is HER2, What's New? The third one is How
 13 to Make an Antibody Work in
 14 Immunohistochemistry. Fourth one is Procedure
 15 Manuals and Quality Assurance Document
 16 Control, and the last one is Challenges in
 17 Providing IHC Service.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, and this is from the National Society
 20 for Histotechnology. What is that
 21 association? What is that group?
 22 MR. GREEN:
 23 A. The National Society of Histotechnology is a
 24 society based in the United States. It
 25 promotes professional and educational services

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1 for the members.
 2 CHAYTOR, Q.C.:
 3 Q. And is this the first time--this is September
 4 2006. Is this the first time you attended one
 5 of their symposiums or conventions?
 6 MR. GREEN:
 7 A. I attended two. One was in 2006, I think
 8 probably one in 2005.
 9 CHAYTOR, Q.C.:
 10 Q. Okay. We saw last day you attended one in
 11 September 2005 as well.
 12 MR. GREEN:
 13 A. Yes.
 14 CHAYTOR, Q.C.:
 15 Q. So that was the same society, was it?
 16 MR. GREEN:
 17 A. Same society.
 18 CHAYTOR, Q.C.:
 19 Q. Same group, okay, and what did you do upon
 20 coming back then from this? Did you undertake
 21 any instruction for the other technologists?
 22 MR. GREEN:
 23 A. After I came back, I presented a lecture in
 24 our academic pathology rounds so that the
 25 technologists and the pathologists would

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1 benefit from some of the information that we
 2 brought back.
 3 CHAYTOR, Q.C.:
 4 Q. And if we could see, please, 2169? And this
 5 is indicated to be from that symposium
 6 convention and there's a number of--there's a
 7 slide presentation here. Is this the
 8 presentation you would have given?
 9 MR. GREEN:
 10 A. Yes.
 11 CHAYTOR, Q.C.:
 12 Q. And was there anything in particular that you
 13 found useful to you at that convention?
 14 MR. GREEN:
 15 A. There was a lot of information that we brought
 16 back. There was a lot of information on
 17 fixation, information on the variables that
 18 affect staining.
 19 CHAYTOR, Q.C.:
 20 Q. And I take it that was new information for
 21 you?
 22 MR. GREEN:
 23 A. Yes.
 24 CHAYTOR, Q.C.:
 25 Q. And if we could have, please, 2168? And this

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1 is entitled Immunohistochemistry Basics, Ken
 2 Green, IHC Laboratory. Who did you give this
 3 presentation to?
 4 MR. GREEN:
 5 A. This presentation was also given in house to
 6 the academic pathology rounds, at the request
 7 of Dr. Bev Carter.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and would this also have been following
 10 a convention that you attended?
 11 MR. GREEN:
 12 A. Yeah, that's also another NSH convention.
 13 CHAYTOR, Q.C.:
 14 Q. Okay. So is it a policy now that if a person
 15 attends a convention, then they're expected to
 16 come back and do a continuing education
 17 presentation for others?
 18 MR. GREEN:
 19 A. That's correct.
 20 CHAYTOR, Q.C.:
 21 Q. And if we could also have, please, 2171? And
 22 is this your presentation or a presentation
 23 you received at the convention?
 24 MR. GREEN:
 25 A. It's my presentation, presentation with

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1 information that I used from different
 2 lectures and put them all together in one.
 3 CHAYTOR, Q.C.:
 4 Q. And you would have done this in house, too, I
 5 take it?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. For the other technologists?
 10 MR. GREEN:
 11 A. Yes.
 12 CHAYTOR, Q.C.:
 13 Q. And anybody else?
 14 MR. GREEN:
 15 A. Pathology residents and pathologists who
 16 wished to attend.
 17 CHAYTOR, Q.C.:
 18 Q. And are there any other presentations that
 19 you've done?
 20 MR. GREEN:
 21 A. Aside from the presentation when I returned
 22 from Jewish General.
 23 CHAYTOR, Q.C.:
 24 Q. Yes, I believe we spoke about that one last
 25 week.

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1 MR. GREEN:
 2 A. Yes, and when students from the College come
 3 through the career lab, they come back to the
 4 IHC department and I will go through the
 5 principles and what we do in the lab down
 6 there.
 7 CHAYTOR, Q.C.:
 8 Q. Okay. Mr. Green, we understand that ER/PR
 9 testing did resume at the Health Sciences
 10 Laboratory in February 2007. Were you
 11 involved in the process getting the lab ready
 12 to resume testing at that time?
 13 MR. GREEN:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. And perhaps you could tell us about that.
 17 What happened in order to prepare the lab for
 18 the resumption of testing?
 19 MR. GREEN:
 20 A. I worked with Dr. Ford Elms. We revalidated
 21 the antibodies involved, ER/PR antibodies. We
 22 ran our protocols against known in-house
 23 patients of which we had the results from
 24 Mount Sinai, and then we ran a series of
 25 slides against our--using our protocols

Page 11

1 against those known results.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. So you ran your protocols against
 4 patients with normal results and that was
 5 based on the results from Mount Sinai?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. Were those the results of the testing that had
 10 been taken place since August 2005, the go-
 11 forward cases from August 2005 at Mount Sinai?
 12 MR. GREEN:
 13 A. It probably could be those, plus other cases,
 14 historical cases that had been sent out for
 15 consult before, and Dr. Robb had done quite a
 16 bit of work on the ER/PR and we had a lot of
 17 his cases that he had known ER/PR results from
 18 external areas, plus he had known results from
 19 FISH.
 20 CHAYTOR, Q.C.:
 21 Q. I'm sorry, Dr. Robb that was?
 22 MR. GREEN:
 23 A. Dr. Robb, Desmond Robb.
 24 CHAYTOR, Q.C.:
 25 Q. Desmond Robb, okay, so he had done that

Page 12

1 obviously quite some time before?
 2 MR. GREEN:
 3 A. Yes.
 4 CHAYTOR, Q.C.:
 5 Q. And what was it of his work that you used?
 6 MR. GREEN:
 7 A. He did work on ER/PR and he had sent his cases
 8 away for external testing and also some of his
 9 cases were also sent away for validation with
 10 FISH, which is the gold standard for checking
 11 out ER/PR.
 12 CHAYTOR, Q.C.:
 13 Q. Where had Dr. Robb sent his tests for external
 14 testing?
 15 MR. GREEN:
 16 A. I'm not sure.
 17 CHAYTOR, Q.C.:
 18 Q. Okay. Do you know what time frame that would
 19 have been?
 20 MR. GREEN:
 21 A. A lot of the blocks that we used were in the
 22 '90s, '96, '97, '98.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and do you know what process those
 25 blocks would have been put through? How would

Page 13

1 they have been processed?

2 MR. GREEN:

3 A. They would have been processed the same as all

4 other blocks at the Health--those were mostly

5 Health Science blocks.

6 CHAYTOR, Q.C.:

7 Q. Okay, and so there was a period of time then

8 that Dr. Robb was sending his ER/PRS out for

9 testing?

10 MR. GREEN:

11 A. He was doing research.

12 CHAYTOR, Q.C.:

13 Q. Yes.

14 MR. GREEN:

15 A. So he would have sent his slides to places

16 that were doing ER/PR. I guess he was

17 correlating his results with theirs.

18 CHAYTOR, Q.C.:

19 Q. And do you know what type of research Dr. Robb

20 was doing?

21 MR. GREEN:

22 A. I'm not sure.

23 CHAYTOR, Q.C.:

24 Q. And who do you think might be able to tell us

25 that?

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1 MR. GREEN:

2 A. The information is probably available at the

3 Health Science, probably Barry Dyer.

4 CHAYTOR, Q.C.:

5 Q. But you understand this was through--this was

6 ER/PR that he was doing research regarding?

7 MR. GREEN:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. And in terms then of starting up in February

11 2007, you said that you revalidated ER/PR.

12 Perhaps you could just tell us basically how--

13 it was you and Dr. Elms, I understand from

14 your answer, worked on that?

15 MR. GREEN:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. How you, in fact, went about it, like what

19 actually had to be done to, as you say,

20 revalidate the ER and PR?

21 MR. GREEN:

22 A. Dr. Elms would do a search on the computer,

23 find patients that were previously done that

24 we had external verification for. We would

25 take those same blocks. We would run our

Page 15

1 antibody. We were using prediluted

2 antibodies, so we couldn't change the antibody

3 dilution, and we would try different primary

4 antibody incubation times and we would try

5 different antigen retrieval.

6 CHAYTOR, Q.C.:

7 Q. So different antigen retrieval times?

8 MR. GREEN:

9 A. Yes.

10 CHAYTOR, Q.C.:

11 Q. Length of times.

12 MR. GREEN:

13 A. When Dr. Elms found the protocol that he was

14 happy with--we would try most of the trials on

15 control blocks first. When we found a

16 protocol that he was happy with, we would take

17 that protocol and run those against the

18 patients that we knew the results of, and he

19 would correlate those results with the results

20 we ran.

21 CHAYTOR, Q.C.:

22 Q. Okay, and did you change your incubation times

23 as well?

24 MR. GREEN:

25 A. The incubation time, primary antibody

Page 16

1 incubation time?

2 CHAYTOR, Q.C.:

3 Q. Yes.

4 MR. GREEN:

5 A. During the validation, we would try different

6 antibody incubation times.

7 CHAYTOR, Q.C.:

8 Q. Okay, and the protocols that you came up with,

9 or the results of the protocol, the slides

10 that you produced, did you involve the Breast

11 Group at all in analysing those? I understand

12 at that point in time Dr. Carter and Dr. Cook

13 were considered the Breast Group, I believe.

14 Were they involved then in the process?

15 MR. GREEN:

16 A. They would be involved too on the--when we set

17 up the criteria for the Breast Group, they

18 would be involved in checking the controls and

19 we also ran a system where we had negative

20 controls on every patient. We set up a system

21 where--by this time, we had been putting

22 positive controls on all slides, so there

23 would be a positive control on each ER and

24 there would be a positive control on each PR,

25 and the Breast Group was involved in checking

Page 17

1 out the--we had a triple control for the ER
 2 and the PR. A triple control consists of an
 3 ER slide which has a patient who has breast
 4 cancer, which is non-expresser, which would be
 5 a negative. We would have an intermediate,
 6 which would be a low expresser or mid line
 7 expresser, and we would have a high expresser
 8 ER on the same slide, and those would be run
 9 as a batch control, in addition to the
 10 positive control and the negative controls per
 11 patient.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and the idea of having the three
 14 different intensities in your control on your
 15 slide, that was taking place prior to 2005, we
 16 understand, or sometime in 2005. Is that
 17 correct?
 18 MR. GREEN:
 19 A. The triple control came later.
 20 CHAYTOR, Q.C.:
 21 Q. It was only one control prior to 2005?
 22 MR. GREEN:
 23 A. Yes, it was only a positive control per
 24 patient.
 25 CHAYTOR, Q.C.:

Page 18

1 Q. Okay. So this idea of the three different--
 2 the triple control, as you call it, that came
 3 in 2007?
 4 MR. GREEN:
 5 A. With the formation of the Breast Group.
 6 CHAYTOR, Q.C.:
 7 Q. With the formation of the Breast Group, okay,
 8 and so that was used for the first time then,
 9 as your--as part of your process when you
 10 resumed in February 2007?
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. At the end of the day, do you know how many
 15 slides, test slides were run prior to resuming
 16 in February 2007?
 17 MR. GREEN:
 18 A. Probably hundreds.
 19 CHAYTOR, Q.C.:
 20 Q. Hundreds, and was there records kept of all of
 21 that?
 22 MR. GREEN:
 23 A. There are records, yes.
 24 CHAYTOR, Q.C.:
 25 Q. And at the end of the day then, prior to

Page 19

1 starting up, was there any difference in the
 2 protocol that ultimately was chosen as
 3 compared to the one that had been running
 4 prior to August 2005?
 5 MR. GREEN:
 6 A. The protocol that we ended up with was very
 7 similar to the one that we had, the 46 and 48
 8 protocol that we had run since starting up the
 9 Ventana. I think the primary antibody
 10 incubation time may have changed by a couple
 11 of minutes.
 12 CHAYTOR, Q.C.:
 13 Q. So other than that, changing the incubation
 14 time of the primary antibody by a couple of
 15 minutes, the protocol was basically protocols
 16 46 and 48 that you had been running since
 17 April of 2004?
 18 MR. GREEN:
 19 A. Yes, same clones, same antibodies, antigen
 20 retrieval, but the primary antibody incubation
 21 time was altered slightly. We also
 22 revalidated again later when one of the
 23 recommendations was to switch from the ER 6F11
 24 clone to the more sensitive SP1.
 25 CHAYTOR, Q.C.:

Page 20

1 Q. Okay, and who was involved in that process of
 2 revalidation at that time?
 3 MR. GREEN:
 4 A. Dr. Ford Elms.
 5 CHAYTOR, Q.C.:
 6 Q. And?
 7 MR. GREEN:
 8 A. And myself.
 9 CHAYTOR, Q.C.:
 10 Q. So same, both of you again?
 11 MR. GREEN:
 12 A. And we used the same protocols we used before,
 13 but when we ended up with the protocol for the
 14 new antibody SP1, the primary antibody
 15 incubation time went back down from 24 minutes
 16 down to the eight minutes.
 17 CHAYTOR, Q.C.:
 18 Q. Down to, I'm sorry?
 19 MR. GREEN:
 20 A. Down to eight minutes.
 21 CHAYTOR, Q.C.:
 22 Q. Eight minutes.
 23 MR. GREEN:
 24 A. So this was a much more sensitive clone.
 25 CHAYTOR, Q.C.:

Page 21

1 Q. And do you know how many tests you ran prior
 2 to being satisfied with that validation
 3 process?
 4 MR. GREEN:
 5 A. It would have been hundreds.
 6 CHAYTOR, Q.C.:
 7 Q. Hundreds as well?
 8 MR. GREEN:
 9 A. Yeah.
 10 CHAYTOR, Q.C.:
 11 Q. And I take it the documentation for that was
 12 kept as well?
 13 MR. GREEN:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. And was the Breast Group also involved? Was
 17 Dr. Carter also involved in that process?
 18 MR. GREEN:
 19 A. Yes, from the beginning, yes.
 20 CHAYTOR, Q.C.:
 21 Q. So I hear what you're saying about there being
 22 very little difference in the protocol that
 23 ultimately was used, other than the incubation
 24 time. I take it though there had been a
 25 number of other changes implemented to the

Page 22

1 laboratory prior to February 2007?
 2 MR. GREEN:
 3 A. Yes, we -- we had endeavoured to keep more
 4 documentation to record the antibodies as they
 5 entered the lab, and all the solutions that we
 6 used in the lab, the pH on the reaction buffer
 7 that we use on the system were all now
 8 recorded.
 9 CHAYTOR, Q.C.:
 10 Q. And had any external proficiency testing taken
 11 place? For example, in doing your validation,
 12 had you sent any of the slides out for any
 13 other laboratory or other pathology group to
 14 review?
 15 MR. GREEN:
 16 A. In December, 2005, we sent out first slides
 17 out to UK NEQAS for external -- that was our
 18 first external quality review, December, 2005,
 19 with UK NEQAS, and part of those antibodies
 20 which we sent out were the ER/PRs.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and you're involved, I take it, or were
 23 you involved at that point in time in the UK
 24 NEQAS program?
 25 MR. GREEN:

Page 23

1 A. Barry Dyer asked me to set up the program in
 2 our lab.
 3 CHAYTOR, Q.C.:
 4 Q. And maybe you can tell us then what exactly is
 5 the UK NEQAS external proficiency program?
 6 MR. GREEN:
 7 A. The UK NEQAS external -- UK NEQAS stands for
 8 the United Kingdom National External Quality
 9 Assessment Service, and it's been in existence
 10 for about thirty years. They send slides to
 11 be interpreted. Pathologists and
 12 technologists will assess the slides. The
 13 pathologists from an interpretive perspective
 14 and the technologist from a technical
 15 perspective. We also stain our in-house
 16 controls. All slides are returned to the UK
 17 for an independent and an objective and
 18 impartial report on their performance enabling
 19 them to identify any weaknesses, and you're
 20 given a code so that there's some -- nobody
 21 knows who sends the slides. So it's kind of a
 22 blind test.
 23 CHAYTOR, Q.C.:
 24 Q. So they send you their slides and you stain
 25 their slides?

Page 24

1 MR. GREEN:
 2 A. That's correct.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and the first batch was done, you said,
 5 December, 2005, and were those specifically
 6 ER/PR slides?
 7 MR. GREEN:
 8 A. ER/PR slides, plus some lymphoma antibodies
 9 also.
 10 CHAYTOR, Q.C.:
 11 Q. What kind of volume, how many slides would
 12 have been sent out?
 13 MR. GREEN:
 14 A. To UK NEQAS?
 15 CHAYTOR, Q.C.:
 16 Q. Yes.
 17 MR. GREEN:
 18 A. They send in maybe 10/12 slides, and on those
 19 slides we will an ER and a PR, and we will use
 20 our in-house tissue, our in-house controls,
 21 and we will use the same protocol on our in-
 22 house slides. We assess the slides and we
 23 give them a mark of 20, and then we send those
 24 slides away, and they will assess our slides -
 25 - independent assessors will assess the slides

Page 25

1 and they will also give them a mark out of 20.
 2 They will comment on any deficiencies they
 3 see.
 4 CHAYTOR, Q.C.:
 5 Q. Okay. So you did this in December, 2005?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. How often is it done?
 10 MR. GREEN:
 11 A. It's done approximately three times a year.
 12 CHAYTOR, Q.C.:
 13 Q. So I take it, there were three more occasions
 14 throughout 2006 that this was done?
 15 MR. GREEN:
 16 A. That's true.
 17 CHAYTOR, Q.C.:
 18 Q. So there would have been four times that UK
 19 NEQAS had been involved prior to the testing
 20 resuming in February, 2007?
 21 MR. GREEN:
 22 A. Probably three or four, yes.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and total of how many ER slides would
 25 have gone to UK NEQAS for review?

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1 MR. GREEN:
 2 A. With our large volume of slides -- because the
 3 way they work, they send their slides so that
 4 we can test our stain, and we send our control
 5 slides at the same time. So you're probably -
 6 - on each module, you're probably only talking
 7 a half dozen slides each time.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and so it's -- and it's their slides,
 10 their tissue that's been processed?
 11 MR. GREEN:
 12 A. That's been processed and fixed under their
 13 conditions.
 14 CHAYTOR, Q.C.:
 15 Q. Under their conditions, and if there's any
 16 fixation issues in your lab, that wouldn't be
 17 picked up on those slides?
 18 MR. GREEN:
 19 A. Well, what we do, we send our control slides
 20 and our control slides are slides which are
 21 normal tissue -- when I say "normal", I mean
 22 breast tissue which is processed the same as
 23 all our regular tissue.
 24 CHAYTOR, Q.C.:
 25 Q. Yes.

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1 MR. GREEN:
 2 A. So those would be subject to our fixation and
 3 our processing.
 4 CHAYTOR, Q.C.:
 5 Q. And in terms of UK NEQAS identifying any
 6 deficiencies, has there been any issues come
 7 back?
 8 MR. GREEN:
 9 A. On the ER/PR we scored quite well on -- with
 10 no major problems.
 11 CHAYTOR, Q.C.:
 12 Q. And any deficiencies at all noted?
 13 MR. GREEN:
 14 A. Not to my knowledge.
 15 CHAYTOR, Q.C.:
 16 Q. Has there been any indication of any issues
 17 regarding fixation?
 18 MR. GREEN:
 19 A. It was never reported on their comments.
 20 First when we started sending slides to UK
 21 NEQAS, we would send three slides; negative,
 22 intermediate and a positive, and they
 23 suggested that we put all three slides on the
 24 one which makes -- I guess it makes it easier
 25 for them to assess.

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1 CHAYTOR, Q.C.:
 2 Q. All three of the controls?
 3 MR. GREEN:
 4 A. Yes.
 5 CHAYTOR, Q.C.:
 6 Q. So that came from their recommendation?
 7 MR. GREEN:
 8 A. Yes.
 9 CHAYTOR, Q.C.:
 10 Q. And were there any other recommendations or
 11 improvements through the external proficiency
 12 testing?
 13 MR. GREEN:
 14 A. None that come to mind.
 15 CHAYTOR, Q.C.:
 16 Q. And are you also involved then -- perhaps
 17 before we leave that, if we could have a look
 18 please at 2161, and perhaps if you could
 19 identify this document for the Commissioner?
 20 MR. GREEN:
 21 A. That is the -- those are the results that UK
 22 NEQAS returned to us.
 23 CHAYTOR, Q.C.:
 24 Q. And this one is indicated to be December,
 25 2005?

Page 29

1 MR. GREEN:
 2 A. December, 2005, yes.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and the assessors total mark is 16, and
 5 is that out of a total of --
 6 MR. GREEN:
 7 A. Twenty.
 8 CHAYTOR, Q.C.:
 9 Q. And the assessor being somebody from UK NEQAS?
 10 MR. GREEN:
 11 A. That's true.
 12 CHAYTOR, Q.C.:
 13 Q. And this is the antibody ER?
 14 MR. GREEN:
 15 A. That's true.
 16 CHAYTOR, Q.C.:
 17 Q. And if we could look too at 2162, please, and
 18 again this is December, 2005?
 19 MR. GREEN:
 20 A. As you look at that sheet there, you will see
 21 that one of these slides will be the slides
 22 sent from UK NEQAS, their slides.
 23 CHAYTOR, Q.C.:
 24 Q. Okay.
 25 MR. GREEN:

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1 A. The other slide will be our in-house control
 2 slide.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and this here shows that this is self-
 5 assessment?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. And technologist mark, but I don't see -- is
 10 that part filled in there? Do you actually
 11 give yourself a score?
 12 MR. GREEN:
 13 A. Yeah, we will score ourselves and send it off.
 14 CHAYTOR, Q.C.:
 15 Q. And where do we find that? Is that on the
 16 document?
 17 MR. GREEN:
 18 A. That would be on the document that we sent to
 19 them.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, so it's not shown on this?
 22 MR. GREEN:
 23 A. No.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. So that's the type of form. I take it

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1 you received similar forms back and forth
 2 throughout 2006 as well?
 3 MR. GREEN:
 4 A. That's correct.
 5 CHAYTOR, Q.C.:
 6 Q. And that's still continuing today, I take it?
 7 MR. GREEN:
 8 A. It is.
 9 CHAYTOR, Q.C.:
 10 Q. And are you involved in any other external
 11 proficiency testing?
 12 MR. GREEN:
 13 A. We're also involved in the CAP testing,
 14 College of American Pathologists.
 15 CHAYTOR, Q.C.:
 16 Q. And what's the difference, what is the CAP
 17 program?
 18 MR. GREEN:
 19 A. The CAP program is a bit different from the UK
 20 NEQAS program. With the UK NEQAS program, our
 21 slides actually leave and go to independent
 22 assessors. The way the --
 23 CHAYTOR, Q.C.:
 24 Q. So your slides, your actual patient slides
 25 which are processed gets sent?

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1 MR. GREEN:
 2 A. Gets sent.
 3 CHAYTOR, Q.C.:
 4 Q. Okay.
 5 MR. GREEN:
 6 A. But the CAP program, they usually send four or
 7 five case studies and with those case studies
 8 they will send a list of antibodies which you
 9 had to perform, plus a H & E stain. The
 10 pathologists and the technologists will gather
 11 around the multi-headed microscopes and they
 12 will look at each antibody and tell if it's
 13 reactive or non-reactive, and at the end of
 14 the exercise, you will -- there's a list of
 15 possible favoured interpretations and the
 16 pathologists will usually pick one of the
 17 favoured interpretations. Usually four or
 18 five case studies probably involved 50 or 60
 19 slides altogether of various antibodies. Some
 20 of them may be ER or PR depending on what case
 21 studies they send. They may send a case study
 22 for lymphoma, they may send a case study for
 23 breast cancer, depending.
 24 CHAYTOR, Q.C.:
 25 Q. And do you know -- have you done a breast

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1 cancer case yet?
 2 MR. GREEN:
 3 A. There were breast -- there were ER/PRs in some
 4 of those case studies, and what happens, you
 5 do not send those slides away, those slides
 6 are kept in house, but you send away the
 7 information and when the results are
 8 published, you compare your information and
 9 how you rank against all the participants in
 10 the study.
 11 CHAYTOR, Q.C.:
 12 Q. Okay. So your slides that you produced
 13 through that process haven't actually been
 14 evaluated externally?
 15 MR. GREEN:
 16 A. Externally, no, they have not.
 17 CHAYTOR, Q.C.:
 18 Q. And what's evaluated is, I guess, the
 19 diagnosis that the pathologist comes up with,
 20 the answers that you come up with.
 21 MR. GREEN:
 22 A. Yes.
 23 CHAYTOR, Q.C.:
 24 Q. And that's done -- you're describing that in
 25 somewhat of a team approach?

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1 MR. GREEN:
 2 A. It is a team approach.
 3 CHAYTOR, Q.C.:
 4 Q. And is there only one pathologist involved in
 5 that or does that vary?
 6 MR. GREEN:
 7 A. We like to have as many as possible, but the
 8 reality being the pathologists are -- there
 9 are so few pathologists and they are so busy,
 10 that it's very difficult to get many
 11 pathologists to sit down at the one time
 12 because they're just -- they're not available
 13 or they don't have the time. So what we do --
 14 Dr. Ford Elms, well, we know he's going to be
 15 there and he will commandeer as many as he can
 16 physically get at the time to check it.
 17 CHAYTOR, Q.C.:
 18 Q. So it's been a situation where it's been a bit
 19 of an issue to get pathologists to take part
 20 because of the workload?
 21 MR. GREEN:
 22 A. Because of the workload and the physical
 23 numbers. They just don't have the
 24 pathologists. The CAP program is more of an
 25 educational and a teaching program.

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1 CHAYTOR, Q.C.:
 2 Q. Yes.
 3 MR. GREEN:
 4 A. Because when you're gathered around a scope
 5 and you discuss the cases, you discuss the
 6 stains, and that way you'll -- you can get
 7 feedback from the pathologists to the
 8 technologists on the quality of the stains
 9 that you're producing, and we --
 10 CHAYTOR, Q.C.:
 11 Q. How valuable -- from a technologist point of
 12 view, how valuable is that to you?
 13 MR. GREEN:
 14 A. It's very valuable because you will get
 15 instant feedback. Ordinarily you will do IHC
 16 stains, send them out to the pathologists.
 17 They may or may get back to you on the
 18 quality, depending on how difficult the case
 19 is to interpret, but if you sit around the
 20 multi-headed scope, you get difference of
 21 opinions from different pathologists, and if a
 22 stain is not what they're looking for, they
 23 can tell you right there, "maybe this is over-
 24 stained, maybe it's under-stained, you know,
 25 it's not doing what we need it to do".

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1 CHAYTOR, Q.C.:
 2 Q. Okay. Other than Dr. Elms then -- how often
 3 does that take place? How often does the CAP
 4 external process --
 5 MR. GREEN:
 6 A. Probably about the same frequency as the UK.
 7 CHAYTOR, Q.C.:
 8 Q. So about three times a year?
 9 MR. GREEN:
 10 A. About three times a year.
 11 CHAYTOR, Q.C.:
 12 Q. And other than Dr. Elms, who else has
 13 participated in that process?
 14 MR. GREEN:
 15 A. Dr. Lynn Morris-Larkin has participated, and
 16 Dr. Dan Fontaine.
 17 CHAYTOR, Q.C.:
 18 Q. That's it?
 19 MR. GREEN:
 20 A. On a regular basis, yeah.
 21 CHAYTOR, Q.C.:
 22 Q. And I take it -- maybe this is more of a
 23 question for Dr. Denic, but there's been no
 24 schedule set up so that a different
 25 pathologist would participate at least once a

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1 year?

2 MR. GREEN:

3 A. No, not to my knowledge. It's only when -- at

4 first when we started the external quality

5 assurance, it was just another job to do. It

6 was more work, but as we got into using it, we

7 found that it was very valuable. Actually it

8 helped -- it was an educational tool and it

9 helped.

10 CHAYTOR, Q.C.:

11 Q. And do all of the -- are all of the

12 technologists expected to take part in the

13 process?

14 MR. GREEN:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. And all three of you -- is it three of you

18 now?

19 MR. GREEN:

20 A. Yes.

21 CHAYTOR, Q.C.:

22 Q. You do. How is your work currently divided

23 up? We've heard about the rotation that you

24 used to go through. When did the rotation

25 stop and how is your work now divided amongst

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1 the three of you?

2 MR. GREEN:

3 A. The rotation -- we don't rotate through

4 general lab any more. We don't do gross.

5 We're dedicated to IHC. We have three people

6 in IH -- well, one person just retired,

7 another person is in the process of retiring.

8 CHAYTOR, Q.C.:

9 Q. I understand Mr. Simms has retired?

10 MR. GREEN:

11 A. Yes.

12 CHAYTOR, Q.C.:

13 Q. And Ms. Butler is in the process of retiring?

14 MR. GREEN:

15 A. She'll be retiring at the end of this month.

16 So basically that will leave me, plus we have

17 two other people who are training.

18 CHAYTOR, Q.C.:

19 Q. And how long have those two people been with

20 you?

21 MR. GREEN:

22 A. One person has been there since probably

23 October/November of last year, and the other

24 person is coming on board now.

25 CHAYTOR, Q.C.:

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1 Q. Okay, and so you're all in the same area now

2 in terms of the IHC lab, and are there -- how

3 does your day normally work, though, in terms

4 of divvying up the tasks that have to take

5 place?

6 MR. GREEN:

7 A. I usually take -- I'm usually the "go to"

8 person in that department now, and the other

9 person that we have there, we split up the

10 work into one week you are actually running

11 the slides, and the other week you're

12 preparing to run the slides, cutting the

13 sections, organizing the work.

14 CHAYTOR, Q.C.:

15 Q. Do you know whether or not through the CAP

16 program any issues have been identified or any

17 recommendations made with respect to ER and

18 PR?

19 MR. GREEN:

20 A. Not that I'm aware of.

21 CHAYTOR, Q.C.:

22 Q. Do the results -- do you see the results when

23 they come back?

24 MR. GREEN:

25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And nothing has been brought to your

3 attention?

4 MR. GREEN:

5 A. No.

6 CHAYTOR, Q.C.:

7 Q. How long does it take the CAP program where

8 you would be looking through the microscope

9 with the pathologist? How long a process is

10 it to do that assessment?

11 MR. GREEN:

12 A. With the CAP program, depending on the number

13 of case studies and the number of slides, you

14 have five--it's typically five case studies,

15 probably ten to twelve slides on each one.

16 You're probably talking fifty to sixty slides.

17 It's not uncommon to spend a couple of hours

18 under the microscope.

19 CHAYTOR, Q.C.:

20 Q. And I take it that, is that a couple of hours

21 for the whole five case studies?

22 MR. GREEN:

23 A. Yes.

24 CHAYTOR, Q.C.:

25 Q. And is there--can you do a case study or one

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1 or two at a time, is there any necessity to do
 2 them all in the same sitting?
 3 MR. GREEN:
 4 A. You could, but logistics of getting everybody
 5 together, again, once you got everybody in
 6 that room, there's a tendency to lock the
 7 door.
 8 CHAYTOR, Q.C.:
 9 Q. And you find two hours straight, than a half
 10 hour here or there.
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, I hear what you're saying. And again,
 15 though, there's no requirement for anybody to
 16 attend in the way of pathologists?
 17 MR. GREEN:
 18 A. No.
 19 CHAYTOR, Q.C.:
 20 Q. And if we could look, please, at P-0050? And
 21 are the technologists required to attend?
 22 MR. GREEN:
 23 A. Yes, they have to attend, unless for some
 24 reason that there is an urgent case that has
 25 to be done and they can't leave the IHC lab,

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1 everybody will go down.
 2 CHAYTOR, Q.C.:
 3 Q. And has there been a good turn out of the
 4 technologists?
 5 MR. GREEN:
 6 A. Yes, they look forward to--well, it's a
 7 learning tool and it's an opportunity to
 8 learn.
 9 CHAYTOR, Q.C.:
 10 Q. Now, Mr. Green, this is a spreadsheet of
 11 recommendations and there is a number of
 12 versions, it's updated from time to time and
 13 this is the most recently updated that we've
 14 had, April 26, 2007. And there is, I think,
 15 52 recommendations altogether and you will see
 16 the recommendations by either Trish
 17 Wegrynowski for the most part or Dr. Banerjee
 18 and/or Dr. Banerjee. Have you seen this
 19 document before?
 20 MR. GREEN:
 21 A. Yes, it may not be the same version, but most
 22 of the--I'm familiar with the recommendations.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and when did you first see this document
 25 or a version of it?

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1 MR. GREEN:
 2 A. My recollection, it would probably be November
 3 of 2007.
 4 CHAYTOR, Q.C.:
 5 Q. November, 2007, so around the time that you
 6 did the interview with myself and Mr. Coffey?
 7 MR. GREEN:
 8 A. Yes, probably around then, shortly before
 9 that.
 10 CHAYTOR, Q.C.:
 11 Q. So in starting up the process in February,
 12 2007, you weren't provided with a copy of the
 13 recommendations?
 14 MR. GREEN:
 15 A. No. Some of them may have been verbally--the
 16 first time I saw the document itself, not the
 17 spreadsheet, was when it was released by the
 18 Commission.
 19 CHAYTOR, Q.C.:
 20 Q. And so in terms of 52 recommendations, were
 21 these otherwise communicated to you, and in
 22 particular in the timeframe and your work
 23 getting ready for starting up the process
 24 again in February, 2007?
 25 MR. GREEN:

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1 A. Some of the, like the external quality
 2 assurance, I know that one is December, 2005.
 3 I wasn't sure it was on the list, but I had
 4 figured that it was on the list.
 5 CHAYTOR, Q.C.:
 6 Q. Because it was taking place.
 7 MR. GREEN:
 8 A. And a lot of things were taking place, I
 9 didn't necessarily know that there was a
 10 structured list, but it wasn't hard to figure
 11 out that these were things that had to be done
 12 and that they needed to be done, documentation
 13 took on a much more of a priority, standard
 14 operating practices were starting to be
 15 written, pHing of the buffers -
 16 CHAYTOR, Q.C.:
 17 Q. So you were figuring out what must have come
 18 out of the external reviews based on the
 19 changes that were happening?
 20 MR. GREEN:
 21 A. Based on the changes that were happening and
 22 the recording of temperatures on the water
 23 batch, recording temperatures of the
 24 refrigerator, all these things now had to be
 25 done, done daily, so even though no one told

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1 me exactly that they had to be done, it wasn't
 2 hard to figure out that these were
 3 recommendations.
 4 CHAYTOR, Q.C.:
 5 Q. So nobody actually sat you and the other
 6 technologists down and gave you a briefing as
 7 to what needed to be done and why it needed to
 8 be done?
 9 MR. GREEN:
 10 A. No.
 11 CHAYTOR, Q.C.:
 12 Q. And who was it that was telling you, though,
 13 that things like temperature and the pH being
 14 checked, who was telling you that those things
 15 would now be necessary?
 16 MR. GREEN:
 17 A. Barry would tell us, you know, make sure we're
 18 recording temperatures.
 19 CHAYTOR, Q.C.:
 20 Q. And Mr. Green, in terms of--and just looking
 21 down through some of this, and you've seen, of
 22 course, the external reviews now, you've since
 23 seen the external review, in particular, Trish
 24 Wegrynowski. How useful would that have been
 25 to you, to have seen prior to November of

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1 2007?
 2 MR. GREEN:
 3 A. Well it's very difficult to do things if you
 4 don't know--if you don't have a copy or you're
 5 not told exactly what to do. If you had a
 6 clear list of things to do, it's much easier
 7 to implement.
 8 CHAYTOR, Q.C.:
 9 Q. And you were involved in the implementation of
 10 some of these recommendations?
 11 MR. GREEN:
 12 A. Almost all of them.
 13 CHAYTOR, Q.C.:
 14 Q. Almost all of them. If we could look, please,
 15 at P-0114? And, Mr. Green, this is a document
 16 of notes and I'm not really sure of the
 17 author, it may be Heather Predham, but it's
 18 regarding a meeting or some feedback received
 19 from immunohistochemistry technologists, so
 20 yourself and, I take it, others, on May 29th,
 21 2007. Do you remember a meeting on May 29th,
 22 2007 in which feedback was provided?
 23 MR. GREEN:
 24 A. It doesn't ring a bell with me.
 25 CHAYTOR, Q.C.:

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1 Q. Do you remember any meeting with Ms. Predham
 2 to discuss any issues? For example, it says
 3 here "Expressed concerns related to co-
 4 ordination of quality assurance activities for
 5 entire immunohistochemical service. Vast
 6 majority of IHC SOP's not signed off. ER/PR
 7 have been completed, no knowledge or feedback
 8 re: external proficiency testing." Any of
 9 those things sound familiar to you?
 10 MR. GREEN:
 11 A. Generally familiar, but on the external
 12 proficiency testing, I would have been aware
 13 of that.
 14 CHAYTOR, Q.C.:
 15 Q. You would have been?
 16 MR. GREEN:
 17 A. Yes.
 18 CHAYTOR, Q.C.:
 19 Q. So I'm just trying to get a sense if you were
 20 in attendance or had any discussions, whether
 21 it's a meeting or individually checking with
 22 you, whether or not you recall this being
 23 raised around May, 2007, those issues that are
 24 listed here? Also says, "No knowledge of
 25 overall action plan or status of same." Would

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1 that have been a concern of yours at that time
 2 period?
 3 MR. GREEN:
 4 A. It probably would have been a concern.
 5 CHAYTOR, Q.C.:
 6 Q. "Recommended training for technologists to
 7 read controls has not occurred as of May 29th,
 8 2007."
 9 MR. GREEN:
 10 A. Yeah, we had no formal training to read
 11 controls.
 12 CHAYTOR, Q.C.:
 13 Q. Has that since happened?
 14 MR. GREEN:
 15 A. Yes, we now--every day Dr. Ford Elms comes
 16 over and we review all controls before they
 17 leave.
 18 CHAYTOR, Q.C.:
 19 Q. And Dr. Elms does that with you?
 20 MR. GREEN:
 21 A. Yes.
 22 CHAYTOR, Q.C.:
 23 Q. And in February, 2007 when the ER/PR started
 24 up, did he do that? Was that going on
 25 throughout 2007?

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1 MR. GREEN:
 2 A. Not on a regular basis, no.
 3 CHAYTOR, Q.C.:
 4 Q. So when did it start on a regular basis that
 5 he now attends daily?
 6 MR. GREEN:
 7 A. Dr. Ford Elms started to spend a lot more time
 8 in the lab within the last year, within the
 9 last few weeks we are looking, specifically
 10 looking at the controls, but once the breast
 11 group took over the ER/PR, they kind of took
 12 control of the controls on those. We would
 13 read the controls and make sure that they
 14 worked, that the ERs and Prs, the positive
 15 controls worked before we sent them over to
 16 the breast group and they would check them
 17 again when they received them over there.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, so the training right now, in the last
 20 few weeks with Dr. Elms, that's not involving
 21 ER/PR?
 22 MR. GREEN:
 23 A. No, that's all the antibodies.
 24 CHAYTOR, Q.C.:
 25 Q. Oh, all right. And what training have you

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1 had, if any, to read the controls for ER/PR?
 2 MR. GREEN:
 3 A. The training that we received was from Dr.
 4 Ejeckam when he was here. He taught us how to
 5 read the external controls, to recognize if
 6 the stain worked. We weren't required to
 7 report on controls and internal controls is
 8 not in our area of expertise, although he did
 9 show us--Dr. Ejeckam did show us internal
 10 controls for our own knowledge, but it wasn't--
 11 it's not part of our scope of duties.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, but Dr. Ejeckam did take the time to
 14 show you what an internal control is and how
 15 to look for it?
 16 MR. GREEN:
 17 A. He taught us how to read the external
 18 controls, how to look for variability in the
 19 controls. He taught us how to--different
 20 types of breast cancer, the internal controls
 21 in a normal ductal epithelium, as just for
 22 general knowledge, he just wanted us to be
 23 knowledgeable about it, even though it wasn't
 24 part of our job.
 25 CHAYTOR, Q.C.:

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1 Q. And did that happen prior to August, 2005?
 2 MR. GREEN:
 3 A. That would have, it probably happened around
 4 that time, I'm not sure when Dr. Ejeckam left.
 5 CHAYTOR, Q.C.:
 6 Q. He would have still been there in August,
 7 September, 2005, on in through.
 8 MR. GREEN:
 9 A. It would have been happening then.
 10 CHAYTOR, Q.C.:
 11 Q. So was it after this issue of ER/PR arose that
 12 Dr. Ejeckam showed you how to read the
 13 controls for ER/PR?
 14 MR. GREEN:
 15 A. Probably would have been after that time, yes.
 16 CHAYTOR, Q.C.:
 17 Q. Bearing in mind that you were continuing to
 18 run the slides for ER/PR, although they
 19 weren't being read at the time, after August,
 20 2005?
 21 MR. GREEN:
 22 A. Yes, that's true.
 23 CHAYTOR, Q.C.:
 24 Q. So it was around that time?
 25 MR. GREEN:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And there's a second bullet here in bold,
 4 says, "Expressed concerns regarding
 5 communication, requests for project type
 6 working coming from numerous sources, i.e.
 7 clinical chief, IHC chief without explanation
 8 or knowledge of manager." Do you know what
 9 that is referring to and did you have any such
 10 issues?
 11 MR. GREEN:
 12 A. Probably the, the way it's structured, the lab
 13 was set up, when the pathologists were asking
 14 for different protocols to be run, different
 15 slides to be run, probably without keeping the
 16 manager of the lab, Barry Dyer, in the loop,
 17 he wasn't aware of all the requests.
 18 CHAYTOR, Q.C.:
 19 Q. "And requests for documentation are coming in
 20 without knowledge of manager and ER/PR testing
 21 restarted without the knowledge of manager.
 22 The manager informed by technologists after
 23 the fact." And I take it, that's referring to
 24 Mr. Dyer?
 25 MR. GREEN:

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1 A. That's true.
 2 CHAYTOR, Q.C.:
 3 Q. And were you aware of that, that it had
 4 resumed without Mr. Dyer being aware?
 5 MR. GREEN:
 6 A. I knew that we were doing it, I didn't
 7 necessarily know that--I wouldn't have known
 8 that Barry didn't know. I would have assumed
 9 that he had been told, it would have been the
 10 normal course of events for the manager to be
 11 informed.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and in terms of the current situation,
 14 are you--do you have any concerns regarding
 15 communication now in the lab?
 16 MR. GREEN:
 17 A. No, communications have improved a lot since
 18 we had--there was a time when we didn't have a
 19 designated pathologist for IHC, but now that
 20 we have a designated pathologist for IHC,
 21 communication is much better.
 22 CHAYTOR, Q.C.:
 23 Q. And, I take it, that's Dr. Elms?
 24 MR. GREEN:
 25 A. Yes.

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1 CHAYTOR, Q.C.:
 2 Q. And so any questions that you have or any
 3 feedback that you have, Dr. Elms is readily
 4 available to you and the other technologists?
 5 MR. GREEN:
 6 A. Yes, if he's not on site, we can get hold to
 7 him by phone.
 8 CHAYTOR, Q.C.:
 9 Q. Were you also involved in, there was a review
 10 carried out by QMPLS in December, 2007?
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. And what was your involvement in that?
 15 MR. GREEN:
 16 A. Before those people came down, I saw a list
 17 of, a spreadsheet with all those
 18 recommendations. We worked on a lot of those
 19 recommendations to make sure they were in
 20 order.
 21 CHAYTOR, Q.C.:
 22 Q. So that's around the time you were shown the
 23 recommendations' list.
 24 MR. GREEN:
 25 A. Yes, I think they came on December 7th, QMPLS.

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1 CHAYTOR, Q.C.:
 2 Q. Okay, so you were then given the
 3 recommendations, the spreadsheet, and your job
 4 was to get things in order prior to the review
 5 taking place?
 6 MR. GREEN:
 7 A. Some of those--some of them are complete, some
 8 of them had been worked on, so, yeah, we were
 9 to clear up a lot of those at that time.
 10 CHAYTOR, Q.C.:
 11 Q. Okay. And if we could just go back, please,
 12 to P-0050? And again, this is the most recent
 13 version, April 26th, 2007. If you could just
 14 look down through and tell me which ones you
 15 would have worked on in December, 2007, before
 16 QMPLS came back or came in, I should say?
 17 MR. GREEN:
 18 A. Number three, rabbit monoclonal SP1, I'm not
 19 quite sure if we had switched over to SP1 by
 20 that time, but I was getting ready for that
 21 one four months ahead because we ordered in
 22 the antibody and we knew that the SF11
 23 antibody from Ventana was going to be
 24 discontinued, so I wanted--I didn't want to
 25 run out of SF11 and have to start from scratch

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1 with SP1, so we were working on that one.
 2 Dedicated pathologists, that was--
 3 technologists already in place.
 4 CHAYTOR, Q.C.:
 5 Q. When did that happen? When did you stop
 6 rotating and the three of you become assigned
 7 to the IHC lab?
 8 MR. GREEN:
 9 A. I don't know exactly, but by this point it had
 10 been happening for quite awhile. Education
 11 conferences, that was ongoing.
 12 CHAYTOR, Q.C.:
 13 Q. How about number seven, implement Tissue-Tek
 14 X-Press?
 15 MR. GREEN:
 16 A. That's not happening.
 17 CHAYTOR, Q.C.:
 18 Q. That's not happening, okay.
 19 MR. GREEN:
 20 A. Re-institute ER/PR service, that was done.
 21 CHAYTOR, Q.C.:
 22 Q. In February.
 23 MR. GREEN:
 24 A. External quality assurance was done.
 25 CHAYTOR, Q.C.:

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1 Q. What about No. 16, "Procedure manual outlining
 2 the SOP's to be created for all IHC antibodies
 3 and methods including the Ventana operator's
 4 manual"?

