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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CHAYTOR, Q.C.:
Q. Good morning, Commissioner. Good morning, Mr. Green.
MR. GREEN:
A. Good morning.
CHAYTOR, Q.C.:
Q. When we broke last time, I believe, Mr. Green, we were looking at some continuing education that you've done in the past couple of years.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. If we could have, please, Registrar, P-2167? And perhaps, Mr. Green, you could tell us what this is, which course this was and when you took this course?
MR. GREEN:
A. This is one of the NSH conferences that I attended.
CHAYTOR, Q.C.:

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Q. Sorry, I'm just going to ask you to speak up because we're competing with the air conditioners today.
MR. GREEN:
A. Okay.
CHAYTOR, Q.C.:
Q. Thank you.
MR. GREEN:
A. These are workshops at the NSH conferences, which I attended. The first one is Fluorescence In Situ Hybridization. Second one is HER2, What's New? The third one is How to Make an Antibody Work in Immunohistochemistry. Fourth one is Procedure Manuals and Quality Assurance Document Control, and the last one is Challenges in Providing IHC Service.
CHAYTOR, Q.C.:
Q. Okay, and this is from the National Society for Histotechnology. What is that association? What is that group?
MR. GREEN:
A. The National Society of Histotechnology is a society based in the United States. It promotes professional and educational services

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for the members.
CHAYTOR, Q.C.:
Q. And is this the first time--this is September 2006. Is this the first time you attended one of their symposiums or conventions?
MR. GREEN:
A. I attended two. One was in 2006, I think probably one in 2005.
CHAYTOR, Q.C.:
Q. Okay. We saw last day you attended one in September 2005 as well.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So that was the same society, was it?
MR. GREEN:
A. Same society.
CHAYTOR, Q.C.:
Q. Same group, okay, and what did you do upon coming back then from this? Did you undertake any instruction for the other technologists?
MR. GREEN:
A. After I came back, I presented a lecture in our academic pathology rounds so that the technologists and the pathologists would

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benefit from some of the information that we brought back.
CHAYTOR, Q.C.:
Q. And if we could see, please, 2169? And this is indicated to be from that symposium convention and there's a number of--there's a slide presentation here. Is this the presentation you would have given?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And was there anything in particular that you found useful to you at that convention?
MR. GREEN:
A. There was a lot of information that we brought back. There was a lot of information on fixation, information on the variables that affect staining.
CHAYTOR, Q.C.:
Q. And I take it that was new information for you?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could have, please, 2168? And this

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is entitled Immunohistochemistry Basics, Ken Green, IHC Laboratory. Who did you give this presentation to?
MR. GREEN:
A. This presentation was also given in house to the academic pathology rounds, at the request of Dr. Bev Carter.
CHAYTOR, Q.C.:
Q. Okay, and would this also have been following a convention that you attended?
MR. GREEN:
A. Yeah, that's also another NSH convention.
CHAYTOR, Q.C.:
Q. Okay. So is it a policy now that if a person attends a convention, then they're expected to come back and do a continuing education presentation for others?
MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. And if we could also have, please, 2171? And is this your presentation or a presentation you received at the convention?
MR. GREEN:
A. It's my presentation, presentation with

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information that I used from different lectures and put them all together in one.

CHAYTOR, Q.C.:

Q. And you would have done this in house, too, I take it?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. For the other technologists?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And anybody else?

MR. GREEN:

A. Pathology residents and pathologists who wished to attend.

CHAYTOR, Q.C.:

Q. And are there any other presentations that you've done?

MR. GREEN:

A. Aside from the presentation when I returned from Jewish General.

CHAYTOR, Q.C.:

Q. Yes, I believe we spoke about that one last week.

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MR. GREEN:

A. Yes, and when students from the College come through the career lab, they come back to the IHC department and I will go through the principles and what we do in the lab down there.

CHAYTOR, Q.C.:

Q. Okay. Mr. Green, we understand that ER/PR testing did resume at the Health Sciences Laboratory in February 2007. Were you involved in the process getting the lab ready to resume testing at that time?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And perhaps you could tell us about that. What happened in order to prepare the lab for the resumption of testing?