5 MR. GREEN:
 6 A. We did a lot on the manual before the QMPLS
 7 people came down.

8 CHAYTOR, Q.C.:
 9 Q. And have you done work on it since?

10 MR. GREEN:
 11 A. It's ongoing. The SOP's will never be
 12 completed, they are living documents, they
 13 will change from year to year, even some of
 14 the new ones that we have in place now, after
 15 they are used, they'll have to be amended and
 16 changed.

17 CHAYTOR, Q.C.:
 18 Q. So what was the status as of December, 2007
 19 when you started working on it, the status of
 20 the SOP's?

21 MR. GREEN:
 22 A. They had been started. I had worked with Dr.
 23 Ford Elms and I did a lot of the ones for the
 24 IHC lab, in particular, the ones that were
 25 specific to IHC. I had written them out,

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1 handwritten those, gave them to him, he had
 2 dictated those onto tape and I think he was
 3 working on secretarial help to put those into
 4 the format that, formalized format for SOP's.

5 CHAYTOR, Q.C.:
 6 Q. And so that was ongoing then after the QMPLS
 7 people came as well?

8 MR. GREEN:
 9 A. Yeah, before, during and after.

10 CHAYTOR, Q.C.:
 11 Q. And I'm going to take you through a manual
 12 that we now have, a lot of the work appears to
 13 be 2008 work, so I take it was the vast
 14 majority of your work done in 2008?

15 MR. GREEN:
 16 A. Probably not the vast majority, but some of it
 17 was ongoing.

18 CHAYTOR, Q.C.:
 19 Q. And you started the process when, December
 20 2007?

21 MR. GREEN:
 22 A. Around there, I would imagine, yes.

23 CHAYTOR, Q.C.:
 24 Q. 18. "Routine equipment maintenance performed
 25 and documented as per company protocols." And

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1 that was completed as of April?

2 MR. GREEN:
 3 A. We now keep those documents, copies on the
 4 walls.

5 CHAYTOR, Q.C.:
 6 Q. "Documented evaluation of IHC antibodies to
 7 ensure sensitivity and specificity of
 8 results".

9 MR. GREEN:
 10 A. That is part and parcel with antibody
 11 validations. We had a lot of antibody
 12 validations going on at the one time. So,
 13 there was a lot of activity in that regard.

14 CHAYTOR, Q.C.:
 15 Q. Okay. Number 29 refers to "laboratory to send
 16 out up to ten cases per month for correlation
 17 of results". Is that to an external lab?

18 MR. GREEN:
 19 A. That is done by the pathologists and for--they
 20 pick ten cases at random. Well, they may not
 21 even pick the cases. I think the QA person
 22 would pick those cases and send them out. I
 23 had no part in that, that would be handled by
 24 the pathologist and the QA.

25 CHAYTOR, Q.C.:

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1 Q. Okay. And then number 31 refers to further
 2 SOPs. Did you also work on those for
 3 accessioning, grossing and fixation?

4 MR. GREEN:
 5 A. I didn't work on those, no.

6 CHAYTOR, Q.C.:
 7 Q. Okay. And 35, "SOPs for tissue processor and
 8 embedding", did you work on those?

9 MR. GREEN:
 10 A. No, the SOPs which I worked on would be IHC
 11 specific.

12 CHAYTOR, Q.C.:
 13 Q. Okay. And so then 37, "SOPs for IHC in
 14 compliance with the clinical and laboratory
 15 standards institute". I take it you worked on
 16 those?

17 MR. GREEN:
 18 A. I worked on those.

19 CHAYTOR, Q.C.:
 20 Q. Okay. And "compilation of antibody
 21 specification sheets".

22 MR. GREEN:
 23 A. I worked on those.

24 CHAYTOR, Q.C.:
 25 Q. "Pipette accuracy and calibration

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1 documentation", number 40, that was in
 2 progress.
 3 MR. GREEN:
 4 A. Yes, I was working on those too.
 5 CHAYTOR, Q.C.:
 6 Q. So, you worked on that as well?
 7 MR. GREEN:
 8 A. Yes.
 9 CHAYTOR, Q.C.:
 10 Q. So, those are some of the things on the list
 11 that you worked on gearing up for QMPLS to
 12 come in.
 13 MR. GREEN:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. Okay. And then the last page, I don't know if
 17 there's anything else there that you can see.
 18 So, when Brian Hewlett came in December 2007,
 19 did you meet with Mr. Hewlett?
 20 MR. GREEN:
 21 A. Yes.
 22 CHAYTOR, Q.C.:
 23 Q. And what was the purpose of your discussions
 24 with Mr. Hewlett?
 25 MR. GREEN:

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1 A. We toured the lab. They looked at our set-up
 2 that we had. They had one person who looked
 3 at the documentation. They had the
 4 pathologists who went over with the breast
 5 group and looked at what they were doing at
 6 St. Clare's. And I met with Brian Hewlett and
 7 Dr. Flynn and the other person there. They
 8 interviewed me for probably three hours, three
 9 to four hours in the afternoon.
 10 CHAYTOR, Q.C.:
 11 Q. And did they also interview the other
 12 technologists, to your knowledge?
 13 MR. GREEN:
 14 A. No, they focused on me.
 15 CHAYTOR, Q.C.:
 16 Q. Focused on you. And do you know why that was?
 17 MR. GREEN:
 18 A. Well, I guess I was probably taking the lead
 19 at that time and I was quite comfortable with
 20 the Ventana system. So, I could answer most
 21 of their questions.
 22 CHAYTOR, Q.C.:
 23 Q. Okay. And we understand they, too, completed
 24 a report. Were you provided a copy of their
 25 report?

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1 MR. GREEN:
 2 A. We were, yes.
 3 CHAYTOR, Q.C.:
 4 Q. You were, after that?
 5 MR. GREEN:
 6 A. Yes.
 7 CHAYTOR, Q.C.:
 8 Q. Okay. Mr. Green, we understand there was a
 9 visual imaging machine also in the lab or
 10 brought into the lab at one point.
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. Was that--do you know who brought it in? Who
 15 was instrumental in having it come in?
 16 MR. GREEN:
 17 A. Dr. Ejeckam was instrumental in approaching
 18 the sales people from Ventana to bring it in
 19 for a in-house education and demonstration.
 20 CHAYTOR, Q.C.:
 21 Q. And what was the purpose of that machine?
 22 What could it be used for?
 23 MR. GREEN:
 24 A. The VIAS is used to--it takes a mathematical
 25 logarithm and the pathologist will view a

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1 piece of tissue on a microscope and there's a
 2 screen set up. He will pick an appropriate
 3 number of screens, probably eight to ten
 4 screens which are suspect. And the machine
 5 will scan those slides and it will give you a
 6 result. And it will take out the human
 7 factor, the variability factor in the reading
 8 of the slides.
 9 CHAYTOR, Q.C.:
 10 Q. And is that machine still at the laboratory?
 11 MR. GREEN:
 12 A. No, it was removed.
 13 CHAYTOR, Q.C.:
 14 Q. And do you know why that--was it ever used
 15 while it was there?
 16 MR. GREEN:
 17 A. It had minimal usage. The reason we know
 18 because the way the system works is it's like
 19 a debit system, a card system with the
 20 machine. And that's how you pay for the
 21 machine. Every time you use the machine, you
 22 debit time from the machine. And when the
 23 debit card is used up, you had to buy a new
 24 debit card. That's how the machine is paid
 25 for. And when the representative came in to

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1 take the machine back, he wasn't very happy
 2 because he said he never this machine a fair
 3 evaluation because there was basically no
 4 usage on your debit card. It was minimal
 5 usage.
 6 CHAYTOR, Q.C.:
 7 Q. Mr. Green, you're aware, of course, about the
 8 issues which arose regarding ER/PR in 2005 and
 9 the number of patients who ultimately had
 10 changed results upon retesting at Mount Sinai.
 11 From a technical point of view, do you have
 12 any opinion as to what may have caused those
 13 changed results?
 14 MR. GREEN:
 15 A. From a technical--I thought about it a lot.
 16 CHAYTOR, Q.C.:
 17 Q. I would think you had a lot of time to think
 18 about it.
 19 MR. GREEN:
 20 A. I've had a lot of time to think about it and I
 21 can give you my thoughts on it. Is that what
 22 you want?
 23 CHAYTOR, Q.C.:
 24 Q. Sure.
 25 MR. GREEN:

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1 A. Okay. These are what I think are possible
 2 contributing factors; fixation, handling of
 3 the surgical specimen from the OR before it
 4 reaches the lab; breast tissue grossing from
 5 bread loafing to the actual size of the
 6 representative block that is submitted and the
 7 fixation required.
 8 From a processing perspective, probably
 9 compromised by large fatty blocks in large
 10 numbers. When you consider that a lot of
 11 specimens are processed at the same time, but
 12 you basically had no problem with all the
 13 other specimens.
 14 From a cutting perspective, breast tissue
 15 being difficult to cut and difficult to adhere
 16 to the slide.
 17 If any of the above are compromised, the
 18 cutting will be compromised and the tissue
 19 specimen will be compromised. So, if the
 20 handling, the grossing, the processing and an
 21 optimal--cutting won't be optimal. Blocks
 22 selection by the pathologist for ER/PR
 23 testing. Blocks should have normal epithelium
 24 and tumour tissue.
 25 Interpretation is a subjective process,

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1 with a 30 percent cutoff point. And a cutoff
 2 point which most people think of positives as
 3 being positives and negative as being
 4 negative. Where in this particular test, if
 5 you had a 30 percent or less positivity, you
 6 would be considered negative. That would be a
 7 factor.
 8 No standardized reporting criteria where
 9 internal controls could be documented or no
 10 statistical correlation to go along with it.
 11 CHAYTOR, Q.C.:
 12 Q. I'm sorry, can you just explain that again or
 13 say that again.
 14 MR. GREEN:
 15 A. Okay. Most statistical or historical
 16 database.
 17 CHAYTOR, Q.C.:
 18 Q. And what do you mean by that?
 19 MR. GREEN:
 20 A. So, if there are statistics that are out there
 21 that a certain percentage of cases in certain
 22 types of cancers should be positive and they
 23 weren't, we had no documentation, no
 24 statistics -
 25 CHAYTOR, Q.C.:

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1 Q. You weren't keeping track of your numbers?
 2 MR. GREEN:
 3 A. Weren't keeping track of those numbers.
 4 CHAYTOR, Q.C.:
 5 Q. And are you doing that now?
 6 MR. GREEN:
 7 A. I'm not sure. I'm not, but it's not in my
 8 area of expertise.
 9 CHAYTOR, Q.C.:
 10 Q. So, the pathologists would be able to answer
 11 that or Barry Dyer?
 12 MR. GREEN:
 13 A. Probably or probably the IT department. I'm
 14 not really sure.
 15 CHAYTOR, Q.C.:
 16 Q. Okay.
 17 MR. GREEN:
 18 A. Dedicated technologists in IHC and dedicated
 19 pathologists to oversee it. The need for
 20 continuing education is ongoing; keep current
 21 with the changes and the methodology and
 22 theory. Like antigen retrieval methodology
 23 which had changed from the DAKO system to the
 24 Ventana system was a major difference which in
 25 hindsight, that we saw. Quality -

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1 CHAYTOR, Q.C.:

2 Q. So, what do you think from the antigen

3 retrieval point of view, could have been an

4 issue with the DAKO system?

5 MR. GREEN:

6 A. Well, when we switched over from DAKO to

7 Ventana, we were right in the middle of the

8 ER/PR episode. And when we started running

9 the ER/PRs on the Ventana system, some people

10 thought that Ventana system was too sensitive.

11 My interpretation is that the Ventana system

12 wasn't too sensitive, it was working the way

13 it should have worked. It seemed to pick up a

14 lot of the specimens that weren't picked up on

15 the old system. And when you compare both

16 systems, the biggest difference was antigen

17 retrieval. The DAKO system having the 20

18 minutes in citrate buffer with a pH 6 and the

19 Ventana system having a standard antigen

20 retrieval which was 60 minutes in a Ph 8.

21 CHAYTOR, Q.C.:

22 Q. Sorry, when you say you switched over to the

23 Ventana, you were right in the middle of the

24 ER/Pr episode.

25 MR. GREEN:

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1 A. Well, I'm not exactly sure of the dates, but I

2 know that -

3 CHAYTOR, Q.C.:

4 Q. You would have switched to the Ventana in

5 April 2004. Was there anything going on with

6 ER/PR at that time?

7 MR. GREEN:

8 A. Not that I know of. I'm looking at it in

9 hindsight, at the systems.

10 CHAYTOR, Q.C.:

11 Q. Okay. So, the issues were going on, is what

12 you're saying, regarding ER/PR, but not

13 detected at that point.

14 MR. GREEN:

15 A. We didn't know and the thing is we didn't know

16 we had a problem until after.

17 CHAYTOR, Q.C.:

18 Q. And in terms of the antigen retrieval, when it

19 was done in the DAKO system, I think you told

20 us before in terms of how that happened and

21 the temperature, the water bath and the length

22 of time for it. How stringent was that in

23 terms of the timing and the temperature for

24 the water bath? How stringent was that and

25 was that something that was really drilled

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1 into you that was a key requirement?

2 MR. GREEN:

3 A. It wasn't stringent in the fact that it was

4 recorded every time, but it was 20 minutes in

5 the antigen retrieval. We didn't vary from

6 that. Now, like, you had to time it with a

7 timer and you had to physically be there when

8 the timer went off. So, there is a

9 possibility for error.

10 CHAYTOR, Q.C.:

11 Q. Yes. And there was a timer and you would have

12 to be there, as you say. Back in your

13 rotation days which you would have been when

14 DAKO machine was there and the more manual

15 process of antigen retrieval, if you weren't

16 there, if you were otherwise engaged, you

17 wouldn't know that the timer went off?

18 MR. GREEN:

19 A. No. The only problem with that is that it

20 would have stayed in antigen retrieval longer

21 than it should have which wouldn't necessarily

22 be a bad thing, in hindsight.

23 CHAYTOR, Q.C.:

24 Q. Yes. It's the under -

25 MR. GREEN:

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1 A. It's the under which would -

2 MR. GREEN:

3 A. Yes, and in terms of gauging the timer or

4 maintenance on the timer or on that equipment,

5 do you know if there was maintenance taking

6 place back in those days?

7 MR. GREEN:

8 A. I don't know, by the time I had--St. Clare's

9 to the Health Science, all the protocols and

10 procedures and validation of those antibodies

11 would have taken place years ahead.

12 CHAYTOR, Q.C.:

13 Q. Yes, but the actual checks on the equipment,

14 ongoing checks on the equipment to make sure

15 that the timers are working, that the

16 temperature is accurate, was any of that

17 taking place?

18 MR. GREEN:

19 A. The only temperature check that we had was a

20 thermometer which we physically put in the

21 solution.

22 CHAYTOR, Q.C.:

23 Q. What if the temperature was too high? Would

24 that have an effect on the tissue or on the

25 antigen retrieval process?

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1 MR. GREEN:
 2 A. No. From my knowledge that I have, knowing
 3 that Mount Sinai now uses a pressure cooker at
 4 121 degrees, a higher temperature probably may
 5 have been an advantage.
 6 CHAYTOR, Q.C.:
 7 Q. Okay. So, a lower temperature -
 8 MR. GREEN:
 9 A. A lower temperature would -
 10 CHAYTOR, Q.C.:
 11 Q. - would be more of a concern.
 12 MR. GREEN:
 13 A. - be more detrimental than a higher
 14 temperature.
 15 CHAYTOR, Q.C.:
 16 Q. And if the heating wasn't long enough?
 17 MR. GREEN:
 18 A. If the heating was too short, it would have
 19 more of an impact than if the temperature had
 20 been too long. If it had been a little bit
 21 longer, you would have more antigen retrieval
 22 time. So, it probably wouldn't have hurt.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. And in those days too, of course, you
 25 would have been diluting your own antibodies?

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1 MR. GREEN:
 2 A. Yes.
 3 CHAYTOR, Q.C.:
 4 Q. ER/PR. And if your dilution was too high or
 5 too low, what effect might that have?
 6 MR. GREEN:
 7 A. The stronger the antibody, the more chance of
 8 getting of more intense reaction. Usually
 9 stronger is better.
 10 CHAYTOR, Q.C.:
 11 Q. And do you remember any discussion about PR
 12 along the way and the PR antibody being too
 13 strong?
 14 MR. GREEN:
 15 A. PR antibody had traditionally been more
 16 intense than the ER antibody.
 17 CHAYTOR, Q.C.:
 18 Q. Okay. I'm sorry, you were giving me a list
 19 then and I stopped you at the antigen
 20 retrieval.
 21 MR. GREEN:
 22 A. These are my observations, yes.
 23 CHAYTOR, Q.C.:
 24 Q. Yes, I understand.
 25 MR. GREEN:

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1 A. Quality assurance program which will be full
 2 time and dedicated would help to attract
 3 trends and keep current information and to
 4 monitor with a technical and a diagnostic
 5 parameters, like a dedicated quality assurance
 6 program which we now have would have helped
 7 back then.
 8 CHAYTOR, Q.C.:
 9 Q. Yes.
 10 MR. GREEN:
 11 A. And technology itself, the new technology
 12 should be embraced to improve and enhance the
 13 science.
 14 One of the workshops that I attended back
 15 in 2005, they were discussing about ER/PR and
 16 the problems with it generally and the
 17 consensus then was that within five years, the
 18 ER/PR technology which we were using would be
 19 obsolete and they would have a new technology.
 20 THE COMMISSIONER:
 21 Q. Sorry, I didn't hear that part, Mr. Green.
 22 You said -
 23 MR. GREEN:
 24 A. Back in 2004/2005 the consensus was that the
 25 technology that we were using then, it would

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1 be obsolete within five years and five years
 2 would bring us up to 2009; that there would be
 3 new technology then, better technology.
 4 THE COMMISSIONER:
 5 Q. Okay.
 6 CHAYTOR, Q.C.:
 7 Q. So, that's on the horizon.
 8 MR. GREEN:
 9 A. Yes. Is there anything else?
 10 MR. GREEN:
 11 A. I think that covers the summation of my
 12 thoughts.
 13 CHAYTOR, Q.C.:
 14 Q. And do you know, is there any plan underway or
 15 in the works to acquire any new technology for
 16 IHC and ER/PR in particular?
 17 MR. GREEN:
 18 A. The future will probably be FISH, in situ
 19 hybridization, but it's a way off yet.
 20 CHAYTOR, Q.C.:
 21 Q. Okay. Thank you. And I'd just like to look
 22 then at the pathology policies, that manual
 23 that we have, Policies and Procedures. This
 24 is P-2157, please, Registrar. And I'm not
 25 going to take you through all of them, but

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1 there are a fair number that you were involved
 2 in the drafting of. So, I'd like to spend a
 3 bit of time on this. It takes a while for it
 4 to come up. Perhaps you can tell us the
 5 volume, the physical copy that I have here is
 6 about an inch and a half thick, say, is there
 7 a book of this nature kept in the laboratory?
 8 MR. GREEN:
 9 A. There's a master copy in the IHC lab.
 10 CHAYTOR, Q.C.:
 11 Q. Okay. And how long has that been the case?
 12 MR. GREEN:
 13 A. It's been there--it had started before the
 14 QMPLS people came down which would be
 15 December of '07 and it's been constantly added
 16 to and updated since then.
 17 CHAYTOR, Q.C.:
 18 Q. Yes. And if it's been revised, does that
 19 appear on the policy, that it's a revised
 20 version.
 21 MR. GREEN:
 22 A. Some of the SOPs will be in draft, will be
 23 stamped "draft", others will be signed off.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. Yes, and a number of those towards the

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1 back are still indicated to be in draft,
 2 there's a number in the back.
 3 MR. GREEN:
 4 A. Yes, that's correct.
 5 CHAYTOR, Q.C.:
 6 Q. Okay. If we could go then to page nine,
 7 please, Registrar? And this is the fixation
 8 policy and I don't think you were involved or
 9 were you in this? It's indicated to have been
 10 Dr. Denic and Mr. Gulliver. And authored by
 11 Catherine Parnell. Were you involved in the
 12 drafting of this?
 13 MR. GREEN:
 14 A. Catherine may have called over and asked
 15 questions from time to time. It was quite
 16 common when she was working on these that if
 17 she wanted something checked, she'd call and I
 18 would check it out for her.
 19 CHAYTOR, Q.C.:
 20 Q. Okay. And this, the original approval date is
 21 indicated to be February 4th, 2008. And it's
 22 to be reviewed February 4th, 2009. So, I take
 23 it there's to be an annual review of the
 24 various policies?
 25 MR. GREEN:

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1 A. Yearly review, yes.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. And the approval date being February
 4 4th, 2008, when the ER/PR testing resumed in
 5 2007, was there a fixation policy in effect
 6 and approved at that point in time?
 7 MR. GREEN:
 8 A. Not to my knowledge.
 9 CHAYTOR, Q.C.:
 10 Q. Currently, I understand that ER/PR is being
 11 sent out again now to Mount Sinai?
 12 MR. GREEN:
 13 A. Yes.
 14 CHAYTOR, Q.C.:
 15 Q. So, it continued up until a few weeks ago,
 16 from February 2007 up until a few weeks ago
 17 though it was taking place in the lab.
 18 MR. GREEN:
 19 A. We still cut the slide sin duplicate and do
 20 the ER/PRs on them before they're sent out.
 21 CHAYTOR, Q.C.:
 22 Q. Okay. So, you're still running a parallel
 23 process in St. John's.
 24 MR. GREEN:
 25 A. Yes. The problem is that we don't have a

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1 breast group anymore.
 2 CHAYTOR, Q.C.:
 3 Q. To read the slides.
 4 MR. GREEN:
 5 A. To read the slides, because one of the
 6 suggestions was we sub-specialize and get a
 7 breast group, but since then, the people who
 8 were involved, one of the pathologists is on
 9 sick leave and the other pathologists has
 10 resigned. So, there is not breast group. We
 11 have to send them out for interpretation.
 12 CHAYTOR, Q.C.:
 13 Q. What's the purpose of running the slides in
 14 St. John's, continuing to do that while
 15 they're being done as well as Mount Sinai.
 16 MR. GREEN:
 17 A. What it does is it keeps our skill up, keep on
 18 doing the slides, when we finally get results
 19 back, we can check those results against the
 20 ones we were sending out to make sure that our
 21 process is still working the way it should
 22 work.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. So, to keep up the technological side
 25 of the skills and then there'd be some

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1 comparison done when the slides come back.
 2 MR. GREEN:
 3 A. Because you don't want to stop and have to
 4 start all over again. At least this way
 5 there's a continuity in the service and there
 6 are duplicate slides there. So, there's no
 7 problem to check those against the ones that
 8 are already done.
 9 CHAYTOR, Q.C.:
 10 Q. And has Dr. Elms or any other pathologist
 11 involved in reading the slides now?
 12 MR. GREEN:
 13 A. No.
 14 CHAYTOR, Q.C.:
 15 Q. So, there's nobody checking the slides as
 16 they're done now?
 17 MR. GREEN:
 18 A. The ER/PR slides?
 19 CHAYTOR, Q.C.:
 20 Q. Yes.
 21 MR. GREEN:
 22 A. Are not checked, no.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. And if we could have page 17, please.
 25 This is handling sub-optimal specimens in

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1 pathology and again the approval date is April
 2 16th, 2008, effective date, April 21st, 2008.
 3 Mr. Green, was there such a policy in place
 4 prior to April of 2008?
 5 MR. GREEN:
 6 A. Not a written policy, no.
 7 CHAYTOR, Q.C.:
 8 Q. Okay. Was there any policy then? What did
 9 you understand then? Was there any policy at
 10 all and if so what did you understand it to
 11 be?
 12 MR. GREEN:
 13 A. For sub-optimal specimens?
 14 CHAYTOR, Q.C.:
 15 Q. Yes.
 16 MR. GREEN:
 17 A. Usually, if there's--we're talking about
 18 labelling here--usually you have to try to
 19 work backwards and find out where the problem
 20 originated, whether it was a fixation problem
 21 or you would have to go back and re-cut the
 22 specimen and start again.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. And you say that was usual, there's
 25 nothing written down and no indication as to

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1 when that would take place?
 2 MR. GREEN:
 3 A. No.
 4 CHAYTOR, Q.C.:
 5 Q. How do you know if a specimen is sub-optimal?
 6 MR. GREEN:
 7 A. Usually the pathologist would bring it to your
 8 attention that the specimen, that they wanted
 9 either a re-cut on a specimen, that means that
 10 the job of a technologist in a pathology lab
 11 is provide the best quality slide for a
 12 pathologist to interpret. If they have a
 13 slide which they are having trouble
 14 interpreting and they will come back and
 15 either ask for it to be re-cut or sometimes if
 16 it's a large specimen, to go back and take
 17 additional blocks. That would be the way that
 18 we would know--that would be the feedback that
 19 we would know that the specimen wasn't
 20 optimal.
 21 CHAYTOR, Q.C.:
 22 Q. Okay. And it says, "specimens received
 23 unfixed for greater than 30 minutes or for an
 24 unknown period of time". Now, I take it
 25 currently, times are recorded.

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1 MR. GREEN:
 2 A. Yes.
 3 CHAYTOR, Q.C.:
 4 Q. When something is put into the fixative and
 5 when it comes out, that's recorded. So, back
 6 prior to this without recording any time, I
 7 take it, you wouldn't know whether or not it
 8 had -
 9 MR. GREEN:
 10 A. There would be no way in knowing.
 11 CHAYTOR, Q.C.:
 12 Q. There'd be no way of knowing. And specimens
 13 in the incorrect fixative or insufficient
 14 volume of fixative, now maybe the insufficient
 15 volume is more apparent, but how would you
 16 know if the specimen is incorrect fixative?
 17 MR. GREEN:
 18 A. It's usually not a problem on the majority of
 19 cases because 10 percent of buffered formalin
 20 is the normal fixative for pathology. If it
 21 came from a small clinic somewhere like that
 22 where someone inadvertently put it in saline
 23 instead of formaldehyde, it would have a
 24 detrimental effect and it probably would not
 25 be picked up until it was at the grossing

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1 bench.
 2 CHAYTOR, Q.C.:
 3 Q. And is there a requirement now that the type
 4 of fixative be recorded?
 5 MR. GREEN:
 6 A. It should be recorded on the specimen bottle
 7 and on the requisition.
 8 CHAYTOR, Q.C.:
 9 Q. And specimens cut by the surgeon in such a way
 10 interfere with the gross or microscopic
 11 evaluation or resection or other clinically
 12 relevant pathological information. That's
 13 something, I take it, the pathologist -
 14 MR. GREEN:
 15 A. You'll have to ask the pathologist about that
 16 one.
 17 CHAYTOR, Q.C.:
 18 Q. Yes, okay. And it says all pathology
 19 specimens are considered precious as sub-
 20 optimal pathology specimen will not be
 21 disregarded. Number three says, "any problems
 22 with fixation, handling, transport, processing
 23 will be addressed as soon as the problem is
 24 identified. Appropriate corrective action
 25 will be taken and the specimen will be

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1 processed as usual. The original problem will
 2 be documented in an occurrence report". So, I
 3 take it, if you know the problem, then an
 4 occurrence report is now required.
 5 MR. GREEN:
 6 A. Yes.
 7 CHAYTOR, Q.C.:
 8 Q. And that's new?
 9 MR. GREEN:
 10 A. Yes.
 11 CHAYTOR, Q.C.:
 12 Q. And what would an appropriate corrective
 13 action be?
 14 MR. GREEN:
 15 A. Corrective action would be to document it so
 16 that we would take that specimen and we would
 17 process it as usual, so that when it went out
 18 to the pathologist, at least they would have
 19 some indication that the specimen they have
 20 may not be optimal, but they will know a
 21 reason why it's not optimal. So, that when
 22 they report it, they can take that into
 23 consideration.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. And if there's a problem with the

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1 processing, what would appropriate corrective
 2 action be for that?
 3 MR. GREEN:
 4 A. It would be very difficult to tell whether the
 5 problem was a processing problem. If you're
 6 talking about tissue processing on the machine
 7 itself, it probably wouldn't be readily
 8 available until it was looked at under the
 9 microscope by the pathologist.
 10 CHAYTOR, Q.C.:
 11 Q. Okay. So, then in terms of number four, "the
 12 reason for a specimen being sub-optimal must
 13 be recorded in the specimen comment status
 14 section", is that a technologist that would be
 15 reporting the reason?
 16 MR. GREEN:
 17 A. That would happen on the gross bench.
 18 Pathologist assistants would take care of
 19 that. That's if they received a specimen
 20 without any fixation, it would be obvious and
 21 they would have to record that in their
 22 dictation so that--they would then put it into
 23 formalin for fixation, but they would have to
 24 make a note of it so that, depending on how
 25 long it was unfixed, the specimen could have

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1 no diagnostic value.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. And is there currently any reprocessing
 4 of specimens taking place?
 5 MR. GREEN:
 6 A. Not that I'm aware of. Now since I dedicated
 7 to IHC, I have very little contact with the
 8 gross bench any more.
 9 CHAYTOR, Q.C.:
 10 Q. Okay.
 11 MR. GREEN:
 12 A. But I'm not aware of any.
 13 CHAYTOR, Q.C.:
 14 Q. So what happens on that end now you're not
 15 familiar with?
 16 MR. GREEN:
 17 A. No.
 18 CHAYTOR, Q.C.:
 19 Q. If we could have page 27, please, and this one
 20 is monitoring temperature dependent equipment,
 21 and the author is Lynn Wade, and original
 22 approval date is February 29th, 2008,
 23 effective date, same date, and review date,
 24 well, we hope not, February 29th, 2009.
 25 MR. GREEN:

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1 A. There might be a problem there.
 2 CHAYTOR, Q.C.:
 3 Q. That's right, and Terry Gulliver is the
 4 issuing authority.
 5 MR. GREEN:
 6 A. We had a lot of SOPs which are being tackled
 7 all at the one time. That's why those dates
 8 are --
 9 CHAYTOR, Q.C.:
 10 Q. Yes, yes. "All pathology laboratory
 11 temperature dependent equipment must be
 12 monitored and the documentation of all checks
 13 and corrective actions must be retained". Now
 14 for ER/PR testing, what equipment would that
 15 be?
 16 MR. GREEN:
 17 A. The ER/PR would be no different than any of
 18 the other antibodies for IHC. We would record
 19 the temperature of the water baths, we float
 20 the sections, the temperature of the oven
 21 which we place the sections in before
 22 staining, the temperature of the refrigerator
 23 where the antibodies are stored. That should
 24 do it.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and it says, "The purpose is to ensure
 2 that each piece of temperature dependent
 3 equipment is maintained in good working order
 4 and operating within the appropriate
 5 temperature range".
 6 MR. GREEN:
 7 A. We now have NISH thermometers for all those
 8 pieces of equipment.
 9 CHAYTOR, Q.C.:
 10 Q. And this includes -- on the next page is
 11 refrigerators, water baths, the tissue
 12 processors, and paraffin dispenser, and the
 13 embedding centre and incubation oven.
 14 MR. GREEN:
 15 A. These SOPs will refer to all specimens, breast
 16 specimens included. They will be treated the
 17 same.
 18 CHAYTOR, Q.C.:
 19 Q. All treated the same, okay. I take it, Mr.
 20 Green, this is new as of February, 2008. So
 21 it's a formal policy now that's to be adhered
 22 to. Throughout February, 2007, onwards, was
 23 this type of recording taking place, the
 24 temperature with respect to all of these?
 25 MR. GREEN:

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1 A. Yes, we've been recording those temperatures
 2 for quite some time, probably 2005.
 3 CHAYTOR, Q.C.:
 4 Q. And in the manner that's indicated in this
 5 particular policy?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. So that's been going on since the issue of
 10 ER/PR arose?
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. Do you know in drafting the policies and
 15 procedures that you were involved with, do you
 16 know whether or not there was any assistance
 17 sought from external agencies or external
 18 laboratories?
 19 MR. GREEN:
 20 A. I know when I drafted the ones that I drafted,
 21 we had some templates from different places to
 22 go by. I wasn't concerned about the template
 23 business. I wanted to get the information
 24 down, so I used the manuals and the procedures
 25 -- manuals that we had there.

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1 CHAYTOR, Q.C.:
 2 Q. And those were -- whose manuals were they?
 3 MR. GREEN:
 4 A. The Ventana manuals for the day to day running
 5 of the IHC lab using the Ventana System. We
 6 had copies of templates, but I left that to
 7 the people who took the information and
 8 entered it into the computer, but we did have
 9 copies of templates to go by.
 10 CHAYTOR, Q.C.:
 11 Q. Okay, and you adapted it, I take it, to your
 12 own circumstance for your own lab?
 13 MR. GREEN:
 14 A. That's true.
 15 CHAYTOR, Q.C.:
 16 Q. Could we have page 42, please. This is a --
 17 we looked at a fixation policy, the first
 18 document I showed you, and this one is a
 19 fixation procedure for pathology specimens and
 20 refers to the 10 percent buffered formalin, 4
 21 percent formaldehyde is the fixative of choice
 22 for most tissues. Exceptions include, and
 23 then it goes on with a list from there, and
 24 then the procedure, "To place the specimen in
 25 formalin as quickly as possible after removal

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1 from the body, and at most within 30 minutes",
 2 and it goes on with four steps there. Was
 3 there a procedure -- a written procedure in
 4 place -- this one is dated March 17th, 2008.
 5 Was there a written procedure prior to March
 6 17th, 2008?
 7 MR. GREEN:
 8 A. Not that -- I wasn't aware of a written
 9 procedure, but the unwritten rule from
 10 everybody in pathology was that the specimen
 11 had to go in 10 percent buffered formalin as
 12 soon as possible because everybody knew that
 13 fixation was the only process that couldn't be
 14 reversed, so -- even though it may not have
 15 been written, everybody was aware of the
 16 importance of putting a specimen into
 17 formaldehyde.
 18 CHAYTOR, Q.C.:
 19 Q. If we could look at page 48, please, and again
 20 this is a procedure and this one is for
 21 pathology tissue, handling breast specimen,
 22 needle localization, and there's special
 23 precautions in bold capital letters, "Needle
 24 localization breast specimens must not be
 25 placed in formalin or any other fixative at

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1 the time of collection. The specimen must be
 2 given directly to a laboratory technologist or
 3 pathologist when it is taken to the biology
 4 lab", and then number two under procedure in
 5 bold, "Do not add formalin or any fixative".
 6 Do you know was that happening, were they
 7 being placed in formalin or other fixative?
 8 MR. GREEN:
 9 A. I'm not aware -- I would assume that if the
 10 surgeons were going to do this, they would
 11 have notified the pathologist and it would be
 12 treated like a frozen section. The
 13 pathologist would be notified upon the
 14 procurement of the specimen.
 15 CHAYTOR, Q.C.:
 16 Q. So you're not aware of whether or not -- I'm
 17 just wondering, the necessity to have this
 18 procedure, you're not aware whether or not
 19 this arose from difficulties of that nature?
 20 MR. GREEN:
 21 A. I'm not aware, no.
 22 CHAYTOR, Q.C.:
 23 Q. Number seven says, "Give the specimen to a
 24 technologist or pathologist. Do not leave a
 25 dry specimen on the bench". Are you aware

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1 whether or not dry specimens were being left
 2 on the bench?
 3 MR. GREEN:
 4 A. Not to my knowledge, and the only reason it
 5 would be given to technologist would be to
 6 bring it directly to the pathologist so they
 7 can handle it.
 8 CHAYTOR, Q.C.:
 9 Q. If we could have page 64, please. This is
 10 effective May 22nd, 2008, and it's called
 11 "Pathology specimen reception", and this
 12 procedure provides instructions for handling
 13 pathology specimens after arrival in the lab,
 14 and there's a detailed list here in terms of
 15 checking the specimen and checking the
 16 requisition. Then coming under -- there's
 17 numbers here up to number 15. Number five
 18 says, "Check the label on the specimen
 19 container and requisition against the
 20 information in the pathology specimen book".
 21 Number 10 is, "Check off each entry
 22 individually and tear off and retain top white
 23 sheet from book. The book itself goes back to
 24 the originating department". Where does the
 25 top -- you retain the top right sheet from the

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1 book. What happens to that?
 2 MR. GREEN:
 3 A. That would be stored in the area where the
 4 specimens are delivered to a lab across from
 5 the gross lab. So what would happen if a
 6 specimen were brought down to the lab and the
 7 label on the specimen did not correspond with
 8 the label on the requisition, whoever is the
 9 data entry person would call back up to the OR
 10 or to the floor and one of those people would
 11 have to come down and they would have to make
 12 the necessary changes.
 13 CHAYTOR, Q.C.:
 14 Q. Yes.
 15 MR. GREEN:
 16 A. If they couldn't make it themselves, they
 17 would have to take the specimen back and make
 18 sure that somebody, whoever filled it out to
 19 make those changes.
 20 CHAYTOR, Q.C.:
 21 Q. And it says under four, roman numeral IV, "if
 22 not corrected within 24 hours, refer case to
 23 lab manager, clinical chief, site chief or his
 24 or her pathologist designate". What happens
 25 to the specimen in the meantime?

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1 MR. GREEN:
 2 A. If it was just a clerical error?
 3 CHAYTOR, Q.C.:
 4 Q. Yes. Well, number four is if there's a
 5 mistake on the requisition or label of a
 6 specimen, wrong name. So it appears to be a
 7 clerical mistake that's being referred to.
 8 MR. GREEN:
 9 A. To my knowledge, if that specimen were in the
 10 correct fixative, but it was just a clerical
 11 error, it would be held until they could make
 12 contact with whoever sent the specimen, and it
 13 will be delayed until the changes could be
 14 made.
 15 CHAYTOR, Q.C.:
 16 Q. Okay. Number 11 says, "If a specimen is
 17 entered in the pathology specimen book, but
 18 the actual specimen is not received next to
 19 the entry on an individual basis". So it's
 20 recorded in the book. Is there anything else
 21 done? Are there any efforts undertaken to try
 22 and actually locate the specimen?
 23 MR. GREEN:
 24 A. I would assume -- I'm not really aware, but I
 25 would assume that they would contact -- if the

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1 specimens came down and it was -- usually they
 2 know when a group of specimens arrive which
 3 area they come from. They would check that
 4 department and try to track down the specimen.
 5 Until we receive the specimen into the lab --
 6 we do not take responsibility for that
 7 specimen until we actually receive it in the
 8 lab.
 9 CHAYTOR, Q.C.:
 10 Q. So that happens before it gets to you?
 11 MR. GREEN:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. If we can look at page 74, please. This is a
 15 procedure again for pathologists -- I'm sorry,
 16 74. So it's pathologist assistants training,
 17 and I take it that's -- you'd have pathologist
 18 assistants in place now who take care of this.
 19 You don't do any grossing now yourself.
 20 MR. GREEN:
 21 A. No, that would be their responsibility.
 22 CHAYTOR, Q.C.:
 23 Q. And you were responsible for doing grossing
 24 prior to becoming dedicated staff?
 25 MR. GREEN:

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1 A. That's true.
 2 CHAYTOR, Q.C.:
 3 Q. And did you have any similar policy in place
 4 for you at that time?
 5 MR. GREEN:
 6 A. No written policies.
 7 CHAYTOR, Q.C.:
 8 Q. Or procedure, I should say, policy or
 9 procedure.
 10 MR. GREEN:
 11 A. And the specimens -- the scope of training for
 12 the pathology assistants is much greater than
 13 the specimens we handled as part of our
 14 grossing duties. They would be handling
 15 larger specimens like breasts, bowel, lungs.
 16 We didn't --
 17 CHAYTOR, Q.C.:
 18 Q. You never grossed breasts?
 19 MR. GREEN:
 20 A. We never grossed large specimens.
 21 CHAYTOR, Q.C.:
 22 Q. If we could have, please, page 115. This is a
 23 procedure for the Tissue TEK VIP5 Tissue
 24 Processor, and is that the tissue processor
 25 used for ER/PR, for the breast tissue?

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1 MR. GREEN:
 2 A. Yeah, that's the processor which all specimens
 3 are processed on.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, and this again is in effect as of May
 6 22nd, 2008, and provides information about the
 7 Tissue TEK VIP5 vacuum infiltration
 8 processors, and materials and equipment
 9 description, and automatic self-contained
 10 tissue processor which is capable of holding
 11 up to 300 sample cassettes. It provides up to
 12 20 different programs for fixing, dehydrating,
 13 clearing, and paraffin impregnation of tissue
 14 specimens. I take it this is something new
 15 too, is it, Mr. Green, this procedure?
 16 MR. GREEN:
 17 A. The procedure itself is new. There was a
 18 manual with the tissue processor which was
 19 next to the processor, which basically --
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and that's what was followed prior to
 22 this?
 23 MR. GREEN:
 24 A. That was what was followed prior to this. It
 25 provided the operating instructions for the

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1 machine, a list of the solutions that were
 2 used on the machine, capacity, and
 3 troubleshooting.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, and this says, "In the case of a power
 6 failure, the VIP5 has a battery back up which
 7 would hold the computer memory as to the
 8 station processor was in at the time of the
 9 failure. On power restoration, the processing
 10 cycle is continued". Has that always been the
 11 case, has it always had --
 12 MR. GREEN:
 13 A. It has. That's part of the system that's
 14 built into the VIP, so that if the -- if the
 15 power were to go or if somebody were to unplug
 16 the machine and move it, when you plugged it
 17 back in, all the protocols that you had put in
 18 there, they would be kept in memory. So you
 19 wouldn't have to reprogram the machine again.
 20 CHAYTOR, Q.C.:
 21 Q. And is there any concern if, for example, the
 22 power interruption is for a number of hours?
 23 Is that of any concern to your processing?
 24 MR. GREEN:

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1 A. No, the way the VIP System is set up, it's a
 2 closed system, so the blocks would be in one
 3 of the solutions, either in alcohol or xylene
 4 or wax, and fixation is the first -- the two
 5 first -- the first and second solution on that
 6 machine, formaldehyde. That's where additional
 7 fixation would take place. Even if the machine
 8 malfunctioned in one of those stations, so
 9 long as it was in formaldehyde, it wouldn't be
 10 a problem. The biggest problem would be your
 11 day's work would be delayed.
 12 CHAYTOR, Q.C.:
 13 Q. But it shouldn't cause any problem to the
 14 tissue --
 15 MR. GREEN:
 16 A. Tissue itself.
 17 CHAYTOR, Q.C.:
 18 Q. Including the fixation stage?
 19 MR. GREEN:
 20 A. No.
 21 CHAYTOR, Q.C.:
 22 Q. And the function of the tissue processor then
 23 is indicated to be to fix, dehydrate, clear,
 24 and wax?
 25 MR. GREEN:

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1 A. Infiltrate with wax, yes.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. Then the instrument itself, and there
 4 are four major components identified to the
 5 instrument; the control panel, the retort, the
 6 paraffin oven, and the reagent cabinet.
 7 Perhaps you could just explain how this --
 8 those different components and how it actually
 9 works?
 10 MR. GREEN:
 11 A. The control panel is the computer part of the
 12 instrument that will hold the protocols if
 13 you're going to use for processing. The
 14 retort actually is a chamber where you will
 15 place your baskets. The solutions will be
 16 pumped in and out of the retort during the
 17 process. The paraffin ovens are ovens which
 18 maintain the wax. So at the last stage of the
 19 processing, these tissues are subject to
 20 paraffin wax which impregnates the tissue, and
 21 the reagent cabinet below will hold all the
 22 reagents which are pumped in and out of the
 23 retort on the top.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and the next on 119, there's a procedure

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1 here for the VIP5 processing schedules, and it
 2 has a difference between overnight and weekend
 3 schedule and a long weekend schedule. What
 4 difference would it make? Why is there a
 5 necessity to have this for overnight, weekend,
 6 and long weekend?
 7 MR. GREEN:
 8 A. The pathology lab doesn't operate -- they
 9 don't usually operate after hours, so it's
 10 usually a nine to five, Monday to Friday
 11 operation. On Monday the specimens are put in
 12 the processor and we have a protocol set up so
 13 that the machine takes approximately 11 hours,
 14 11.5 hours, to go through the full cycle. So
 15 the way the machine works, you program in the
 16 end -- you program in the end time, the time
 17 that you want to take your blocks off. The
 18 machine will calculate backwards and tell you
 19 the time you have to start the machine.
 20 Monday, Tuesday, Wednesday, and Thursday, not
 21 a problem, the same protocol. It'll be the
 22 same protocol for the weekend or long weekend,
 23 with the exception that you set up the machine
 24 on a timer delay and you also put in the time
 25 that you want the machine to finish. So then

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1 it will start off in formalins, and that's
 2 where it'll be kept. It'll go through
 3 formalin, be kept in alcohol until -- it sits
 4 in one of those solutions until the start up
 5 time. Like, on a weekend, it will start
 6 sometime early -- late Sunday, finish 11 hours
 7 later, and end up around 5:30 or 6:00 o'clock
 8 on Monday. If it was a long weekend and
 9 nobody was available on Monday, it would be an
 10 extra 24 hour delay set on the machine. So
 11 there's three different protocols set up.
 12 CHAYTOR, Q.C.:
 13 Q. So it's set up so that it wouldn't--the
 14 process wouldn't actually finish until Monday?
 15 Is that the idea?
 16 MR. GREEN:
 17 A. Yeah, it will hold the process from starting
 18 so it will finish on--it would finish, on a
 19 long weekend, it would finish on a Tuesday
 20 morning. On a regular weekend, it would
 21 finish on a Monday morning.
 22 CHAYTOR, Q.C.:
 23 Q. So same amount of times for each of these
 24 steps?
 25 MR. GREEN:

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1 A. Yes, it's the -
 2 CHAYTOR, Q.C.:
 3 Q. But the machine is programmed -
 4 MR. GREEN:
 5 A. The end time is how the--you work backwards,
 6 so you program in the time you want it to
 7 finish and the machine does the rest.
 8 CHAYTOR, Q.C.:
 9 Q. Yes, that's what I was curious about because
 10 when I looked at it, I couldn't see--it would
 11 seem to be the same amounts of time.
 12 MR. GREEN:
 13 A. All the times are the same. It's timed. The
 14 only difference is that the--when you set up
 15 the machine on a Friday, you put all the
 16 specimens in the retort and press delay. It
 17 goes into the formalin and goes through the
 18 fixation stage. Then it will hold it into the
 19 alcohol stage and will pick up from there and
 20 process.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and is that written in here somewhere?
 23 Because when I looked at these graphs, they
 24 all appeared to be the same.
 25 MR. GREEN:

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1 A. Yeah, they are all the same. The only
 2 difference is in the -
 3 CHAYTOR, Q.C.:
 4 Q. When you would actually start the process?
 5 MR. GREEN:
 6 A. When you would tell the machine when to
 7 finish.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, but that's not written in here?
 10 MR. GREEN:
 11 A. No.
 12 THE COMMISSIONER:
 13 Q. Sorry, I just want to make sure I understood
 14 that point. So are you saying that the
 15 specimens from Friday would get to stage three
 16 on Friday. Then there would be a pause?
 17 MR. GREEN:
 18 A. Yeah.
 19 THE COMMISSIONER:
 20 Q. Until some point on Sunday evening, so that,
 21 in the case of a regular weekend, so that they
 22 would be held in alcohol at stage three until
 23 that point on Friday evening and they would
 24 finish in the normal course for the Monday
 25 morning operation?

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1 MR. GREEN:
 2 A. Yes, exactly.
 3 THE COMMISSIONER:
 4 Q. All right, thank you.
 5 CHAYTOR, Q.C.:
 6 Q. Thank you. And the last graph in this policy,
 7 page six of eight, I'll just bring you down to
 8 that. It's reprocessing schedule number ten.
 9 What's that about?
 10 MR. GREEN:
 11 A. That's if you were to have a specimen and for
 12 some reason it didn't reprocess properly, you
 13 could -
 14 CHAYTOR, Q.C.:
 15 Q. Sorry, it didn't process properly?
 16 MR. GREEN:
 17 A. Didn't process properly, you could start off
 18 and use this protocol and basically since it
 19 wasn't a fixation problem, since it was
 20 already fixed in formalin, you could skip the--
 21 and alcohols on the machine, although they
 22 are--their main purpose is to remove the
 23 water, ethanol is also a fixative. So you
 24 wouldn't be necessary to give it extra
 25 fixation, so you would jump the program and

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1 start off in ethanol and -
 2 CHAYTOR, Q.C.:
 3 Q. Start in step five?
 4 MR. GREEN:
 5 A. Yes.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and is that--was that the process being
 8 used before, if reprocessing had to take
 9 place?
 10 MR. GREEN:
 11 A. That would be--that's not the reprocessing
 12 schedule that I'm familiar with. The one at
 13 St. Clare's that we use, we would take the
 14 specimens, particularly breast specimens had
 15 to be reprocessed and we would put them--we
 16 would remove the wax, put them in formalin and
 17 go through the whole process again.
 18 CHAYTOR, Q.C.:
 19 Q. So you would have done the whole thing again?
 20 MR. GREEN:
 21 A. Yeah.
 22 CHAYTOR, Q.C.:
 23 Q. And are you aware of any particular danger in
 24 doing that now?
 25 MR. GREEN:

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1 A. No.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. So why steps one to four have been cut
 4 out?
 5 MR. GREEN:
 6 A. I would say that would be to expediate the
 7 process. If you had specimens that--and there
 8 was a processing problem, not a fixation
 9 problem, you wouldn't--you would cut off
 10 probably a couple of hours from the procedure
 11 by going this way.
 12 CHAYTOR, Q.C.:
 13 Q. And whether or not--how common reprocessing is
 14 right now, you're not able to say? You're not
 15 on that -
 16 MR. GREEN:
 17 A. I'm not on that station, but from what I'm
 18 aware, it happens--I don't know if it happens
 19 at all at the Health Science or very rarely.
 20 CHAYTOR, Q.C.:
 21 Q. If we could have, please, page 131? And this
 22 is called troubleshooting tissue processing,
 23 and again, I take it you're not on this end,
 24 and you weren't involved in coming up with
 25 this particular procedure?

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1 MR. GREEN:
 2 A. No.
 3 CHAYTOR, Q.C.:
 4 Q. And the procedure provides a list of potential
 5 processing problems and their possible causes
 6 and solutions and then there's a chart which
 7 gives a problem, cause and solution. Was
 8 there anything similar in effect for you when
 9 you were involved in the processing phase?
 10 MR. GREEN:
 11 A. I would say most of these were taken right
 12 from the manufacturer's manual.
 13 CHAYTOR, Q.C.:
 14 Q. So there would be the manufacturer's manual -
 15 MR. GREEN:
 16 A. It would have been in the manual, which would
 17 be in the room with the processor.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, and this appears to be very similar to
 20 the manufacturer's manual?
 21 MR. GREEN:
 22 A. They look very similar to the manufacturer's.
 23 I don't know the reference on the bottom, but
 24 I would be surprised if it wasn't.
 25 CHAYTOR, Q.C.:

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1 Q. Sorry, here we go. Here's the reference. It
 2 refers to the -
 3 MR. GREEN:
 4 A. Yeah, look familiar.
 5 CHAYTOR, Q.C.:
 6 Q. And there's also a couple of other techs
 7 referred to as well. Okay. The next one I
 8 believe you were the author, Determining
 9 Specific Gravity of Alcohols for Tissue
 10 Processor, and this is--this procedure
 11 provides instructions for checking specific
 12 gravity of alcohols used on tissue processor.
 13 So what's the--why would you be involved in
 14 this particular procedure?
 15 MR. GREEN:
 16 A. That would be when you already have your
 17 processing schedule set up so you know what
 18 the--if you're going to use 70 percent or 100
 19 percent. So what you want to do, you want to
 20 make sure that if you make up a 70 percent
 21 alcohol that it is exactly 70 percent, so you
 22 could use the specific gravity of it to check
 23 the 70 percent and the 80 percent. Then when
 24 you make it up daily, you got a reference to
 25 check it to.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and the next one is still in keeping

3 with processing. It's troubleshooting, Tissue

4 Tek VIP5 processor troubleshooting, in effect

5 May 22nd, 2008, and it provides instructions

6 for dealing with problems that can occur with

7 the processor. And again, was there such a

8 policy in place or is this something new?

9 MR. GREEN:

10 A. This looks like it came from the manual. I

11 would say the processor is probably alarmed to

12 the switchboard at the Health Science, so if

13 it were to malfunction during the middle of

14 the night, the person on the switchboard would

15 call the on-call person.

16 CHAYTOR, Q.C.:

17 Q. Okay, and has that always been the case, that

18 it's connected to the switchboard?

19 MR. GREEN:

20 A. It hasn't always been the case, but it's been

21 like it for a few years. Not exactly sure

22 what time it was set up.

23 CHAYTOR, Q.C.:

24 Q. So this says "when an error is detected, an

25 alarm sounds for about ten seconds, repeating

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1 every minute until the error is cleared. The

2 error number warning message is to flash

3 repeatedly on the warning line. To stop the

4 internal alarm, you press the alarm off. If

5 the instrument is left unattended for longer

6 than five minutes after the internal alarm

7 sounds, an external alarm, if connected, is

8 activated. Slide the retort bar to the left

9 and then to the right to turn off the external

10 alarm." So the external alarm would be the

11 switchboard?

12 MR. GREEN:

13 A. Switchboard.

14 CHAYTOR, Q.C.:

15 Q. Okay, and if -

16 MR. GREEN:

17 A. If it was -

18 CHAYTOR, Q.C.:

19 Q. - if connected.

20 MR. GREEN:

21 A. The reason for the hook up to the switchboard,

22 because since there's nobody there after

23 hours, nobody would--and this happens

24 overnight.

25 CHAYTOR, Q.C.:

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1 Q. And the tissue processing, of course, does

2 take place overnight?

3 MR. GREEN:

4 A. Yes.

5 CHAYTOR, Q.C.:

6 Q. Did you ever know for the external alarm not

7 to be connected?

8 MR. GREEN:

9 A. After it's been--after it was put in place, I

10 have not been aware of any problems with the

11 external alarm.

12 CHAYTOR, Q.C.:

13 Q. And number nine talks about if a problem had

14 occurred, then ensure the tissue blocks are

15 not adversely affected. How would you know if

16 the tissue blocks had been adversely affected?

17 MR. GREEN:

18 A. I think you'd have to go to the next line that

19 says "if you're unable to start the

20 processor." So you have to--there are--you

21 got two options at that point. You can leave

22 the blocks in whatever station they are or you

23 can manually process those blocks, which means

24 that you'd have to take the blocks and put

25 them in individual--the same solutions that

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1 were on the machine and you can have--you

2 could carry them through by hand. But it's

3 not a very practical solution because you're

4 dealing with a large number of blocks and it's

5 time consuming. So you're better off either

6 getting that machine fixed or sending the

7 blocks to your other machine, because we have

8 two machines and starting up the processing

9 and going on from there.

10 CHAYTOR, Q.C.:

11 Q. So to determine--my question being whether or

12 not the tissue blocks are adversely affected,

13 is there anything that you would look for?

14 How would you be able to make that

15 determination?

16 MR. GREEN:

17 A. At that stage, I'm not aware of any way that

18 you could tell.

19 CHAYTOR, Q.C.:

20 Q. Okay, and number ten says "if tissues are in

21 absolute alcohol or xylene when the processor

22 stops, check the length of time the tissues

23 were in that solution. Do not allow the

24 tissues to stay in either absolute alcohol or

25 xylene for an extended period of time, more

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1 than the allotted times on the processors.
 2 The tissues may be irreparably damaged if left
 3 too long in either one."
 4 MR. GREEN:
 5 A. Yeah, what would happen, if they were left in
 6 alcohol, alcohol is a fixative and the tissues
 7 would become harder than they usually would
 8 need to be.
 9 CHAYTOR, Q.C.:
 10 Q. So if the problem did occur with the processor
 11 over night, then it could cause damage to the
 12 tissue if they're left in the absolute alcohol
 13 or xylene?
 14 MR. GREEN:
 15 A. Absolute alcohol, it would have to be there a
 16 long time for to be damaged that would be
 17 irreparable.
 18 CHAYTOR, Q.C.:
 19 Q. And were you aware of that when you were
 20 running the tissue processor?
 21 MR. GREEN:
 22 A. I've never had an experience where they were
 23 left in alcohol.
 24 CHAYTOR, Q.C.:
 25 Q. But were you aware that that could case

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1 irreparable damage?
 2 MR. GREEN:
 3 A. I was aware of the fact that the only stage
 4 that was irreversible would be fixation. If
 5 it was adequately fixed, we were under the
 6 impression that we could repair the damage to
 7 any tissues.
 8 CHAYTOR, Q.C.:
 9 Q. And this now requires--this policy requires
 10 that an occurrence report be completed. Was
 11 that the case prior to May of 2008?
 12 MR. GREEN:
 13 A. No.
 14 CHAYTOR, Q.C.:
 15 Q. If we look then, the next policy at 139, you
 16 are the author, and this is a policy for
 17 accommodating longer fixation time on the
 18 processor, and why would this procedure be
 19 necessary?
 20 MR. GREEN:
 21 A. It would probably be necessary if the tissue--
 22 if from the gross room, from the gross bench
 23 that you saw that the tissues were not fixed
 24 at that point and that if you were to put
 25 those on the machine with the regular

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1 processing schedule that they would not--
 2 because on the regular processing schedule, I
 3 think there's maybe one-two hours maximum
 4 fixation and that will not be enough.
 5 CHAYTOR, Q.C.:
 6 Q. Okay. So this allows extra fixation time if
 7 tissues come to you which have not been
 8 adequately--or have not fixed long enough?
 9 MR. GREEN:
 10 A. Yeah.
 11 CHAYTOR, Q.C.:
 12 Q. This allows extra fixation time to take place
 13 within the processor?
 14 MR. GREEN:
 15 A. You would have to--with this program here, you
 16 would have to process those tissues alone on
 17 the processor, not with the regular blocks on
 18 the processing schedule.
 19 CHAYTOR, Q.C.:
 20 Q. Okay.
 21 THE COMMISSIONER:
 22 Q. Ms. Chaytor, wherever you can find a good
 23 time, we'll take the break.
 24 CHAYTOR, Q.C.:
 25 Q. Thank you. And again, how would you know? I

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1 take it the times are now documented. Is that
 2 how you would know?
 3 MR. GREEN:
 4 A. If--how would I know if sections needed longer
 5 fixation times?
 6 CHAYTOR, Q.C.:
 7 Q. Yes.
 8 MR. GREEN:
 9 A. That would have--now, that would either have
 10 to come from the pathologist or the
 11 pathologist assistant. They would be handling
 12 that, and these would be--have to be larger
 13 specimens.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, and if we look then at the next page,
 16 141, the next procedure, it's the manual
 17 deparaffinization of tissue blocks and
 18 reprocessing, and then on--and I realize
 19 you're not the author of these. Then on 143,
 20 it's a procedure for handling tissue blocks
 21 which were not dehydrated processed properly
 22 on the tissue processor. So it's reprocessing
 23 tissue blocks not properly dehydrated. The
 24 first one is a manual process.
 25 MR. GREEN:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. Are you able to say when you would use one as
 4 opposed to the one found at 143? When would
 5 you use the manual process?
 6 MR. GREEN:
 7 A. You would use the manual process if you had a
 8 particular specimen that you needed some
 9 urgency on the diagnosis. So rather than wait
 10 and reprocess it with the regular processing
 11 schedule, which would put you into the next
 12 day.
 13 CHAYTOR, Q.C.:
 14 Q. Depending on the urgency then of the matter?
 15 MR. GREEN:
 16 A. The urgency of the matter. You could go ahead
 17 and do it by hand, especially if there's a
 18 small number of blocks and that way, before
 19 the end of the day, you could have the
 20 sections ready for the pathologist to
 21 interpret.
 22 CHAYTOR, Q.C.:
 23 Q. Okay, and if we look at page 142, there's a
 24 section of this procedure which is in bold,
 25 and it says "the reprocessing should not be

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1 performed with the standard overnight process
 2 typically used with fresh tissue. The extent
 3 of chemical exposure renders the specimens
 4 dangerously over-dehydrated to the point that
 5 they may become unsuitable for diagnosis. The
 6 shorter program should be used with immersion
 7 times at least half the original ones." Would
 8 that apply in any way to breast tissue?
 9 MR. GREEN:
 10 A. That would--I would imagine that would apply
 11 to any tissue, regardless of what type of
 12 tissue it would be.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, and were you aware of that?
 15 MR. GREEN:
 16 A. No, it's not the reprocessing that we had used
 17 at St. Clare's.
 18 CHAYTOR, Q.C.:
 19 Q. I'm sorry, it wasn't the process you used, the
 20 reprocess?
 21 MR. GREEN:
 22 A. It's not the reprocessing schedule that we
 23 used at St. Clare's.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. This is a good place, please,

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1 Commissioner.
 2 THE COMMISSIONER:
 3 Q. We'll take the morning break.
 4 (RECESS)
 5 THE COMMISSIONER:
 6 Q. Ms. Chaytor.
 7 CHAYTOR, Q.C.:
 8 Q. Thank you, Commissioner. Page 145, please,
 9 Registrar? Mr. Green, this is a procedure
 10 regarding the use of B-5 fixative in pathology
 11 and it provides instructions for the use of B-
 12 5 fixative. When would -
 13 THE COMMISSIONER:
 14 Q. (Inaudible) communicating with him to turn
 15 down some of that equipment.
 16 CHAYTOR, Q.C.:
 17 Q. Thank you.
 18 THE COMMISSIONER:
 19 Q. Thank you. There we go. That's better.
 20 CHAYTOR, Q.C.:
 21 Q. Much better, thank you. When would B-5
 22 fixative be used? It says here it's routinely
 23 used for bone marrow biopsies and some lymph
 24 nodes when lymphomas are suspected and may be
 25 used for other--with other tissues, at the

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1 discretion of the pathologist or pathologist's
 2 assistant. Is it ever used in breast tissue?
 3 MR. GREEN:
 4 A. Not to my knowledge.
 5 CHAYTOR, Q.C.:
 6 Q. And had it ever been in any involvement you've
 7 had? You've never--it's never been used in
 8 breast tissue?
 9 MR. GREEN:
 10 A. It's possible to have a specimen fixed in B-5
 11 if it was a--if they did a mastectomy and they
 12 were checking lymph nodes with the same
 13 specimen, that it could be a B-5 fixed
 14 specimen. It's not the optimum choice for IHC
 15 studies.
 16 CHAYTOR, Q.C.:
 17 Q. And why is that?
 18 MR. GREEN:
 19 A. Because of the fixative. It's a bit harsher
 20 than formaldehyde. It's used for nuclear
 21 detail and the -
 22 CHAYTOR, Q.C.:
 23 Q. I'm sorry, I didn't hear you.
 24 MR. GREEN:
 25 A. B-5 fixative is used for nuclear detail on

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1 some of the lymphomas and on bone marrows.
 2 It's quite commonly used on bone marrows, but
 3 I think they have rethought their policy now.
 4 Most bone marrows are not fixed in B-5 any
 5 more. So if you did IHC on a B-5 fixed block,
 6 it should be noted that it's B-5.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and why is that? Why would you note it?
 9 MR. GREEN:
 10 A. You may not get optimal results from B5
 11 fixative, as opposed to formaldehyde because
 12 your protocols are set up and your controls
 13 are used on formalin fixed tissue.
 14 CHAYTOR, Q.C.:
 15 Q. If we could have, please, page 161? And this
 16 you are the author of and this says,
 17 "Effective this procedure as of May 22nd, 2008
 18 and its pH meter daily calibration and use."
 19 And it provides instructions for the daily
 20 calibration and use of the pH meter. And it's
 21 written here, "The pH of the solution will
 22 affect its reactivity, some stains and
 23 reactions will only occur if the solution is
 24 at the correct pH. A pH meter is used to
 25 accurately measure pH." And I realize now

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1 this procedure only came into effect in May of
 2 2008, this written procedure.
 3 MR. GREEN:
 4 A. Yes.
 5 CHAYTOR, Q.C.:
 6 Q. Was this happening in any event prior to May
 7 22nd, 2008, what we see written here?
 8 MR. GREEN:
 9 A. That is the normal procedure for standardizing
 10 the pH meter, using the pH meter, if you were
 11 the first one to use it in the day, you would
 12 standardize it using those three buffers that
 13 are there, pH 4,7 and 10. That would be the
 14 standard practice.
 15 CHAYTOR, Q.C.:
 16 Q. And was that happening prior to May of 2008?
 17 MR. GREEN:
 18 A. Yes.
 19 CHAYTOR, Q.C.:
 20 Q. And was, for example, it goes on in terms of
 21 there's ten steps to the procedure and--sorry,
 22 17 steps to the procedure and then another
 23 eight steps to use pH meter to measure pH of
 24 the solution and there's eight more steps
 25 there. Was there anything similar written

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1 down for anybody to use, there's 17 steps and
 2 then another eight steps, was there anything
 3 in writing prior to May of 2008?
 4 MR. GREEN:
 5 A. No, there was no written protocol, just the
 6 manufacturer's instructions.
 7 CHAYTOR, Q.C.:
 8 Q. And was, in fact, the pH being checked, the pH
 9 meter being calibrated each day?
 10 MR. GREEN:
 11 A. Each day it was used. If you didn't use the
 12 pH meter that day, there was no need to
 13 calibrate it, but you always calibrate it
 14 before use.
 15 CHAYTOR, Q.C.:
 16 Q. And that was the practice for how long?
 17 MR. GREEN:
 18 A. Since I had moved to the Health Science, that
 19 was the practice set over there.
 20 CHAYTOR, Q.C.:
 21 Q. In 2002?
 22 MR. GREEN:
 23 A. Yes.
 24 CHAYTOR, Q.C.:
 25 Q. And was there any way of--was it required that

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1 it be recorded that you in fact had done such
 2 calibration?
 3 MR. GREEN:
 4 A. No.
 5 CHAYTOR, Q.C.:
 6 Q. If we could look then, please, at 167, page
 7 167? And this is a procedure, the author is
 8 Catherine Parnell and it's a procedure for
 9 paraffin tissue embedding, "All routine tissue
 10 sections must be correctly oriented and
 11 embedded in wax after processing." And then
 12 there's a number of steps, all the way up to
 13 21, as to how that is to happen. And this is
 14 March 17th, 2008. Was this procedure written
 15 down anywhere prior to March of 2008?
 16 MR. GREEN:
 17 A. No.
 18 CHAYTOR, Q.C.:
 19 Q. No. 18 says, "incorrectly embedded paraffin
 20 blocks, such as floating sections, air bubbles
 21 or cracked blocks should be melted down by
 22 leaving the blocks in a metal mould inside the
 23 warming chamber of the embedding centre. When
 24 melted re-embed, carefully following any
 25 instructions exactly. For example, turn 90

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1 degrees or place on edge." Is that something
 2 you would have been aware of?
 3 MR. GREEN:
 4 A. Yeah, that's the normal practice. Some
 5 specimens had to be embedded in a certain--
 6 most specimens are embedded in a--the way they
 7 are put into a cassette. The are specimens
 8 like vas deferens sections or tubaligation
 9 sections, which had to be embedded so that you
 10 get a cross section or you can see a lumen in
 11 the tissue. So if you were embedding a
 12 fallopian tube and it happened to fall down on
 13 its side, you would have to re-embed it and
 14 stand it up, so that when it was cut, you
 15 would see a whole in the centre, or a lumen.
 16 CHAYTOR, Q.C.:
 17 Q. And if we could have, please, 173? This
 18 refers to a QC number. Can you tell us what's
 19 the QC number?
 20 MR. GREEN:
 21 A. QC is a quality control number. In this
 22 reference here, it's for H&E stain slides, H&E
 23 is the routine slide on all pathology
 24 specimens, QC number we apply every day,
 25 that's in the routine lab which I usually

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1 don't have much dealing with anymore.
 2 CHAYTOR, Q.C.:
 3 Q. And there's a QC number in the IHC lab?
 4 MR. GREEN:
 5 A. We apply a QC number at the end of the
 6 process, but with the H&E slides, they have
 7 one slide for the whole day. In the IHC lab,
 8 we have control on each slide, so each slide
 9 has its own quality control.
 10 CHAYTOR, Q.C.:
 11 Q. That's the process now.
 12 MR. GREEN:
 13 A. Yeah, that's the process now.
 14 CHAYTOR, Q.C.:
 15 Q. So I just want to be clear, what--before that,
 16 before you actually had your control slide,
 17 what's the purpose of a--sorry, the control on
 18 your patient slide, what was the purpose of
 19 your QC number? What purpose would that -
 20 MR. GREEN:
 21 A. The QC number, that was applied in, not in IHC
 22 but general pathology, that was assigned to
 23 that day, so that you know that all slides
 24 that you ran a particular slide and checked
 25 the slide and checked that the H&E stain was

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1 working properly and all slides that came out
 2 on that day were assigned that QC number.
 3 CHAYTOR, Q.C.:
 4 Q. All slides, so regardless of patient, they all
 5 have -
 6 MR. GREEN:
 7 A. Yeah, all patients ran that day would have the
 8 same QC number.
 9 CHAYTOR, Q.C.:
 10 Q. Would have the same QC number. And was there
 11 a similar practice in place in the IHC lab so
 12 that all tests that were run in a particular
 13 batch would all have the same QC number?
 14 MR. GREEN:
 15 A. No, in the IHC lab, when we had batch
 16 controls, like in the case of ER when there
 17 was one batch ran, the only thing that was
 18 done was the date was written on the slide,
 19 but there was no QC number assigned to it.
 20 CHAYTOR, Q.C.:
 21 Q. So you couldn't try and track patients who had
 22 their tests done in the same batch through a
 23 QC number in IHC?
 24 MR. GREEN:
 25 A. No.

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1 CHAYTOR, Q.C.:
 2 Q. And is that still the case, is there any QC
 3 number used in the IHC lab?
 4 MR. GREEN:
 5 A. No, what we have now is since we have a
 6 control on every slide, that is our quality
 7 control for that patient.
 8 CHAYTOR, Q.C.:
 9 Q. But if something else happened in the process
 10 along the way and you wanted to be able to
 11 determine which patients were also put through
 12 the same process, there's no common QC number?
 13 MR. GREEN:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. And what's the purpose of having a QC number?
 17 MR. GREEN:
 18 A. A QC number in general pathology, what it does
 19 is it's a reference so that what you will do,
 20 you will look at the H&E stain and if there's
 21 a problem with the staining, you won't run
 22 your slides, rather than run all your slides
 23 and find out that there's a problem with the
 24 hematoxylin eosin stain. So the QC slide is
 25 run first and checked, and if that checks out,

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1 then you can run your whole day slides to be
 2 confident that your solutions are working the
 3 way they are working. And you can keep that
 4 QC slide and you can compare yesterday's slide
 5 with today's and you will also have that slide
 6 there for tomorrow when you run your slides--
 7 run a comparison to see if there are subtle
 8 differences in your stain.
 9 THE COMMISSIONER:
 10 Q. I guess I missed something, you're saying the
 11 QC slide is run first?
 12 MR. GREEN:
 13 A. The QC slide is--in the routine pathology lab,
 14 you will run one--you will take a slide--
 15 probably a piece of appendix and you will run
 16 a H&E on that slide and check it under the
 17 scope.
 18 THE COMMISSIONER:
 19 Q. Uh-hm.
 20 MR. GREEN:
 21 A. If your blues and your pinks and everything
 22 work out fine, then you can go ahead with your
 23 day's work and run all those through.
 24 THE COMMISSIONER:
 25 Q. All right.

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1 CHAYTOR, Q.C.:
 2 Q. And if we could have then, please, page 177?
 3 And this is a policy entitled "Corrective
 4 Action for IHC Occurrences" and again, the
 5 approval date is February 29th, '08. And a
 6 review date that I'm sure will be revised.
 7 And the policy, "all issues regarding quality
 8 of IHC staining and all corrective actions
 9 undertaken must be documented." And this is
 10 going to laboratory technologists, as well as
 11 pathologists. And the policy is intended to
 12 provide guidance for the reporting and
 13 documentation of sub-optimal staining and
 14 corrective actions undertaken. And then
 15 there's a list of steps to take, three steps
 16 to take, including entering the issue into,
 17 onto the record of quality issue's form in the
 18 Corrective Actions Log Book. The idea of a
 19 Corrective Action Log Book, when did that
 20 first come into being?
 21 MR. GREEN:
 22 A. That would have taken place after Trish had
 23 come down to the lab, it was one of her
 24 recommendations, so we probably started around
 25 the same time that we started keeping a log of

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1 all the temperatures. And the purpose of the
 2 Corrective Action Log is that if you make a
 3 mistake there, at least you've shown that
 4 you've done troubleshooting and you know how
 5 to fix the error and if the error happens
 6 again, you can pick up trends and also it
 7 brings the technologists and the technologists
 8 together, so that if there's a problem, they
 9 can work out any problems.
 10 CHAYTOR, Q.C.:
 11 Q. So when in fact did the IHC lab get a
 12 Corrective Action Log Book? I understand the
 13 idea arose out of Trish Wegrynowski's review,
 14 when did this become--the policy is dated just
 15 February of '08, but when did this actually
 16 become in practice?
 17 MR. GREEN:
 18 A. It's probably been into effect, we've had that
 19 log maybe since 2005, early '2006 probably.
 20 CHAYTOR, Q.C.:
 21 Q. And is this, to your knowledge, is this
 22 actually taking place when there's an issue?
 23 MR. GREEN:
 24 A. Yes.
 25 CHAYTOR, Q.C.:

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1 Q. And the Corrective Action Log Book is being
 2 filled out?
 3 MR. GREEN:
 4 A. Yes.
 5 CHAYTOR, Q.C.:
 6 Q. And is it being reviewed at least monthly by
 7 the clinical director?
 8 MR. GREEN:
 9 A. Yes, Dr. Elms.
 10 CHAYTOR, Q.C.:
 11 Q. Sorry?
 12 MR. GREEN:
 13 A. Dr. Ford Elms is reviewing it. And then on
 14 page 181, we have the external controls for
 15 immunohistochemistry staining policy. And
 16 this one also came into effect on February
 17 29th, 2008. And this one, the testing though
 18 resumed, the ER/PR testing resumed a year
 19 before that, so was there policy in effect
 20 when the testing resumed in February, 2007?
 21 MR. GREEN:
 22 A. This policy here wasn't into effect then.
 23 CHAYTOR, Q.C.:
 24 Q. This wasn't?
 25 MR. GREEN:

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1 A. No.
 2 CHAYTOR, Q.C.:
 3 Q. And so in terms of external controls, what was
 4 the policy at that point in time?
 5 MR. GREEN:
 6 A. External controls are run on all IHC slides.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, so it was just that, the policy was that
 9 an external control was run for each antibody?
 10 MR. GREEN:
 11 A. Yes.
 12 CHAYTOR, Q.C.:
 13 Q. The policy says that "appropriate external
 14 controls will be run with all batches of
 15 slides for immunohistochemistry staining."
 16 And who determines what is appropriate
 17 external controls? How many and which
 18 controls?
 19 MR. GREEN:
 20 A. Which controls? We've got a manufacturer's
 21 recommended control, in the case of an ER
 22 positive is a known positive ER case; in the
 23 case of lymphomas, most of them would be
 24 tonsils. The manufacturer supplies the
 25 antibody, lists a control, a recommended

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1 control. We will use that control for our
 2 tests and the pathologist, in this case Dr.
 3 Ford Elms, he will check the control and if
 4 he's satisfied that it's demonstrating what we
 5 want to demonstrate, well that's the control
 6 that we'll use. And that's the way we set up
 7 our control bank.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and on to page 182, it talks about
 10 positive controls and negative controls and
 11 each antibody, with the exception of the
 12 quantitative antibodies listed below, will
 13 have a negative control run on a regular
 14 basis. But then under quantitative
 15 antibodies, it refers to a negative control
 16 will be run with each case for quantitative
 17 antibodies, and that includes the HER2/neu and
 18 the ER/PR. So a negative control is now run.
 19 MR. GREEN:
 20 A. Routinely run on every patient.
 21 CHAYTOR, Q.C.:
 22 Q. And was that the case in February, 2007, when
 23 the testing resumed?
 24 MR. GREEN:
 25 A. Yes.

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1 CHAYTOR, Q.C.:
 2 Q. And that continues, well I know you're not
 3 doing ER/PR now, although you're doing ER/PR,
 4 but it's not being read.
 5 MR. GREEN:
 6 A. Yeah.
 7 CHAYTOR, Q.C.:
 8 Q. So that continues to be your practice.
 9 MR. GREEN:
 10 A. Even the ones that we're doing in duplicate
 11 now, we run negative controls on those and
 12 batch controls and positive controls.
 13 CHAYTOR, Q.C.:
 14 Q. And do you follow all of the procedures and
 15 policies for the ER/PR that you're doing now,
 16 even though it's not going to be read, I take
 17 it you still follow your policies and
 18 procedures?
 19 MR. GREEN:
 20 A. We don't deviate from the policy at all.
 21 CHAYTOR, Q.C.:
 22 Q. Okay. And this talks about batch controls
 23 "sausage". "For ER/PR purposes, a batch
 24 control consisting of three resulted tissues,
 25 multi-tissue block and known positive and

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1 known negative and a known weak expressor
 2 tissue are placed on a separate slide and run
 3 in duplicate. One batch slide is sent to the
 4 breast tissue group and one remains in the lab
 5 for reference."
 6 MR. GREEN:
 7 A. That's the triple control which I referred to
 8 before.
 9 CHAYTOR, Q.C.:
 10 Q. Right, but it is contained, your triple
 11 control is contained on the same slide as your
 12 patient tissue?
 13 MR. GREEN:
 14 A. No, triple control is run with a batch of all
 15 the ER patients. Each patient has its own
 16 positive control and each patient has its own
 17 negative control and the batch control, the
 18 triple control is for the whole run.
 19 CHAYTOR, Q.C.:
 20 Q. Okay, so right now in running an ER test, you
 21 would have the patient's tissue and a positive
 22 control and a negative control, so it's three
 23 pieces of tissue on that slide, on the patient
 24 slide, is that right?
 25 MR. GREEN:

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1 A. Yes, we'll have a -
 2 CHAYTOR, Q.C.:
 3 Q. The patient tissue, and then the positive
 4 tissue and your negative.
 5 MR. GREEN:
 6 A. Patient tissue, and on top of that was
 7 positive control.
 8 CHAYTOR, Q.C.:
 9 Q. Yes.
 10 MR. GREEN:
 11 A. We'll have a patient tissue alone, which would
 12 be a negative control.
 13 CHAYTOR, Q.C.:
 14 Q. Okay.
 15 MR. GREEN:
 16 A. And we'll have one triple control which would
 17 be run with our--two triple controls. One
 18 that we ran with our batch, one is sent over
 19 to the breast group and the other is kept in
 20 our lab. So we can compare the next batch be
 21 run to that one.
 22 CHAYTOR, Q.C.:
 23 Q. So the only thing contained on the patient
 24 tissue slide, other than the patient tissue,
 25 is the positive -

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1 MR. GREEN:
 2 A. The positive control.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and is that a weak positive, a strong
 5 positive, what is that?
 6 MR. GREEN:
 7 A. That would be a strong positive.
 8 CHAYTOR, Q.C.:
 9 Q. That's a strong positive. And then there's a
 10 separate slide which contains your triple
 11 control and that's run for the entire batch.
 12 MR. GREEN:
 13 A. Yeah, and that would contain a negative which
 14 is, that's a breast case which there are no ER
 15 reaction, an intermediate which is weaker than
 16 the strong positive and the strong positive.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and there's two batch slides, and one is
 19 sent to -
 20 MR. GREEN:
 21 A. One is sent to the breast group.
 22 CHAYTOR, Q.C.:
 23 Q. Okay, where does it go now?
 24 MR. GREEN:
 25 A. Well right now we file them at St. Clare's.

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1 CHAYTOR, Q.C.:
 2 Q. So it's all just being filed right now.
 3 MR. GREEN:
 4 A. Yes.
 5 CHAYTOR, Q.C.:
 6 Q. And one remains in the lab then for reference?
 7 MR. GREEN:
 8 A. Yes.
 9 CHAYTOR, Q.C.:
 10 Q. And where is it kept in the lab?
 11 MR. GREEN:
 12 A. The reference, we--what we do after the run is
 13 complete, from the Ventana system, we'll print
 14 of a, what we call a run report. Print off
 15 two copies of the run report, we'll keep one
 16 run report on file and we'll write the run
 17 number on our triple control. We'll send the
 18 other copy to St. Clare's with the ER/PR
 19 slides when the breast group starts--when the
 20 breast group is functioning, we sent a copy to
 21 them, had all those patients and a run number
 22 of it and a run control.
 23 CHAYTOR, Q.C.:
 24 Q. So if you wanted to go and find the control
 25 slides that were run with a particular batch

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1 last month, how would you go about doing that?
 2 MR. GREEN:
 3 A. We've got a file set up at St. Clare's and we
 4 would look up the date that we ran on the
 5 machine. We know the run number. We can go in
 6 on the machine and print off that particular
 7 run and that will give us a list of all the
 8 patients, or we can just flip through out file
 9 that we have there. All patients we run, we
 10 keep a copy of the runs too now.
 11 CHAYTOR, Q.C.:
 12 Q. So it's now in the computer that you can put
 13 in the run number and get all the patients
 14 that day?
 15 MR. GREEN:
 16 A. That ran that day.
 17 CHAYTOR, Q.C.:
 18 Q. And you would also be given the --
 19 MR. GREEN:
 20 A. We've got a hard copy also there.
 21 CHAYTOR, Q.C.:
 22 Q. But also in terms of the control slide or the
 23 batch slide that was run with the batch, that
 24 would also be inputted into the computer?
 25 MR. GREEN:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And whose responsibility is it to do that?
 4 MR. GREEN:
 5 A. It would be the technologist who runs the
 6 ER/PR.
 7 CHAYTOR, Q.C.:
 8 Q. And your reference for this was David Dabbs?
 9 MR. GREEN:
 10 A. Dabbs.
 11 CHAYTOR, Q.C.:
 12 Q. Your supporting document, David Dabbs. The
 13 policy for appropriate handling and optimal
 14 fixation of tissue specimens that ensure
 15 optimal results is communicated to those sites
 16 that refer tissues to this centre, and is that
 17 happening?
 18 MR. GREEN:
 19 A. I would assume that all the -- since we're a
 20 reference centre for the island and we get
 21 slides -- blocks/slides from all over, I would
 22 assume these copies have been sent to those
 23 hospitals, but it would not be my
 24 responsibility to do that.
 25 CHAYTOR, Q.C.:

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1 Q. Okay. We have a list here with key words;
 2 negative control, positive control, in-house
 3 control. What do you mean by the in-house
 4 control?
 5 MR. GREEN:
 6 A. The in-house control is the positive control
 7 which is put on every patient's slide.
 8 CHAYTOR, Q.C.:
 9 Q. That's the one on the patient's slide?
 10 MR. GREEN:
 11 A. Yeah, and the in-house control is a control
 12 that's treated in exactly the same way as your
 13 patient's tissue.
 14 CHAYTOR, Q.C.:
 15 Q. And, of course, batch control we just spoke
 16 about. Key words -- so could you go in then
 17 on the -- what's the purpose of key words?
 18 Can I go -- can you go in and do a search of
 19 these key words?
 20 MR. GREEN:
 21 A. I'm not familiar with recovering the
 22 information using those key words on the
 23 Meditec System.
 24 CHAYTOR, Q.C.:
 25 Q. Okay. And there it is, there's your

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1 definition of in-house control.
 2 COMMISSIONER:
 3 Q. What's the difference between in-house control
 4 and what used to be called an external
 5 control?
 6 MR. GREEN:
 7 A. The same -- there is no difference.
 8 COMMISSIONER:
 9 Q. Just new phraseology, but the same thing?
 10 MR. GREEN:
 11 A. Yeah. In-house is a term we picked up from
 12 NEQAS when doing the external QA.
 13 COMMISSIONER:
 14 Q. All right, thank you.
 15 CHAYTOR, Q.C.:
 16 Q. And the next, page 185, is selection of
 17 external controls for ER/PR and Her-2-neu
 18 immunohistochemistry. So there's a specific
 19 policy geared towards ER/PR and Her-2-neu?
 20 MR. GREEN:
 21 A. Yeah.
 22 CHAYTOR, Q.C.:
 23 Q. And this is brought into effect again February
 24 29th, 2008?
 25 MR. GREEN:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. Was there any policy in place in February,
 4 2007, when testing for ER/PR resumed?
 5 MR. GREEN:
 6 A. Yeah, this -- the ER/PR policy that I referred
 7 to with the negative controls and the triple
 8 control, and each patient control, that was
 9 all into effect at that time.
 10 CHAYTOR, Q.C.:
 11 Q. Was it reduced to writing at that time?
 12 MR. GREEN:
 13 A. Pardon?
 14 CHAYTOR, Q.C.:
 15 Q. Was it in writing?
 16 MR. GREEN:
 17 A. No, not in the -- only probably would have
 18 been in my handwriting, written writing, not
 19 in the format that we have here.
 20 CHAYTOR, Q.C.:
 21 Q. So I take it the practice was adhered to, but
 22 there was no written policy as such?
 23 MR. GREEN:
 24 A. No.
 25 CHAYTOR, Q.C.:

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1 Q. And this talks about positive and negative and
 2 weak expresser control tissues must be
 3 processed on runs with patient tissue for
 4 ER/PR and Her-2-neu. Control tissues are
 5 selected from archive patient tissue. All
 6 cases for ER/PR and Her-2-neu receptor
 7 antibodies must contain known positive and
 8 known negative.
 9 MR. GREEN:
 10 A. Yeah.
 11 CHAYTOR, Q.C.:
 12 Q. And that's what we discussed?
 13 MR. GREEN:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. And the purpose being to ensure that
 17 appropriate controls are identified and run
 18 with each ER/PR and Her-2-neu case, and then
 19 the procedure to follow, there are six steps.
 20 The first being that the assigned technologist
 21 will search Meditec for known cases for ER and
 22 PR. So this is looking for, I take it, in
 23 order for you to be able to identify and
 24 prepare controls?
 25 MR. GREEN:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And the pathologist director of the IHC
 4 laboratory will review the identified cases
 5 and select the appropriate tissue. So I take
 6 it, you or one of your colleagues would search
 7 to try and find a known case and then you
 8 bring it to Dr. Elms, and he decides if it's
 9 suitable, is that correct?
 10 MR. GREEN:
 11 A. You may do a search and you may find several
 12 cases there. We would do an ER/PR on those
 13 cases and Dr. Ford Elms would look at the
 14 cases and say -- we may have a half dozen. He
 15 may say, well, three or four of these are good
 16 to use, and then we'll use those blocks.
 17 Those will be our -- part of our inventory for
 18 controls.
 19 CHAYTOR, Q.C.:
 20 Q. And the rest, I think, is self-explanatory
 21 there. Number six says, "When an in-house
 22 control". So that's the control that --
 23 that's not the in-house control.
 24 MR. GREEN:
 25 A. Yeah.

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1 CHAYTOR, Q.C.:
 2 Q. That's just a control meaning within your own
 3 institution.
 4 MR. GREEN:
 5 A. Yeah.
 6 CHAYTOR, Q.C.:
 7 Q. So when an in-house control is not available
 8 from the laboratory tissue supply, efforts
 9 will be made to purchase a commercial control
 10 or the tissue will be sent to a reference
 11 laboratory for testing. So if you're not able
 12 to come up with a suitable control, is there
 13 any criteria then in coming up with what would
 14 be an appropriate control from a commercial
 15 control or from another laboratory?
 16 MR. GREEN:
 17 A. Commercial controls are usually what we call
 18 cell line controls in that those controls are
 19 cells which are grown for that particular
 20 purpose and use. They're a -- they're a good
 21 test of your system to see that your system is
 22 working, but it's not the optimal test because
 23 you do not have tissues which are fixed and
 24 processed in the same manner as the patient's
 25 tissue. So wherever possible, you would

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1 endeavour to use your own in-house controls.
 2 CHAYTOR, Q.C.:
 3 Q. And in terms of your own process in terms of
 4 looking back within your own institution for
 5 controls, do you only use tissue which has
 6 been processed according to current standards?
 7 MR. GREEN:
 8 A. Yes, according to the -- which is fixed and
 9 processed in the same way as the patient's
 10 tissue, yes.
 11 CHAYTOR, Q.C.:
 12 Q. As the patient's tissue.
 13 MR. GREEN:
 14 A. Yeah.
 15 CHAYTOR, Q.C.:
 16 Q. So in terms of any changes that has happened
 17 to the process in the past few months or year,
 18 you can't go back beyond that to find --
 19 MR. GREEN:
 20 A. No.
 21 CHAYTOR, Q.C.:
 22 Q. Okay. So it's very recent tissue that has
 23 been processed in the past year that you would
 24 use for your controls?
 25 MR. GREEN:

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1 A. Well, we're -- with a control bank, you're
 2 always updating your controls. So you're
 3 always looking for new blocks to try -- like,
 4 each time you try a new batch, the pathologist
 5 will look at them and check them out.
 6 CHAYTOR, Q.C.:
 7 Q. And is that -- is that limitation expressed
 8 anywhere in your policy?
 9 MR. GREEN:
 10 A. Not that I'm aware of.
 11 CHAYTOR, Q.C.:
 12 Q. The importance for the patient tissue or the
 13 control tissue to be processed and fixed in
 14 the same manner as the patient tissue?
 15 MR. GREEN:
 16 A. I'm sure it's written down here somewhere, but
 17 an in-house control, by definition, I think --
 18 I think the definition of the in-house control
 19 probably says that it's fixed and processed in
 20 the same.
 21 CHAYTOR, Q.C.:
 22 Q. And we had that on the last page, page 184,
 23 there was in-house control.
 24 MR. GREEN:
 25 A. Yeah.