MR. GREEN:

A. I worked with Dr. Ford Elms. We revalidated the antibodies involved, ER/PR antibodies. We ran our protocols against known in-house patients of which we had the results from Mount Sinai, and then we ran a series of slides against our--using our protocols

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against those known results.

CHAYTOR, Q.C.:

Q. Okay. So you ran your protocols against patients with normal results and that was based on the results from Mount Sinai?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Were those the results of the testing that had been taken place since August 2005, the go-forward cases from August 2005 at Mount Sinai?

MR. GREEN:

A. It probably could be those, plus other cases, historical cases that had been sent out for consult before, and Dr. Robb had done quite a bit of work on the ER/PR and we had a lot of his cases that he had known ER/PR results from external areas, plus he had known results from FISH.

CHAYTOR, Q.C.:

Q. I'm sorry, Dr. Robb that was?

MR. GREEN:

A. Dr. Robb, Desmond Robb.

CHAYTOR, Q.C.:

Q. Desmond Robb, okay, so he had done that

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obviously quite some time before?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And what was it of his work that you used?

MR. GREEN:

A. He did work on ER/PR and he had sent his cases away for external testing and also some of his cases were also sent away for validation with FISH, which is the gold standard for checking out ER/PR.

CHAYTOR, Q.C.:

Q. Where had Dr. Robb sent his tests for external testing?

MR. GREEN:

A. I'm not sure.

CHAYTOR, Q.C.:

Q. Okay. Do you know what time frame that would have been?

MR. GREEN:

A. A lot of the blocks that we used were in the '90s, '96, '97, '98.

CHAYTOR, Q.C.:

Q. Okay, and do you know what process those blocks would have been put through? How would

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they have been processed?
MR. GREEN:
A. They would have been processed the same as all other blocks at the Health--those were mostly Health Science blocks.
CHAYTOR, Q.C.:
Q. Okay, and so there was a period of time then that Dr. Robb was sending his ER/PRs out for testing?
MR. GREEN:
A. He was doing research.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. So he would have sent his slides to places that were doing ER/PR. I guess he was correlating his results with theirs.
CHAYTOR, Q.C.:
Q. And do you know what type of research Dr. Robb was doing?
MR. GREEN:
A. I'm not sure.
CHAYTOR, Q.C.:
Q. And who do you think might be able to tell us that?

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MR. GREEN:
A. The information is probably available at the Health Science, probably Barry Dyer.
CHAYTOR, Q.C.:
Q. But you understand this was through--this was ER/PR that he was doing research regarding?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And in terms then of starting up in February 2007, you said that you revalidated ER/PR. Perhaps you could just tell us basically how--it was you and Dr. Elms, I understand from your answer, worked on that?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. How you, in fact, went about it, like what actually had to be done to, as you say, revalidate the ER and PR?
MR. GREEN:
A. Dr. Elms would do a search on the computer, find patients that were previously done that we had external verification for. We would take those same blocks. We would run our

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antibody. We were using prediluted antibodies, so we couldn't change the antibody dilution, and we would try different primary antibody incubation times and we would try different antigen retrieval.
CHAYTOR, Q.C.:
Q. So different antigen retrieval times?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Length of times.
MR. GREEN:
A. When Dr. Elms found the protocol that he was happy with--we would try most of the trials on control blocks first. When we found a protocol that he was happy with, we would take that protocol and run those against the patients that we knew the results of, and he would correlate those results with the results we ran.
CHAYTOR, Q.C.:
Q. Okay, and did you change your incubation times as well?
MR. GREEN:
A. The incubation time, primary antibody