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1 CHAYTOR, Q.C.:
 2 Q. So known positive tissue that has been
 3 subjected to the same fixation processing as
 4 the test specimen?
 5 MR. GREEN:
 6 A. Yeah.
 7 CHAYTOR, Q.C.:
 8 Q. So that is for finding any external control to
 9 be used in the process?
 10 MR. GREEN:
 11 A. Any external control, yeah.
 12 CHAYTOR, Q.C.:
 13 Q. And not just the one that goes on the patient
 14 tissue? The positive control that's put on
 15 the patient tissue --
 16 MR. GREEN:
 17 A. Yes.
 18 CHAYTOR, Q.C.:
 19 Q. Has to be treated in the same manner as the
 20 patient's tissue?
 21 MR. GREEN:
 22 A. Yes.
 23 CHAYTOR, Q.C.:
 24 Q. What about your batch controls?
 25 MR. GREEN:

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1 A. The same -- same conditions apply.
 2 CHAYTOR, Q.C.:
 3 Q. Right, okay. So the same condition applies
 4 whether it's your batch control or --
 5 MR. GREEN:
 6 A. Or the positive, yes.
 7 CHAYTOR, Q.C.:
 8 Q. Right. So this definition here of in-house
 9 control means any external control?
 10 MR. GREEN:
 11 A. Any control -- any external control.
 12 CHAYTOR, Q.C.:
 13 Q. That's the one I just took you to. So page
 14 189, investigating false positive and false
 15 negative immunohistochemistry staining, and
 16 this came into effect on February 29th, 2008.
 17 It says, "In the event of a suspected false
 18 positive or false negative result, all
 19 investigative and corrective actions must be
 20 documented", and the purpose is to ensure
 21 appropriate follow-up and corrective actions
 22 are undertaken when IHC staining errors are
 23 suspected. Then the procedure has eight
 24 steps, and the following steps -- follow the
 25 steps below to investigate and document false

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1 positive or false negative IHC staining.
 2 Number one is the pathologist will identify
 3 suspected staining error on an IHC slide. Two,
 4 the pathologist must report the situation to
 5 the staff of the immunohistochemistry lab.
 6 Mr. Green, in looking back on what happened in
 7 2005, and there were a number of retests run
 8 in-house in 2005 after the index case, did any
 9 pathologist report that situation to the staff
 10 of the immunohistochemistry lab?
 11 MR. GREEN:
 12 A. No.
 13 CHAYTOR, Q.C.:
 14 Q. "The cases documented and the reviews
 15 undertaken by an IHC technologist and the
 16 director of IHC laboratory". Fourthly,
 17 "evaluate the immunohistochemical staining run
 18 in which the slide staining was generated".
 19 Do you know to your knowledge whether or not
 20 the immunohistochemical staining run which
 21 generated the slide was investigated in 2005?
 22 MR. GREEN:
 23 A. Not that I'm aware of.
 24 CHAYTOR, Q.C.:
 25 Q. "Review controls for the identified run". Six,

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1 "Review the documented staining protocol for
 2 the slide in question on the day in which it
 3 was tested". Are you aware of whether or not
 4 that happened?
 5 MR. GREEN:
 6 A. Staining protocol would not have changed.
 7 Once we set a staining protocol number, we
 8 don't vary from that protocol.
 9 CHAYTOR, Q.C.:
 10 Q. And I believe you've told us that your
 11 protocol is basically the same now with some
 12 adjustment basically to the incubation period?
 13 It's the same as what you had in place in
 14 April of 2004, in any event?
 15 MR. GREEN:
 16 A. When we do -- now when we do ER/PRs, the
 17 protocol number that we are using will be the
 18 same on all patient slides from week to week,
 19 month to month.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and then seven, "If the issue is not
 22 resolved, review all documentation about the
 23 slide, including excisioning of the sample and
 24 the identification of the tissue block from
 25 which the slide was cut, and then document in

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1 the corrective action logbook all actions
 2 undertaken, results of review, and any
 3 corrective actions taken", and the supporting
 4 documents for that include CCHSA, Ventana
 5 operators manual, and David Dabbs".
 6 MR. GREEN:
 7 A. David Dabbs.
 8 CHAYTOR, Q.C.:
 9 Q. The Ventana's operators manual, to your
 10 knowledge in 2005, did the Ventana operators
 11 manual have a procedure for investigating
 12 suspected false positive or false negative
 13 stains?
 14 MR. GREEN:
 15 A. There was a troubleshooting section in there
 16 which would have included those, which are
 17 basically general guidelines which means that
 18 you go backward and check your protocol, check
 19 your slides that were run, check your
 20 controls.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and in terms of there now being a
 23 corrective action logbook, from the time the
 24 testing resumed in February, 2007, up until it
 25 stopped just this spring or summer of 2008,

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1 are you aware of whether or not there has been
 2 any investigations for false positive or false
 3 negative IHC stains?
 4 MR. GREEN:
 5 A. For ER/PR or in general?
 6 CHAYTOR, Q.C.:
 7 Q. ER/PR is what started since February of '07.
 8 MR. GREEN:
 9 A. No. There will be slides from time to time
 10 which you won't get the expected result, and
 11 then the usual practise is to repeat that
 12 test, and if then you have a problem, then you
 13 will start backtracking and try to find out
 14 problems somewhere back in the system, but
 15 that would be the -- we repeat the test, and
 16 if the test the second time was fine, your
 17 problem would be solved and you just record
 18 that in your corrective action, specimen
 19 number whatever repeated.
 20 CHAYTOR, Q.C.:
 21 Q. So you haven't had the occasion to have to go
 22 through this procedure for ER/PR?
 23 MR. GREEN:
 24 A. No.
 25 CHAYTOR, Q.C.:

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1 Q. Have you had to go through it for other IHC
 2 stains?
 3 MR. GREEN:
 4 A. There have been stains which we've had
 5 problems with which we have to go back and
 6 repeat the test and try different protocols to
 7 optimize the antibodies.
 8 CHAYTOR, Q.C.:
 9 Q. Attached here is definitions of false positive
 10 and false negative, and a negative
 11 immunohistochemistry result for an antigen in
 12 a tissue in which that antigen exists. So I
 13 take it the definition of negative is -- and
 14 positive then, an appropriately intense
 15 positive stain for antigen in a tissue in
 16 which that antigen does not exist.
 17 MR. GREEN:
 18 A. Yes.
 19 CHAYTOR, Q.C.:
 20 Q. Who decides what's an appropriately intense
 21 positive stain?
 22 MR. GREEN:
 23 A. That would be the pathologist.
 24 CHAYTOR, Q.C.:
 25 Q. In terms of negative, I take it there's no

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1 percentage issue here any more, it's whether
 2 or not it's totally negative?
 3 MR. GREEN:
 4 A. Yeah, that's right.
 5 CHAYTOR, Q.C.:
 6 Q. If we could have, please, page 201. This is a
 7 -- you are the author of this document, and
 8 perhaps you can just explain what this is,
 9 take us through it?
 10 MR. GREEN:
 11 A. That's from the time a request is made for a
 12 IHC stain. So you will get a written request
 13 for IHC stain for a pathologist. The blocks
 14 are retrieved from the filing system. We make
 15 the slides -- we make the sections using
 16 positive slides, cut out three microns. Those
 17 slides, we generate a bar code with the
 18 patient's information on it, surgical number.
 19 They are put on the -- you pick the
 20 appropriate protocol to run. They are put on
 21 the benchmark auto stainer. External control
 22 is put on top of the slide.
 23 CHAYTOR, Q.C.:
 24 Q. So this is -- your external quality control
 25 check process is the actual putting the

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1 external control on --
 2 MR. GREEN:
 3 A. External control on the slide.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, and then what's your QC check, okay?
 6 What's that?
 7 MR. GREEN:
 8 A. After the slides are stained, we will check to
 9 make sure that that positive control works,
 10 that it's positive. if it doesn't work, we
 11 repeat it, we won't send it out. We won't
 12 send it from the lab. If it works, it goes to
 13 the pathologist for interpretation, and once
 14 it goes to the pathologist, it's signed out --
 15 read and signed out by the pathologist.
 16 CHAYTOR, Q.C.:
 17 Q. So the technologist checking the external
 18 controls, is it just the external controls you
 19 check?
 20 MR. GREEN:
 21 A. Yes.
 22 CHAYTOR, Q.C.:
 23 Q. You don't check the internal control?
 24 MR. GREEN:
 25 A. No, that's the domain of the pathologist.

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1 CHAYTOR, Q.C.:
 2 Q. So you check the external control, and if it
 3 doesn't -- if you're not satisfied, then you
 4 go in this direction in quality control review
 5 and corrective actions take place?
 6 MR. GREEN:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. And when did it become the process or the
 10 procedure for the technologist to check the
 11 external controls prior to sending out to the
 12 technologist?
 13 MR. GREEN:
 14 A. It probably happened when Dr. Ejeckam was in
 15 charge and he started teaching us to check the
 16 controls, how to check the controls, and by
 17 that time we were putting positive controls on
 18 each patient, so it would have happened around
 19 then.
 20 CHAYTOR, Q.C.:
 21 Q. So when you get down to this block here, QC
 22 check, okay, do you document in any way that
 23 you've looked at the external control and it
 24 is, in fact, okay?
 25 MR. GREEN:

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1 A. On the original requisition that comes from
 2 the pathologist, the technologist will sign
 3 that requisition. When they send that
 4 requisition, they say they have completed the
 5 work and checked the controls.
 6 CHAYTOR, Q.C.:
 7 Q. Okay.
 8 MR. GREEN:
 9 A. External controls.
 10 CHAYTOR, Q.C.:
 11 Q. Does it say that anywhere in your policy or
 12 your procedure here?
 13 MR. GREEN:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. And is there anywhere on the form where it
 17 would be indicated that you have to sign off?
 18 MR. GREEN:
 19 A. On the bottom of the form, it says
 20 technologist signature and the date.
 21 CHAYTOR, Q.C.:
 22 Q. And that's been the case for some time,
 23 though?
 24 MR. GREEN:
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. So by signing it, it now means that you've

3 checked. Not only did you do the process, you

4 are the technologist responsible for the

5 process, but you also checked the external

6 controls?

7 MR. GREEN:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. But how does the pathologist know that or the

11 person reading the slides?

12 MR. GREEN:

13 A. When the pathologist gets those slides and the

14 requisition and it's signed, it means that

15 we've done the work and they would assume that

16 we would not have sent the control out to them

17 if the control didn't work.

18 CHAYTOR, Q.C.:

19 Q. So there's nothing written anywhere to

20 document that?

21 MR. GREEN:

22 A. No.

23 CHAYTOR, Q.C.:

24 Q. To make sure that new people coming in are of

25 that understanding; for example, new

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1 pathologists coming. How would they then know

2 -- without it being a written policy, how

3 would they know that that, in fact, is the

4 practise at the Health Sciences IHC lab?

5 MR. GREEN:

6 A. They probably wouldn't know unless we told

7 them or another pathologist told them.

8 COMMISSIONER:

9 Q. The external control you check before it goes

10 out and that is the external control on the

11 patient's slide?

12 MR. GREEN:

13 A. Yes.

14 COMMISSIONER:

15 Q. Do you have any role in respect of the batch

16 slides?

17 MR. GREEN:

18 A. We don't do batch slides any more. The only

19 batch slides that we do are the ones with the

20 ER/PR triple controls.

21 COMMISSIONER:

22 Q. Yes. Do you have any role with those?

23 MR. GREEN:

24 A. We will check those to make sure that they --

25 the staining works on those before we send

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1 them to the breast group, but the breast group

2 has the final responsibility. They will not

3 accept those slides if the controls don't

4 work.

5 COMMISSIONER:

6 Q. So when you're sending them to the breast

7 group, you in addition to sending -- you send

8 that slide as well?

9 MR. GREEN:

10 A. Yes.

11 COMMISSIONER:

12 Q. Although you will have been expected to check

13 yourself?

14 MR. GREEN:

15 A. Yes.

16 COMMISSIONER:

17 Q. In a preliminary way in respect of that slide

18 before you send it out to them, but they get

19 the final call?

20 MR. GREEN:

21 A. That's true.

22 COMMISSIONER:

23 Q. Have I got that right?

24 MR. GREEN:

25 A. Yes.

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1 COMMISSIONER:

2 Q. Okay, thank you.

3 CHAYTOR, Q.C.:

4 Q. So the external batch control, that actually

5 goes to the pathologist as well?

6 MR. GREEN:

7 A. Yes, for ER/PR.

8 CHAYTOR, Q.C.:

9 Q. So the pathologist reads IHC slides. So that

10 is intended to include the batch control slide

11 as well as the patient slide?

12 MR. GREEN:

13 A. Yes.

14 CHAYTOR, Q.C.:

15 Q. Then there's just a number of others that

16 you're involved in, you're the author of them.

17 This one is ancillary products records and

18 it's keeping track of information on ancillary

19 products.

20 MR. GREEN:

21 A. All this information, although it's -- with

22 the system that we have now, the Ventana

23 System, it's electronically stored. This is a

24 backup manual paper record.

25 CHAYTOR, Q.C.:

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1 Q. Okay, so this is a backup manual -- paper
 2 record for in case it's lost on the system, on
 3 the Ventana System?
 4 MR. GREEN:
 5 A. Yes, and the system itself electronically back
 6 up the system itself by using zip disk. Once
 7 a year we'll download all the information on
 8 the Ventana System and that's stored.
 9 CHAYTOR, Q.C.:
 10 Q. And I take it there hasn't been any problem
 11 with the system or loss of any information?
 12 MR. GREEN:
 13 A. We have never lost any information.
 14 CHAYTOR, Q.C.:
 15 Q. And then there's ordering glass slides
 16 procedure, there's EZ prep dilution, and you
 17 have a procedure for -- on page 209, reaction
 18 buffer dilution for benchmark?
 19 MR. GREEN:
 20 A. Yes.
 21 CHAYTOR, Q.C.:
 22 Q. And that procedure provides instructions for
 23 reaction buffer dilution?
 24 MR. GREEN:
 25 A. That's correct.

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1 CHAYTOR, Q.C.:
 2 Q. And was this procedure in writing prior to
 3 March of 2008?
 4 MR. GREEN:
 5 A. Only in the Ventana Manual, but not as a
 6 separate standalone document.
 7 CHAYTOR, Q.C.:
 8 Q. Okay. Then on page 211, there's a procedure
 9 dealing with bar code labels, and then on 213,
 10 we have antibody protocols, and you are the
 11 author of this as well, and it's in effect as
 12 of March 19, 2008, and each antibody has it
 13 own specific protocol which is optimized and
 14 customized through our laboratory conditions
 15 and environment, and it's strictly followed.
 16 The protocol is used to demonstrate a specific
 17 antigen and specific tissue elements. I take
 18 it, Mr. Green, this is new?
 19 MR. GREEN:
 20 A. Yes.
 21 CHAYTOR, Q.C.:
 22 Q. As of March of 2008?
 23 MR. GREEN:
 24 A. It's been into effect for quite some while.
 25 CHAYTOR, Q.C.:

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1 Q. And as of when, as of March of 2008? Is that
 2 when this came into effect or into use?
 3 MR. GREEN:
 4 A. It's probably been into effect before that.
 5 That's when it finally got typed and put into
 6 the format.
 7 CHAYTOR, Q.C.:
 8 Q. And do you know whether or not it was in
 9 effect in February, 2007, when testing
 10 resumed?
 11 MR. GREEN:
 12 A. It was.
 13 CHAYTOR, Q.C.:
 14 Q. So it's been in effect for over a year?
 15 MR. GREEN:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. But reduced to writing in March of this year,
 19 okay. The idea of optimizing and customizing
 20 each antibody or the protocol for each
 21 antibody to your own lab and environment,
 22 that's something that came about, I take it,
 23 the realization of that came about and the
 24 actual practice of doing that came about after
 25 the issues arose in 2005?

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1 MR. GREEN:
 2 A. The issue of optimizing an antibody to each
 3 laboratory was well known long before that.
 4 When the manufacturer sends an antibody, they
 5 send general guidelines and specifications to
 6 be followed and a most likely recipe to
 7 follow, but each laboratory would take that
 8 recipe and use the antigen retrieval and the
 9 antibody dilution and the antibody incubation
 10 time which works best for their laboratory.
 11 Like there's not a one-size-fits-all for each,
 12 but I mean, basically, the basic DTLs will be
 13 the same. Our laboratory here may use a
 14 primary antibody incubation time of 24
 15 minutes. Another lab may use 26 or 28,
 16 depending on the pathologists who read it.
 17 Some may like it a little bit stronger or a
 18 little bit weaker than others. But the same
 19 basic rules will apply.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and we know that Dr. Ejeckam did some
 22 tweaking to the ER/PR antibodies back in 2003.
 23 MR. GREEN:
 24 A. Yes.
 25 CHAYTOR, Q.C.:

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1 Q. And other than that, and I realize you only
 2 went there in 2002, but were you aware of any
 3 other optimizing or customizing ER/PR to fit
 4 your laboratory conditions?
 5 MR. GREEN:
 6 A. No.
 7 CHAYTOR, Q.C.:
 8 Q. And I guess since then, that has happened of
 9 course through Dr. Elms and yourself in what
 10 you did to bring ER/PR back online?
 11 MR. GREEN:
 12 A. That's true.
 13 CHAYTOR, Q.C.:
 14 Q. And this next procedure at page 215 is
 15 diluting antibodies using a prep kit. Does
 16 that pertain to ER or PR?
 17 MR. GREEN:
 18 A. No, the ER and the PR antibodies that we're
 19 using are predilutes. These are for
 20 antibodies--on the Ventana system, they will
 21 supply varying amount of antibodies. There
 22 are some antibodies which they do not supply.
 23 So you can use anybody's manufactured--any
 24 manufacturer's antibody, but you have to put
 25 it into Ventana's packaging and their system

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1 so it will run on the Ventana system. So if
 2 we were to take an antibody not supplied by
 3 Ventana, we could use this system here to run
 4 it on the system.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, and at 219, we have--you're the author
 7 of this procedure, which is retiring
 8 antibodies, and what's the purpose of having a
 9 procedure for retiring antibodies?
 10 MR. GREEN:
 11 A. Well, when you retire an antibody, it can be
 12 retired for any reasons. They may come out
 13 with an antibody which has a better clone or a
 14 manufacturer may stop producing that antibody.
 15 In the case of PR6F11, which is the antibody
 16 we used before we went to the SP1, we have now
 17 retired that antibody. So what we will--when
 18 we retire that antibody, you will keep a list
 19 of the protocol that you used for that
 20 antibody while it was in use and I think two
 21 years we keep a retired antibody
 22 documentation. That means that you will keep
 23 a copy of the protocol that you use and in
 24 that protocol, it will tell you the antigen
 25 retrieval time that you used, the primary

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1 antibody, incubation time and all the
 2 particulars of that particular protocol, so
 3 that if you wanted to go back and look at--if
 4 you had patients that were stained with that
 5 antibody a year ago, you could go back and
 6 find out the information that you used and
 7 protocols that you used.
 8 CHAYTOR, Q.C.:
 9 Q. And we could go back for up to two years?
 10 MR. GREEN:
 11 A. Two years.
 12 CHAYTOR, Q.C.:
 13 Q. And what about we needed, for example, what
 14 happened with the retesting process here, went
 15 back several years, what happens if you need
 16 to go back more than two years? Is that
 17 information otherwise recorded anywhere?
 18 MR. GREEN:
 19 A. This policy wasn't into effect at that time
 20 and there was no policy for retired
 21 antibodies.
 22 CHAYTOR, Q.C.:
 23 Q. I realize that, but was there any
 24 consideration--why the two years now in
 25 bringing in this procedure, why two years?

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1 MR. GREEN:
 2 A. I think that that documentation for retired
 3 antibodies, in the literature it says must be
 4 kept for a minimum of two years. You can keep
 5 it for as long as you wish.
 6 CHAYTOR, Q.C.:
 7 Q. And the operating manual Ventana system, it
 8 was used as a reference, so was this part of
 9 the operating manual for Ventana system, that
 10 such information would be kept for two years?
 11 MR. GREEN:
 12 A. I'm not exactly sure on that, but I could
 13 check it out for you.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, and the idea of the type of antibodies
 16 and incubation period that the antigen
 17 retrieval process, is that recorded on the
 18 patients record anywhere?
 19 MR. GREEN:
 20 A. If the patients--any slide that's run on the
 21 Ventana system will have a bar code on that
 22 slide and a protocol number. By referring to
 23 that protocol number, if it was a retired
 24 antibody, we could check and see which
 25 protocol was used. As long as you have the

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1 patient's slide with that bar code on the top.
 2 CHAYTOR, Q.C.:
 3 Q. And that's for anything done on Ventana?
 4 MR. GREEN:
 5 A. Yes, because in order for the slide to be run
 6 on the Ventana, it has to be bar coded.
 7 CHAYTOR, Q.C.:
 8 Q. And the current process, you'd be able to go
 9 back and check for two years, according to
 10 this protocol?
 11 MR. GREEN:
 12 A. On retired antibodies, yes.
 13 CHAYTOR, Q.C.:
 14 Q. Yes, on retired antibodies, and Dr. Ford Elms
 15 brought in page 221 as the issuing authority
 16 and you're the author, and this is request for
 17 immunohistochemistry staining, and I take it
 18 it's query diagnosis. Is that -
 19 MR. GREEN:
 20 A. That means query diagnosis, yes.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, so, and then on the--sorry, 223, we have
 23 cutting of immunohistochemistry slides and
 24 this procedure is to provide instructions for
 25 the cutting of the slides and there's seven

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1 steps in your procedure. In terms of this
 2 being the procedure for the slides and, for
 3 example, "cut tissue sections at three microns
 4 thickness. Float on a water bath at 42
 5 degrees." How does this procedure compare to
 6 what was in place back in 2005 or pre 2005
 7 issues arising?
 8 MR. GREEN:
 9 A. Pre 2005?
 10 CHAYTOR, Q.C.:
 11 Q. Yes.
 12 MR. GREEN:
 13 A. Ever since the Ventana system came into
 14 effect, this would be the procedure that we
 15 followed. The major difference with this and
 16 before is that before the slides were not
 17 necessarily used--did not necessarily use plus
 18 slides or charged slides. Those slides do a
 19 better job of keeping the tissue on the slide,
 20 and somebody in the general lab would have
 21 been assigned a task of cutting the
 22 immunoperoxidase slides for that day. Now
 23 that task is exclusively done in the IHC lab.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and you're the author of this procedure

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1 as well at page 225 for dehydrating, clearing
 2 and mounting IHC slides, and there's eight, I
 3 believe, steps here. Is this something new or
 4 is it just new that it's reduced to writing?
 5 MR. GREEN:
 6 A. The basics are the same, but it's customized
 7 to fit with the Ventana system because with
 8 the Ventana system, we use what we call a
 9 liquid cover slip, which is an oil which coats
 10 the slides between each step and oil has to be
 11 removed before the tissues can be dehydrated
 12 clear of the mount. So that's why you use the
 13 liquid dish detergent.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, and 229, again you're the author, and
 16 this is staining immunohistochemistry slides
 17 on the Ventana Benchmark and this is
 18 instructions for such staining of slides, and
 19 you have a special precaution here, "slide
 20 label positioning is a critical procedure to
 21 ensure that the appropriate volume of reagent
 22 is placed onto the slide." So what would
 23 happen if that was--if the procedure that's
 24 set out here, and I think there's a number of
 25 six steps, if that wasn't adhered to, is there

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1 any possibility that the appropriate volume of
 2 reagent would not be placed on the slide and
 3 would the machine warn you in any way?
 4 MR. GREEN:
 5 A. There is no warning. The onus is on the
 6 person who applies the bar code label. The
 7 bar code label retains the bar code which
 8 tells the machine which protocol to use and it
 9 contains the patient information. The system
 10 is designed to work so that the label is put
 11 on top of the slide and press the label to the
 12 top of the slide and the machine will use 100
 13 microlitres of antibody to flood the slide and
 14 if that label is not stuck on properly, some
 15 of the reagent can go up underneath the label
 16 and the volume will be affected. So it's not
 17 just the label that's there. It's the
 18 positioning of the label and with the theory
 19 of the Ventana system, as it goes through its
 20 various steps there are mixing stages and
 21 antigen antibody--antibody reagents applied.
 22 The antigen retrieval solution is applied and
 23 it goes through the whole series of steps and
 24 it's designed to use that space from the top,
 25 from the bottom of the slide to the top of the

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1 label. That's the importance of the label.
 2 CHAYTOR, Q.C.:
 3 Q. Okay, and if we could have, please, page 237?
 4 And this is a procedure for troubleshooting
 5 immunohistochemistry staining and the
 6 procedure then, it suggests that you follow
 7 the activities below to troubleshoot any
 8 suboptimal immunohistochemistry staining. If
 9 there's over staining, under staining, non-
 10 staining of a particular antibody or non-
 11 staining of all antibodies and what should
 12 happen in those events, and again, Mr. Green,
 13 this is in effect as of March 19th, 2008, and
 14 I take it this is a new procedure?
 15 MR. GREEN:
 16 A. Yeah, this--although it's dated March 19th,
 17 this has been in effect since we've had the
 18 Ventana system. This was part of the training
 19 manual from Ventana.
 20 CHAYTOR, Q.C.:
 21 Q. So this is taken right out of the training
 22 manual of the Ventana?
 23 MR. GREEN:
 24 A. That's correct.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and it's indicated here to be the
 2 Ventana Benchmark troubleshooting guide?
 3 MR. GREEN:
 4 A. That's correct.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, and was that happening, a technologist
 7 working in the IHC area, was this happening
 8 that -
 9 MR. GREEN:
 10 A. That would be the normal course of events to
 11 follow when you had trouble with a stain, and
 12 if all--if you went through all these steps
 13 here and you didn't find a resolution, you
 14 would call Ventana and ask for their customer
 15 technical department.
 16 CHAYTOR, Q.C.:
 17 Q. And it says here "non-staining of particular
 18 antibody referred to the Ventana Benchmark
 19 troubleshooting guide." Why wouldn't the
 20 steps or the information from the Ventana
 21 Benchmark be--why wouldn't it just be included
 22 here along with the other information?
 23 MR. GREEN:
 24 A. Well, I guess, it would be--these steps that
 25 you see, these are for under staining and over

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1 staining.
 2 CHAYTOR, Q.C.:
 3 Q. Right, so we have -
 4 MR. GREEN:
 5 A. And like if you had non-staining -
 6 CHAYTOR, Q.C.:
 7 Q. - over staining, under staining and non-
 8 staining of a particular antibody and then
 9 non-staining of all antibodies in the run.
 10 MR. GREEN:
 11 A. When you have non-staining of all antibodies,
 12 usually you got a--if you got non-staining of
 13 all antibodies, there's probably a problem
 14 with not a particular antibody, but with the
 15 detection system or with the equipment itself.
 16 Then you would have a series of checks to go
 17 through to check out the equipment. That's
 18 when you would call in the Ventana technical
 19 people.
 20 CHAYTOR, Q.C.:
 21 Q. Right, but the non-staining of a particular
 22 antibody, so for example, if you have your ER
 23 and you check your external control and it
 24 hasn't worked, there hasn't been any staining,
 25 what--it says here "refer to the Ventana

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1 Benchmark troubleshooting guide." So what
 2 would that tell me? What would I find out?
 3 MR. GREEN:
 4 A. If you had non-staining of one particular
 5 antibody?
 6 CHAYTOR, Q.C.:
 7 Q. Yes.
 8 MR. GREEN:
 9 A. Well then, you would go through the steps to
 10 see if your--first thing you would check is
 11 your antibody itself to see if you had enough
 12 volume of antibody. That would be the most
 13 obvious check to make, because even though
 14 these antibodies come predilute from the
 15 manufacturer, then they may come with enough
 16 antibody to do 250 tests, but the onus is
 17 still on the operator to check and make sure
 18 that there is sufficient volume in that to do
 19 those tests.
 20 CHAYTOR, Q.C.:
 21 Q. So if you went looking to the Ventana
 22 Benchmark troubleshooting guide, would you
 23 find specific information to help you with a
 24 particular antibody?
 25 MR. GREEN:

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1 A. Not with a particular antibody, no.
 2 CHAYTOR, Q.C.:
 3 Q. So I'm just wondering why the steps wouldn't
 4 be recorded here. Like you have a number of
 5 bullets for each, but with respect to non-
 6 staining of a particular antibody, you've
 7 suggested just refer to the Ventana Benchmark
 8 troubleshooting guide. I'm just wondering why
 9 it wouldn't be reproduced here into your
 10 procedure.
 11 MR. GREEN:
 12 A. I would probably figure that that would be my
 13 clue to call the Ventana people, after you
 14 checked out to make sure that you had
 15 sufficient antibody to run the test.
 16 CHAYTOR, Q.C.:
 17 Q. 239, we have a run log procedure, instructions
 18 for keeping a daily log of the antibodies run,
 19 and this came into effect March 19th, 2008,
 20 and the following information that must be
 21 included in the immunohistochemistry run log.
 22 Where is this run log kept?
 23 MR. GREEN:
 24 A. Those run logs are kept in the immuno lab.
 25 CHAYTOR, Q.C.:

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1 Q. Are they kept in electronic format or paper or
 2 both?
 3 MR. GREEN:
 4 A. They're just kept in paper. What you will do,
 5 you'll go into the computer at the end of the
 6 day and you will run the total number of
 7 immunos run that day. When it says QC number,
 8 that's the QC number that it will be
 9 generated. It will tell you on July the 15th
 10 that you ran 80 immunohistochemistry slides,
 11 and that's the QC number that will be
 12 generated, but it will not link it to any
 13 particular patient.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, and I take it that's in addition to your
 16 worksheets, is that right? That's something
 17 different over and above your worksheets?
 18 MR. GREEN:
 19 A. Yes. Well, the run log, that's what I'm
 20 talking about, the run log. That's
 21 information I take from the run log and put
 22 into the computer and those sheets are just
 23 filed in the lab.
 24 CHAYTOR, Q.C.:
 25 Q. And then IHC electronic data at page 241, the

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1 procedure for managing Ventana Benchmark
 2 electronic data includes "the Ventana
 3 Benchmark computer will electronically store
 4 the run data on the hard drive." So what
 5 would the run data include?
 6 MR. GREEN:
 7 A. The run data will include everything, every
 8 patient that has been run on that system. It
 9 will include all the reagents that had been
 10 used on that system, expiry dates and lot
 11 numbers, plus every patient that has been run
 12 on the system.
 13 CHAYTOR, Q.C.:
 14 Q. Okay.
 15 MR. GREEN:
 16 A. Every antibody that's been run.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and then the Ventana has an archive
 19 electronic data binder that the disk is stored
 20 in?
 21 MR. GREEN:
 22 A. Yes, that's correct.
 23 CHAYTOR, Q.C.:
 24 Q. So do you know whether or not there was any
 25 check of the run data which was being archived

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1 by the Ventana system? I guess that went back
 2 to April 2004 when the Ventana came in
 3 operation. Do you know if there was any check
 4 for any run data which may have been archived
 5 back to April 2004 with respect to the ER/PR
 6 tests that were found to be necessary to
 7 rerun?
 8 MR. GREEN:
 9 A. I gave that zip disk to Barry who brought it
 10 to our IT department to duplicate that.
 11 CHAYTOR, Q.C.:
 12 Q. So you did do that? You brought the disk to
 13 Barry Dyer?
 14 MR. GREEN:
 15 A. Yeah.
 16 CHAYTOR, Q.C.:
 17 Q. And that was given, to your knowledge, to the
 18 IT department?
 19 MR. GREEN:
 20 A. Who were going to--they were supposed to print
 21 out a hard copy of all the information which
 22 would have been--which would have reported all
 23 the information from the first day that the
 24 system went into operation.
 25 CHAYTOR, Q.C.:

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1 Q. And have you seen the results of that? Have
 2 you seen anything?
 3 MR. GREEN:
 4 A. I have not.
 5 CHAYTOR, Q.C.:
 6 Q. So after passing that in--when did you give
 7 that to Mr. Dyer?
 8 MR. GREEN:
 9 A. It's been a while ago. I don't know exactly
 10 when.
 11 CHAYTOR, Q.C.:
 12 Q. Okay. I don't think we have that either. I
 13 don't know if maybe Mr. Simmons can check?
 14 MR. SIMMONS:
 15 Q. I can check.
 16 CHAYTOR, Q.C.:
 17 Q. Check on that, thank you. We're almost to the
 18 end, Mr. Green. There are a number--I'm just
 19 looking through here, but they're still in
 20 draft form and the authors are other than
 21 yourself, so we'll have other people that we
 22 can ask some questions of regarding those.
 23 Mr. Green, whose responsibility is it to
 24 ensure that--there's now been a lot of work
 25 done on these procedures and policies and

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1 whose responsibility is it to ensure or what
 2 checks and balances are built into the system
 3 to ensure that the policies and procedures
 4 are, in fact, followed?
 5 MR. GREEN:
 6 A. We have a QA department now which are
 7 basically responsible for making sure that
 8 these standard operating procedures are in
 9 place. It is the manager's responsibility to--
 10 I guess it's the QA's responsibility to make
 11 sure that they are delivered to the lab and
 12 it's probably the manager's responsibility to
 13 make sure that everybody has read and signed
 14 off on the--read the procedure.
 15 CHAYTOR, Q.C.:
 16 Q. So, for example, you've had a new person start
 17 and you have someone else who's just recently
 18 started. You had somebody start last fall and
 19 have you been involved in the training of
 20 those people at all?
 21 MR. GREEN:
 22 A. Yes.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and what do you do to ensure that they
 25 are familiar with the procedures?

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1 MR. GREEN:
 2 A. When they come into the lab, they're required
 3 to physically sit down and go through these
 4 procedures as they come in, and as you can
 5 see, a lot of these have only come in
 6 recently, so they're -
 7 CHAYTOR, Q.C.:
 8 Q. Yes, and how, in terms of their training, and
 9 I realize one person has just recently
 10 started, but the person who started some six
 11 months or more ago, how does their training
 12 compare--their training in the IHC processes
 13 compare to what you received when you joined
 14 in 2002?
 15 MR. GREEN:
 16 A. It is a much more hands-on approach. I will
 17 take the time to make sure that the person
 18 who's training understands the operation of
 19 the equipment, understands the
 20 troubleshooting, understands the importance of
 21 the different components and they're
 22 encouraged to go to the educational sessions.
 23 They're encouraged to take part in the
 24 educational sessions. We're now doing
 25 distance education from NSH and I've been

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1 informed that there will be a formal system
 2 set up for the--set up in the fall of this
 3 year, formalized sequential system set up for
 4 people who are coming into the system, so that
 5 they will be assessed on an ongoing basis.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and has there--have they been sent, the
 8 person in particular who started last fall,
 9 has that person been sent for any training
 10 elsewhere or have they been sent to a
 11 convention or symposium?
 12 MR. GREEN:
 13 A. Yes, the person that has been there now for
 14 the last six months or so, she's been sent to
 15 the 2007 NSH conference in Colorado.
 16 CHAYTOR, Q.C.:
 17 Q. And do you know if there's a requirement that
 18 any new hires into--technologists into the IHC
 19 lab are to receive such training and
 20 education?
 21 MR. GREEN:
 22 A. Yeah, that will be the normal practice from
 23 here on in. Part of the funding is already in
 24 place to send at least one person a year from
 25 the IHC to one of those conferences.

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1 CHAYTOR, Q.C.:

2 Q. And Mr. Green, I appreciate you've done a lot

3 of work on these procedures, and from what

4 you've told us, it appears you became involved

5 in December 2007, shortly before QMPLS came

6 in. Do you know why it took so long to create

7 and bring into effect these policies and

8 procedures?

9 MR. GREEN:

10 A. I would guess because we didn't have a

11 dedicated person on staff who could handle the

12 workload.

13 CHAYTOR, Q.C.:

14 Q. Thank you for your time. Those are my

15 questions, and I'm sure some of the other

16 lawyers may have questions for you.

17 MR. GREEN:

18 A. Thank you.

19 THE COMMISSIONER:

20 Q. Mr. Pritchard?

21 MR. PRITCHARD:

22 Q. Thank you, Commissioner. I don't have any

23 questions for Mr. Green. Thank you very much.

24 THE COMMISSIONER:

25 Q. Mr. Browne?

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1 MR. BROWNE:

2 Q. I do have some questions, Commissioner.

3 THE COMMISSIONER:

4 Q. Do you want to take the luncheon break first?

5 If you want to do that, I'm quite happy to

6 accommodate--it's the normal point.

7 MR. BROWNE:

8 Q. Sure. That's what I'm just wondering, whether

9 it would be -

10 THE COMMISSIONER:

11 Q. Well, it's probably easier on Mr. Green if we

12 gave him lunch before he had to -

13 MR. BROWNE:

14 Q. I would think that would be fair.

15 THE COMMISSIONER:

16 Q. All right then. Can we do the rounds of the

17 room and see how much time we're going to

18 require this afternoon?

19 MR. BROWNE:

20 Q. I anticipate I'll be about 20-25 minutes.

21 THE COMMISSIONER:

22 Q. All right. Mr. Pritchett?

23 MR. PRITCHETT:

24 Q. We don't anticipate any questions,

25 Commissioner.

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1 THE COMMISSIONER:

2 Q. Ms. Newbury?

3 MS. NEWBURY:

4 Q. About ten minutes or so.

5 THE COMMISSIONER:

6 Q. Mr. Pike?

7 MR. PIKE:

8 Q. No questions.

9 THE COMMISSIONER:

10 Q. Mr. Simmons, do you want to weigh in?

11 MR. SIMMONS:

12 Q. I'll probably be no more than five minutes,

13 depending on what happens.

14 THE COMMISSIONER:

15 Q. All right, then I guess we can schedule the

16 next witness with that in mind, and we'll

17 start at two. Thank you all.

18 (LUNCH BREAK)

19 THE COMMISSIONER:

20 Q. Mr. Browne.

21 MR. KENNETH GREEN, EXAMINATION BY MR. PETER BROWNE

22 MR. BROWNE:

23 Q. Good afternoon, Mr. Green.

24 MR. GREEN:

25 A. Good afternoon.

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1 MR. BROWNE:

2 Q. I'm Peter Browne. I think we've met

3 previously. I represent a number of the

4 individual physicians who've been asked to

5 give evidence here for the Commission, and

6 there's a couple of areas I want to cover with

7 you, and before I begin, if there's some

8 redundancy here, I apologize. I understand in

9 your profession or at least in the medical

10 profession, redundancy is not a bad thing. In

11 our profession, it's kind of frowned upon. So

12 I apologize if I am redundant.

13 I want to begin with your training in

14 2002. We heard from Ms. Welsh, who I

15 understood you confirmed that she was the

16 person who trained you into the job in 2002,

17 and Ms. Welsh, in giving her testimony to the

18 Commissioner, remarked, I think, that during

19 the time she was at the Health Sciences, it

20 was common knowledge not to go looking for

21 continuing education funding because the money

22 wasn't there. Now you were both at St.

23 Clare's and at Health Sciences Centre. What's

24 your impressions about the time, I guess let's

25 look at the '90s and into the point of 2005,

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1 we'll use it as a cut off--what's your
 2 impressions with regard to Mrs. Welsh's
 3 comments?
 4 MR. GREEN:
 5 A. I would agree with that statement. There
 6 wasn't a lot of extra money for educational
 7 purposes or any other purpose for that matter.
 8 MR. BROWNE:
 9 Q. Okay, and that was both your experience at St.
 10 Clare's and Health Sciences?
 11 MR. GREEN:
 12 A. It would be the same for both. You would get-
 13 -you were afforded money for local conferences
 14 for registration at those conferences, but
 15 anything else, hotel accommodations, anything
 16 else, you would have to cover on your own
 17 expense.
 18 MR. BROWNE:
 19 Q. And did you ever make inquiries about why the
 20 money wasn't there or go looking for money for
 21 these conferences and get, you know, refused
 22 or anything like that?
 23 MR. GREEN:
 24 A. It was just that the money wasn't there.
 25 MR. BROWNE:

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1 Q. Okay, and that was--that sort of, it was made
 2 known to all and sundry that this was the
 3 case. Is that right?
 4 MR. GREEN:
 5 A. It was common knowledge.
 6 MR. BROWNE:
 7 Q. Okay. What about opportunities to--when you
 8 came over to the Health Sciences in 2002 and
 9 started doing immunohistochemistry, did you
 10 realize that that was sort of quite a
 11 different field from what you'd been doing
 12 previously at St. Clare's?
 13 MR. GREEN:
 14 A. It was all new.
 15 MR. BROWNE:
 16 Q. Okay. Were you ever given the opportunity to
 17 read about the subject, either around the time
 18 Ms. Welsh was training you or afterwards?
 19 MR. GREEN:
 20 A. There was never any free time to read or there
 21 wasn't any time set specifically for reading
 22 or study.
 23 MR. BROWNE:
 24 Q. Now we've heard the notion of protected time.
 25 Is that something you've heard about as well,

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1 is that a term--and let me ask you, as the
 2 technologist who's now sort of overseeing
 3 this, the most senior technologist, the notion
 4 of getting people such as yourself and your
 5 colleagues protected time, do you have any
 6 thoughts on that subject?
 7 MR. GREEN:
 8 A. It would be invaluable. It probably would be
 9 the only opportunity that some people will get
 10 to get additional information, to study theory
 11 and to check out articles, you know. With
 12 being so busy and just trying to get the day's
 13 work done, if you could take an hour and have
 14 a designated time, it would be invaluable.
 15 MR. BROWNE:
 16 Q. And I guess that potential is there with the
 17 Health Sciences library nearby that if there
 18 are textbooks or whatever that are not
 19 necessarily in the lab, that those could be
 20 available, journals could be available through
 21 the Health Sciences Centre as well?
 22 MR. GREEN:
 23 A. That's true.
 24 MR. BROWNE:
 25 Q. Now pathologists have been, I think, at some

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1 point given a period of time for continuing
 2 medical education. One point is one week, I
 3 think we've heard from some pathologists. Do
 4 you have an equivalent period of time where
 5 you can go off and do -
 6 MR. GREEN:
 7 A. There's no designated time.
 8 MR. BROWNE:
 9 Q. Okay. Again, is that something that would be
 10 worthwhile?
 11 MR. GREEN:
 12 A. It would be invaluable.
 13 MR. BROWNE:
 14 Q. In terms of your--and just staying with your
 15 knowledge base and how it has changed since
 16 2002, reflecting back on your evidence the
 17 other day, am I correct in stating that, I
 18 guess, the main sources of your increased
 19 knowledge since that time were Dr. Ejeckam in
 20 2003 onward?
 21 MR. GREEN:
 22 A. That's true.
 23 MR. BROWNE:
 24 Q. Your Ventana training in 2004 in Arizona?
 25 MR. GREEN:

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1 A. True.
 2 MR. BROWNE:
 3 Q. Your IHC conferences in 2005, 2006?
 4 MR. GREEN:
 5 A. That's true.
 6 MR. BROWNE:
 7 Q. And then Montreal Jewish General, your time
 8 you spent there. So that would be sort of the
 9 major sort of knowledge base?
 10 MR. GREEN:
 11 A. Yes.
 12 MR. BROWNE:
 13 Q. Now the time you spent in Arizona in 2004, I
 14 think you had commented, and I'm not sure, and
 15 I apologize if this was canvassed by Ms.
 16 Chaytor, but you learnt about the theory of
 17 antigen retrieval. Is that right?
 18 MR. GREEN:
 19 A. We learnt about the theory of IHC in general.
 20 MR. BROWNE:
 21 Q. Okay, sorry, and was there anything in
 22 particular about antigen retrieval that you
 23 learned there in 2004?
 24 MR. GREEN:
 25 A. Not specifically, but generally.

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1 MR. BROWNE:
 2 Q. Okay, and the person who taught you this
 3 course and gave you this information was a
 4 technologist? Is that right?
 5 MR. GREEN:
 6 A. I'm not sure if it was a technologist, but
 7 that's what I assumed.
 8 MR. BROWNE:
 9 Q. And in terms of learning about internal
 10 controls, that's not something you learned
 11 until 2005, did I understand that today?
 12 MR. GREEN:
 13 A. I would have no knowledge of internal controls
 14 until Dr. Ejeckam showed me.
 15 MR. BROWNE:
 16 Q. And that was in 2005?
 17 MR. GREEN:
 18 A. Yeah.
 19 MR. BROWNE:
 20 Q. Okay. Now you also mentioned, I think the
 21 other day, your experience at Montreal Jewish
 22 General that the technologists or at least the
 23 technologist who you interacted with was
 24 trained to look at both external internal
 25 controls?

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1 MR. GREEN:
 2 A. Yes. I don't know about trained, but she had
 3 knowledge in that area, but she had spent
 4 approximately 30 years in that field, so her
 5 knowledge would have been cumulative. But I
 6 really don't know how she learned about
 7 internal control.
 8 MR. BROWNE:
 9 Q. And you don't know whether or not, or did you
 10 inquire as to whether or not she had any
 11 responsibility in conjunction with the
 12 pathologist to check internal controls in
 13 conjunction with the external control?
 14 MR. GREEN:
 15 A. From my visit there, I was under the
 16 impression that she was not obligated to check
 17 internal controls because they were in the
 18 patient's tissue and that wasn't part of her -
 19 MR. BROWNE:
 20 Q. I was unclear on that point. Now the practice
 21 in St. John's, and again, let's use the
 22 demarkation of 2005, from 2002 to 2005, did I
 23 understand your evidence the other day that
 24 you were checking the external control under
 25 the microscope to see if it was positive

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1 before sending it out? Is that right?
 2 MR. GREEN:
 3 A. To see that there was a reaction.
 4 MR. BROWNE:
 5 Q. See there was a reaction, and then you would
 6 then show the controls to pathologists before
 7 sending them out?
 8 MR. GREEN:
 9 A. Show the controls -
 10 MR. BROWNE:
 11 Q. The external control?
 12 MR. GREEN:
 13 A. Out-of-town cases or -
 14 MR. BROWNE:
 15 Q. Well, let's--the in-town cases, you would just
 16 put in -
 17 MR. GREEN:
 18 A. Put in their mail box in the reading room.
 19 MR. BROWNE:
 20 Q. And the out-of-town cases, you would do what?
 21 MR. GREEN:
 22 A. We would check with one of the pathologists
 23 before we sent them out.
 24 MR. BROWNE:
 25 Q. Right, okay, and I think there was some--at

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1 some point, you mentioned that that wouldn't
 2 always be the case. Is that right? Did I
 3 understand you that sometimes it's possible
 4 you may have sent it out without checking it
 5 with a pathologist?
 6 MR. GREEN:
 7 A. Probably not likely. Most likely I would
 8 check with the pathologist.
 9 MR. BROWNE:
 10 Q. Okay, and just if you were asked again the
 11 other day by Ms. Chaytor, if a pathologist had
 12 a problem with an external control not
 13 working, the process you would go through--
 14 again now, this is between 2002-2005, you
 15 would repeat the test?
 16 MR. GREEN:
 17 A. That would be the most obvious step.
 18 MR. BROWNE:
 19 Q. Okay. I think you also mentioned troubleshoot
 20 to find out what the problem was.
 21 MR. GREEN:
 22 A. Yes.
 23 MR. BROWNE:
 24 Q. Okay. Did you ever do that under the DAKO
 25 regime? I'll use the term DAKO--distinguish

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1 between DAKO and Ventana for the moment.
 2 MR. GREEN:
 3 A. The initial repeat, it would be the same on
 4 either system.
 5 MR. BROWNE:
 6 Q. Okay, no, the troubleshooting.
 7 MR. GREEN:
 8 A. And the troubleshooting wouldn't be so easy on
 9 the DAKO system because I was not as familiar
 10 with the DAKO system. At that time, I
 11 probably would have only had one year's
 12 experience and out of that, one-third of the
 13 time was actually spent on the machine. But
 14 most of my knowledge was developed on the
 15 Ventana system.
 16 MR. BROWNE:
 17 Q. Do you recall ever having an instance where
 18 you were required to troubleshoot on the DAKO
 19 machine?
 20 MR. GREEN:
 21 A. Nothing in particular, but I'm sure there have
 22 been cases where we would have had to have
 23 repeats.
 24 MR. BROWNE:
 25 Q. Okay, and was there--you mentioned today that

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1 the Ventana had a guide on troubleshooting.
 2 Was there an equivalent guide under the DAKO?
 3 MR. GREEN:
 4 A. I have never seen it.
 5 MR. BROWNE:
 6 Q. Okay, and I think you mentioned as well that
 7 if it was brought to your attention an
 8 external control failed, there was no--and
 9 this is again in answer to a question from Ms.
 10 Chaytor the other day, no automatic policy to
 11 rerun all the slides for that batch?
 12 MR. GREEN:
 13 A. That's correct.
 14 MR. BROWNE:
 15 Q. And I think you said as part of that answer,
 16 because it was the pathologist's
 17 responsibility to pick up appropriate--to pick
 18 the appropriate block with the appropriate
 19 internal control, that they would read the
 20 internal control?
 21 MR. GREEN:
 22 A. Yes.
 23 MR. BROWNE:
 24 Q. But you wouldn't have known about internal
 25 controls until 2005.

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1 MR. GREEN:
 2 A. That's true.
 3 MR. BROWNE:
 4 Q. So you wouldn't have known that piece of
 5 information?
 6 MR. GREEN:
 7 A. No, I would not, that's true.
 8 MR. BROWNE:
 9 Q. Okay, and when you trained with Ms. Welsh,
 10 there was no discussion about the notion, at
 11 least for ER/PR, and I guess so I'm clear on
 12 this, when you were trained by Ms. Welsh, you
 13 were trained generally in IHC? Is that right?
 14 MR. GREEN:
 15 A. Yes.
 16 MR. BROWNE:
 17 Q. Would that training period have included
 18 potentially ER and PR, do you know?
 19 MR. GREEN:
 20 A. ER/PR would have been run during that period,
 21 along with all the other antibodies. I'm sure
 22 it would be.
 23 MR. BROWNE:
 24 Q. And the notion of the nuclear staining,
 25 importance of nuclear staining, was that ever

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1 discussed between you and Ms. Welsh?
 2 MR. GREEN:
 3 A. No, at that stage, the basic training was on
 4 running the equipment.
 5 MR. BROWNE:
 6 Q. Okay. Now in terms of showing the external
 7 controls to a pathologist, would you just walk
 8 through that process with me, if you could for
 9 a minute. You'd show the slide, the external
 10 control slide. Is that right?
 11 MR. GREEN:
 12 A. Are we talking DAKO or Ventana?
 13 MR. BROWNE:
 14 Q. Again, let's stay with DAKO for the time
 15 being, pre--yes, because I keep forgetting
 16 between--let's use the--let me rephrase this.
 17 Instead of using 2005, let's go 2004, pre
 18 2004.
 19 MR. GREEN:
 20 A. Okay.
 21 MR. BROWNE:
 22 Q. The external control under DAKO, when you went
 23 to a pathologist with the external control,
 24 would you bring any other documentation with
 25 you?

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1 MR. GREEN:
 2 A. No. Now there was a time at the Health
 3 Science where the controls were all put in the
 4 reading room for a pathologist to check. So
 5 when that occurred, you would not go to a
 6 particular pathologist. You know, you would
 7 not have any interaction with them at all.
 8 You would just put the controls out in the
 9 reading room.
 10 MR. BROWNE:
 11 Q. Okay, but the times where you did go to
 12 pathologists and ask a pathologist to check
 13 the external controls, can you tell me would
 14 you--besides giving the slide to the
 15 pathologist, would you give him any other
 16 documentation?
 17 MR. GREEN:
 18 A. Not that--I can't remember doing so.
 19 MR. BROWNE:
 20 Q. What would you tell the pathologist?
 21 MR. GREEN:
 22 A. You'd be telling him that--depending on which
 23 antibody you were running, you could ask him
 24 to check the control, because sometimes not
 25 all controls are of equal value. They'll ask

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1 him a control--if this was a good control, and
 2 if it wasn't a good control, they would say
 3 "well, it could be better" or could have that
 4 conversation.
 5 MR. BROWNE:
 6 Q. Would that be your practice every time you
 7 spoke to a pathologist?
 8 MR. GREEN:
 9 A. No, not--no, a lot of controls worked
 10 regularly all the time and you would just say
 11 "can you check this for me?"
 12 MR. BROWNE:
 13 Q. Okay, and would there be anything else, but
 14 just say "just check this"?
 15 MR. GREEN:
 16 A. Yeah.
 17 MR. BROWNE:
 18 Q. That would be -
 19 MR. GREEN:
 20 A. You might ask them for their opinion and they
 21 would say it's fine.
 22 MR. BROWNE:
 23 Q. Okay, what about on reruns, would you let the
 24 pathologist know that this was rerun?
 25 MR. GREEN:

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1 A. On a rerun, you mean a repeat?
 2 MR. BROWNE:
 3 Q. Yes.
 4 MR. GREEN:
 5 A. Usually the pathologist would--we would--
 6 unless there was something obviously wrong,
 7 the pathologist would get the slides and they
 8 would be the one to request a repeat.
 9 MR. BROWNE:
 10 Q. Right, but if you were--if it was somebody
 11 outside the Health Sciences asking for a
 12 repeat, would the pathologist--would you check
 13 that with the pathologist before sending it
 14 out to the outside, if it was a repeat?
 15 MR. GREEN:
 16 A. Not necessarily, no more than checking with a
 17 normal--a repeat wouldn't be--wouldn't
 18 necessarily send up a flag or anything.
 19 MR. BROWNE:
 20 Q. But would you tell the pathologist that it was
 21 a repeat and the reasons for the repeat?
 22 MR. GREEN:
 23 A. You may, depending on what the circumstances
 24 were.
 25 MR. BROWNE:

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1 Q. Now antigen retrieval, again, I want to just
 2 be clear on a point. Did you--when you were
 3 testifying the other day, was the control
 4 slide exposed to the same antigen retrieval
 5 technique as all the other slides? Again,
 6 DAKO, so we're clear on this.
 7 MR. GREEN:
 8 A. DAKO control slides, yes, it would, because if
 9 you're using an ER, the protocol for that ER
 10 would have to be the same as the protocol for
 11 the -
 12 THE COMMISSIONER:
 13 Q. Are you talking about a separate control
 14 slide?
 15 MR. BROWNE:
 16 Q. Yes, separate control slide.
 17 MR. GREEN:
 18 A. Yes, it would have to be treated the same way.
 19 MR. BROWNE:
 20 Q. Okay, and are they done--just so--we heard
 21 about batches. Is the antigen retrieval
 22 process for each patient slide, again under
 23 the DAKO system, done at the same time as the
 24 control slide?
 25 MR. GREEN:

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1 A. Yes.
 2 MR. BROWNE:
 3 Q. Okay, and you'd mentioned there was some
 4 occasions where the robotic arm on the DAKO
 5 machine, there was some difficulties with it.
 6 Were these ever reported to your superiors at
 7 all or would you just--the responsibility
 8 would be with you to contact maintenance or
 9 DAKO?
 10 MR. GREEN:
 11 A. If we had a problem, we would contact--usually
 12 contact the biomedical department and they
 13 would send somebody down to do the necessary
 14 repairs.
 15 MR. BROWNE:
 16 Q. So there was no sort of reporting mechanism to
 17 your superiors about problems or anything like
 18 that?
 19 MR. GREEN:
 20 A. No.
 21 MR. BROWNE:
 22 Q. Now tissue processing, Mr. Green, I just want
 23 to go over that for a minute, just so I'm
 24 clear on a couple of points. If a block was
 25 reprocessed, it would not be distinguishable

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1 from an ordinary block that wasn't? Is that
 2 right?
 3 MR. GREEN:
 4 A. Not normally, no.
 5 MR. BROWNE:
 6 Q. Okay, and that sometime in the '80s, while you
 7 were at St. Clare's, a particular pathologist,
 8 I think it's Dr. Tadross, is that -
 9 MR. GREEN:
 10 A. That's correct.
 11 MR. BROWNE:
 12 Q. - mentioned about reprocessing blocks?
 13 MR. GREEN:
 14 A. That's true.
 15 MR. BROWNE:
 16 Q. And I think you said it became policy after
 17 that?
 18 MR. GREEN:
 19 A. After that, it was common practice.
 20 MR. BROWNE:
 21 Q. Common practice, it wasn't a policy?
 22 MR. GREEN:
 23 A. No.
 24 MR. BROWNE:
 25 Q. There was no written policy?

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1 MR. GREEN:
 2 A. No.
 3 MR. BROWNE:
 4 Q. Okay, and was that made known to every
 5 pathologist that came through St. Clare's?
 6 MR. GREEN:
 7 A. They would have known if their breast
 8 specimen, if they were waiting on their breast
 9 specimen and it was delayed, but they would
 10 not necessarily be notified otherwise.
 11 MR. BROWNE:
 12 Q. So how would -- so they -- you're saying the
 13 inference would be that if it was delayed,
 14 that would mean it was reprocessed?
 15 MR. GREEN:
 16 A. That would be one of the reasons for it being
 17 reprocessed.
 18 MR. BROWNE:
 19 Q. Would that be communicated?
 20 MR. GREEN:
 21 A. Not necessarily. No, you would not -- a
 22 pathologist if he or she had a busy workload
 23 and there were a lot of cases, he may not be
 24 expecting to get to a case for a couple of
 25 days, so he may never know it was reprocessed.

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1 MR. BROWNE:
 2 Q. Okay, thanks. Likewise, if there was a problem
 3 with the tissue processor, would you be able
 4 to tell from the block, by looking at the
 5 block there was a problem with the tissue
 6 processor?
 7 MR. GREEN:
 8 A. Not -- sometimes it's not obvious until the
 9 pathologist will look at it under the
 10 microscope, you know. You can't always tell.
 11 MR. BROWNE:
 12 Q. And you mentioned this morning -- I just want
 13 to deal now with the positively charged
 14 slides, and if you could clarify for me, the
 15 importance of using positively charged slides
 16 for IHC is what?
 17 MR. GREEN:
 18 A. The positively charged slide helps adhere the
 19 tissue to the slide because the slides that
 20 are subject to antigen retrieval have a higher
 21 tendency to wash off or lose part of the
 22 tissue. In the old system under the DAKO, we
 23 used what we call an adhesive called
 24 histogrip. It was used for slides which were
 25 going to receive antigen retrieval. Now if

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1 somebody sent in a slide from out of town and
 2 they wanted that slide -- an ER/PR done on
 3 that slide, chances are it wouldn't be an
 4 histogrip slide and it wouldn't be a positive
 5 charged slide. So you would go ahead and do
 6 that. The chances would increase that you
 7 would lose tissue on a slide.
 8 MR. BROWNE:
 9 Q. And in terms of Eastern Health and its
 10 predecessor, Health Care Corporation, who
 11 would be in charge of ordering slides for a
 12 lab?
 13 MR. GREEN:
 14 A. Ordering slides for the lab?
 15 MR. BROWNE:
 16 Q. Yeah, and the positively charged slides and so
 17 on, whose responsibility is that?
 18 MR. GREEN:
 19 A. The positively charged slides right now we
 20 would just set up so we order them every
 21 couple of months, but back then I'm not really
 22 sure who was responsible.
 23 MR. BROWNE:
 24 Q. And the notion of having positively charged
 25 slides, when was that brought to your

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1 attention?
 2 MR. GREEN:
 3 A. I became aware of it when we brought in the
 4 Ventana System. The very first day we went
 5 through on the system and the person who was
 6 installing the system said we're going to need
 7 some slides, so I go and bring down some
 8 regular slides and she says, oh, no, we can't
 9 use these slides, we need positively charged
 10 slides because the system is compatible with
 11 those. So up to that point --
 12 MR. BROWNE:
 13 Q. And did you disseminate that information to
 14 anybody else like your superiors, your
 15 managers, or anything like that?
 16 MR. GREEN:
 17 A. Well, my manager was there with me at the
 18 time, so Barry would have been aware of it at
 19 the same time that I was.
 20 MR. BROWNE:
 21 Q. And was that -- do you know if that
 22 information was ever disseminated around the
 23 island to other labs?
 24 MR. GREEN:
 25 A. I remember we used to receive slides from

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1 Corner Brook -- most outside hospitals would
 2 send in the blocks and we would cut the
 3 blocks, so it wasn't a problem.
 4 MR. BROWNE:
 5 Q. Okay.
 6 MR. GREEN:
 7 A. But Western Memorial, they would send in
 8 slides of their own because I guess when they
 9 cut the slides, they wanted to make sure that
 10 if they didn't have a lot of tissue, it was
 11 easier for them to cut those slides and send
 12 them in. When they first started to send them
 13 in, they were on regular slides. So we
 14 mentioned it to the -- I guess we mentioned it
 15 to the manager and they probably called them
 16 or sent them a memo, and we sent out samples
 17 of slides that we were using and asked them to
 18 order their own.
 19 MR. BROWNE:
 20 Q. Would that have been in 2004 after the Ventana
 21 came on line?
 22 MR. GREEN:
 23 A. It would have been after Ventana came on line
 24 because that's the only time it was an issue.
 25 MR. BROWNE:

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1 Q. And just going back, you mentioned as well the
 2 histogrip, and you found out about the
 3 histogrip slides when you came over to the
 4 Health Science?
 5 MR. GREEN:
 6 A. Over to the Health Science. We didn't use
 7 them at St. Clare's.
 8 MR. BROWNE:
 9 Q. Was that ever communicated back to St.
 10 Clare's, do you know?
 11 MR. GREEN:
 12 A. Not that I'm aware of.
 13 MR. BROWNE:
 14 Q. Is there any reason why that wasn't
 15 communicated back to St. Clare's?
 16 MR. GREEN:
 17 A. In the beginning, St. Clare's would cut their
 18 own slides and send over, but somewhere along
 19 the process the policy changed and the blocks
 20 were sent to the Health Sciences, so that the
 21 issue probably took care of itself.
 22 COMMISSIONER:
 23 Q. Mr. Green, are you saying that the positively
 24 charged slides were a requirement for the use
 25 of the Ventana machine?

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1 MR. GREEN:
 2 A. It is, yes.
 3 COMMISSIONER:
 4 Q. As opposed to somebody saying really you ought
 5 not use a ordinary slide when you're doing
 6 antigen retrieval?
 7 MR. GREEN:
 8 A. No, the --
 9 COMMISSIONER:
 10 Q. Do you get my difference?
 11 MR. GREEN:
 12 A. The Ventana system required it. You didn't
 13 run regular slides.
 14 COMMISSIONER:
 15 Q. Okay, thank you.
 16 MR. BROWNE:
 17 Q. Again I apologize for going back to antigen
 18 retrieval on the DAKO System. What was the
 19 method that you employed at the Health
 20 Sciences for antigen retrieval?
 21 MR. GREEN:
 22 A. Antigen retrieval was performed in the water
 23 bath.
 24 MR. BROWNE:
 25 Q. Water bath?

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1 MR. GREEN:
 2 A. We had a water bath which was set up which was
 3 heated to between 95 and 100 degrees. In that
 4 water bath we would put a glass dish and the
 5 antigen retrieval solution was in the glass
 6 dish, and then used a thermometer to check the
 7 temperature of the antigen retrieval, not of
 8 the water.
 9 MR. BROWNE:
 10 Q. Okay.
 11 MR. GREEN:
 12 A. So then you would put the slides that you had
 13 for antigen retrieval into the coplin jar
 14 inside the water bath and set your timer for
 15 20 minutes.
 16 MR. BROWNE:
 17 Q. And this was big enough to, I guess, hold the
 18 whole batch, was it?
 19 MR. GREEN:
 20 A. It was big enough to hold a rack of slides.
 21 MR. BROWNE:
 22 Q. Okay. Now just on that point -- and you found
 23 out subsequent through Mount Sinai that they
 24 use a different method, they use the pressure
 25 cooker?

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1 MR. GREEN:
 2 A. Yes.
 3 MR. BROWNE:
 4 Q. Can we just -- Registrar, can I have Exhibit
 5 P-2155, please. Do you see the ER/PR section
 6 here. This is for the DAKO machine, is it,
 7 Mr. Green?
 8 MR. GREEN:
 9 A. Yes.
 10 MR. BROWNE:
 11 Q. It mentions somewhere here Visionware boiling
 12 method. Is that what you were using? Do you
 13 see that there, third line?
 14 MR. GREEN:
 15 A. I would assume that it's the boiling method
 16 that we were using at the Health Science, yes.
 17 MR. BROWNE:
 18 Q. But you're not certain of that, are you?
 19 MR. GREEN:
 20 A. I'm not certain. I wouldn't -- no, I'm not
 21 certain.
 22 MR. BROWNE:
 23 Q. Do you know what it was called, the particular
 24 water bath? Did it have a -- did it have a --
 25 MR. GREEN:

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1 A. It was always referred to as the water bath
 2 method.
 3 MR. BROWNE:
 4 Q. And when you talked about -- I think it was
 5 the other day when Ms. Chaytor was asking you
 6 some questions about a run. That would be the
 7 whole process, would it be?
 8 MR. GREEN:
 9 A. A run would be all the slides.
 10 MR. BROWNE:
 11 Q. From start to finish --
 12 MR. GREEN:
 13 A. From start to finish.
 14 MR. BROWNE:
 15 Q. Through the whole process.
 16 MR. GREEN:
 17 A. A run could be 48 slides or it may be 10
 18 slides.
 19 MR. BROWNE:
 20 Q. Fair enough, but it would be -- so I'm clear
 21 as to what you're saying, that would mean the
 22 whole antibody -- employment of the primary
 23 and secondary antibody?
 24 MR. GREEN:
 25 A. Yes.

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1 MR. BROWNE:
 2 Q. The antigen retrieval?
 3 MR. GREEN:
 4 A. Yeah, start to --
 5 MR. BROWNE:
 6 Q. Start to finish?
 7 MR. GREEN:
 8 A. Correct.
 9 MR. BROWNE:
 10 Q. Okay, thanks, and that usually took about
 11 three hours?
 12 MR. GREEN:
 13 A. Depending on the number of slides, around
 14 three to three and a half hours.
 15 MR. BROWNE:
 16 Q. Were there various points where you would have
 17 to intervene in that process and you would
 18 have to time and so on?
 19 MR. GREEN:
 20 A. Once the system is set up and you had your
 21 antigen retrieval slides, the slides -- when
 22 you set up your run, you divide it into what
 23 we call AR slides and non AR slides. The non
 24 AR slides didn't have anything to -- we just
 25 took those from the oven, dehydrated those,

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1 took the -- removed the wax from them, brought
 2 them to water (phonetic). They're ready to go
 3 on the machine, they're kept in water, and
 4 then we would do the antigen retrieval slides
 5 which means that they had to be dehydrated,
 6 wax removed, brought to water. They'd be --
 7 you do the antigen retrieval process and take
 8 those -- then you would catch up all your
 9 slides, then load them all on the machine, and
 10 then your run would start.
 11 MR. BROWNE:
 12 Q. I guess what I'm unclear on is were there
 13 points in there where you had to be in the
 14 room at all times?
 15 MR. GREEN:
 16 A. No, the only point that you wanted to monitor
 17 was when you put the slides for antigen
 18 retrieval in the antigen retrieval solution
 19 and then you set a clock for twenty minutes.
 20 MR. BROWNE:
 21 Q. So that's the one where you had to be there?
 22 MR. GREEN:
 23 A. That's the point where you would want to
 24 remove your slides from antigen retrieval.
 25 MR. BROWNE:

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1 Q. Thank you. When you started in 2002, as well
 2 -- and prior to that time over at St. Clare's,
 3 formalin was made in-house, I think, up until
 4 about 2003, is that right?
 5 MR. GREEN:
 6 A. That's true.
 7 MR. BROWNE:
 8 Q. Were you following -- and you had a crossover
 9 period both at Health Sciences and at St.
 10 Clare's?
 11 MR. GREEN:
 12 A. True.
 13 MR. BROWNE:
 14 Q. Were you involved in performing the
 15 preparation at both institutions?
 16 MR. GREEN:
 17 A. Not at the Health Science at all. That wasn't
 18 part of my job over there. At St. Clare's, it
 19 was very infrequently. The lab assistant's
 20 job was to make up the formalin.
 21 MR. BROWNE:
 22 Q. Was there a particular protocol in place at
 23 St. Clare's, do you know, for --
 24 MR. GREEN:
 25 A. There was a recipe to follow.

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1 MR. BROWNE:
 2 Q. I'm almost there. Just a few more questions.
 3 Now antigen retrieval, that was the
 4 responsibility of the technologist to do?
 5 MR. GREEN:
 6 A. It was.
 7 MR. BROWNE:
 8 Q. And I think you answered to Ms. Chaytor the
 9 other day that there was no pathologist
 10 suggested any changes to antigen retrieval.
 11 Why would a pathologist suggest changes to
 12 antigen retrieval?
 13 MR. GREEN:
 14 A. If a particular pathologist was fairly
 15 familiar with an antibody and it probably
 16 wasn't performing to what they expected it to
 17 perform, especially on a particular patient,
 18 they would probably suggest something
 19 different, but not -- most of the pathologists
 20 would not have that knowledge. It would be
 21 only someone like Dr. Ejeckam who would.
 22 MR. BROWNE:
 23 Q. Would a pathologist, in fact, be able by
 24 looking at the slide determine antigen
 25 retrieval?

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1 MR. GREEN:
 2 A. No.
 3 MR. BROWNE:
 4 Q. You were asked -- I'll actually come back to
 5 this, Mr. Green. Registrar, could we show Mr.
 6 Green Exhibit P-1576, please, page three. You
 7 were asked, I think both the other day and
 8 today, about the quality assurance in the lab,
 9 and if you would look at the item there it's
 10 new business. It says -- and this is
 11 September 24, 2003, Minutes of the Division of
 12 Anatomic Pathology. It says, "Laboratory
 13 technical quality". This was discussed with
 14 Barry Dyer, Terry Gulliver, and Dr. D. Cook.
 15 "The discussion included technical quality of
 16 the slides, error of labelling, floater, and
 17 others. Some of these issues have been
 18 documented. Dr. G. Ejeckam has given a
 19 lecture on quality assurance at the laboratory
 20 which was attended by one senior
 21 technologist". I'll stop there. Mr. Green, do
 22 you know anything about this, were you aware
 23 of this going on in 2003?
 24 MR. GREEN:
 25 A. This information would be of no great

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1 surprise. Those types of things could happen
 2 in any laboratory.
 3 MR. BROWNE:
 4 Q. Right, but this is Dr. Ejeckam giving a
 5 lecture on quality assurance in the lab, which
 6 it seems like one technologist attended. Were
 7 you that technologist?
 8 MR. GREEN:
 9 A. I attended one lecture with Dr. Ejeckam. It
 10 did cover quality issues like floaters and I
 11 remember lymph nodes, in particular, you know,
 12 on the -- and problems with some tissue
 13 sectioning, but that's pretty general
 14 knowledge, but it's probably the same one that
 15 I did attend.
 16 MR. BROWNE:
 17 Q. And it goes on, "Programs available for all
 18 the lab technical staff at a suitable time, if
 19 interested". Do you know if others availed of
 20 this program that Dr. Ejeckam prepared?
 21 MR. GREEN:
 22 A. The lecture that I attended with Dr. Ejeckam,
 23 there were a few technologists there,
 24 actually. So I don't know if it was a repeat
 25 of the first one, but he may have gave the

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1 same one again, but there were definitely more
 2 technologists there than me.
 3 MR. BROWNE:
 4 Q. And then it mentions in the last sentence, "A
 5 logbook is available in the reporting room to
 6 record all problems". This is what we saw --
 7 is that similar to the document we saw in the
 8 current policies in terms of reporting
 9 difficulties with slides, because if you look
 10 at top of this, it's talking about reporting
 11 the technical quality of slides, error of
 12 labelling, and so on? Is that notion --
 13 MR. GREEN:
 14 A. This logbook that we're referring to here is
 15 not the same logbook. The logbook here was a
 16 logbook which the pathologists would record
 17 defects and stuff like that.
 18 MR. BROWNE:
 19 Q. Right, so the pathologists were writing this
 20 information in?
 21 MR. GREEN:
 22 A. Yes.
 23 MR. BROWNE:
 24 Q. Presumably to get that back to technologists?
 25 MR. GREEN:

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1 A. Yes.
 2 MR. BROWNE:
 3 Q. Okay. Were you aware of that logbook and was
 4 that information getting back to you?
 5 MR. GREEN:
 6 A. I became aware of the logbook at some point in
 7 time, but unless you went and physically
 8 looked at the book and looked for problems,
 9 you may not know.
 10 MR. BROWNE:
 11 Q. Was there anybody on the technical side in
 12 charge of looking at that and communicating
 13 that information back to technologists or was
 14 that the responsibility of the technologists
 15 to go look?
 16 MR. GREEN:
 17 A. Probably the responsibility of all the
 18 technologists because the -- the issues in
 19 this logbook may not necessarily refer to IHC.
 20 They would be anything from what we call
 21 floaters -- that means that a piece of tissue
 22 appears on the slide that doesn't belong on
 23 the slide, or it could be a fold in the
 24 tissue, or it could be a surgical number that
 25 went out and instead of saying 1234, it might

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1 have said 1243. So those would be all errors,
 2 clerical errors, or any type of defect.
 3 MR. BROWNE:
 4 Q. Mr. Green, you were asked this morning by Ms.
 5 Chaytor about your opinion on the various
 6 possible causes of what occurred here. Now --
 7 and I think there was some discussion as well
 8 about antigen retrieval. If I could just ask
 9 you for a minute --and you've learned a lot,
 10 as you said, since 2005. Assuming that there
 11 were a large number of conversions or -- let's
 12 stay away from that word, but test results
 13 that changed, and in this case the same blocks
 14 -- because you mentioned fixation is one of
 15 the issues, but if the same blocks -- I think
 16 we know on the retest were used, if at all
 17 possible, the same original blocks were sent
 18 off to Mount Sinai, correct?
 19 MR. GREEN:
 20 A. That's true.
 21 MR. BROWNE:
 22 Q. Okay. So if it were fixation and Mount Sinai
 23 were able to get a test result change -- and
 24 they used a DAKO semi-automatic, correct?
 25 MR. GREEN:

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1 A. That's true.
 2 MR. BROWNE:
 3 Q. Would that reduce fixation as a problem and
 4 raise issues such as antibody concentration
 5 and antigen retrieval as possible causes?
 6 MR. GREEN:
 7 A. It's probably a combination of factors, but,
 8 like, from my opinion, I think if fixation --
 9 fixation is the only step that's irreversible.
 10 So if you could take the same block and retest
 11 it and get an interpretable result, you would
 12 have to assume along the way that some
 13 fixation was adequate.
 14 MR. BROWNE:
 15 Q. And then lastly, Mr. Green, can you tell the
 16 Commissioner or are you able to tell the
 17 Commissioner what percentage of the lab IHC
 18 workload would have constituted ER/PR over the
 19 years? Are you able to comment on that?
 20 MR. GREEN:
 21 A. From the numbers of IHC that we do, the ER/PR
 22 would probably be less than 2 percent.
 23 MR. BROWNE:
 24 Q. Thank you, Mr Green. That's all the questions
 25 I have. I appreciate your answers.

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1 MR. GREEN:
 2 A. Thank you.
 3 MR. BROWNE:
 4 Q. Thank you, Commissioner.
 5 COMMISSIONER:
 6 Q. Thank you, Mr. Browne. Ms. Newbury.
 7 MR. KENNETH GREEN, EXAMINATION BY MS. JENNIFER NEWBURY
 8 MS. NEWBURY:
 9 Q. Good afternoon, Mr. Green.
 10 MR. GREEN:
 11 A. Good afternoon.
 12 MS. NEWBURY:
 13 Q. Jennifer Newbury for the Canadian Cancer
 14 Society. I just have a few questions for you
 15 this morning, and I want to start first with
 16 the alarm on the DAKO System. You'd mentioned
 17 that there was an alarm that sounded when
 18 there was a problem with the reagent volume?
 19 MR. GREEN:
 20 A. Yes.
 21 MS. NEWBURY:
 22 Q. Were there any other alarms on this equipment
 23 that you're aware of?
 24 MR. GREEN:
 25 A. Not that I'm aware of.

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1 MS. NEWBURY:
 2 Q. Okay.
 3 MR. GREEN:
 4 A. I had very little experience with the DAKO
 5 System, and probably Mary Butler will probably
 6 be able to answer that question better than I.
 7 MS. NEWBURY:
 8 Q. And do you know if there had been any policies
 9 and procedures in place that required that
 10 this machine be attended throughout the three
 11 and a half hour run or the three hour run?
 12 MR. GREEN:
 13 A. No, there was no requirement to stand and
 14 watch the machine or anything; it was set and
 15 once it was set to go, you could do other
 16 duties.
 17 MS. NEWBURY:
 18 Q. Okay, and was there any practice of trying to
 19 stay, at least, you know, in close proximity
 20 to the machine, even if you are doing other
 21 activities?
 22 MR. GREEN:
 23 A. No, it was never an issue.
 24 MS. NEWBURY:
 25 Q. So it's possible then that the alarm might

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1 sound and a technologist may not be there to
 2 hear it?
 3 MR. GREEN:
 4 A. During regular work hours with most of the
 5 IHC, if the alarm sounded, it was quite likely
 6 that somebody would be there to get the person
 7 who was doing the immunoperoxidase that week.
 8 MS. NEWBURY:
 9 Q. Okay. And in terms of the prospective testing
 10 after August, 2005, you had indicated that the
 11 technologists in the IHC lab continued to
 12 prepare slides for all prospective patients.
 13 MR. GREEN:
 14 A. That's true.
 15 MS. NEWBURY:
 16 Q. Do you know if any of the pathologists were
 17 made aware that you were continuing to prepare
 18 these slides?
 19 MR. GREEN:
 20 A. Not that I'm aware of, we continued on doing
 21 the slides as normal, just that they weren't
 22 sent to St. Clare's.
 23 MS. NEWBURY:
 24 Q. Okay. And what was the purpose of continuing
 25 to do those slides?

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1 MR. GREEN:
 2 A. We wanted to compare the results, when the
 3 Mount Sinai results came back with our slides
 4 that we were running, which would give us some
 5 measure of confidence in our system.
 6 MS. NEWBURY:
 7 Q. Okay, and that wasn't done under the guidance
 8 of any pathologist?
 9 MR. GREEN:
 10 A. No.
 11 MS. NEWBURY:
 12 Q. And you had mentioned that on occasion a
 13 pathologist would request a repeat of an ER/PR
 14 test because different results had been
 15 received than what had been expected by the
 16 pathologist?
 17 MR. GREEN:
 18 A. It's possible.
 19 MS. NEWBURY:
 20 Q. Is it possible or do you actually recall that
 21 that happened?
 22 MR. GREEN:
 23 A. I don't really recall specifically, no.
 24 MS. NEWBURY:
 25 Q. Okay, so you can't recall a pathologist ever

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1 elaborating on that with you, saying I
 2 expected different results for some reason or
 3 another?
 4 MR. GREEN:
 5 A. No. Can you ever recall a situation where
 6 there was a third request for an ER/PR test, a
 7 third repeat, I guess?
 8 MR. GREEN:
 9 A. Not to my knowledge.
 10 MS. NEWBURY:
 11 Q. Okay. You've mentioned that after the flood
 12 that occurred in the lab at Eastern Health,
 13 the medical school lab was used by the
 14 technologists from the IHC lab.
 15 MR. GREEN:
 16 A. Yes.
 17 MS. NEWBURY:
 18 Q. Do you know if the medical school has its own
 19 equipment, any of its own equipment to use for
 20 IHC testing?
 21 MR. GREEN:
 22 A. Not that I'm aware of.
 23 MS. NEWBURY:
 24 Q. Okay, so you don't know if they do any of
 25 their own testing for research purposes?

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1 MR. GREEN:
 2 A. They do research at the medical school, yes.
 3 MS. NEWBURY:
 4 Q. Okay, but you have no idea what type of
 5 equipment, whether they use a manual process?
 6 MR. GREEN:
 7 A. No, I don't think it's an automated equipment.
 8 MS. NEWBURY:
 9 Q. Okay. Is there ever any collaboration with
 10 the medical school for any reason in relation
 11 to immunohistochemical testing?
 12 MR. GREEN:
 13 A. We run the--since we have an automated system,
 14 from time to time we will do research work for
 15 those people and we will run some of their
 16 antibodies.
 17 MS. NEWBURY:
 18 Q. Okay, and so it's done for research purposes,
 19 but it's all done by the same technologist
 20 within the IHC lab?
 21 MR. GREEN:
 22 A. Yes.
 23 MS. NEWBURY:
 24 Q. So you never have someone from the medical
 25 school coming over to use your equipment?

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1 MR. GREEN:
 2 A. Never, they don't operate our equipment.
 3 MS. NEWBURY:
 4 Q. Is there ever any sharing of educational
 5 resources or anything of that sort for
 6 immunohistochemical testing? Do you ever
 7 attend seminars together with anyone at the
 8 medical school?
 9 MR. GREEN:
 10 A. Not since I've been involved?
 11 MS. NEWBURY:
 12 Q. And you had indicated that Dr. Robb had been
 13 doing a lot of work with respect to ER/PR
 14 testing and do you know what the purpose of
 15 this work was?
 16 MR. GREEN:
 17 A. No, I don't.
 18 MS. NEWBURY:
 19 Q. Okay, so you don't know if it was for a
 20 validation of any of your procedures or
 21 research or -
 22 MR. GREEN:
 23 A. I assumed it was research, one of his research
 24 projects that he had on the go.
 25 MS. NEWBURY:

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1 Q. Okay, and where did he do this work? Was it
 2 done in your own lab?
 3 MR. GREEN:
 4 A. It was done before I came over at the Health
 5 Science, like we had a copy of his results, so
 6 his work was already finished.
 7 MS. NEWBURY:
 8 Q. Okay. So you don't know whether or not that
 9 had ever been used for diagnostic or
 10 prognostic purposes for patients?
 11 MR. GREEN:
 12 A. Don't know, maybe Mary or Peggy would probably
 13 be able to shed some light on that for you.
 14 MS. NEWBURY:
 15 Q. Okay, and after the flood, do you know if
 16 there were any steps to revalidate the DAKO
 17 equipment?
 18 MR. GREEN:
 19 A. Not that I'm aware of.
 20 MS. NEWBURY:
 21 Q. I wanted to ask you a few questions about
 22 external proficiency testing and quality
 23 assurance. Now you described a couple of
 24 programs this morning, one of which is the
 25 College of American Pathologist Program, CAP.

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1 MR. GREEN:
 2 A. That's true.
 3 MS. NEWBURY:
 4 Q. Would you consider that program that Eastern
 5 Health is participating in to be an external
 6 proficiency program?
 7 MR. GREEN:
 8 A. It is an external proficiency program, but the
 9 emphasis would be on educational content.
 10 MS. NEWBURY:
 11 Q. Okay, and is that educational content both for
 12 the benefit of technologists and pathologists?
 13 MR. GREEN:
 14 A. It is, yes.
 15 MS. NEWBURY:
 16 Q. And does it have any means of evaluating the
 17 technical skills of a technologist involved in
 18 immunohistochemical testing?
 19 MR. GREEN:
 20 A. Only from the aspect where you've got a round
 21 table-type discussion where you're comparing
 22 the results of the particular antibody and
 23 getting some various opinions on it, but it's
 24 not an independent arm's length unbiased look
 25 at the slides.

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1 MS. NEWBURY:
 2 Q. Okay, so it's a group activity, first of all.
 3 MR. GREEN:
 4 A. Yes, exactly.
 5 MS. NEWBURY:
 6 Q. And when Eastern Health receives the slides
 7 that are sent from CAP, do the technologist do
 8 anything with those slides?
 9 MR. GREEN:
 10 A. We received the slides from CAP and then we--
 11 there is a list of antibodies that goes with
 12 each case study. The technologist job is to
 13 run those slides and what we will do, we will
 14 run some of our own--those slides don't have
 15 controls, so we run our set of controls again
 16 with those slides and they will review it with
 17 the pathologist and the technologist.
 18 MS. NEWBURY:
 19 Q. So are these antibodies that are currently
 20 being used by Eastern Health?
 21 MR. GREEN:
 22 A. Yes, they're normal every day antibodies.
 23 MS. NEWBURY:
 24 Q. Okay, so they are the normal antibodies that
 25 you use.

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1 MR. GREEN:
 2 A. Yes, normal protocols.
 3 MS. NEWBURY:
 4 Q. So the technologist's role then would be to
 5 test the slides from CAP with the antibodies
 6 that you have in your lab.
 7 MR. GREEN:
 8 A. Yes.
 9 MS. NEWBURY:
 10 Q. And also to prepare your own external control
 11 slides.
 12 MR. GREEN:
 13 A. Controls to go with those slides.
 14 MS. NEWBURY:
 15 Q. Okay. And then rather than sending them off
 16 to be tested, getting a score card like with
 17 the NEQAS program, you have a system of self-
 18 assessment by comparing the results from your
 19 test -
 20 MR. GREEN:
 21 A. What, the way the package works, when the,
 22 you'll do a work up and do all the case
 23 studies and when we go down underneath the
 24 scope, we will look at each case study and
 25 there will be a list of--each antibody that's

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1 in that list will be recorded as reactive and
 2 non-reactive or any comments. At the end of
 3 the list, there are favourite interpretations.
 4 The pathologist will pick a favourite
 5 interpretation, depending on after reading the
 6 slides, depending on--they're basically
 7 diagnosed from each patient from the
 8 information that's there, and the slides
 9 themselves are not sent out. The slides
 10 themselves are kept, but the information is
 11 sent out and at the end of the day, well the
 12 end of the week when this process is over, the
 13 report will come back and you can compare your
 14 institution to the responses of all the other
 15 institutions.
 16 MS. NEWBURY:
 17 Q. Okay, so you run comparison, although you do
 18 send the information to the College of
 19 American Pathologists?
 20 MR. GREEN:
 21 A. Yes.
 22 MS. NEWBURY:
 23 Q. So they can check that as well?
 24 MR. GREEN:
 25 A. Yes, they check the information, but not

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1 physically the slides.
 2 MS. NEWBURY:
 3 Q. Okay. And with the CAP program, would there
 4 be any role in evaluating any pre-analytical
 5 work for ER/PR testing?
 6 MR. GREEN:
 7 A. Only if one of the cases happened to be a case
 8 study that involved doing ER/PR, which has
 9 been known to, depending upon which case
 10 studies are requested.
 11 MS. NEWBURY:
 12 Q. Okay.
 13 MR. GREEN:
 14 A. But you couldn't specifically say that,
 15 request an ER/PR case study, they determine
 16 which case studies you could do.
 17 MS. NEWBURY:
 18 Q. Okay, so you have no idea what's coming.
 19 MR. GREEN:
 20 A. No.
 21 MS. NEWBURY:
 22 Q. Until you receive it.
 23 MR. GREEN:
 24 A. That's true.
 25 MS. NEWBURY:

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1 Q. And the other program that your lab
 2 participates in is the QMPLS and now I
 3 understand that that organization has an
 4 external quality assurance program, as well as
 5 the laboratory accreditation division?
 6 MR. GREEN:
 7 A. True.
 8 MS. NEWBURY:
 9 Q. Now, I understand that in 2007, you had your
 10 lab reviewed by this organization?
 11 MR. GREEN:
 12 A. That's true.
 13 MS. NEWBURY:
 14 Q. Has your lab ever participated in any external
 15 proficiency testing programs offered under
 16 their quality assurance division?
 17 MR. GREEN:
 18 A. We are starting to do that now.
 19 MS. NEWBURY:
 20 Q. Okay, and that's with respect to ER/PR
 21 testing, specifically or IHC testing?
 22 MR. GREEN:
 23 A. IHC testing in general.
 24 MS. NEWBURY:
 25 Q. Will it include ER/PR do you know?