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incubation time?
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. During the validation, we would try different antibody incubation times.
CHAYTOR, Q.C.:
Q. Okay, and the protocols that you came up with, or the results of the protocol, the slides that you produced, did you involve the Breast Group at all in analysing those? I understand at that point in time Dr. Carter and Dr. Cook were considered the Breast Group, I believe. Were they involved then in the process?
MR. GREEN:
A. They would be involved too on the--when we set up the criteria for the Breast Group, they would be involved in checking the controls and we also ran a system where we had negative controls on every patient. We set up a system where--by this time, we had been putting positive controls on all slides, so there would be a positive control on each ER and there would be a positive control on each PR, and the Breast Group was involved in checking

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out the--we had a triple control for the ER and the PR. A triple control consists of an ER slide which has a patient who has breast cancer, which is non-expresser, which would be a negative. We would have an intermediate, which would be a low expresser or mid line expresser, and we would have a high expresser ER on the same slide, and those would be run as a batch control, in addition to the positive control and the negative controls per patient.

CHAYTOR, Q.C.:

Q. Okay, and the idea of having the three different intensities in your control on your slide, that was taking place prior to 2005, we understand, or sometime in 2005. Is that correct?

MR. GREEN:

A. The triple control came later.

CHAYTOR, Q.C.:

Q. It was only one control prior to 2005?

MR. GREEN:

A. Yes, it was only a positive control per patient.

CHAYTOR, Q.C.:

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Q. Okay. So this idea of the three different--the triple control, as you call it, that came in 2007?

MR. GREEN:

A. With the formation of the Breast Group.

CHAYTOR, Q.C.:

Q. With the formation of the Breast Group, okay, and so that was used for the first time then, as your--as part of your process when you resumed in February 2007?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. At the end of the day, do you know how many slides, test slides were run prior to resuming in February 2007?

MR. GREEN:

A. Probably hundreds.

CHAYTOR, Q.C.:

Q. Hundreds, and was there records kept of all of that?

MR. GREEN:

A. There are records, yes.

CHAYTOR, Q.C.:

Q. And at the end of the day then, prior to starting up, was there any difference in the protocol that ultimately was chosen as compared to the one that had been running prior to August 2005?

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MR. GREEN:

A. The protocol that we ended up with was very similar to the one that we had, the 46 and 48 protocol that we had run since starting up the Ventana. I think the primary antibody incubation time may have changed by a couple of minutes.

CHAYTOR, Q.C.:

Q. So other than that, changing the incubation time of the primary antibody by a couple of minutes, the protocol was basically protocols 46 and 48 that you had been running since April of 2004?

MR. GREEN:

A. Yes, same clones, same antibodies, antigen retrieval, but the primary antibody incubation time was altered slightly. We also revalidated again later when one of the recommendations was to switch from the ER 6F11 clone to the more sensitive SP1.

CHAYTOR, Q.C.:

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Q. Okay, and who was involved in that process of revalidation at that time?

MR. GREEN:

A. Dr. Ford Elms.

CHAYTOR, Q.C.:

Q. And?

MR. GREEN:

A. And myself.

CHAYTOR, Q.C.:

Q. So same, both of you again?

MR. GREEN:

A. And we used the same protocols we used before, but when we ended up with the protocol for the new antibody SP1, the primary antibody incubation time went back down from 24 minutes down to the eight minutes.

CHAYTOR, Q.C.:

Q. Down to, I'm sorry?

MR. GREEN:

A. Down to eight minutes.

CHAYTOR, Q.C.:

Q. Eight minutes.

MR. GREEN:

A. So this was a much more sensitive clone.

CHAYTOR, Q.C.:

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Q. And do you know how many tests you ran prior to being satisfied with that validation process?
MR. GREEN:
A. It would have been hundreds.
CHAYTOR, Q.C.:
Q. Hundreds as well?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And I take it the documentation for that was kept as well?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And was the Breast Group also involved? Was Dr. Carter also involved in that process?
MR. GREEN:
A. Yes, from the beginning, yes.
CHAYTOR, Q.C.:
Q. So I hear what you're saying about there being very little difference in the protocol that ultimately was used, other than the incubation time. I take it though there had been a number of other changes implemented to the