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1 MR. GREEN:
 2 A. I would assume that will be one of the
 3 antibodies, but I am not totally sure.
 4 MS. NEWBURY:
 5 Q. Okay.
 6 MR. GREEN:
 7 A. When you talk to Dr. Ford Elms, he will be
 8 able to tell you that.
 9 MS. NEWBURY:
 10 Q. Okay, so he's the one that's in charge of
 11 starting that new external proficiency.
 12 MR. GREEN:
 13 A. He set up that one, yes.
 14 MS. NEWBURY:
 15 Q. And do you have any idea when that is supposed
 16 to commence?
 17 MR. GREEN:
 18 A. I think we've already done one test, one pilot
 19 program with those already.
 20 MS. NEWBURY:
 21 Q. And when was that done?
 22 MR. GREEN:
 23 A. Probably earlier this year.
 24 MS. NEWBURY:
 25 Q. Back to the College of American Pathologists,

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1 one quick question I overlooked. Do each of
 2 the technologists get involved in preparing
 3 the slides that are, not only the slides that
 4 are sent from CAP, but also in preparing the
 5 external control slides?
 6 MR. GREEN:
 7 A. That would be my--upon 'til now, that was my
 8 responsibility.
 9 MS. NEWBURY:
 10 Q. So you are the only technologist that has done
 11 anything with the external control slides.
 12 MR. GREEN:
 13 A. So far, yes.
 14 MS. NEWBURY:
 15 Q. So far, okay, and have any of the other
 16 technologists prepared any of the slides that
 17 are sent from CAP, in terms of applying the
 18 antibodies, or is that something that you have
 19 only done to date?
 20 MR. GREEN:
 21 A. When the slides are ready to be stained,
 22 whatever technologist is using the machine at
 23 that time, I just passed the slides over, say
 24 if you've got room, put these on with your
 25 regular slides and they'll be run, there's

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1 nothing--there's no special run or anything,
 2 they're treated the same as all other slides.
 3 MS. NEWBURY:
 4 Q. And is there any reason why you're the only
 5 technologist to date that has been involved in
 6 doing the external control slides for that
 7 program?
 8 MR. GREEN:
 9 A. When we started the program, I was given the
 10 responsibility to do that. One technologist
 11 has retired, the other technologist retiring
 12 this month and so far, I'm training in a new
 13 technologist, so it's just -
 14 MS. NEWBURY:
 15 Q. The timing, okay.
 16 MR. GREEN:
 17 A. Yes,
 18 MS. NEWBURY:
 19 Q. And do you know if there are plans to--when
 20 the new technologists are trained and read to
 21 go, that they will also be involved in
 22 preparing the external control slides for -
 23 MR. GREEN:
 24 A. They will probably be involved, but most
 25 likely we've just acquired a new position,

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<p>1 Ph.D position and that person will be 2 responsible for external quality assurance and 3 for antibody validation. 4 MS. NEWBURY: 5 Q. Okay. 6 THE COMMISSIONER: 7 Q. I'm sorry, a new what kind of position? 8 MR. GREEN: 9 A. A Ph.D. 10 THE COMMISSIONER: 11 Q. Thank you. That person is not on board yet, 12 is - 13 MR. GREEN: 14 A. Yes, she is, yes. 15 THE COMMISSIONER: 16 Q. Oh, okay. 17 MS. NEWBURY: 18 Q. Will there ever be a situation where there are 19 technologists who are in the day-to-day 20 testing, IHC testing, preparing external 21 control slides, but not participating in the 22 CAP program? 23 MR. GREEN: 24 A. Not in our department, now everybody will be 25 versed on everything.</p>	<p>1 a couple of means, number one by the staining 2 of the slides that are sent by the UK to 3 Eastern Health. 4 MR. GREEN: 5 A. Yes. 6 MS. NEWBURY: 7 Q. And they ultimately get evaluated because they 8 do get sent back to the UK, and then the 9 preparation and staining of in-house external 10 controls, which originate from Eastern Health 11 and are also sent to the UK for evaluation. 12 MR. GREEN: 13 A. That's true. 14 MS. NEWBURY: 15 Q. Okay, and are the in-house external controls 16 used for this external proficiency testing 17 always used specifically for that purpose? 18 MR. GREEN: 19 A. They are the regular controls that we run 20 every day with everything else, they're no 21 different. 22 MS. NEWBURY: 23 Q. And are older control slides ever used for the 24 NEQAS external proficiency testing? Do you 25 ever go back into your bank of controls and</p>
<p style="text-align: right;">Page 254</p> <p>1 MS. NEWBURY: 2 Q. Everything, okay. 3 MR. GREEN: 4 A. From all aspects. 5 MS. NEWBURY: 6 Q. And in the NEQAS program that has been used by 7 the immunohistochemical lab, are each of the 8 technologists also involved in the external 9 proficiency testing offered by that program? 10 MR. GREEN: 11 A. Right now the bulk of it is handled by myself. 12 MS. NEWBURY: 13 Q. Okay, and it's the same timing issue. 14 MR. GREEN: 15 A. Same timing issue. 16 MS. NEWBURY: 17 Q. And once the new technologists come on board, 18 do you think they will, too, be participating 19 - 20 MR. GREEN: 21 A. They will all be versed and incorporated into 22 the system. 23 MS. NEWBURY: 24 Q. And I understand under that program that the 25 skills of technologists are evaluated through</p>	<p style="text-align: right;">Page 256</p> <p>1 look for something? 2 MR. GREEN: 3 A. No, we'll use current slides. 4 MS. NEWBURY: 5 Q. And there's just one more area, I just wanted 6 to make sure that I understand the controls 7 that are currently being used because I got a 8 little confused between last week and today. 9 As I understand your evidence, there are 10 currently four patient specific slides being 11 used for ER and PR testing, two for ER and two 12 for PR testing and these are specific to the 13 patient? 14 MR. GREEN: 15 A. That's true. 16 MS. NEWBURY: 17 Q. And also there are two triple batch control 18 slides used, run with each batch of tests? 19 MR. GREEN: 20 A. That's true. 21 MS. NEWBURY: 22 Q. Okay, and on one of the patient specific 23 slides for ER testing, that slide would 24 contain patient tissue, which includes the 25 tumour, plus normal epithelial tissue which</p>

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1 acts as an internal positive control?
 2 MR. GREEN:
 3 A. That's true.
 4 MS. NEWBURY:
 5 Q. That's one of the specimens on, one of the
 6 patient specific slides. And on that same
 7 slide, is there an external positive control,
 8 which is a strong positive control?
 9 MR. GREEN:
 10 A. That's true.
 11 MS. NEWBURY:
 12 Q. Okay, and then the second patient specific
 13 slide for the ER test contains a patient
 14 tissue without the primary antibody applied?
 15 MR. GREEN:
 16 A. That's true, that's the negative control.
 17 MS. NEWBURY:
 18 Q. And that's the negative internal control?
 19 MR. GREEN:
 20 A. That's the negative patient control.
 21 MS. NEWBURY:
 22 Q. Okay.
 23 MR. GREEN:
 24 A. It's a negative patient reagent control.
 25 MS. NEWBURY:

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1 Q. Okay. And it is a piece of tissue from that
 2 very same patient.
 3 MR. GREEN:
 4 A. Yes, when the block is cut, one piece is put
 5 on a tissue by, a slide by itself and the very
 6 next piece is put on--or they put the positive
 7 control.
 8 MS. NEWBURY:
 9 Q. And the reason why a separate slide is used
 10 for the negative internal control is because
 11 you don't apply the primary antibody -
 12 MR. GREEN:
 13 A. Primary antibody, there's no primary
 14 antibodies applied, there should be no antigen
 15 antibody reaction.
 16 MS. NEWBURY:
 17 Q. Okay, and is this normal patient tissue that's
 18 used for that negative control?
 19 MR. GREEN:
 20 A. It's the same block that we're testing for
 21 ER/PR.
 22 MS. NEWBURY:
 23 Q. So is there a need to make sure that it has
 24 tumour and normal tissue or one or the other?
 25 MR. GREEN:

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1 A. The pathologists would choose a block that we
 2 would run on ER/PR, so they would know that
 3 from looking at their H&E slide, they would
 4 submit the appropriate block.
 5 MS. NEWBURY:
 6 Q. Okay, so they pick then, the piece of tissue
 7 that acts as the negative internal control,
 8 which is placed on the separate slide.
 9 MR. GREEN:
 10 A. Yes, that's run by the pathologist.
 11 MS. NEWBURY:
 12 Q. And then the triple batch control would be
 13 used for a number of patients who are all
 14 being tested at the same time?
 15 MR. GREEN:
 16 A. For all the patients that are run that week.
 17 MS. NEWBURY:
 18 Q. And that slide would contain three external
 19 controls, the one which is ER negative.
 20 MR. GREEN:
 21 A. True.
 22 MS. NEWBURY:
 23 Q. One which is ER intermediate.
 24 MR. GREEN:
 25 A. True.

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1 MS. NEWBURY:
 2 Q. And the third is ER positive?
 3 MR. GREEN:
 4 A. That's correct.
 5 MS. NEWBURY:
 6 Q. That's a strong positive, I take it?
 7 MR. GREEN:
 8 A. Yes.
 9 MS. NEWBURY:
 10 Q. And then the PR slides is basically the same
 11 as with the ER -
 12 MR. GREEN:
 13 A. Same thing, yeah.
 14 MS. NEWBURY:
 15 Q. Just that you use a PR antibody, an antibody
 16 for PR testing?
 17 MR. GREEN:
 18 A. That's true.
 19 MS. NEWBURY:
 20 Q. And you use PR positive specimens as external
 21 controls, is that -
 22 MR. GREEN:
 23 A. Yes.
 24 MS. NEWBURY:
 25 Q. Thank you, I just wanted to be clear on that.

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1 Those are all the questions I have, thank you
 2 very much.
 3 MR. GREEN:
 4 A. Thank you.
 5 THE COMMISSIONER:
 6 Q. Mr. Pritchett, have you changed your mind or
 7 are you still not wishing to question?
 8 MR. PRITCHETT:
 9 Q. I have no questions, Commissioner.
 10 THE COMMISSIONER:
 11 Q. Mr. Crosbie, do you have any questions for
 12 this witness?
 13 CROSBIE, Q.C.:
 14 Q. No questions, thank you.
 15 THE COMMISSIONER:
 16 Q. Are you still of the same view, Mr. Pike?
 17 MR. PIKE:
 18 Q. I stand firm on my (unintelligible).
 19 THE COMMISSIONER:
 20 Q. All right.
 21 MR. SIMMONS:
 22 Q. Thank you, Commissioner.
 23 MR. KENNETH GREEN, EXAMINATION BY MR. DANIEL SIMMONS
 24 MR. SIMMONS:
 25 Q. Good afternoon, Mr. Green. I have just a few

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1 things for you.
 2 MR. GREEN:
 3 A. Good afternoon.
 4 MR. SIMMONS:
 5 Q. First of all, can we have Exhibit P-0113,
 6 please? Mr. Green, Ms. Chaytor showed you
 7 this exhibit which has a number of memos on
 8 it. And the first two she showed you were
 9 ones from Dr. Ejeckam on April 4th, 2003 and
 10 May 2nd, 2003 and I believe you told us you
 11 hadn't seen either of those before.
 12 MR. GREEN:
 13 A. That's correct.
 14 MR. SIMMONS:
 15 Q. There is a third memo and it is here on page
 16 five and it's dated June 19th, 2003. Now, I
 17 have had an opportunity to show you this memo
 18 prior to your coming here to give evidence.
 19 And can you tell me whether you recognize that
 20 memo, having seen it on any previous occasion?
 21 MR. GREEN:
 22 A. I have seen this memo.
 23 MR. SIMMONS:
 24 Q. Can you tell me the circumstances under which
 25 you saw it, please?

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1 MR. GREEN:
 2 A. I've had occasion to go to Dr. Ejeckam's
 3 office to bring some IHC slides for him to
 4 look at and he was in one of his moods that
 5 day, which was kind of agitated. So, after he
 6 looked at the slides and a conversation ensued
 7 and he goes to this filing cabinet and he
 8 shows me this memo. And he was kind of upset
 9 because there were things he wanted done and
 10 they didn't seem to be happening as fast he'd
 11 like them to happen. So -
 12 MR. SIMMONS:
 13 Q. Do you know what sort of things he wanted
 14 done?
 15 MR. GREEN:
 16 A. He wanted a separate IHC lab. He wanted
 17 dedicated technologists for the area and those
 18 were the type of things he was looking for.
 19 MR. SIMMONS:
 20 Q. Okay. Was this the first you'd heard of him
 21 speak about wanting those things done or was
 22 that an issue that you'd know he had -
 23 MR. GREEN:
 24 A. I was aware that those were his feelings.
 25 MR. SIMMONS:

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1 Q. Okay. This memo is dated June, 2003. Do you
 2 know how close it was to that time that he
 3 showed you the memo?
 4 MR. GREEN:
 5 A. I don't know exactly because at the time I saw
 6 the memo, the time didn't make a difference to
 7 me, you know.
 8 MR. SIMMONS:
 9 Q. Did you see it before the IHC operation was
 10 moved into the separate space that it occupies
 11 now?
 12 MR. GREEN:
 13 A. I don't think we were separate at that time.
 14 MR. SIMMONS:
 15 Q. Okay. So, that would have been before the
 16 Ventana machine was acquired, in that case,
 17 would it have been?
 18 MR. GREEN:
 19 A. June 19th, 2003, probably.
 20 MR. SIMMONS:
 21 Q. Okay. Now, when Dr. Ejeckam showed you the
 22 memo under those circumstances, did you have
 23 any discussion or did he give you any
 24 explanation of the circumstances that led to
 25 him writing that memo?

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1 MR. GREEN:
 2 A. He was probably upset and probably went to
 3 administration or to management and there
 4 probably weren't funds there and he wanted
 5 this stuff done and they seemed to be dragging
 6 their heels. And the might have wanted to
 7 light a fire under them to get them to move
 8 ahead.
 9 MR. SIMMONS:
 10 Q. Did he tell you anything about having any
 11 concerns or not about any of the testing that
 12 had been done previously in the lab?
 13 MR. GREEN:
 14 A. No, he was concerned about changes, the
 15 physical location and stuff like the, he
 16 wanted done.
 17 MR. SIMMONS:
 18 Q. Did he tell you anything about having
 19 suspended any of the testing at any point
 20 prior to this?
 21 MR. GREEN:
 22 A. No.
 23 MR. SIMMONS:
 24 Q. Okay. Exhibit P-2149, please, page 24. Ms.
 25 Chaytor showed you this requisition also.

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1 It's dated June 21st, 2002. This would have
 2 been how long after you moved from St. Clare's
 3 to the Health Science Centre?
 4 MR. GREEN:
 5 A. I moved over in April of 2002.
 6 MR. SIMMONS:
 7 Q. So, this would have been within a couple of
 8 months of you first beginning to do IHC
 9 testing.
 10 MR. GREEN:
 11 A. Yes.
 12 MR. SIMMONS:
 13 Q. The pathologist there is Dr. Dalton. Do you
 14 know where Dr. Dalton practised medicine?
 15 MR. GREEN:
 16 A. Central Newfoundland.
 17 MR. SIMMONS:
 18 Q. And when you go down to the side, there's the
 19 notation that you were referred to that says
 20 controls checked, KG. And I believe you
 21 identified that as being your initials.
 22 MR. GREEN:
 23 A. That would be mine.
 24 MR. SIMMONS:
 25 Q. Okay. And I think you identified earlier that

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1 that would mean that you looked at the
 2 positive control slide before returning this
 3 requisition with slides to Dr. Dalton.
 4 MR. GREEN:
 5 A. That would be the most likely prospect.
 6 MR. SIMMONS:
 7 Q. Okay. Now, does this mean that you looked at
 8 the control slide and kept it in St. John's or
 9 does it mean you looked at the control slide
 10 before sending it to Dr. Dalton with slides
 11 for the patient sample?
 12 MR. GREEN:
 13 A. Looking at the time on that requisition being
 14 over there only probably two months, I don't
 15 think I would have had the knowledge or the
 16 expertise to check it myself. I probably sent
 17 it off with the surgical.
 18 MR. SIMMONS:
 19 Q. Okay. So, you're saying it's most likely that
 20 the control slide went to Dr. Dalton despite
 21 the fact that you've noted "checked controls"
 22 -
 23 MR. GREEN:
 24 A. Yes, I probably--yes. That's the most likely
 25 case.

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1 MR. SIMMONS:
 2 Q. Yes. Now, can you recall, on any occasion,
 3 ever checking a control yourself for an out-
 4 of-town test and not having it also checked by
 5 a pathologist?
 6 MR. GREEN:
 7 A. No.
 8 THE COMMISSIONER:
 9 Q. Sorry, can you run that by me again? I
 10 thought we were saying originally that when
 11 you said controls checked, KG, that was
 12 indicating that I could conclude that only you
 13 had checked them within the St. John's.
 14 MR. GREEN:
 15 A. Within town.
 16 THE COMMISSIONER:
 17 Q. Okay.
 18 MR. GREEN:
 19 A. Out-of-town, we always ran them by a
 20 pathologist.
 21 MR. SIMMONS:
 22 Q. And the difference -
 23 THE COMMISSIONER:
 24 Q. So, I guess that's my question back again.
 25 When it says "controls checked, KG", does that

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1 mean that you checked them or that somebody
 2 else checked them and you wrote your initials
 3 there?
 4 MR. GREEN:
 5 A. It could have been someone could have checked
 6 them, I could have checked them to make sure
 7 there was brown staining and send them off
 8 with the surgical -
 9 THE COMMISSIONER:
 10 Q. The writing under that where it says, "slides
 11 and block returned".
 12 MR. GREEN:
 13 A. Yes.
 14 THE COMMISSIONER:
 15 Q. Is that yours?
 16 MR. GREEN:
 17 A. Yes.
 18 THE COMMISSIONER:
 19 Q. So, why wouldn't you write slides and block
 20 and control returned or is slides meant to
 21 include control?
 22 MR. GREEN:
 23 A. Well, when we wrote slides and blocks
 24 returned, we would send the slides and block
 25 back to whatever institution sent them in.

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1 Sometimes you would hold the blocks for a week
 2 or so, or sometimes we would send the slides
 3 and blocks out. If they wanted more work,
 4 they'd have to send the slides, blocks back
 5 in. So, that would expedite it. And
 6 sometimes they would call looking for their
 7 slides and blocks. And if we didn't write
 8 down that we sent them back, sometimes they
 9 would blame us for not sending them back.
 10 THE COMMISSIONER:
 11 Q. Okay. When you write "slides and block", is
 12 the word "slides" large enough to encompass
 13 the controls or if you had sent controls
 14 separately, would you note that as "controls,
 15 slides and block"?
 16 MR. GREEN:
 17 A. I can't be sure if it's--I can't be specific
 18 either way.
 19 THE COMMISSIONER:
 20 Q. All right. Thank you.
 21 MR. SIMMONS:
 22 Q. And just to be clear, can you recall ever
 23 sending slides with patient tissue results on
 24 it to an out-of-town pathologist with either,
 25 without sending the controls or without having

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1 a St. John's pathologist check the controls?
 2 MR. GREEN:
 3 A. We have sent them out after we started using
 4 the Ventana system and putting controls on the
 5 slides.
 6 MR. SIMMONS:
 7 Q. And that's the only circumstance?
 8 MR. GREEN:
 9 A. Yes. It would be routinely--after we start
 10 putting controls on the slides, we would send
 11 them out to those out-of-town hospitals.
 12 MR. SIMMONS:
 13 Q. Okay. You told us about the training you
 14 received when you moved from St. Clare's to
 15 the General Hospital site, from Ms. Welsh and
 16 that was, I guess, essentially on-the-job
 17 training.
 18 MR. GREEN:
 19 A. That's true.
 20 MR. SIMMONS:
 21 Q. Now, at that point you had considerable
 22 experience as a laboratory technologist. I
 23 believe you'd also had ten years involved in
 24 the provincial association -
 25 MR. GREEN:

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1 A. That's true.
 2 MR. SIMMONS:
 3 Q. - as well, on the executive and as president.
 4 At that time, do you know if there were any
 5 educational institutions, any schools,
 6 colleges or otherwise where a person could go
 7 for a course of IHC training?
 8 MR. GREEN:
 9 A. To my knowledge, there was no formal training
 10 available for IHC.
 11 MR. SIMMONS:
 12 Q. Right. So, was there any alternative
 13 available other than on-the-job training in
 14 order to learn to do IHC?
 15 MR. GREEN:
 16 A. Not that I'm aware of.
 17 MR. SIMMONS:
 18 Q. Okay. And the opportunity that you had
 19 eventually to go to Jewish General and observe
 20 their immunohistochemistry laboratory there,
 21 was there anything really different about that
 22 or was that really an opportunity for on-the-
 23 job training, but at a different institution
 24 other than your own.
 25 MR. GREEN:

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1 A. On-the-job training at a different institution
 2 who use the same equipment as we did.
 3 MR. SIMMONS:
 4 Q. Okay. Now, there's two new technologists now
 5 in your laboratory; one has been there for six
 6 months and one who's fairly new. Is there
 7 anywhere else you can turn now to send them,
 8 either than for annual conventions, such as
 9 NSH, or perhaps to a manufacturers facility.
 10 Is there anywhere else you can send them, to a
 11 school, for them to learn IHC training or is
 12 the on-the-job training -
 13 MR. GREEN:
 14 A. The on-the-training is the only training
 15 available. There's no formal training in IHC.
 16 MR. SIMMONS:
 17 Q. Thank you, very much, Mr. Green. I don't know
 18 if you have anything else that you'd like to
 19 add yourself or if there is any other
 20 statement that you'd like to make -
 21 MR. GREEN:
 22 A. Well, just -
 23 MR. SIMMONS:
 24 Q. - a chance to say enough already.
 25 MR. GREEN:

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1 A. Well, I just got a couple of comments. They
 2 are going to be very brief. I would like to
 3 reiterate the issue of training. All our
 4 laboratory technologists are trained and
 5 qualified to work in our laboratories. They
 6 have all completed the required education and
 7 have passed national exams the same as our
 8 counterparts throughout Canada. The training
 9 we receive on the job and on new equipment is
 10 the same in every laboratory. People are
 11 trained and they train their colleagues.
 12 There are no formal training institutions for
 13 IHC. We, who work in pathology are reminded
 14 every day with every specimen, the importance
 15 of doing our work to the best of our ability.
 16 For we all have families who are affected by
 17 cancer, by sickness and disease.
 18 I would like to thank the Commission for
 19 giving me the opportunity to give some insight
 20 into the day-to-day workings of the pathology
 21 lab. Thank you.
 22 MR. SIMMONS:
 23 Q. Thank you very much, Mr. Green.
 24 THE COMMISSIONER:
 25 Q. Ms. Chaytor, is anything arising?

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1 CHAYTOR, Q.C.:
 2 Q. Just a couple of points.
 3 MR. KENNETH GREEN, RE-EXAMINATION BY SANDRA CHAYTOR, Q.C.
 4 CHAYTOR, Q.C.:
 5 Q. Mr. Green, you indicated that Western would
 6 send in their own slides to be stained.
 7 MR. GREEN:
 8 A. That's true.
 9 CHAYTOR, Q.C.:
 10 Q. And was that throughout the whole time that
 11 you were there from 2002, when you first went
 12 there, I mean?
 13 MR. GREEN:
 14 A. Probably more closely to recent--I've noticed
 15 it more recently than previously.
 16 CHAYTOR, Q.C.:
 17 Q. Okay. And so up until the time that it shut
 18 down--well, you weren't doing it since 2007,
 19 they didn't resume with you in 2007. So, when
 20 you say more recently, you mean 2005, back in
 21 2005, back August -
 22 MR. GREEN:
 23 A. Not back that far.
 24 CHAYTOR, Q.C.:
 25 Q. Not back that far. So, when is it that

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1 Western would send in their own slides for
 2 staining?
 3 MR. GREEN:
 4 A. When?
 5 CHAYTOR, Q.C.:
 6 Q. Yes.
 7 MR. GREEN:
 8 A. I'm not sure specifically what date. We would
 9 have a problem with staining slides that
 10 weren't on plus slides because chances are we
 11 would lose some of the tissue. So, we made a
 12 point of sending out a package of our slides
 13 for them to use with the information where
 14 they could order their own and that's what
 15 they do to this day.
 16 CHAYTOR, Q.C.:
 17 Q. Okay, but they don't -
 18 THE COMMISSIONER:
 19 Q. Is this for IHC generally?
 20 MR. GREEN:
 21 A. For IHC only.
 22 CHAYTOR, Q.C.:
 23 Q. Were they doing that then for ER/PR tests,
 24 including ER/PR tests?
 25 MR. GREEN:

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1 A. Not usually. They would usually send their
 2 own blocks.
 3 CHAYTOR, Q.C.:
 4 Q. They'd send blocks--that's what I'm trying to
 5 figure out, if there were certain hospitals
 6 which were sending actual slides to you to be
 7 stained as opposed to the blocks for you to
 8 create the slides, for ER/PR testing in
 9 particular?
 10 MR. GREEN:
 11 A. Western Memorial is the only one that comes to
 12 mind. Sometimes they would have a particular
 13 piece of tissue and the only slides they would
 14 have would probably be the ones that were
 15 already on slides. So, then you would have to
 16 try to do a IHC stain on some of those.
 17 CHAYTOR, Q.C.:
 18 Q. Okay.
 19 MR. GREEN:
 20 A. So, I can't specifically say that there were
 21 any ER/PR slides that we handled that way.
 22 CHAYTOR, Q.C.:
 23 Q. Okay. So, you're not saying that Western ever
 24 sent slides for ER/PR testing, you created the
 25 slides for Western.

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1 MR. GREEN:
 2 A. Usually, yes.
 3 CHAYTOR, Q.C.:
 4 Q. For ER/PR?
 5 MR. GREEN:
 6 A. That would be the norm.
 7 CHAYTOR, Q.C.:
 8 Q. Now, you also said in the beginning, St.
 9 Clare's would also send their slides. When
 10 you're back at St. Clare's, before 2002, and
 11 ordering ER/PR testing or arranging for that
 12 to happen for the pathologists at St. Clare's,
 13 were you sending slides to the Health Science
 14 to be stained or were you sending blocks?
 15 MR. GREEN:
 16 A. In the beginning we would send slides,
 17 sometime during the course of events, we
 18 stopped sending slides and sent the tissue
 19 over there.
 20 CHAYTOR, Q.C.:
 21 Q. Okay. And how close to when you left in 2002-
 22 -I take it when you left in 2002, the practice
 23 was to send blocks?
 24 MR. GREEN:
 25 A. Yes.

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1 CHAYTOR, Q.C.:
 2 Q. Okay. And how long have that practice been
 3 going on that it was blocks, not slides?
 4 MR. GREEN:
 5 A. I'm not exactly sure. You could probably
 6 check with Les on that; Les will probably know
 7 more about that.
 8 CHAYTOR, Q.C.:
 9 Q. Okay. You mentioned that Dr. Ejeckam--this
 10 was a question Mr. Browne asked you about
 11 antigen retrieval and you said someone like
 12 Dr. Ejeckam would have the knowledge base to
 13 be able to determine if you should be changing
 14 or tweaking your antigen retrieval times.
 15 MR. GREEN:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. What were you able to tell or what do you know
 19 about that level of knowledge of other
 20 pathologists and why is it that you think they
 21 might not have that knowledge base?
 22 MR. GREEN:
 23 A. Unless they had the technical background in
 24 IHC, they probably wouldn't know the day-to-
 25 day operations which they would not know which

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1 antibody required antigen retrieval unless
 2 they specifically looked it up. It would not
 3 be in their area of expertise.
 4 CHAYTOR, Q.C.:
 5 Q. But have you had enough interaction with them
 6 to be able to make that determination?
 7 MR. GREEN:
 8 A. Are you asking for my opinion?
 9 CHAYTOR, Q.C.:
 10 Q. Yes. You said that it depends on their
 11 knowledge base. And I would take it that you
 12 know Dr. Ejeckam well enough to say it.
 13 MR. GREEN:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. So, I'm just wondering well what's your source
 17 of knowledge as to the knowledge base of other
 18 pathologists with respect to IHC?
 19 MR. GREEN:
 20 A. I wouldn't know the knowledge base of any
 21 pathologists.
 22 CHAYTOR, Q.C.:
 23 Q. Okay. And I take it now you would have some
 24 familiarity with Dr. Elms however, and his
 25 knowledge base?

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1 MR. GREEN:
 2 A. Yes.
 3 THE COMMISSIONER:
 4 Q. So, that's a question of somebody really
 5 turning up in the lab and demonstrating and
 6 their interest in IHC, is it?
 7 MR. GREEN:
 8 A. Yes, they would have to ask a particular
 9 question, be specific enough to ask that
 10 question about an antibody.
 11 CHAYTOR, Q.C.:
 12 Q. And if we could have please, P-1576. Mr.
 13 Browne, I believe it was also took you to this
 14 document, page three, the reference to "a log
 15 book is available in the reporting room to
 16 record all problems". And you became aware,
 17 you said, at some point that such a log book
 18 existed. Was that a log book only for
 19 pathologists to record issues in or was that
 20 also a log book for technologists to record -
 21 MR. GREEN:
 22 A. Technologists would not record in that book.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. So, this was left in the reporting
 25 room. And if the pathologist had an issue,

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1 they would record the problems. Was it
 2 intended--who was it intended to communicate
 3 with? Was it intended for the technologists
 4 to see what they had written?
 5 MR. GREEN:
 6 A. It was probably a way to feedback problems
 7 that they were having to the technologists,
 8 but it was not specifically for IHC. It was
 9 for all pathology. And most of the problems
 10 that would be in that book would be related to
 11 section cutting, probably floaters, technical
 12 property of that and maybe clerical errors.
 13 CHAYTOR, Q.C.:
 14 Q. How did you become aware that such a book
 15 existed?
 16 MR. GREEN:
 17 A. I don't know. Probably at the end of one of
 18 these meetings, manager probably said the
 19 pathologists are having problems with some
 20 sections or something. We're going to create
 21 a log and keep track of this.
 22 CHAYTOR, Q.C.:
 23 Q. And then did the technologists have any duty
 24 to check this on a daily or weekly basis to
 25 see what issues may be raised?

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1 MR. GREEN:
 2 A. I'm not sure whose responsibility it was to
 3 check it and relay it back to the staff.
 4 CHAYTOR, Q.C.:
 5 Q. Okay. And did that happen? Did you get any
 6 feedback back from this logbook? Was anybody
 7 checking it and letting the technologists know
 8 what was written?
 9 MR. GREEN:
 10 A. Not that I'm aware of.
 11 CHAYTOR, Q.C.:
 12 Q. And are you aware whether or not any problems
 13 with respect to the IHC was recorded in this
 14 book?
 15 MR. GREEN:
 16 A. I'm not aware of any.
 17 CHAYTOR, Q.C.:
 18 Q. Do you know if these--it's probably books at
 19 this point--do you know if this logbook or
 20 books still exists?
 21 MR. GREEN:
 22 A. I don't--I haven't seen it. I don't think it
 23 exists.
 24 CHAYTOR, Q.C.:
 25 Q. Why is that? Have you made inquiries about

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1 it?
 2 MR. GREEN:
 3 A. \No, I haven't seen it in the recording room.
 4 CHAYTOR, Q.C.:
 5 Q. And is there any similar book or any similar
 6 system now for pathologists to relay concerns
 7 to the technologists?
 8 MR. GREEN:
 9 A. Not that I'm aware of.
 10 CHAYTOR, Q.C.:
 11 Q. So, if they have any complaints today, how is
 12 that handled?
 13 MR. GREEN:
 14 A. If there's a--if a pathologist has a complaint
 15 about the quality of a slide, they will
 16 usually ask for a re-cut which means that they
 17 will submit a form and sometimes in that form
 18 they will put on it, query floater or
 19 something like that.
 20 CHAYTOR, Q.C.:
 21 Q. Okay. The issue with respect to--and this was
 22 a question through Ms. Newbury, the issue of
 23 continuing to prepare slides beyond August
 24 2005 for the prospective slides that went on
 25 to Mount Sinai for the prospective testing.

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1 You've indicated that that wasn't done under
 2 the guidance of any pathologists. Did anyone
 3 ask you to do that?
 4 MR. GREEN:
 5 A. No.
 6 CHAYTOR, Q.C.:
 7 Q. So, this is something the technologists took
 8 on themselves to do?
 9 MR. GREEN:
 10 A. We only received one memo. And the memo said
 11 that there would be a hold on reporting. So,
 12 nobody ever told us to stop staining the
 13 slides.
 14 CHAYTOR, Q.C.:
 15 Q. So, that's how you interpreted Dr. Cook's
 16 August 8th memo, that you would continue to
 17 prepare the slides, but that the pathologists
 18 wouldn't be reporting?
 19 MR. GREEN:
 20 A. That's correct.
 21 CHAYTOR, Q.C.:
 22 Q. And there was no communication to the contrary
 23 to the technical staff. So, you kept
 24 preparing the slides.
 25 MR. GREEN:

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1 A. That's true.
 2 CHAYTOR, Q.C.:
 3 Q. Mr. Simmons asked you or showed you P-0113,
 4 the third memo that Dr. Ejeckam wrote, June
 5 19th, 2003. If we could just bring that up
 6 for a second, Registrar? So, did you read
 7 this memo that day in Dr. Ejeckam's office?
 8 MR. GREEN:
 9 A. Dr. Ejeckam did most of the reading.
 10 CHAYTOR, Q.C.:
 11 Q. Okay. And the very first sentence then is,
 12 "following persistent erratic results of
 13 immunostains in our laboratory, I accepted to
 14 work closely with the technical staff in order
 15 to rectify this problem". Were you surprised,
 16 perturbed or how did you feel to hear that he
 17 had written to Mr. Gulliver saying "persistent
 18 erratic results of immunostains", had anyone
 19 ever brought that to your attention before?
 20 MR. GREEN:
 21 A. No, that--I just perceived that to be his way
 22 of getting attention.
 23 CHAYTOR, Q.C.:
 24 Q. And why is it that you perceived it to be that
 25 as opposed to a serious concern by Dr.

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1 Ejeckam?
 2 MR. GREEN:
 3 A. I don't necessarily think that it wasn't
 4 serious. Does this memo have two pages?
 5 CHAYTOR, Q.C.:
 6 Q. This memo has at least two, let's just see,
 7 three pages.
 8 MR. GREEN:
 9 A. I think the third page is the most -
 10 CHAYTOR, Q.C.:
 11 Q. This is the third page here.
 12 MR. GREEN:
 13 A. Yes. This was the area that he seemed to
 14 concentrate on.
 15 CHAYTOR, Q.C.:
 16 Q. On the third page?
 17 MR. GREEN:
 18 A. Yeah.
 19 CHAYTOR, Q.C.:
 20 Q. Okay. So, this page here, for example, number
 21 six, he says "it is pertinent to mention that
 22 results of immuno stains are extremely
 23 important in histopathologic diagnosis,
 24 especially where classification of lymphomas
 25 and determination of benign or malignancy of

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1 certain lesions, for example, in the prostate
 2 biopsies given (sic.) on crisp, reliable and
 3 reproducible staining, results. Diagnosis
 4 based on inappropriate immuno stain will
 5 surely jeopardize patient care and may even
 6 expose the HCCSJ to the litigation.
 7 Therefore, it will be ill advised to operate
 8 an unreliable and erratic immunohistochemical
 9 procedures in our laboratory".
 10 So, you recall him specifically bringing
 11 that to your attention?
 12 MR. GREEN:
 13 A. Yeah, it seems to be the area that was--
 14 because when I saw that memo, that's the only
 15 area that I seemed to realize that I had seen
 16 the memo before. And then I realized that I
 17 had seen it in his office and he had taken it
 18 from his file and showed me that particular
 19 memo, flick through it.
 20 CHAYTOR, Q.C.:
 21 Q. So, did you actually have the memo in your
 22 possession, to read through?
 23 MR. GREEN:
 24 A. No.
 25 CHAYTOR, Q.C.:

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1 Q. Okay. So, you saw Dr. Ejeckam with the memo.
 2 MR. GREEN:
 3 A. Yes.
 4 CHAYTOR, Q.C.:
 5 Q. And he read out portions of this to you?
 6 MR. GREEN:
 7 A. He read out bits and pieces of it.
 8 CHAYTOR, Q.C.:
 9 Q. And through that encounter with Dr. Ejeckam,
 10 were you concerned about the product that your
 11 laboratory was producing?
 12 MR. GREEN:
 13 A. I didn't get that impression from him. I got
 14 the impression from him that he was frustrated
 15 at the lack of, at the speed at which the
 16 things that he wanted, if at all, were being
 17 performed.
 18 CHAYTOR, Q.C.:
 19 Q. Did you, after speaking with Dr. Ejeckam that
 20 day, relay that information to anybody else?
 21 MR. GREEN:
 22 A. No.
 23 CHAYTOR, Q.C.:
 24 Q. So you didn't speak to your manager, Mr. Dyer
 25 about it?

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1 MR. GREEN:
 2 A. No.
 3 CHAYTOR, Q.C.:
 4 Q. And you didn't tell any of the other the lab
 5 technologists what Dr. Ejeckam had just told
 6 you?
 7 MR. GREEN:
 8 A. No, because I didn't know if he showed me that
 9 letter in confidence because I knew who the
 10 letter was addressed to and so, I didn't
 11 discuss it with anybody.
 12 CHAYTOR, Q.C.:
 13 Q. Those are my questions, Commissioner, thank
 14 you very much.
 15 THE COMMISSIONER:
 16 Q. Mr. Green, thank you very much for assisting
 17 us in this process.
 18 MR. GREEN:
 19 A. Thank you.
 20 CHAYTOR, Q.C.:
 21 Q. Thank you, Mr. Green.
 22 MR. GREEN:
 23 A. Thank you.
 24 THE COMMISSIONER:
 25 Q. Why don't we take the afternoon break and then

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1 we can proceed with the next witness.
 2 (RECESS)
 3 THE COMMISSIONER:
 4 Q. Ms. Chaytor?
 5 CHAYTOR, Q.C.:
 6 Q. Thank you, Commissioner. The next witness is
 7 Mr. Les Simms.
 8 MR. LESLIE SIMMS, SWORN, EXAMINATION BY SANDRA CHAYTOR,
 9 Q.C.
 10 REGISTRAR:
 11 Q. Would you please state and spell your complete
 12 name for the Commission?
 13 MR. SIMMS:
 14 A. Leslie Simms, L-E-S-L-I-E, Simms, S-I-M-M-S.
 15 REGISTRAR:
 16 Q. Thank you.
 17 MR. SIMMS:
 18 A. Thank you.
 19 CHAYTOR, Q.C.:
 20 Q. Good afternoon, Mr. Simms.
 21 MR. SIMMS:
 22 A. Good afternoon, Ms. Chaytor.
 23 CHAYTOR, Q.C.:
 24 Q. Commissioner, there's one new exhibit that I
 25 would ask, please, to have entered through

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1 this witness and it's P-2175.
 2 THE COMMISSIONER:
 3 Q. Entered.
 4 EXHIBIT ENTERED AND MARKED P-2175
 5 CHAYTOR, Q.C.:
 6 Q. That's a good sign, Mr. Simms, I have one new
 7 exhibit. Perhaps we can begin, if you would,
 8 tell us about your educational and career
 9 background.
 10 MR. SIMMS:
 11 A. Education and career background. Graduated
 12 high school in St. Anthony on the Northern
 13 Peninsula in '66. At that time, I was
 14 considering a teaching career, but didn't know
 15 if I wanted to spend that time without having
 16 some involvement, so at that time, they had a-
 17 -I don't know if anybody remembers it or not,
 18 they had a summer school training where you
 19 could come to St. John's, train for six weeks
 20 and get a teaching certificate and go out in
 21 the smaller communities and teach school, and
 22 I went to Englee, on the Northern Peninsula
 23 again, kindergarten to grade six, one room,
 24 pot bellied stove. That sort of ended my
 25 desire to be a teacher.

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1 Came to St. John's, worked at the Grace
 2 for a while in physiotherapy, then went into
 3 the nursing assistant program at the Grace,
 4 and that's where I was introduced to the
 5 laboratory, and always having a fascination
 6 with science, I thought this would be
 7 interesting, so I applied to CONA, College of
 8 Trades and Technology at that time, where
 9 there was a three-year program, a six-semester
 10 program being offered, and I applied and met
 11 the requirements, did that program, graduated
 12 in 1972, and after writing the provincial and
 13 national examinations, which qualified me to
 14 work anywhere in Canada, some parts of the
 15 U.S.A. and the United Kingdom. Took a job
 16 back to St. Anthony and mainly to get some
 17 experience in all departments, because in the
 18 smaller hospitals, a new technologist coming
 19 out would practice in all departments. I
 20 worked mainly in hematology, but continued to
 21 do all departments and cover call.
 22 Job opening at--always was mostly
 23 interested in pathology. St. Clare's had an
 24 opening in 1977 that I applied for and got
 25 that position. So I moved in December of '77,

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1 pretty sure, to St. Clare's in the pathology
 2 department. Being there, I became involved
 3 with the CSLT, spent two terms as president of
 4 the provincial body, and one term as
 5 provincial director, that being a
 6 representative of Newfoundland and Labrador on
 7 the national body. Did a couple of continuing
 8 education courses offered from the CSLT, and
 9 then in 2003, amalgamation was coming about
 10 and everything and the senior technologist at
 11 the Health Science was leaving for another job
 12 and being the most senior technologist, I was
 13 persuaded to take up the challenge because
 14 this would be a challenge, moving to the
 15 Health Science, because I had done general
 16 pathology before. I had no problem with, this
 17 was after 25 years experience with pathology.
 18 However, moving to the Health Science meant
 19 going into the immunohistochemistry
 20 department, which I had very little knowledge
 21 of, and also doing some gross and, even moving
 22 into a new lab, basically the procedures are
 23 the same, but everything is different. So you
 24 had three--I had three challenges. I had to
 25 adjust to a new lab. I had to do gross and a

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1 new, and the IHC. And I stayed at the Health
 2 Science until I retired, May the 30th this
 3 year.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, so just this past six weeks?
 6 MR. SIMMS:
 7 A. Right.
 8 CHAYTOR, Q.C.:
 9 Q. Okay. Mr. Simms, you indicated that you were
 10 most interested in pathology and when you saw
 11 the opening then, I believe you said it was
 12 1977, you applied and was successful in
 13 getting the position at St. Clare's. In your
 14 course of studies, did you concentrate at all
 15 in pathology? Was there any such thing as a
 16 concentration?
 17 MR. SIMMS:
 18 A. No, there was no concentration in particular
 19 in pathology, but no more than any of the
 20 other departments, in the other disciplines.
 21 CHAYTOR, Q.C.:
 22 Q. And your program back then was a three-year
 23 program?
 24 MR. SIMMS:
 25 A. Three-year program, full three years. There

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1 was six semesters.
 2 CHAYTOR, Q.C.:
 3 Q. Okay, and you wrote both a provincial and a
 4 national exam?
 5 MR. SIMMS:
 6 A. I did.
 7 CHAYTOR, Q.C.:
 8 Q. And the national exam entitled you, I take it,
 9 to work wherever in the country?
 10 MR. SIMMS:
 11 A. Wherever in the country.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and you were persuaded, you said, to
 14 move after over 25 years at St. Clare's. You
 15 were persuaded to move to the Health Sciences,
 16 and who persuaded you to do that?
 17 MR. SIMMS:
 18 A. Barry Dyer.
 19 CHAYTOR, Q.C.:
 20 Q. Barry Dyer, okay.
 21 MR. SIMMS:
 22 A. Who was the manager at the Health Science at
 23 that time.
 24 CHAYTOR, Q.C.:
 25 Q. And was there any particular reason why you

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1 were targeted for that position?
 2 MR. SIMMS:
 3 A. Because I was the most senior person around in
 4 pathology at that time.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, and I take it in terms of looking for
 7 someone who would have experience in IHC,
 8 those technologists would be few and far
 9 between?
 10 MR. SIMMS:
 11 A. There were none.
 12 CHAYTOR, Q.C.:
 13 Q. There were none, okay. So you were senior and
 14 it's not like there was anyone else out there
 15 that could have had IHC experience?
 16 MR. SIMMS:
 17 A. Right.
 18 CHAYTOR, Q.C.:
 19 Q. Okay. Now I understand there had been a brief
 20 period of time at St. Clare's when IHC was
 21 introduced there. What do you recall about
 22 those days and what experience or exposure did
 23 you have to IHC at that point in time?
 24 MR. SIMMS:
 25 A. There was very little exposure. We decided--

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1 they were using kits at the time. We were
 2 doing kits, a fully manual method, and I got
 3 my information from the spec sheets and from
 4 literature that I read myself. The
 5 pathologists, most of them didn't have any
 6 more information on it than we did, so it was
 7 just a self-learning process, and after a
 8 while, it became evident that we didn't have
 9 enough knowledge to really continue with this.
 10 It wasn't economical and it was very time
 11 consuming.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and how long was it that St. Clare's
 14 carried out any IHC procedures?
 15 MR. SIMMS:
 16 A. I can't recall exact time, but a very short
 17 period, six months.
 18 CHAYTOR, Q.C.:
 19 Q. And was ER/PR, ER and/or PR part of the
 20 antibodies?
 21 MR. SIMMS:
 22 A. I don't remember doing ER/PR.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and was there one particular pathologist
 25 at that time that introduced the IHC or

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1 anybody showing the lead?
 2 MR. SIMMS:
 3 A. No.
 4 CHAYTOR, Q.C.:
 5 Q. And you say the little bit that you did learn
 6 about it was self taught through reading
 7 whatever was involved. Was it done through
 8 kits at that point in time?
 9 MR. SIMMS:
 10 A. It was kits at that time.
 11 CHAYTOR, Q.C.:
 12 Q. And so you read whatever instructions came
 13 with the kits?
 14 MR. SIMMS:
 15 A. The spec sheets were invaluable.
 16 CHAYTOR, Q.C.:
 17 Q. Okay, and I take it nobody else had had any
 18 experience with IHC, none of the other
 19 technical staff?
 20 MR. SIMMS:
 21 A. At St. Clare's?
 22 CHAYTOR, Q.C.:
 23 Q. At St. Clare's, at that time?
 24 MR. SIMMS:
 25 A. No.

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1 CHAYTOR, Q.C.:
 2 Q. Okay, and was there any learnings from--Health
 3 Science, I guess, was already doing the IHC.
 4 Was there any communication with the Health
 5 Sciences to try and assist St. Clare's in
 6 that?
 7 MR. SIMMS:
 8 A. We would talk to Peggy and Mary. When I say
 9 "we" I mean Ken and I, right, we would talk to
 10 Mary and Peggy if we had any questions that we
 11 thought, you know, they could help us with.
 12 CHAYTOR, Q.C.:
 13 Q. And when you were at St. Clare's, your
 14 position there, other than IHC, that was only
 15 a six-month--were you assigned specifically to
 16 IHC or that was just part of your overall
 17 duties?
 18 MR. SIMMS:
 19 A. That was part of our overall duties, Ken and
 20 myself.
 21 CHAYTOR, Q.C.:
 22 Q. And -
 23 MR. SIMMS:
 24 A. Because at that time, around that time, Ken
 25 and I worked together for 30 plus years and

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1 even at St. Clare's, there was basically, you
 2 know, most of the time, only two of us. So we
 3 sort of shared--we sort of did whatever.
 4 CHAYTOR, Q.C.:
 5 Q. So two of you in the pathology lab?
 6 MR. SIMMS:
 7 A. Yes, but there was assistants and so on, but
 8 there was two technologists.
 9 CHAYTOR, Q.C.:
 10 Q. Okay. There were pathology assistants?
 11 MR. SIMMS:
 12 A. No, no, laboratory assistants.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, and did you--you indicated coming over
 15 to the Health Sciences, you had to also then
 16 gross. So there wasn't--grossing wasn't part
 17 of your duties at St. Clare's, I take it?
 18 MR. SIMMS:
 19 A. Not at St. Clare's. I assisted with the
 20 gross, but that was only to put specimens in
 21 cassettes and label cassettes, etcetera, but
 22 no direct involvement with the gross, no.
 23 CHAYTOR, Q.C.:
 24 Q. So at St. Clare's, in the pathology
 25 department, you'd be responsible though for

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1 doing blocks, slides, special stains, H & E
 2 slides, all of that would have been part of
 3 your regular duties?
 4 MR. SIMMS:
 5 A. Everything that was involved in pathology.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, all right. And you retired. Did you
 8 eventually become a laboratory technician two?
 9 MR. SIMMS:
 10 A. That came about--it's ironic because that was--
 11 part of getting that reclassification was the
 12 fact that I was a senior tech at the time at
 13 St. Clare's and when we introduced the
 14 immunohisto--the immunoperoxidase, it was
 15 called then, staining, that was added to my
 16 duties, so that I was upgraded to a
 17 technologist two.
 18 CHAYTOR, Q.C.:
 19 Q. And what did it mean to be a technologist two?
 20 MR. SIMMS:
 21 A. You would do more of the specialized area.
 22 More of the general work would be left for
 23 other people to do.
 24 CHAYTOR, Q.C.:
 25 Q. So in reality, did--how did your job change?

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1 MR. SIMMS:
 2 A. Not a great deal.
 3 CHAYTOR, Q.C.:
 4 Q. Okay. So after St. Clare's stopped doing IHC
 5 or I take it that St. Clare's continued to use
 6 the Health Sciences for most, if not all, of
 7 its IHC requirements?
 8 MR. SIMMS:
 9 A. All of it, yes.
 10 CHAYTOR, Q.C.:
 11 Q. Okay, and would you be involved in arranging
 12 that, arranging for slides to be sent over?
 13 MR. SIMMS:
 14 A. For, and I can't remember how long, we were
 15 sending slides over and I would be involved in
 16 that too, along with Ken, and then somewhere
 17 along the line, we just sent blocks. I think
 18 because the Health Science, Peggy and Mary, I
 19 think, wanted to keep everything in line so
 20 that they would cut the blocks along with
 21 their own. They went on their own slides and
 22 so on. So we would--at the point, we were
 23 only sending blocks.
 24 CHAYTOR, Q.C.:
 25 Q. Yes, so that came up while you were here today

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1 with Mr. Green's evidence, that at some point,
 2 St. Clare's was actually--you were still
 3 producing your own slides and just sending the
 4 slides for IHC staining?
 5 MR. SIMMS:
 6 A. Yes.
 7 CHAYTOR, Q.C.:
 8 Q. And are you able to shed any light on when
 9 that practice stopped and you started actually
 10 sending blocks over to be processed?
 11 MR. SIMMS:
 12 A. Period of time wise you mean?
 13 CHAYTOR, Q.C.:
 14 Q. Yes.
 15 MR. SIMMS:
 16 A. No.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and you, yourself, moved in 2003?
 19 MR. SIMMS:
 20 A. Yes.
 21 CHAYTOR, Q.C.:
 22 Q. So it had stopped before that?
 23 MR. SIMMS:
 24 A. Yes.
 25 CHAYTOR, Q.C.:

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1 Q. When you arrived at the Health Science in
 2 2003, St. Clare's was then sending blocks, I
 3 take it?
 4 MR. SIMMS:
 5 A. Um-hm. We were only sending slides for a
 6 short period of time. I don't remember when
 7 we actually--when we started sending to the
 8 Health Science. I gather it was the--I don't
 9 know when we started sending, but it was only
 10 a short period of time we were sending slides.
 11 CHAYTOR, Q.C.:
 12 Q. Okay. When did you actually start--what was
 13 your start date at the Health Sciences Centre?
 14 MR. SIMMS:
 15 A. Paddy's Day, that's why I remember. March the
 16 18th, 2003.
 17 CHAYTOR, Q.C.:
 18 Q. March 18th, 2003?
 19 MR. SIMMS:
 20 A. Yeah.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and so when you went there, what
 23 training did you then receive in IHC?
 24 MR. SIMMS:
 25 A. My training then was--Peggy was the lead tech

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1 there, that was my understanding from when I
 2 moved in, and I was--the first week I was
 3 there, I don't think I was on IHC the first
 4 week I was there. I think it was the second
 5 week, and I followed Peggy around while she
 6 actually did the stains. I made my own notes
 7 and followed there and for that week and the
 8 following week, if I remember correctly, then
 9 I did them and Peggy kept an eye on what I was
 10 doing.
 11 CHAYTOR, Q.C.:
 12 Q. Okay. So your first week, you think you were
 13 doing something other than IHC?
 14 MR. SIMMS:
 15 A. Probably just getting orientated into the
 16 laboratory.
 17 CHAYTOR, Q.C.:
 18 Q. Into the lab, yes, okay, and the second week
 19 then, you job shadowed, for lack of a better
 20 term, you job shadowed Peggy Welsh during the
 21 IHC procedures?
 22 MR. SIMMS:
 23 A. That's right.
 24 CHAYTOR, Q.C.:
 25 Q. And then the week after, you went back to the

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1 IHC portion of the lab and then she observed
 2 while you did the procedures?
 3 MR. SIMMS:
 4 A. That's what I recall.
 5 CHAYTOR, Q.C.:
 6 Q. That's what you recall, okay, and how long was
 7 it then before you were left on your own then
 8 to do I--when were you next back into the IHC
 9 portion of the lab and were you then on your
 10 own doing the tests?
 11 MR. SIMMS:
 12 A. I could only assume that it was--you know,
 13 then after Mary did--the third week after, I
 14 would assume that then I did it on my own, but
 15 at that point in time, I was completely new at
 16 it, so I was never on my own, even if, you
 17 know, if I was setting up a machine on
 18 whatever, I would sometimes ask Ken to check
 19 it or Mary, whoever was around, just to make
 20 sure, just to double check and triple check
 21 because unfortunately or fortunately, I am a
 22 perfectionist and sometimes that's detrimental
 23 because you just check, recheck, check again,
 24 but I would--if I had any problems or wasn't
 25 absolutely sure of something, I would ask Ken

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1 or Mary.
 2 CHAYTOR, Q.C.:
 3 Q. Okay, and so they were nearby?
 4 MR. SIMMS:
 5 A. Yes.
 6 CHAYTOR, Q.C.:
 7 Q. Even though they weren't in the rotation, you
 8 were in there by yourself, you could check
 9 with them?
 10 MR. SIMMS:
 11 A. They were in shouting distance.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and did you frequently then have to
 14 consult with them or ask them questions?
 15 MR. SIMMS:
 16 A. No, not often, because what I did first, I
 17 remember taking--setting up my run for the
 18 next day or whatever, I would take my work
 19 home with me and go over it three or four
 20 times to make sure that the dilutions were
 21 correct and I had everything lined up properly
 22 and so on.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and using the DAKO machine, I take it,
 25 would that have been the first time you used

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1 such a machine?
 2 MR. SIMMS:
 3 A. Yes, it was.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, and Peggy taught you to use that, I take
 6 it?
 7 MR. SIMMS:
 8 A. She did.
 9 CHAYTOR, Q.C.:
 10 Q. Okay, and other than actually using the
 11 machine, what else were you--what other
 12 instruction, in terms of IHC, were you given
 13 or was the focus mostly on the operation of
 14 the machine or were you given anything in
 15 terms of the theory, for example, of IHC?
 16 MR. SIMMS:
 17 A. The focus was mainly on the machine, the
 18 operation of the machine. It was my own, my
 19 responsibility to find textbooks and so on and
 20 the theory, if I was so interested, you know,
 21 in the theory at that time, I would focus--it
 22 was my responsibility to go, find textbooks
 23 and journals and whatever else.
 24 CHAYTOR, Q.C.:
 25 Q. And did you do that?

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1 MR. SIMMS:
 2 A. Yes, I did.
 3 CHAYTOR, Q.C.:
 4 Q. So you sought out extra information?
 5 MR. SIMMS:
 6 A. I sought out extra reading material, yes.
 7 CHAYTOR, Q.C.:
 8 Q. And when you began then in March of 2003, how
 9 many antibodies were there approximately?
 10 MR. SIMMS:
 11 A. Between 70 and 80.
 12 CHAYTOR, Q.C.:
 13 Q. And what documentation--you say you took your
 14 own notes. Were you provided any
 15 documentation as to how to do the procedures
 16 and the protocols for the 70 to 80 antibodies?
 17 MR. SIMMS:
 18 A. Only on the technical manual. There was no
 19 written policy or written procedure that you
 20 could go and pick up and say, you know, that I
 21 could--that I knew of anyway, so I made my own
 22 notes in conjunction with what Peggy would
 23 state.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and what was the technical manual? What

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1 was that?
 2 MR. SIMMS:
 3 A. The machine, the manual that came with the
 4 machine, you know, troubleshooting the machine
 5 and operating the machine and what everything
 6 was used for, basically the technical manual.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and how about the actual protocols for
 9 the antibodies, where were those?
 10 MR. SIMMS:
 11 A. They were all fit in--they were in the
 12 machine. I can't even--I can never remember.
 13 Remember, see, for one thing that now we're
 14 talking about a very short period of time, I
 15 was involved in the DAKO bit, right. I mean,
 16 you're only talking eight to ten months.
 17 CHAYTOR, Q.C.:
 18 Q. Yes.
 19 MR. SIMMS:
 20 A. So it was very quick and I was just getting my
 21 feet wet.
 22 CHAYTOR, Q.C.:
 23 Q. So it's eight to ten months from March 2003
 24 for the rest of 2003.
 25 MR. SIMMS:

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1 A. Until we got into the Ventana.
 2 CHAYTOR, Q.C.:
 3 Q. It's almost a year. It's April '04 then
 4 before the Ventana comes on.
 5 MR. SIMMS:
 6 A. Yeah, and in that year, I would only do it
 7 every third week.
 8 CHAYTOR, Q.C.:
 9 Q. Yes.
 10 MR. SIMMS:
 11 A. So I probably only did anywhere from 12 to 15
 12 runs.
 13 CHAYTOR, Q.C.:
 14 Q. Right, and I take it in that, the week that
 15 you watched Ms. Welsh and then a week that you
 16 did the work and she watched, you would not
 17 have processed all 70 or 80 antibodies in
 18 those two weeks?
 19 MR. SIMMS:
 20 A. Oh no, absolutely not.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and so in terms of how you would know to
 23 do the other--how to do the other antibodies,
 24 those protocols, you're saying would have been
 25 put into the computer of the machine?

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1 MR. SIMMS:
 2 A. They're all put into the computer and
 3 basically the protocols for most of the
 4 antibodies are pretty well all the same,
 5 except for antigen retrieval.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and what were you taught about antigen
 8 retrieval? Had you been involved for--first of
 9 all, had you been involved for--first of all,
 10 had you been involved in antigen retrieval
 11 prior to 2003?
 12 MR. SIMMS:
 13 A. No.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, and what did you--what did Ms. Welsh
 16 then teach you about antigen retrieval?
 17 MR. SIMMS:
 18 A. We had a water bath and I called it the
 19 boiling technique, where we boil it in a
 20 buffer, in a buffer for--citrate buffer for 20
 21 minutes and then let it cool off to room
 22 temperature.
 23 CHAYTOR, Q.C.:
 24 Q. And then you let it cool to room temperature?
 25 MR. SIMMS:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. And 20 minutes at what temperature?
 4 MR. SIMMS:
 5 A. 97 to 100.
 6 CHAYTOR, Q.C.:
 7 Q. And how stringent were you or how religious
 8 were you in terms of did you understand the
 9 timing and the temperature had to be strictly
 10 adhered to?
 11 MR. SIMMS:
 12 A. Very stringent.
 13 CHAYTOR, Q.C.:
 14 Q. And you understood that from Ms. Welsh?
 15 MR. SIMMS:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. And what if -- was there any alarm system that
 19 would let you know when your twenty minutes
 20 were up or how would you do that? Was there a
 21 timer?
 22 MR. SIMMS:
 23 A. We had timers. We had timers in the lab, and
 24 being we had a timer, I would always check. I
 25 would always wear a watch as well, right. So

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1 there was a couple of checks that I did. I
 2 would note the time -- what I would usually do
 3 is note the time on a piece of paper or on my
 4 sheet that I was -- the day's log. I would
 5 note the time that I put them in, plus set the
 6 clock, or the timer.
 7 CHAYTOR, Q.C.:
 8 Q. And the ER and PR, of course, are two
 9 antibodies that require antigen retrieval?
 10 MR. SIMMS:
 11 A. Yes.
 12 CHAYTOR, Q.C.:
 13 Q. And while watching Ms. Welsh that first week,
 14 do you know whether or not she did any ER or
 15 PRs?
 16 MR. SIMMS:
 17 A. I couldn't tell because ER/PR at that time was
 18 just another -- you know, to me, it was just
 19 another antibody. There was nothing specific,
 20 nothing different about the ER/PR at that
 21 point in time.
 22 CHAYTOR, Q.C.:
 23 Q. So there were others, I take it, that also
 24 required antigen retrieval besides ER/PR?
 25 MR. SIMMS:

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1 A. Yes.
 2 CHAYTOR, Q.C.:
 3 Q. So you don't know whether or not the first
 4 time you did ER or PR tests, that you were on
 5 your own doing it, or whether or not it was
 6 done alongside Ms. Welsh?
 7 MR. SIMMS:
 8 A. I couldn't recall that.
 9 CHAYTOR, Q.C.:
 10 Q. Okay. You said that you set a timer for doing
 11 your antigen retrieval, and what if you
 12 weren't in the general area when the twenty
 13 minutes were up?
 14 MR. SIMMS:
 15 A. I never knew of any time -- if I was
 16 responsible for the DAKO machine, I never knew
 17 of any time I wasn't in the area. I was never
 18 out of hearing shot of the timer if I was
 19 responsible for the IHC.
 20 CHAYTOR, Q.C.:
 21 Q. How much time did you overlap then with Ms.
 22 Welsh? She left at, I believe, in --
 23 MR. SIMMS:
 24 A. Five weeks.
 25 CHAYTOR, Q.C.:

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1 Q. And this whole process of the antigen
 2 retrieval, what was your impression at the
 3 time of coming over from St. Clare's? What
 4 was your impression of the method of antigen
 5 retrieval at the Health Science?
 6 MR. SIMMS:
 7 A. I don't understand what you mean by "my
 8 impression of it".
 9 CHAYTOR, Q.C.:
 10 Q. What did you think of the technique that was
 11 being used or did you have any impression of
 12 the technique?
 13 MR. SIMMS:
 14 A. I just thought it was very aggressive,
 15 aggressive, the boiling and that, right. It
 16 was very hard on the tissue, which is
 17 sometimes why we would get pieces of tissue
 18 floating off or some tissue floating off
 19 altogether because it was exposed to this
 20 boiling technique and you would lose tissue.
 21 CHAYTOR, Q.C.:
 22 Q. And you were --
 23 MR. SIMMS:
 24 A. So it's a very aggressive technique.
 25 CHAYTOR, Q.C.:

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1 Q. It was an aggressive technique, and did you
 2 have reason to read up on other methods of
 3 antigen retrieval?
 4 MR. SIMMS:
 5 A. I did not.
 6 CHAYTOR, Q.C.:
 7 Q. You did not, and you weren't otherwise aware
 8 of any through your own personal experience,
 9 other methods of antigen retrieval?
 10 MR. SIMMS:
 11 A. No.
 12 CHAYTOR, Q.C.:
 13 Q. Now we also have heard that while the DAKO
 14 machine was in operation, the antibodies, ER
 15 and PR, were not pre-diluted. So what were
 16 you taught in terms of how to dilute the
 17 antibodies?
 18 MR. SIMMS:
 19 A. I knew -- from general practice, I knew how to
 20 make dilutions. So those dilutions were no
 21 different than any other dilutions that I
 22 would make in the laboratory, which is just
 23 another dilution. You make a dilution. If
 24 it's 1 in 50, you do 1 in 50. If it's --
 25 CHAYTOR, Q.C.:

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1 Q. And how would you know what the appropriate
 2 dilution was?
 3 MR. SIMMS:
 4 A. In my case, I had a list of the antibodies
 5 myself. I had the dilutions written next to
 6 them, plus the fact that on the bottle itself,
 7 it was written on the bottle, and it was
 8 written on the spec sheet.
 9 CHAYTOR, Q.C.:
 10 Q. And during your time, you say like eight
 11 months or more that you used the DAKO machine,
 12 do you recall whether or not the dilution ever
 13 changed for ER?
 14 MR. SIMMS:
 15 A. The ER -- from what I recall, to think about,
 16 the ER may have changed, but like I said, I
 17 was new there and I think that change came
 18 about when Dr. Ejeckam suggested that they
 19 could have some problems with a few of the
 20 antibodies, including ER/PR.
 21 CHAYTOR, Q.C.:
 22 Q. Okay.
 23 MR. SIMMS:
 24 A. I was not involved. I wouldn't be involved in
 25 that, you know, reevaluating them because I

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1 was new there. I didn't know much about it,
 2 so I -- from my understanding, it was Mary and
 3 Barry did that, and if I remember correctly,
 4 that was the only thing that changed was the
 5 ER dilution.
 6 CHAYTOR, Q.C.:
 7 Q. The ER dilution, okay, and did you even
 8 understand that that had to be done from time
 9 to time or that there would be validation from
 10 time to time of the antibody?
 11 MR. SIMMS:
 12 A. Not at the beginning.
 13 CHAYTOR, Q.C.:
 14 Q. Okay.
 15 MR. SIMMS:
 16 A. Right. That wasn't taught to me at the
 17 beginning, but after a couple of three months
 18 into it, then I started -- you know, I was
 19 made aware that, you know.
 20 CHAYTOR, Q.C.:
 21 Q. And --
 22 MR. SIMMS:
 23 A. But that would be the responsibility of the
 24 lead tech.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and after Ms. Welsh left, who was that?
 2 MR. SIMMS:
 3 A. Mary.
 4 CHAYTOR, Q.C.:
 5 Q. Ms. Butler, Mary Butler?
 6 MR. SIMMS:
 7 A. Uh-hm, sorry.
 8 CHAYTOR, Q.C.:
 9 Q. And at the end then of your couple of weeks
 10 with Ms. Welsh, how comfortable did you feel
 11 in your training in IHC?
 12 MR. SIMMS:
 13 A. Not comfortable at all.
 14 CHAYTOR, Q.C.:
 15 Q. And at any point in time, did your comfort
 16 level increase, and if so, how -- how is it
 17 that you became more comfortable in doing what
 18 you were doing?
 19 MR. SIMMS:
 20 A. My comfort level increased and I became more
 21 aware of what I was doing was when I got
 22 involved with Ventana.
 23 CHAYTOR, Q.C.:
 24 Q. And that's in 2004?
 25 MR. SIMMS:

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1 A. That began -- I think December of 2003
 2 probably, but it was into 2004 before we
 3 actually started using it, but in preparation
 4 for the Ventana System coming, of course, we
 5 had reading material, we had documentation --
 6 you know, we had various things to read, and
 7 Barry was very good at that, supplying
 8 information that way. Then I was -- it was
 9 new to everyone, so I didn't feel out of
 10 place. You know, I was learning the same
 11 thing as everybody else was learning with the
 12 Ventana, "this is a new system, this is the
 13 way we do it, and this is why we do it, this
 14 is how we do it".
 15 CHAYTOR, Q.C.:
 16 Q. Okay, and why is it that then you felt more
 17 comfortable? Is it because everybody was
 18 starting off at the same base?
 19 MR. SIMMS:
 20 A. Same level, yes.
 21 CHAYTOR, Q.C.:
 22 Q. Same knowledge level?
 23 MR. SIMMS:
 24 A. Yes, yes.
 25 CHAYTOR, Q.C.:

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1 Q. So it wasn't necessarily the system itself, it
 2 was just that you felt you're getting in at
 3 the ground level with everyone else in trying
 4 to learn the new system?
 5 MR. SIMMS:
 6 A. That's right.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and --
 9 MR. SIMMS:
 10 A. And basically the procedures never changed --
 11 the procedure don't change, anyway. We're
 12 doing the same procedure I was doing with the
 13 KIT method back in the early 90s, basically
 14 the same as when we started running the
 15 Ventana, the actual procedure itself, you
 16 know, the antibody -- primary antibody,
 17 tertiary, you know, these were pretty much the
 18 same.
 19 CHAYTOR, Q.C.:
 20 Q. Yes.
 21 MR. SIMMS:
 22 A. With just a few technological developments,
 23 but basically the procedure remained the same.
 24 CHAYTOR, Q.C.:
 25 Q. And do you recall the first time that you ran

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1 out of an antibody and you had to actually be
 2 involved in validating a new batch or bringing
 3 a new batch on?
 4 MR. SIMMS:
 5 A. Uh-hm.
 6 CHAYTOR, Q.C.:
 7 Q. And do you recall how far into the process
 8 were you at that point?
 9 MR. SIMMS:
 10 A. I was into Ventana before I did that. I never
 11 did that with DAKO.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and I take it, was there someone who
 14 assisted you then to be able to do that?
 15 MR. SIMMS:
 16 A. With the first validation I did?
 17 CHAYTOR, Q.C.:
 18 Q. Yes.
 19 MR. SIMMS:
 20 A. Yes, absolutely.
 21 CHAYTOR, Q.C.:
 22 Q. And who was that?
 23 MR. SIMMS:
 24 A. Ken Green.
 25 CHAYTOR, Q.C.:

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1 Q. Do you recall were there expiry dates on the
 2 vials of antibodies?
 3 MR. SIMMS:
 4 A. There were.
 5 CHAYTOR, Q.C.:
 6 Q. And did you ever have a difference of opinion
 7 with anyone over the significance of expiry
 8 dates?
 9 MR. SIMMS:
 10 A. Most of the antibodies, it did not reach the
 11 expiry date because they were used before --
 12 they were used up before the expiry date came
 13 about. There were a couple of them that was
 14 done very -- not very often, and -- yeah, I
 15 can remember a couple being used with the
 16 expiry date, not ER/PR.
 17 CHAYTOR, Q.C.:
 18 Q. And what do you recall about that? What
 19 discussion did you have around that?
 20 MR. SIMMS:
 21 A. I thought it was unusual, but it was a --
 22 these things are really very expensive, and
 23 the cost savings -- you know, it was a cost
 24 saving measure because -- now don't get me
 25 wrong. If we did do a run with an expired

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1 date, say, we did, we always made sure that
 2 the control was the same as it was prior to
 3 before.
 4 CHAYTOR, Q.C.:
 5 Q. And so you are aware of a couple of times when
 6 antibodies that were expired were used, but
 7 they weren't ER/PR?
 8 MR. SIMMS:
 9 A. If I remember correctly.
 10 CHAYTOR, Q.C.:
 11 Q. And whether or not that ever happened with ER
 12 and PR as well, you're not aware?
 13 MR. SIMMS:
 14 A. Not to my knowledge.
 15 CHAYTOR, Q.C.:
 16 Q. Okay.
 17 MR. SIMMS:
 18 A. And on the Ventana, that never happened at
 19 all. There was never any expiry date problem.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and who was it that indicated to you
 22 about the cost and expensive the antibodies?
 23 MR. SIMMS:
 24 A. I can't recall specifically who, but most
 25 likely Peggy.

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1 CHAYTOR, Q.C.:
 2 Q. Did you have in that first year or so, your
 3 first year, say, because then the Ventana is
 4 brought on, how much interaction would you
 5 have in that time period with pathologists?
 6 MR. SIMMS:
 7 A. Not a great deal the first year I was there,
 8 not a great deal, because that was -- again
 9 like I said, I was new, so I didn't -- they
 10 didn't come to me.
 11 CHAYTOR, Q.C.:
 12 Q. Okay, and how frequent would it be for
 13 pathologists to come to the pathology lab,
 14 other than Dr. Ejeckam? We'll talk about him
 15 in a minute, but was it a common occurrence to
 16 have pathologists in the pathology lab?
 17 MR. SIMMS:
 18 A. Yeah, they would -- yes, yeah.
 19 CHAYTOR, Q.C.:
 20 Q. And if they came looking for anything or
 21 talking or with any questions, you didn't tend
 22 to be the one in the early days that they
 23 approached, I take it?
 24 MR. SIMMS:
 25 A. That's right.

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1 CHAYTOR, Q.C.:
 2 Q. And how about -- your manager, I guess, would
 3 have been Barry Dyer at the time?
 4 MR. SIMMS:
 5 A. It was.
 6 CHAYTOR, Q.C.:
 7 Q. And how much contact would you have had with
 8 Mr. Dyer?
 9 MR. SIMMS:
 10 A. A good amount of contact, daily contact.
 11 CHAYTOR, Q.C.:
 12 Q. So he was there frequently, there on a daily
 13 basis?
 14 MR. SIMMS:
 15 A. Absolutely.
 16 CHAYTOR, Q.C.:
 17 Q. During the DAKO days then, what was the --
 18 what was taught to you about external
 19 controls?
 20 MR. SIMMS:
 21 A. External controls back then, and from the DAKO
 22 days especially, right, all that I understood
 23 of external controls was you look at a slide
 24 under the microscope and you get a chemical
 25 reaction, a brown reaction. That was it. I

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<p>1 had no specific details as to which cells were 2 staining or anything else, it was just the 3 reaction. 4 CHAYTOR, Q.C.: 5 Q. So you were taught that you would look at the 6 control slides after you run a batch to see 7 whether or not there has been any reaction, 8 and you were just taught to look for brown 9 staining? 10 MR. SIMMS: 11 A. That's it. 12 CHAYTOR, Q.C.: 13 Q. But not in any particular areas? 14 MR. SIMMS: 15 A. No. 16 CHAYTOR, Q.C.: 17 Q. Okay, and who taught you that? 18 MR. SIMMS: 19 A. Peggy. 20 CHAYTOR, Q.C.: 21 Q. That was Peggy? 22 MR. SIMMS: 23 A. Yes. 24 CHAYTOR, Q.C.: 25 Q. And how many controls were run per batch? If</p>	<p>1 every batch for every antibody. 2 CHAYTOR, Q.C.: 3 Q. So every antibody that was on the machine had 4 a control for that antibody, and sometimes, I 5 take it, there might be more than one control, 6 is that right? 7 MR. SIMMS: 8 A. Yeah, it depends on the case too. You may 9 have one antibody there, you may have five, 10 but it was from five -- there was one control 11 run with every antibody, but not necessarily 12 every case. 13 CHAYTOR, Q.C.: 14 Q. Right. 15 MR. SIMMS: 16 A. There was one control run per antibody, yes. 17 CHAYTOR, Q.C.: 18 Q. And you might have more than one control 19 depending on where -- who had ordered the 20 test? 21 MR. SIMMS: 22 A. If it was from out of town, yes, you would run 23 an extra one. I don't think we ran an extra 24 one if it was from St. Clare's, if I remember 25 correctly.</p>
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<p>1 you have, say, five different antibodies on a 2 batch, how many controls were run? 3 MR. SIMMS: 4 A. There would be five controls run. 5 CHAYTOR, Q.C.: 6 Q. So there was one control run for each batch? 7 MR. SIMMS: 8 A. For each antibody. 9 CHAYTOR, Q.C.: 10 Q. Sorry, for each antibody, yes. Was there ever 11 a time period when there was only one control 12 run -- one control run per batch? 13 MR. SIMMS: 14 A. I don't understand the question. 15 CHAYTOR, Q.C.: 16 Q. Do you recall ever having a time or a concern 17 that there was only one control run per batch 18 irregardless of how many antibodies were on 19 the machine? 20 MR. SIMMS: 21 A. Not that I recall. I had some problem with 22 that question back when it was first asked of 23 me, right, and I couldn't recall if I did or 24 not, but thinking about it, I don't think so. 25 I think it was run -- the control was run with</p>	<p>1 CHAYTOR, Q.C.: 2 Q. I'm sorry? 3 MR. SIMMS: 4 A. I don't think we ran an extra one if it was 5 from St. Clare's. 6 CHAYTOR, Q.C.: 7 Q. So what would happen in that case, how would 8 the pathologist at St. Clare's become informed 9 about the external controls? 10 MR. SIMMS: 11 A. We would -- I would mark on the requisition, 12 right, that we had the controls, and somebody 13 had another case -- usually if I didn't send 14 over the control, somebody else had another 15 case. If I just had that antibody and no 16 other person had this particular antibody 17 ordered in the hospital, then I would send it 18 over to St. Clare's, but if -- if there was 19 another pathologist that ordered it at the 20 Health Science, it would stay at the Health 21 Science and I would inform on the requisition 22 -- usually on the requisition who they were to 23 call at the Health Science and say, you know, 24 who checked the control. 25 CHAYTOR, Q.C.:</p>

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1 Q. So your practice was to mark on the
 2 requisition that was going back to St. Clare's
 3 that Dr. so and so had the controls, so that
 4 then the pathologist at St. Clare's could
 5 contact that physician and talk about the
 6 controls?
 7 MR. SIMMS:
 8 A. I did.
 9 CHAYTOR, Q.C.:
 10 Q. And so you didn't have a pathologist read the
 11 control before you sent off the patient's
 12 slides to St. Clare's?
 13 MR. SIMMS:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. While you were at St. Clare's and involved in
 17 ordering ER/PR tests for the pathologists
 18 there or arranging that, did you have occasion
 19 to request that controls be sent over?
 20 MR. SIMMS:
 21 A. Not that I recall.
 22 CHAYTOR, Q.C.:
 23 Q. Did any pathologist there ever express any
 24 concern that they were receiving patient
 25 slides without the controls?

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1 MR. SIMMS:
 2 A. No.
 3 CHAYTOR, Q.C.:
 4 Q. Do you recall having any discussions with Ms.
 5 Welsh then around that issue while you were
 6 still at St. Clare's and discussing with her
 7 whether or not there were -- you were going to
 8 receive the external controls?
 9 MR. SIMMS:
 10 A. Sometimes, right, a couple of times I remember
 11 calling and asking Peggy if she would send
 12 over the controls, yes.
 13 CHAYTOR, Q.C.:
 14 Q. So that was on your own initiative.
 15 MR. SIMMS:
 16 A. My own initiative.
 17 CHAYTOR, Q.C.:
 18 Q. Not because any pathologist asked for it.
 19 MR. SIMMS:
 20 A. No.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and what was Ms. Welsh's response to
 23 your inquiries in that regard?
 24 MR. SIMMS:
 25 A. If the pathologist needs them, I'll send them

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1 over, but only if the pathologist needs it.
 2 She wasn't going to send them over to me.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and in that context, did she ever
 5 mention internal controls to you?
 6 MR. SIMMS:
 7 A. I've wracked my brain around this issue too
 8 for internal controls because I know it's come
 9 up so often. I know I became aware of or more
 10 aware of internal controls when Dr. Ejeckam
 11 came on the scene, but I seem to recall Peggy
 12 telling me at certain points in time, you
 13 know, well, we may not have a good external
 14 control for this particular antibody, we're
 15 still working on it, but if I'm doing a piece
 16 of bowel or a piece of lung, it's okay because
 17 there is a built in control. A built in
 18 control, she called it, right. Now whether or
 19 not she meant that to be an internal control,
 20 I don't know, but she said it's okay sometimes
 21 because there's a built in control in this
 22 particular tissue.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and this is while you're still at St.
 25 Clare's and you're having a phone

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1 conversation, I take it, with Ms. Welsh?
 2 MR. SIMMS:
 3 A. No, this was when -
 4 CHAYTOR, Q.C.:
 5 Q. Oh, this is after you're moved over, okay.
 6 MR. SIMMS:
 7 A. Having a discussion with Peggy concerning
 8 internal controls at St. Clare's.
 9 CHAYTOR, Q.C.:
 10 Q. So on occasions when there may have been some
 11 concern that the external control wasn't that
 12 good, she was saying that there's a built in
 13 control?
 14 MR. SIMMS:
 15 A. That's what I would recall.
 16 CHAYTOR, Q.C.:
 17 Q. Which could be the internal control and so the
 18 pathologist would have that safeguard, is that
 19 what you took that to mean?
 20 MR. SIMMS:
 21 A. That was my understanding, right, but I had no
 22 idea what an internal control looked like,
 23 again, I would probably have just looked down
 24 to see if there was any reaction. But I
 25 couldn't speak on internal controls at that

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1 point in time.

2 CHAYTOR, Q.C.:

3 Q. And was there any rule or did you understand

4 that you weren't supposed to send the tests

5 out to the pathologists unless you, yourself,

6 had checked the external controls, was there

7 any rule or any guidelines along that?

8 MR. SIMMS:

9 A. There was no set rule for that. We checked,

10 you know, I checked the external controls just

11 to see if the test procedure was working, that

12 was my only reason for checking external

13 controls and if there was any reaction, it was

14 working, it there wasn't, it wasn't working.

15 And if it wasn't working, if there was no, if

16 there was no staining in the control at all,

17 then I would go to Ken or Mary or Barry,

18 whoever, and say, you know, there's no point--

19 is there any point in sending this out,

20 there's no reaction here, right.

21 CHAYTOR, Q.C.:

22 Q. And did that happen from time to time?

23 MR. SIMMS:

24 A. Very seldom, no, once or twice probably in the

25 whole time.

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1 CHAYTOR, Q.C.:

2 Q. And what would happen in that case?

3 MR. SIMMS:

4 A. And then we would do a repeat, right, and see

5 if you would get the same result as you got.

6 CHAYTOR, Q.C.:

7 Q. And was there any investigation carried out to

8 try and back track to find out why it hadn't

9 worked the first time?

10 MR. SIMMS:

11 A. There would be. If it worked the second time,

12 right, yes, you would go back and try to find

13 out what happened.

14 CHAYTOR, Q.C.:

15 Q. And do you recall ever detecting any problems?

16 Ever figuring out why something, why an

17 external control had never stained?

18 MR. SIMMS:

19 A. No.

20 CHAYTOR, Q.C.:

21 Q. You indicated that you only knew to look for

22 brown staining and later on Dr. Ejeckam, I

23 believe you said, taught you what exactly to

24 look for.

25 MR. SIMMS:

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1 A. That's right.

2 CHAYTOR, Q.C.:

3 Q. When did Dr. Ejeckam do that? Was that before

4 everything happened in 2005 or after?

5 MR. SIMMS:

6 A. After.

7 CHAYTOR, Q.C.:

8 Q. It was after, okay. And what did Dr. Ejeckam

9 teach you then to look for?

10 MR. SIMMS:

11 A. To be more specific in external controls,

12 which cells were staining, which independent

13 cells were staining--or which were supposed to

14 stain. And that was a very brief teaching as

15 well. You know, he tried his best but he

16 didn't have too long to do it and we were much

17 too busy to really take the time out to be

18 taught, unfortunately, right. Where I learned

19 most of my knowledge on external controls, now

20 we're talking Ventana now.

21 CHAYTOR, Q.C.:

22 Q. Yes.

23 MR. SIMMS:

24 A. Is the Ventana is a catalogue of their

25 antibodies which has a coloured photograph of

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1 a certain piece of tissue and the way it

2 should look as an explanation of the antibody

3 that's used, the clone, a brief statement on

4 what is stained and in which cancers it stains

5 in, right, and so that's where I developed

6 most of my knowledge or a fair amount of my

7 knowledge for external controls, was there,

8 and if you could reproduce the same picture,

9 day after day, after day, well you sort of got

10 used to it after awhile and you would notice

11 any slightest change, you would pick it up.

12 CHAYTOR, Q.C.:

13 Q. And when did you start doing that? Was that

14 also after everything happened in 2005?

15 MR. SIMMS:

16 A. That's when we started the Ventana.

17 CHAYTOR, Q.C.:

18 Q. So that was in April, 2004, around then? So

19 early in 2004?

20 MR. SIMMS:

21 A. Right, so prior to Dr. Ejeckam attempting to

22 teach us, we were still at that for the year

23 before.

24 CHAYTOR, Q.C.:

25 Q. And you would study the pictures that were

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1 provided by Ventana?
 2 MR. SIMMS:
 3 A. Yes, and Ventana also supplied a great
 4 technical support, you could pick up the phone
 5 any time and call Ventana, they had technical
 6 people on hand all the time.
 7 CHAYTOR, Q.C.:
 8 Q. And was there usually one person that you
 9 would contact at Ventana or was it someone
 10 different?
 11 MR. SIMMS:
 12 A. There was two that I recall.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, and who were they?
 15 MR. SIMMS:
 16 A. I can't remember their names.
 17 CHAYTOR, Q.C.:
 18 Q. And we've heard the name Carol Quevillon?
 19 MR. SIMMS:
 20 A. That was the lady who would come in, yeah, she
 21 was a representative from Ventana, come in
 22 from Montreal to assist us in setting up the
 23 machine.
 24 CHAYTOR, Q.C.:
 25 Q. And was she someone that you could also

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1 contact if you had any questions?
 2 MR. SIMMS:
 3 A. If necessary.
 4 CHAYTOR, Q.C.:
 5 Q. You have, so you indicate that there may have
 6 been a couple of occasions where there was an
 7 issue with the controls not staining. Do you
 8 recall whether or not that was ever ER/PR?
 9 MR. SIMMS:
 10 A. No, it wasn't ER/PR.
 11 CHAYTOR, Q.C.:
 12 Q. It wasn't ER/PR.
 13 MR. SIMMS:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. Do you ever recall anyone complaining to you
 17 about the quality of ER/PR slides?
 18 MR. SIMMS:
 19 A. In--what are we talking DAKO or Ventana?
 20 CHAYTOR, Q.C.:
 21 Q. At any point in time prior to everything
 22 happening in 2005?
 23 MR. SIMMS:
 24 A. Quality of the slides, oh yes, oh yes.
 25 CHAYTOR, Q.C.:

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1 Q. And specifically about ER/PR?
 2 MR. SIMMS:
 3 A. Not specifically.
 4 CHAYTOR, Q.C.:
 5 Q. That's what I'm wondering, whether or not
 6 there was any--so you had concerns expressed
 7 about the quality of IHC slides.
 8 MR. SIMMS:
 9 A. Yes.
 10 CHAYTOR, Q.C.:
 11 Q. But not necessarily or not specifically ER/PR/
 12 MR. SIMMS:
 13 A. Not necessarily ER/PR, but ER/PR were included
 14 in some of these statements.
 15 CHAYTOR, Q.C.:
 16 Q. And who raised those concerns and what were
 17 the concerns?
 18 MR. SIMMS:
 19 A. Different pathologists and the concerns were
 20 that the tissues were washing, you know, may
 21 have washed off the slide or all the tissue
 22 wasn't present, no--at that point they didn't
 23 look at internal controls, but no, just tumour
 24 tissue, no normal tissue around to compare
 25 with the tumour.

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1 CHAYTOR, Q.C.:
 2 Q. And a pathologist would raise that as a
 3 concern?
 4 MR. SIMMS:
 5 A. Yes.
 6 CHAYTOR, Q.C.:
 7 Q. And what would cause the tissue to wash off
 8 the slide from a technical point of view?
 9 MR. SIMMS:
 10 A. Because, well from fixation and processing
 11 because if you're cutting breast tissue, if
 12 you don't get a proper sample, if you don't
 13 get a fairly thin smaller sample of tissue
 14 with tumour and normal tissue attached to it,
 15 you get a lot of fatty tissue, and fatty
 16 tissue is very difficult to fix, very
 17 difficult to process and very difficult to
 18 cut.
 19 CHAYTOR, Q.C.:
 20 Q. So I take it in the discussions of it being
 21 brought to your attention that there is issue
 22 with the tissue coming off the slides, there
 23 would be a discussion about the poor fixation
 24 or the poor processing of the tissue?
 25 MR. SIMMS:

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1 A. Or possibly that that's what was causing it,
 2 because, as you know, we weren't involved in
 3 the fixation. All we got was a paraffin block
 4 to work with and sometimes we would cut it, we
 5 would know immediately this is going to be
 6 trouble because you could see the tissue was
 7 fatty and not fixed properly or not processed
 8 properly and you knew it was going to give you
 9 trouble and many times, not many times, but at
 10 times we would actually mark on the
 11 requisition itself, when it went back, you
 12 know, suboptimal tissue, right. Sometimes we
 13 would call the pathologist. I've called over
 14 to Bev Carter, Don Cook. I've called several
 15 people and said, look, this particular block
 16 here is not very good quality, can we try
 17 another block.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, and that was particularly true of breast
 20 tissue, I take it?
 21 MR. SIMMS:
 22 A. Yes, and it would be mostly breast tissue.
 23 Most of the other specimens, most all the
 24 other antibodies or the tissue we did was
 25 fine, right, but ER/PR and being the type of

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1 tissue it was, it would cause some concern.
 2 CHAYTOR, Q.C.:
 3 Q. And that was subject of discussion amongst the
 4 technologists.
 5 MR. SIMMS:
 6 A. Oh absolutely.
 7 CHAYTOR, Q.C.:
 8 Q. And also amongst technologists and
 9 pathologists that there was issues regarding
 10 fixation with, in particular, the breast
 11 tissue?
 12 MR. SIMMS:
 13 A. Yeah, or Ken and I would often say to each
 14 other, look, you know, we're wasting our time
 15 by supplying this slide to them.
 16 CHAYTOR, Q.C.:
 17 Q. And, Mr. Simms, to your knowledge was anything
 18 done about it?
 19 MR. SIMMS:
 20 A. Not up to the point that I left.
 21 CHAYTOR, Q.C.:
 22 Q. Up until you left this year?
 23 MR. SIMMS:
 24 A. Uh-hm.
 25 CHAYTOR, Q.C.:

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1 Q. Nothing done to address -
 2 MR. SIMMS:
 3 A. Not really, they tried various things, but
 4 they're still getting suboptimal tissue,
 5 whether it's from the fixation or not
 6 acquiring a proper technique for a proper
 7 piece of tissue or tissue too big or too
 8 thick, you know, but now they have PAS now who
 9 are supposedly being trained to cut, give the
 10 proper tissue to us or to the IHC lab for
 11 cutting.
 12 CHAYTOR, Q.C.:
 13 Q. So up until you left your job in May of 2008,
 14 you still had concern about the quality of
 15 tissue that you were seeing?
 16 MR. SIMMS:
 17 A. It had improved but it still wasn't up to
 18 where we wanted it.
 19 CHAYTOR, Q.C.:
 20 Q. And back in the pre-2005 days, before all this
 21 came to light, so pre to mid 2005 anyhow, when
 22 issues of fixation were discussed or raised
 23 about the suboptimal quality of the tissue, do
 24 you know if there was any efforts back in
 25 those days to try and address the issue?