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laboratory prior to February 2007?
MR. GREEN:
A. Yes, we -- we had endeavoured to keep more documentation to record the antibodies as they entered the lab, and all the solutions that we used in the lab, the pH on the reaction buffer that we use on the system were all now recorded.
CHAYTOR, Q.C.:
Q. And had any external proficiency testing taken place? For example, in doing your validation, had you sent any of the slides out for any other laboratory or other pathology group to review?
MR. GREEN:
A. In December, 2005, we sent out first slides out to UK NEQAS for external -- that was our first external quality review, December, 2005, with UK NEQAS, and part of those antibodies which we sent out were the ER/PRs.
CHAYTOR, Q.C.:
Q. Okay, and you're involved, I take it, or were you involved at that point in time in the UK NEQAS program?
MR. GREEN:

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

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MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. Okay, and the first batch was done, you said, December, 2005, and were those specifically ER/PR slides?
MR. GREEN:
A. ER/PR slides, plus some lymphoma antibodies also.
CHAYTOR, Q.C.:
Q. What kind of volume, how many slides would have been sent out?
MR. GREEN:
A. To UK NEQAS?
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. They send in maybe 10/12 slides, and on those slides we will an ER and a PR, and we will use our in-house tissue, our in-house controls, and we will use the same protocol on our in-house slides. We assess the slides and we give them a mark of 20, and then we send those slides away, and they will assess our slides -- - independent assessors will assess the slides

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and they will also give them a mark out of 20. They will comment on any deficiencies they see.

CHAYTOR, Q.C.:

Q. Okay. So you did this in December, 2005?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. How often is it done?

MR. GREEN:

A. It's done approximately three times a year.

CHAYTOR, Q.C.:

Q. So I take it, there were three more occasions throughout 2006 that this was done?

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. So there would have been four times that UK NEQAS had been involved prior to the testing resuming in February, 2007?

MR. GREEN:

A. Probably three or four, yes.

CHAYTOR, Q.C.:

Q. Okay, and total of how many ER slides would have gone to UK NEQAS for review?

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MR. GREEN:

A. With our large volume of slides -- because the way they work, they send their slides so that we can test our stain, and we send our control slides at the same time. So you're probably -- on each module, you're probably only talking a half dozen slides each time.

CHAYTOR, Q.C.:

Q. Okay, and so it's -- and it's their slides, their tissue that's been processed?

MR. GREEN:

A. That's been processed and fixed under their conditions.

CHAYTOR, Q.C.:

Q. Under their conditions, and if there's any fixation issues in your lab, that wouldn't be picked up on those slides?

MR. GREEN:

A. Well, what we do, we send our control slides and our control slides are slides which are normal tissue -- when I say "normal", I mean breast tissue which is processed the same as all our regular tissue.

CHAYTOR, Q.C.:

Q. Yes.

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MR. GREEN:

A. So those would be subject to our fixation and our processing.

CHAYTOR, Q.C.:

Q. And in terms of UK NEQAS identifying any deficiencies, has there been any issues come back?

MR. GREEN:

A. On the ER/PR we scored quite well on -- with no major problems.

CHAYTOR, Q.C.:

Q. And any deficiencies at all noted?

MR. GREEN:

A. Not to my knowledge.

CHAYTOR, Q.C.:

Q. Has there been any indication of any issues regarding fixation?

MR. GREEN:

A. It was never reported on their comments. First when we started sending slides to UK NEQAS, we would send three slides; negative, intermediate and a positive, and they suggested that we put all three slides on the one which makes -- I guess it makes it easier for them to assess.

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CHAYTOR, Q.C.:

Q. All three of the controls?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So that came from their recommendation?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And were there any other recommendations or improvements through the external proficiency testing?

MR. GREEN:

A. None that come to mind.

CHAYTOR, Q.C.:

Q. And are you also involved then -- perhaps before we leave that, if we could have a look please at 2161, and perhaps if you could identify this document for the Commissioner?