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1 MR. SIMMS:
 2 A. If there was an effort, it was made on us, we
 3 would suggest, keep suggesting to the
 4 residents or whoever is cutting the particular
 5 piece of tissue, you know, we would say can
 6 you make it this size, can you make sure you
 7 got a piece of tumour and normal tissue? We
 8 would suggest to them that, you know, look, if
 9 you keep giving us these huge chunks of
 10 material, we're going to have problems.
 11 CHAYTOR, Q.C.:
 12 Q. And was there ever any record kept of that?
 13 MR. SIMMS:
 14 A. No.
 15 CHAYTOR, Q.C.:
 16 Q. And we've heard reference here today of Mr.
 17 Green, the issue of a log book in the
 18 reporting room, did you ever see that log
 19 book?
 20 MR. SIMMS:
 21 A. Never saw it.
 22 CHAYTOR, Q.C.:
 23 Q. Okay.
 24 MR. SIMMS:
 25 A. Now also bearing in mind too that that was a

<p style="text-align: right;">Page 349</p> <p>1 log book for the general lab, that wasn't 2 specific for IHC, the log book that was the 3 pathology reporting. 4 CHAYTOR, Q.C.: 5 Q. No, we understood that was for any issues. 6 MR. SIMMS: 7 A. For any issue. I never seen it, no. 8 CHAYTOR, Q.C.: 9 Q. And did you know it exists or that it existed 10 and perhaps you should look through it to see 11 whether or not any issues were coming up? 12 MR. SIMMS: 13 A. I knew it existed from the fact that Barry, 14 who had a meeting with the general staff, had 15 suggested that this was what he was going to 16 try, because there was some issues in the 17 general lab, so I'm going to try putting a log 18 book in and they can write their complaints in 19 it. And from my understanding, it was Barry 20 who was going to check it, you know, being the 21 manager. 22 CHAYTOR, Q.C.: 23 Q. Okay, so you didn't understand that there was 24 any responsibility on the technologists to 25 check it?</p>	<p style="text-align: right;">Page 351</p> <p>1 Q. Okay. Do you recall any particular 2 difficulties with the DAKO machine? 3 MR. SIMMS: 4 A. No. 5 CHAYTOR, Q.C.: 6 Q. Did it always seem to operate properly? Do 7 you recall any times when it wasn't operating? 8 MR. SIMMS: 9 A. The runs that I did, the ten--like I said, the 10 12, 14, 15 runs that I did on it, it never 11 failed, it never malfunctioned. 12 CHAYTOR, Q.C.: 13 Q. It never caused you any problem. And Mr. 14 Green mentioned some issues with the robotic 15 arm. Were you aware of any issues with the 16 robotic arm? 17 MR. SIMMS: 18 A. I was aware of that. 19 CHAYTOR, Q.C.: 20 Q. You were? 21 MR. SIMMS: 22 A. I was made aware by Ken, probably. 23 CHAYTOR, Q.C.: 24 Q. So you never had the experience yourself of a 25 run being interrupted because of difficulty</p>
<p style="text-align: right;">Page 350</p> <p>1 MR. SIMMS: 2 A. No, I did not. 3 CHAYTOR, Q.C.: 4 Q. And was there ever any issues brought forward 5 to you from that log book? 6 MR. SIMMS: 7 A. Not to my knowledge. 8 CHAYTOR, Q.C.: 9 Q. Okay, and now, of course, there are policies 10 in place and that's most of which appears to 11 be around the time you were leaving or after 12 you left. 13 MR. SIMMS: 14 A. That's right. 15 CHAYTOR, Q.C.: 16 Q. - at those with Mr. Green this morning and 17 there is policies to actually keep track of 18 any occurrences or any issues that may arise 19 and in particular with respect to suboptimal 20 tissues. I take it there was no policy or 21 procedure in place in your day for that to 22 happen? 23 MR. SIMMS: 24 A. No, there was not. 25 CHAYTOR, Q.C.:</p>	<p style="text-align: right;">Page 352</p> <p>1 with the robotic arm? 2 MR. SIMMS: 3 A. No, I did not. 4 CHAYTOR, Q.C.: 5 Q. And other than that, you weren't aware of any 6 issues with the machine? 7 MR. SIMMS: 8 A. The machine ran very well, if you maintained 9 it properly, but I never had any issues with 10 that particular machine, no. 11 CHAYTOR, Q.C.: 12 Q. Was it your practice to always place the 13 control slides in a particular area on the 14 machine? 15 MR. SIMMS: 16 A. Personally, I would always place them at the 17 end, I would have my run log, number one to 48 18 and usually the last six or eight, however 19 many was at the end, I would have them at the 20 end. 21 CHAYTOR, Q.C.: 22 Q. So I take it if you do that and there's a 23 problem with the robotic arm or a glitch in it 24 and then it continues on, you would know if 25 there were a problem and it didn't get to the</p>

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1 end because your control slides wouldn't
 2 stain.
 3 MR. SIMMS:
 4 A. Right, wouldn't stain properly. But it was
 5 very--even if you had an interruption like
 6 that with a robotic arm, if I was running the
 7 IHCs for them, it wouldn't go undetected. I'm
 8 not that far out, no, it wouldn't go
 9 undetected. You would pay more attention than
 10 that to it.
 11 CHAYTOR, Q.C.:
 12 Q. Yes, you didn't leave the machine?
 13 MR. SIMMS:
 14 A. No, not really.
 15 CHAYTOR, Q.C.:
 16 Q. So how long would it take to run the machine
 17 in a regular batch?
 18 MR. SIMMS:
 19 A. The procedure itself?
 20 CHAYTOR, Q.C.:
 21 Q. Yes, if there's 48 slides.
 22 MR. SIMMS:
 23 A. Three to three and a half hours.
 24 CHAYTOR, Q.C.:
 25 Q. And what would you do while the machine is

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1 running?
 2 MR. SIMMS:
 3 A. I may do some cutting, I don't know, I don't
 4 know what my duties would be, it was various
 5 things, right.
 6 CHAYTOR, Q.C.:
 7 Q. And if you had other duties though to do, or
 8 carry out, would they be done in the vicinity
 9 of that machine?
 10 MR. SIMMS:
 11 A. If I was on the IHC machine, if I was on that
 12 particular week, that was my job. I may have
 13 done other things around, I may have went up
 14 around the corner of the bench and cut some,
 15 you know, help with some cutting or whatever
 16 and that stuff, right, but running the IHC
 17 machine took all your time anyway. It's easy
 18 to say--or not easy to say, but I can
 19 understand people thinking, okay, this thing
 20 is on there now for three hours, right, what
 21 do you do in the meantime? The other things
 22 is you get ready for the next day, for one
 23 thing, you get, you know, see what you got for
 24 the next day and so there's always preparation
 25 to be done. And I would never, like I said,

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1 if I went out to help, I would never roam far
 2 from the machine.
 3 CHAYTOR, Q.C.:
 4 Q. Were there any alarms on the machine?
 5 MR. SIMMS:
 6 A. I'm told there was; I never heard one.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and what do you know, it was equipped
 9 for an alarm in what event?
 10 MR. SIMMS:
 11 A. I don't know that either, I just know that
 12 sometimes there was an alarm that would go
 13 off. My understanding was there was an alarm
 14 that would go off if there was insufficient
 15 solution.
 16 CHAYTOR, Q.C.:
 17 Q. And when did you learn that?
 18 MR. SIMMS:
 19 A. Couldn't tell you, Ken might have mentioned it
 20 somewhere along the line.
 21 CHAYTOR, Q.C.:
 22 Q. Is it since all of this issue arose or did you
 23 know that at the time you were operating -
 24 MR. SIMMS:
 25 A. No, he probably told me back then.

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1 CHAYTOR, Q.C.:
 2 Q. You knew it when you were operating the DAKO
 3 machine?
 4 MR. SIMMS:
 5 A. Yes.
 6 CHAYTOR, Q.C.:
 7 Q. Was the machine ever allowed to run overnight?
 8 MR. SIMMS:
 9 A. I never did an overnight run.
 10 CHAYTOR, Q.C.:
 11 Q. Are you aware that there were overnight runs?
 12 MR. SIMMS:
 13 A. There were overnight runs because I remember
 14 we had to put two waste baskets because we
 15 found out quite clearly that, did an overnight
 16 run and it overflowed, so we needed another
 17 waste container.
 18 CHAYTOR, Q.C.:
 19 Q. What does that mean, I haven't heard that
 20 before.
 21 MR. SIMMS:
 22 A. A waste container is when the rinse is off,
 23 one that keeps the specimens wet during the
 24 night, right, during the whole process, it
 25 takes more solution to keep, you know, because

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<p>1 you don't want your slides to dry out, so you 2 just keep continuously wetting - 3 CHAYTOR, Q.C.: 4 Q. And you learned at some point that you needed 5 two waste baskets for that? 6 MR. SIMMS: 7 A. Yeah, I can remember that. 8 CHAYTOR, Q.C.: 9 Q. And I'm sorry, what is the waste basket doing, 10 what was it used for? 11 MR. SIMMS: 12 A. Just collecting the waste reagents, it has got 13 to go somewhere, these things that are washed 14 and the solutions that are used, once they're 15 used, they run down into the machine and run 16 out into a waste, right. 17 CHAYTOR, Q.C.: 18 Q. And I take it at some point you realized one 19 wasn't enough, so you came in, in the morning, 20 and there's a mess. 21 MR. SIMMS: 22 A. Yes, if you're doing an overnight run, but I 23 personally can't recall, like I said, I didn't 24 do all that many runs on the DAKO and I can't 25 remember doing an overnight run to be honest</p>	<p>1 CHAYTOR, Q.C.: 2 Q. What about any difficulties with respect to 3 the tissue processor? 4 MR. SIMMS: 5 A. No. 6 CHAYTOR, Q.C.: 7 Q. And when you first realized when you finished 8 your career, you were dedicated to the IHC 9 lab, but I take it in 2003 when you first went 10 there, you would also have to operate the 11 tissue processor? 12 MR. SIMMS: 13 A. I didn't operate a tissue processor. 14 CHAYTOR, Q.C.: 15 Q. At the Health Science at all? 16 MR. SIMMS: 17 A. No. 18 CHAYTOR, Q.C.: 19 Q. Okay. 20 MR. SIMMS: 21 A. I did at the Health Science, I did the gross, 22 did some general cutting, some special stains; 23 the IHC, kidney biopsies, frozen sections, all 24 that stuff, but I didn't do the processor 25 because, you know, are you talking about in</p>
<p>Page 358</p> <p>1 with you. I may have, but I don't recall it. 2 CHAYTOR, Q.C.: 3 Q. Okay, but you recall someone else doing an 4 overnight run with - 5 MR. SIMMS: 6 A. I can remember Mary mentioning it. 7 CHAYTOR, Q.C.: 8 Q. And other than the issue of needing an extra 9 waste basket, do you recall any other problems 10 or concerns about doing overnight runs? 11 MR. SIMMS: 12 A. No. 13 CHAYTOR, Q.C.: 14 Q. Other than the fixation then that we've spoken 15 about, do you recall any other issues about 16 IHC testing or any concerns about IHC testing 17 and the quality of the slides being brought to 18 your attention? 19 MR. SIMMS: 20 A. No. 21 CHAYTOR, Q.C.: 22 Q. No other difficulties in relation to the 23 process itself? 24 MR. SIMMS: 25 A. No.</p>	<p>Page 360</p> <p>1 the filling of it and changing it and - 2 CHAYTOR, Q.C.: 3 Q. Yes. 4 MR. SIMMS: 5 A. No, I didn't do that. 6 CHAYTOR, Q.C.: 7 Q. You weren't involved. 8 MR. SIMMS: 9 A. No, there was a person there who did that. 10 CHAYTOR, Q.C.: 11 Q. Okay, and the times in which, you said there 12 were times when tests had to be repeated, the 13 communication from the pathologists on that, 14 were there ever any reasons told to you as to 15 why repeats were necessary or were there 16 inquiries made of you as to why the test 17 needed to be repeated? 18 MR. SIMMS: 19 A. At the beginning 'til at least until I became 20 more knowledgeable in the IHC, I was--we need 21 this repeated, it doesn't work, that was the 22 extent. 23 CHAYTOR, Q.C.: 24 Q. And meaning it doesn't work, meaning the 25 controls didn't work?</p>

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1 MR. SIMMS:
 2 A. No, meaning the procedure didn't work.
 3 CHAYTOR, Q.C.:
 4 Q. And how would the, how would anyone know that
 5 if the procedure hadn't worked? Wouldn't it
 6 have to be the controls?
 7 MR. SIMMS:
 8 A. Because the picture didn't fit what they
 9 thought it should be.
 10 CHAYTOR, Q.C.:
 11 Q. So pathologists were bringing to your
 12 attention that they wanted a test repeated
 13 because the outcome of the test wasn't in
 14 keeping what they felt it should have been.
 15 MR. SIMMS:
 16 A. Expected, yes.
 17 CHAYTOR, Q.C.:
 18 Q. And do you recall that ever being true of
 19 ER/PR tests?
 20 MR. SIMMS:
 21 A. No.
 22 CHAYTOR, Q.C.:
 23 Q. And how is it that, is it that it wasn't or
 24 you don't recall which test it was?
 25 MR. SIMMS:

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1 A. I don't recall which test it was.
 2 CHAYTOR, Q.C.:
 3 Q. So it could have been ER/PR?
 4 MR. SIMMS:
 5 A. Could have been.
 6 CHAYTOR, Q.C.:
 7 Q. Could have been something else.
 8 MR. SIMMS:
 9 A. Uh-hm. Because I remember that being specific
 10 because we finally eliminated that problem of
 11 coming back and saying this is not working.
 12 Once we got into the Ventana system and
 13 started running external controls, if someone
 14 came back, a pathologist came back, whomever,
 15 and said this particular procedure is not
 16 working, right, the first question I would say
 17 or the first thing I would ask, well is your
 18 external control working? And if they say
 19 yes, well I say the procedure is working.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, so there were times when you were asked
 22 to repeat a test where the external control
 23 had worked, but the pathologist still wanted
 24 the test repeated because the outcome wasn't
 25 what he or she expected?

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1 MR. SIMMS:
 2 A. Yes.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and so you satisfy yourself that the
 5 procedure was working because the external
 6 control had worked.
 7 MR. SIMMS:
 8 A. Uh-hm.
 9 CHAYTOR, Q.C.:
 10 Q. Okay.
 11 MR. SIMMS:
 12 A. And I was happy to rerun it or redo it because
 13 I knew if the procedure was working, I would
 14 get the same result or I had better get the
 15 same result, so that was a test for us as
 16 well. We rerun it, you should, if your
 17 external control is working properly at the
 18 first run, well, why wouldn't you get the
 19 exact same picture in the second run.
 20 CHAYTOR, Q.C.:
 21 Q. And Mr. Simms, do you recall on those
 22 occasions rerunning the test and being told
 23 the outcome of the repeat?
 24 MR. SIMMS:
 25 A. No.

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1 CHAYTOR, Q.C.:
 2 Q. So whether or not there was a change in the
 3 result, that was never communicated to you?
 4 MR. SIMMS:
 5 A. No. The only way I would know if there was
 6 any change in result is from my own knowledge
 7 from looking at it under the scope, which I
 8 did, but that was for professional -
 9 CHAYTOR, Q.C.:
 10 Q. And you were looking at external controls
 11 under the scope?
 12 MR. SIMMS:
 13 A. Yes. May look at the patient's tissue as
 14 well, for my own professional curiosity.
 15 CHAYTOR, Q.C.:
 16 Q. And do you recall whether or not a pathologist
 17 ever indicated that he or she suspected
 18 something wasn't right because the internal
 19 control hadn't worked?
 20 MR. SIMMS:
 21 A. Never ever mentioned internal controls.
 22 CHAYTOR, Q.C.:
 23 Q. Never heard them mention internal controls.
 24 Did you notice whether or not ER/PR tests were
 25 being asked to be repeated more so than other

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1 IHC tests?
 2 MR. SIMMS:
 3 A. No.
 4 CHAYTOR, Q.C.:
 5 Q. You indicated that fixation, of course, was
 6 more of an issue with breast tissue.
 7 MR. SIMMS:
 8 A. Uh-hm.
 9 CHAYTOR, Q.C.:
 10 Q. But it didn't stand out in your mind that
 11 ER/PR are being asked to be repeated more
 12 often?
 13 MR. SIMMS:
 14 A. They seem to accept the poor quality stains.
 15 CHAYTOR, Q.C.:
 16 Q. Who is "they"?
 17 MR. SIMMS:
 18 A. Poor quality slides. The pathologists seem to
 19 accept that this is a poor quality slide, but
 20 this is the best I can get.
 21 CHAYTOR, Q.C.:
 22 Q. How were the relations between the technical
 23 staff and the medical staff at the Health
 24 Sciences?
 25 MR. SIMMS:

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1 A. Good. I had no problem with it.
 2 CHAYTOR, Q.C.:
 3 Q. And did you notice any difference between the
 4 working atmosphere between the two at the
 5 Health Sciences from the St. Clare's?
 6 MR. SIMMS:
 7 A. St. Clare's was a different atmosphere
 8 working, it was a smaller unit, so it was more
 9 of a--I had to use this term, but more of a
 10 family unit, everybody worked, you know, were
 11 together; whereas at the Health Science there
 12 were many more pathologists and they were
 13 scattered all over the place. At St. Clare's
 14 we were all in close proximity to each other,
 15 we could just--if you thought there was a
 16 problem, we could just dart across the hall
 17 and they would do the same for us, right.
 18 CHAYTOR, Q.C.:
 19 Q. So there was more opportunity to interact in
 20 the smaller atmosphere?
 21 MR. SIMMS:
 22 A. Absolutely.
 23 CHAYTOR, Q.C.:
 24 Q. Okay. Were you aware of any tension between
 25 the technical staff and the medical staff, the

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1 pathologists?
 2 MR. SIMMS:
 3 A. No tension, there may be times when there was
 4 various discussions on various things, but it
 5 wasn't such tension, they were--both groups
 6 were professionals, so there was, no. But we
 7 all have our days.
 8 CHAYTOR, Q.C.:
 9 Q. Yes. Did you feel that your advice or
 10 feedback was welcomed by pathologists?
 11 MR. SIMMS:
 12 A. I don't know how to answer that one because,
 13 there was no feedback. If I took the
 14 opportunity of telling someone, well I think
 15 this such and such and such and such, right,
 16 whatever, I think this may have happened or
 17 that may have happened, the usual answer was
 18 okay, that's okay, I'll take care of it.
 19 CHAYTOR, Q.C.:
 20 Q. So did you sense that there was any issue as
 21 to you trying to offer your opinion as to what
 22 may have caused the problem?
 23 MR. SIMMS:
 24 A. Again, I don't know, rephrase the question.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, well did you sense any attitude towards
 2 you that that perhaps wasn't your territory,
 3 that that was better left to pathologists to
 4 determine?
 5 MR. SIMMS:
 6 A. Yes, but that could have been just my way of
 7 thinking. I can't speak for anybody else, but
 8 sometimes I did feel that way, yes.
 9 CHAYTOR, Q.C.:
 10 Q. You felt that way.
 11 MR. SIMMS:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. And so it may have been something that you
 15 perceived as opposed to it being someone's
 16 actual attitude?
 17 MR. SIMMS:
 18 A. Absolutely.
 19 THE COMMISSIONER:
 20 Q. Mr. Simms, what about the other way around,
 21 were there pathologists who encouraged you to
 22 make comments about the slides or the quality
 23 of what you saw or problems that you might
 24 have observed as a technology within the
 25 laboratory?

1 MR. SIMMS:
 2 A. No.
 3 CHAYTOR, Q.C.:
 4 Q. And is that also true of Dr. Ejeckam?
 5 MR. SIMMS:
 6 A. Dr. Ejeckam, that's a different story. He was
 7 very encouraging, very helpful. I was only
 8 speaking to the point in time--I didn't think
 9 we had gotten to Ejeckam yet, that was that
 10 period of time.
 11 CHAYTOR, Q.C.:
 12 Q. Yes, so he was an exception to the rule?
 13 MR. SIMMS:
 14 A. Yes, he was, big exception to the rule.
 15 CHAYTOR, Q.C.:
 16 Q. Did you feel at the Health Sciences then if
 17 you had a problem or an issue or a concern
 18 about, other than Dr. Ejeckam, that there was
 19 a pathologist that you could go to or that the
 20 pathologist would be approachable to your
 21 issues?
 22 MR. SIMMS:
 23 A. Most of them were approachable. I had no
 24 trouble approaching any of them, believe me,
 25 I'd approach any of them, just got different

1 Q. And that was true on both sides of the
 2 equation, I take it?
 3 MR. SIMMS:
 4 A. Both sides, yes.
 5 CHAYTOR, Q.C.:
 6 Q. And so you were feeling that you were getting
 7 directions or instructions or requests from a
 8 number of different avenues.
 9 MR. SIMMS:
 10 A. Uh-hm.
 11 CHAYTOR, Q.C.:
 12 Q. And your response would be you would have to
 13 go through my manager, Barry Dyer?
 14 MR. SIMMS:
 15 A. Yes. And it got worse than when the ER/PR
 16 tissue or situation arose, because then you
 17 had all kinds of things needed to be done, can
 18 you recheck this, can you recheck that,
 19 because everyone, you know, each pathologist
 20 took, and rightfully so, things personal. So,
 21 you know, can you check this for me or can you
 22 find that for me, you know, along with their
 23 trying to do the everyday work and at that
 24 time, when the ER/PR issue arose in '06, for
 25 instance in '06, there was only three of us in

1 reactions from some. Some of them were more
 2 helpful than others.
 3 CHAYTOR, Q.C.:
 4 Q. And did you have direct contact with the
 5 pathologist in expressing to you whether or
 6 not they had a problem, or would that normally
 7 go through Mr. Dyer?
 8 MR. SIMMS:
 9 A. They would usually walk in the IHC lab and
 10 tell us, that became a bit of a nuisance too
 11 because we were stuck, you know, at points we
 12 were stuck to, who do we answer to here, we'd
 13 have people coming, you know, saying we need
 14 this done, we need that done, we need this
 15 changed, we need that changed, from various
 16 people, pathologists and administration,
 17 whatever, right, and our answer would always
 18 be the same, you would have to check with
 19 Barry. If there's any changes to be made, it
 20 would go through Barry, right. So the
 21 structure seemed to be, really offbeat, it was
 22 a thorn in everyone's side, the way it was
 23 structured. No one seemed to know who to
 24 answer to.
 25 CHAYTOR, Q.C.:

1 the lab anyway, myself, Ken and Mary and then
 2 Mary sort of moved, getting the ER/PR stuff
 3 ready and prepared and, you know, digging out
 4 slides, digging out blocks, so that left Ken
 5 and I in the immunohistochemistry lab trying
 6 to do the regular routine, so now we had to
 7 sit down and say, okay, now, two of us can't
 8 keep just going off in various tentacles, so
 9 we're going to have to assign--you know, we're
 10 going to have to sit here and say, okay, you
 11 take this project, I'll take that project, you
 12 take this project, I'll take the other
 13 project. So we sorted it out ourselves, Ken
 14 took validation and standard operating
 15 procedures; I took control of the control
 16 bank, the tissues for the control bank, so we
 17 sort of had to divide out and then you had, at
 18 that point in time, you know, other
 19 pathologists coming and saying we need this,
 20 we need that. So it got irritating at times
 21 because, you know, go to the manager and let
 22 the manger come and say, "Les, I want you to
 23 do this and Ken, I want you to do that."
 24 CHAYTOR, Q.C.:
 25 Q. Okay, so the being pulled in different

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1 directions, you said got worse after 2005 when
 2 the ER/PR issue arose.
 3 MR. SIMMS:
 4 A. Uh-hm.
 5 CHAYTOR, Q.C.:
 6 Q. And you said, because in addition to your
 7 daily workload, pathologists were coming to
 8 you wanting you to check things. And what
 9 were you being asked to check? Was it
 10 historical cases? What exactly were you being
 11 asked to do?
 12 MR. SIMMS:
 13 A. Not as much of cases itself, but it was, you
 14 know, for Ken to getting validations and
 15 revalidating stuff, doing the ER/PRs, you
 16 know, we did so many protocols, so many slides
 17 on ER/PR that it was getting astronomical, we
 18 were just doing different protocols to see if
 19 there was a problem because we assumed, you
 20 know, at that point in time, Ken and I assumed
 21 that oh oh, you know, did we mess up here, you
 22 know, did we not get the procedures right?
 23 Because we never heard anything about it,
 24 nobody ever came to us and said, you know,
 25 this procedure is wrong or this result is

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1 wrong, right? We would send the slides out
 2 and we wouldn't hear about it again, so you
 3 would assume that, okay, that's fine, they
 4 must be reading them all. So it was incoming
 5 and for different projects because by this
 6 time now, they needed new validation, make
 7 sure that work--and at that same time, at that
 8 time then, we were trying to get the
 9 recommendations in place that came from Trish
 10 and from Dr. Banerjee and so on.
 11 CHAYTOR, Q.C.:
 12 Q. So that's into the fall of 2005?
 13 MR. SIMMS:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. So people coming to you with specific
 17 requests, what was that about?
 18 MR. SIMMS:
 19 A. Just different older blocks to recheck, some
 20 cases to recheck and redo, right, and I don't
 21 know if it was related to the ER/PRs that, you
 22 know, supposedly converted or not, I don't
 23 know that.
 24 CHAYTOR, Q.C.:
 25 Q. So you were being asked to do retests on older

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1 blocks.
 2 MR. SIMMS:
 3 A. Let me back up a little, it wasn't so much as
 4 being asked to do things, it was projects to
 5 be done that they were coming directly to us,
 6 rather than going to the proper structure and
 7 letting somebody organize this. We were
 8 becoming disorganized, we had, you know, ten,
 9 twelve different things going on. We were
 10 working ten and twelve hours a day.
 11 CHAYTOR, Q.C.:
 12 Q. So individual pathologists were coming to you
 13 instead of it being streamlined through the
 14 normal process?
 15 MR. SIMMS:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. So this wasn't -- for example, this wasn't Dr.
 19 Carter or Dr. Cook asking you to do a batch of
 20 retests?
 21 MR. SIMMS:
 22 A. That included too. That was part of it too.
 23 CHAYTOR, Q.C.:
 24 Q. That was part of it?
 25 MR. SIMMS:

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1 A. That was part of it.
 2 CHAYTOR, Q.C.:
 3 Q. But this is something over and above that,
 4 individual pathologists were coming to you?
 5 MR. SIMMS:
 6 A. Right.
 7 CHAYTOR, Q.C.:
 8 Q. With requests for retest on older blocks?
 9 MR. SIMMS:
 10 A. Right, yes, and saying these particular stains
 11 weren't working. If they had a problem with
 12 their everyday cases -- we were still doing
 13 everyday cases, so we would still get
 14 pathologists coming in concerned with a
 15 particular case, current cases.
 16 CHAYTOR, Q.C.:
 17 Q. Their current cases?
 18 MR. SIMMS:
 19 A. Not necessarily ER/PR.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and the request, though, on the older
 22 blocks, were they for ER/PR tests?
 23 MR. SIMMS:
 24 A. From what I recall, yes, some of them were.
 25 CHAYTOR, Q.C.:

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1 Q. Okay.
 2 MR. SIMMS:
 3 A. But I can't speak for the reason. You would
 4 have to ask the particular pathologist that.
 5 CHAYTOR, Q.C.:
 6 Q. Yes, but there were requests -- well, who are
 7 they then, who are the particular pathologists
 8 who asked you to do retests on older blocks in
 9 that time period?
 10 MR. SIMMS:
 11 A. Nash - Dr. Denic, Dr. Cook, and Dr. Carter.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and in through -- I'll talk to you a
 14 little more about what happened in 2005 and
 15 what you were aware of was happening, and what
 16 you may not have been aware of was happening,
 17 and we'll come to that. If we could just
 18 stick to the issue of before all of that
 19 happened, the relations between the
 20 pathologists and the technologists. Do you
 21 recall any issue between any particular
 22 technologist and technologist?
 23 COMMISSIONER:
 24 Q. Technologist and --
 25 CHAYTOR, Q.C.:

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1 Q. I'm sorry, did I say technologist and
 2 technologist? It's getting late, isn't it?
 3 Technologist and pathologist, sorry. Do you
 4 recall any issue between, for example, Ms.
 5 Butler and Dr. Carter?
 6 MR. SIMMS:
 7 A. Ms. Butler will have to speak to that. I will
 8 not speak to any --
 9 CHAYTOR, Q.C.:
 10 Q. And whether or not you were involved in that,
 11 and do you have anything to say about that?
 12 MR. SIMMS:
 13 A. No.
 14 CHAYTOR, Q.C.:
 15 Q. You had no involvement?
 16 MR. SIMMS:
 17 A. No.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, you have knowledge of that?
 20 MR. SIMMS:
 21 A. I have knowledge of that, yes, but you'll have
 22 to speak to Ms. Butler on that.
 23 CHAYTOR, Q.C.:
 24 Q. Yes, and we will indeed, but you in terms of -
 25 - was there ever a period of time when you

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1 refused to do certain work for Ms. Carter in
 2 backing up her -- for lack of a better word,
 3 backing up Ms. Butler with her issues?
 4 MR. SIMMS:
 5 A. Absolutely not, never refused to do any work
 6 for any pathologist that was ever requested.
 7 I may have referred her to the manager, but I
 8 never refused any work.
 9 CHAYTOR, Q.C.:
 10 Q. May have referred the pathologist to the
 11 manager?
 12 MR. SIMMS:
 13 A. May have been referred, yeah, referred to the
 14 manager, you know, or if it was -- any
 15 pathologist, if they wanted some certain
 16 project done or whatever, okay, well, go to
 17 Barry and if he ok's it, I'll gladly do it for
 18 you.
 19 CHAYTOR, Q.C.:
 20 Q. And was that in the context of the issue that
 21 Ms. Butler was having?
 22 MR. SIMMS:
 23 A. I can't comment on that either. I don't know.
 24 CHAYTOR, Q.C.:
 25 Q. Why? You don't know?

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1 MR. SIMMS:
 2 A. No, I don't know.
 3 CHAYTOR, Q.C.:
 4 Q. So you don't know -- you don't know what I'm
 5 speaking of in terms of --
 6 MR. SIMMS:
 7 A. No.
 8 CHAYTOR, Q.C.:
 9 Q. You being involved in any issue?
 10 MR. SIMMS:
 11 A. No.
 12 COMMISSIONER:
 13 Q. Mr. Simms, could you be a little more specific
 14 about this business of the organization and
 15 people coming directly to you as opposed to
 16 through the manager? What was your view of
 17 how it was supposed to work during that time
 18 frame? If a pathologist wanted something
 19 done, were you preferring that they go via Mr.
 20 Dyer or was it just that there got to be so
 21 many individual requests that nobody was
 22 giving it priority? What was the problem
 23 here?
 24 MR. SIMMS:
 25 A. In my 35 years of service, right, as a bench

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1 technologist, all my direction came from the
 2 manager.
 3 COMMISSIONER:
 4 Q. Okay.
 5 MR. SIMMS:
 6 A. Right. So if I got a request or if someone
 7 came in, again for lack of a better term,
 8 complaining about certain issues, I would
 9 point them in the direction of the manager.
 10 COMMISSIONER:
 11 Q. So in your view, there was an order to things
 12 and that the lab would work better if
 13 everybody kept to the order that it was
 14 supposed to be in?
 15 MR. SIMMS:
 16 A. Absolutely, because we had -- we had the
 17 everyday work to do and we had various
 18 projects to do, and it was no point in coming
 19 to us and saying can you fit this in for me,
 20 this is only going to take ten minutes, can
 21 you do this, can you do that. So, no, there
 22 was no point in doing that because then
 23 everybody would get less. So my - I always
 24 stuck to the idea if you want something done,
 25 if you want me to do it, I'll gladly do it for

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1 you, but it'll have to go through the proper
 2 channels.
 3 CHAYTOR, Q.C.:
 4 Q. I just want to ask you then about Dr. Ejeckam,
 5 and I take it he took a particular interest in
 6 the technologists and in teaching you various
 7 things?
 8 MR. SIMMS:
 9 A. He did.
 10 CHAYTOR, Q.C.:
 11 Q. Did he seem knowledgeable to you in IHC?
 12 MR. SIMMS:
 13 A. He seemed very knowledgeable in IHC.
 14 CHAYTOR, Q.C.:
 15 Q. And was there a point in time where both Dr.
 16 Ejeckam and Dr. Carter were trying to teach
 17 the technologists?
 18 MR. SIMMS:
 19 A. There was a point in time when both of them
 20 were trying to teach, yes.
 21 CHAYTOR, Q.C.:
 22 Q. And perhaps you could tell the Commissioner
 23 about that?
 24 MR. SIMMS:
 25 A. I don't know how to go at that one. There was

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1 various times we were sitting around the table
 2 and, you know, teaching us and it was a great
 3 idea, but -- and he would be showing us
 4 specific things, but Dr. Ejeckam and Dr.
 5 Carter tended to disagree on what they were
 6 looking at, right. They were trying to teach
 7 us -- or he was trying to teach us, and they
 8 would have disagreements. So it came to the
 9 point we're saying this is pointless, all
 10 right; if you're telling me this is this, and
 11 Dr. Carter is there questioning it, well, how
 12 am I supposed to learn or whose word am I
 13 supposed to take. So that was -- the teaching
 14 area, that was for a very short period of
 15 time. It was a great idea, it just didn't
 16 work.
 17 CHAYTOR, Q.C.:
 18 Q. Okay. At that time, do you remember what time
 19 period was that? Was that before everything
 20 arose in 2005?
 21 MR. SIMMS:
 22 A. Before that?
 23 CHAYTOR, Q.C.:
 24 Q. It was before 2005?
 25 MR. SIMMS:

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1 A. Yeah.
 2 CHAYTOR, Q.C.:
 3 Q. And what were you concentrating on in that
 4 time period? Was that ER and PR that was
 5 being looked at?
 6 MR. SIMMS:
 7 A. ER/PR.
 8 CHAYTOR, Q.C.:
 9 Q. Okay. So it was a teaching exercise for ER and
 10 PR?
 11 MR. SIMMS:
 12 A. It was.
 13 CHAYTOR, Q.C.:
 14 Q. And that predated the 2005 issue?
 15 MR. SIMMS:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. And overall, as you've described, it didn't
 19 turn out -- while it was a great idea, it
 20 didn't turn out to be a valuable learning
 21 experience to you?
 22 MR. SIMMS:
 23 A. Right.
 24 CHAYTOR, Q.C.:
 25 Q. Were the other techs involved in that as well?

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1 MR. SIMMS:
 2 A. Yeah, Ken and Mary. Yes, they were.
 3 CHAYTOR, Q.C.:
 4 Q. Okay.
 5 MR. SIMMS:
 6 A. And there is a -- I don't know if the
 7 Commission has it or not, there is a logbook
 8 available where we had various teachings.
 9 It's a teaching logbook where we would write
 10 in because Ejeckam was a stickler on
 11 documentation, and he made me -- not made me,
 12 but asked me to get a book and we would write
 13 in the case number and any comments that him
 14 or Bev made would be written in it, and I
 15 would write down what we were supposed to look
 16 at and what we were supposed to see. So there
 17 is a --
 18 CHAYTOR, Q.C.:
 19 Q. A teaching log book?
 20 MR. SIMMS:
 21 A. A teaching log book somewhere around, yes.
 22 CHAYTOR, Q.C.:
 23 Q. Do we have that? No, I don't think we have
 24 that. Perhaps we could ask Mr. Simmons, if he
 25 can make inquiries about that.

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1 MR. SIMMS:
 2 A. With various comments in it.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and that would also tell us the time
 5 frame that this was happening?
 6 MR. SIMMS:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. Yes, okay.
 10 MR. SIMMS:
 11 A. It will, it's all dated.
 12 CHAYTOR, Q.C.:
 13 Q. Okay.
 14 THE COMMISSIONER:
 15 Q. Ms. Chaytor, wherever you want to find a spot,
 16 we'll break for the day.
 17 CHAYTOR, Q.C.:
 18 Q. Sure. Okay, did Dr. Ejeckam continue on then
 19 with his efforts to try and instruct and teach
 20 the lab technologists?
 21 MR. SIMMS:
 22 A. As much as he could, for the time that we had,
 23 yes, and we could always--and I found with Dr.
 24 Ejeckam, we could always go to him, if we came
 25 up with something, if we wanted to know

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1 something, we could go to him and he would
 2 only be too happy to -
 3 CHAYTOR, Q.C.:
 4 Q. To help you?
 5 MR. SIMMS:
 6 A. - to help us.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and was Dr. Ejeckam trying to invoke
 9 certain changes in the IHC process or in the
 10 IHC portion of the lab?
 11 MR. SIMMS:
 12 A. Certain changes?
 13 CHAYTOR, Q.C.:
 14 Q. Yes.
 15 MR. SIMMS:
 16 A. In which?
 17 CHAYTOR, Q.C.:
 18 Q. Do you recall whether or not--did he discuss
 19 with you anything that he was trying to see
 20 happen with respect to IHC?
 21 MR. SIMMS:
 22 A. Oh yes, he wanted--he was quite specific and
 23 he told everyone in ear shot that he wanted
 24 its own department and its own dedicated
 25 staff. That was his two main objectives in

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1 life.
 2 CHAYTOR, Q.C.:
 3 Q. And did you ever sense that Dr. Ejeckam was
 4 becoming frustrated in his goals?
 5 MR. SIMMS:
 6 A. Oh yes.
 7 CHAYTOR, Q.C.:
 8 Q. And did he speak to you about that? What did
 9 you understand -
 10 MR. SIMMS:
 11 A. Various times.
 12 CHAYTOR, Q.C.:
 13 Q. And what did you understand the source of his
 14 frustration to be?
 15 MR. SIMMS:
 16 A. That he couldn't get moving fast enough, that
 17 he couldn't get the powers to be to move to do
 18 anything. He would write letters. He would
 19 talk to them. He would write letters. He
 20 would make suggestions, but they--you know, he
 21 just couldn't get people to move. Now at
 22 least not in the--as fast as he wanted them
 23 to.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and we've had here, if we could just

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1 bring up P-0113, please? There's a series of
 2 three memos that Dr. Ejeckam wrote back in
 3 April of 2003.
 4 MR. SIMMS:
 5 A. Um-hm.
 6 CHAYTOR, Q.C.:
 7 Q. Did you ever--were you aware that these memos
 8 had been written?
 9 MR. SIMMS:
 10 A. Which one? This one first?
 11 CHAYTOR, Q.C.:
 12 Q. This one here, April 4th, 2003, and this one
 13 is actually suspending certain stains which
 14 included ER and PR.
 15 MR. SIMMS:
 16 A. This one, no, and I can understand this one
 17 not coming to my knowledge because I was only-
 18 -that was only like a month after I got there,
 19 so I wouldn't have been involved in -
 20 CHAYTOR, Q.C.:
 21 Q. So this one is indicated to be copied though
 22 to Barry Dyer and all technical staff on
 23 immunohistochemistry.
 24 MR. SIMMS:
 25 A. Um-hm, yeah.

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1 CHAYTOR, Q.C.:
 2 Q. But you didn't receive that?
 3 MR. SIMMS:
 4 A. Being a rookie, I wouldn't have had a whole
 5 lot to do with this one.
 6 CHAYTOR, Q.C.:
 7 Q. Okay. So you think you were overlooked in
 8 this distribution because you were the new
 9 person on the block?
 10 MR. SIMMS:
 11 A. Yeah.
 12 CHAYTOR, Q.C.:
 13 Q. Okay. The other one is dated May 2nd, 2003,
 14 and it's not indicated that it would have gone
 15 to you. It's pathologists, Health Science,
 16 St. Clare's, out of town, and this is a three-
 17 page memo. Oh, I'm sorry, it is. Yes, it is,
 18 all technical staff in immunohistochemistry
 19 and Barry Dyer, and the site chief at both
 20 Health Science and St. Clare's. So did you
 21 receive this memo?
 22 MR. SIMMS:
 23 A. Didn't see that memo either.
 24 CHAYTOR, Q.C.:
 25 Q. You didn't see this memo?

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1 MR. SIMMS:
 2 A. No.
 3 CHAYTOR, Q.C.:
 4 Q. This one is May 2nd, 2003. Didn't receive
 5 that?
 6 MR. SIMMS:
 7 A. No.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and then the last one is dated June
 10 19th, 2003 and this one is just to Mr.
 11 Gulliver and, sorry, it's copied to a number
 12 of doctors and Mr. Dyer. Did you receive a
 13 copy of this memo?
 14 MR. SIMMS:
 15 A. I didn't receive or see a copy of this memo.
 16 However, I was read various parts of it when
 17 it was in its handwritten form.
 18 CHAYTOR, Q.C.:
 19 Q. When it was in its handwritten form?
 20 MR. SIMMS:
 21 A. Um-hm.
 22 CHAYTOR, Q.C.:
 23 Q. Okay, and who read that out to you?
 24 MR. SIMMS:
 25 A. Dr. Ejeckam.

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1 CHAYTOR, Q.C.:
 2 Q. Okay, and this is dated June 19th, 2003.
 3 MR. SIMMS:
 4 A. Um-hm.
 5 CHAYTOR, Q.C.:
 6 Q. So I take it that was prior--that was sometime
 7 prior or around about June 19th, 2003 or
 8 before June 19th, 2003?
 9 MR. SIMMS:
 10 A. Yes, around there, might have been only a
 11 couple, a day or a couple of days before.
 12 CHAYTOR, Q.C.:
 13 Q. And how did that come to be that Dr. Ejeckam
 14 read out portions to you?
 15 MR. SIMMS:
 16 A. I was--because he was--you know, he used to
 17 keep saying this every other day about this,
 18 you needed to--we need our own department, we
 19 need this, we need that, and I don't know, I
 20 carried--I guess I carried some slides over to
 21 him, you know, and he said "Les, what do you
 22 think of this?" and then he proceeded to read
 23 a few things, right, and my comment was "they
 24 should stand up and listen to that."
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and the idea that he's saying "following
 2 persistent erratic results of immunostains in
 3 our laboratory, I accepted to work closely
 4 with the technical staff in order to rectify
 5 these problems."
 6 MR. SIMMS:
 7 A. He didn't read me that part. He used to
 8 remind me of that part every day.
 9 CHAYTOR, Q.C.:
 10 Q. He would remind you that -
 11 MR. SIMMS:
 12 A. That we needed--he wanted to work closely with
 13 the technical staff.
 14 CHAYTOR, Q.C.:
 15 Q. Did he also inform you that he perceived there
 16 to be persistent erratic results of the
 17 immunostains?
 18 MR. SIMMS:
 19 A. No.
 20 CHAYTOR, Q.C.:
 21 Q. Were you aware that there was any such concern
 22 regarding the product coming out of the lab?
 23 MR. SIMMS:
 24 A. No.
 25 CHAYTOR, Q.C.:

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1 Q. Did he read to you the part, paragraph six on
 2 page three, page seven of the exhibit,
 3 "finally, it is pertinent to mention that
 4 results of immunostains are extremely
 5 important in histopathological diagnosis,
 6 especially where classification of lymphomas
 7 and determination of benign or malignancy of
 8 certain lesions, for example, in prostate
 9 biopsies, demand crisp, reliable and
 10 reproducible staining results. Diagnosis
 11 based on inappropriate immunostain will surely
 12 jeopardize patient care and may even expose
 13 the HCCSJ to litigation. Therefore it will be
 14 ill-advised to operate an unreliable and
 15 erratic immunochemical procedure in our
 16 laboratory." Did he read that to you?
 17 MR. SIMMS:
 18 A. He specifically read me that number six.
 19 That's when I said "now they should stand up
 20 and listen."
 21 CHAYTOR, Q.C.:
 22 Q. Okay, Commissioner, that's a good place to
 23 take a break.
 24 THE COMMISSIONER:
 25 Q. Okay. We'll meet at 9:30 in the morning.

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1 CHAYTOR, Q.C.:
 2 Q. Thank you.

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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 15th day of July, 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 15th day of July, A.D., 2008
 13 Judy Moss

<p style="text-align: center;">-&-</p> <hr/> <p>& [2] 32:9 302:1</p> <hr/> <p style="text-align: center;">-?-</p> <hr/> <p>'04 [1] 312:3 '06 [2] 371:24,25 '07 [2] 77:15 159:7 '08 [2] 134:5 135:15 '2006 [1] 135:19 '66 [1] 292:13 '77 [1] 293:25 '80s [1] 215:6 '90s [2] 12:22 196:25 '96 [1] 12:22 '97 [1] 12:22 '98 [1] 12:22 'til [2] 251:7 360:19</p> <hr/> <p style="text-align: center;">---</p> <hr/> <p>-and [1] 108:21 -I [3] 190:10 278:22 292:17 -it's [1] 50:11 -part [1] 302:11 -that [1] 389:18 -you [1] 197:13</p> <hr/> <p style="text-align: center;">-1-</p> <hr/> <p>1 [2] 318:24,24 10 [6] 84:19 92:20 93:11 95:21 126:13 225:17 10/12 [1] 24:18 100 [4] 112:18 180:12 223:3 314:5 11 [3] 97:16 104:13 105:6 11.5 [1] 104:14 115 [1] 99:22 119 [1] 103:25 12 [2] 312:11 351:10 121 [1] 73:4 1234 [1] 233:25 1243 [1] 234:1 131 [1] 110:21 139 [1] 118:15 14 [1] 351:10 141 [1] 120:16 142 [1] 121:23 143 [2] 120:19 121:4 145 [1] 123:8 15 [4] 1:4 95:17 312:11 351:10 15th [3] 186:9 396:5,12 16 [2] 29:4 57:1 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