MR. GREEN:

A. That is the -- those are the results that UK NEQAS returned to us.

CHAYTOR, Q.C.:

Q. And this one is indicated to be December, 2005?

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MR. GREEN:
A. December, 2005, yes.
CHAYTOR, Q.C.:
Q. Okay, and the assessors total mark is 16, and is that out of a total of --
MR. GREEN:
A. Twenty.
CHAYTOR, Q.C.:
Q. And the assessor being somebody from UK NEQAS?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. And this is the antibody ER?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. And if we could look too at 2162, please, and again this is December, 2005?
MR. GREEN:
A. As you look at that sheet there, you will see that one of these slides will be the slides sent from UK NEQAS, their slides.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:

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A. The other slide will be our in-house control slide.
CHAYTOR, Q.C.:
Q. Okay, and this here shows that this is self-assessment?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And technologist mark, but I don't see -- is that part filled in there? Do you actually give yourself a score?
MR. GREEN:
A. Yeah, we will score ourselves and send it off.
CHAYTOR, Q.C.:
Q. And where do we find that? Is that on the document?
MR. GREEN:
A. That would be on the document that we sent to them.
CHAYTOR, Q.C.:
Q. Okay, so it's not shown on this?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Okay. So that's the type of form. I take it

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you received similar forms back and forth throughout 2006 as well?
MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. And that's still continuing today, I take it?
MR. GREEN:
A. It is.
CHAYTOR, Q.C.:
Q. And are you involved in any other external proficiency testing?
MR. GREEN:
A. We're also involved in the CAP testing, College of American Pathologists.
CHAYTOR, Q.C.:
Q. And what's the difference, what is the CAP program?
MR. GREEN:
A. The CAP program is a bit different from the UK NEQAS program. With the UK NEQAS program, our slides actually leave and go to independent assessors. The way the --
CHAYTOR, Q.C.:
Q. So your slides, your actual patient slides which are processed gets sent?

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MR. GREEN:
A. Gets sent.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. But the CAP program, they usually send four or five case studies and with those case studies they will send a list of antibodies which you had to perform, plus a H & E stain. The pathologists and the technologists will gather around the multi-headed microscopes and they will look at each antibody and tell if it's reactive or non-reactive, and at the end of the exercise, you will -- there's a list of possible favoured interpretations and the pathologists will usually pick one of the favoured interpretations. Usually four or five case studies probably involved 50 or 60 slides altogether of various antibodies. Some of them may be ER or PR depending on what case studies they send. They may send a case study for lymphoma, they may send a case study for breast cancer, depending.
CHAYTOR, Q.C.:
Q. And do you know -- have you done a breast

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cancer case yet?
MR. GREEN:
A. There were breast -- there were ER/PRs in some of those case studies, and what happens, you do not send those slides away, those slides are kept in house, but you send away the information and when the results are published, you compare your information and how you rank against all the participants in the study.
CHAYTOR, Q.C.:
Q. Okay. So your slides that you produced through that process haven't actually been evaluated externally?
MR. GREEN:
A. Externally, no, they have not.
CHAYTOR, Q.C.:
Q. And what's evaluated is, I guess, the diagnosis that the pathologist comes up with, the answers that you come up with.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And that's done -- you're describing that in somewhat of a team approach?

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MR. GREEN:
A. It is a team approach.
CHAYTOR, Q.C.:
Q. And is there only one pathologist involved in that or does that vary?
MR. GREEN:
A. We like to have as many as possible, but the reality being the pathologists are -- there are so few pathologists and they are so busy, that it's very difficult to get many pathologists to sit down at the one time because they're just -- they're not available or they don't have the time. So what we do -- Dr. Ford Elms, well, we know he's going to be there and he will commandeer as many as he can physically get at the time to check it.
CHAYTOR, Q.C.:
Q. So it's been a situation where it's been a bit of an issue to get pathologists to take part because of the workload?
MR. GREEN:
A. Because of the workload and the physical numbers. They just don't have the pathologists. The CAP program is more of an educational and a teaching program.

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CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. Because when you're gathered around a scope and you discuss the cases, you discuss the stains, and that way you'll -- you can get feedback from the pathologists to the technologists on the quality of the stains that you're producing, and we --
CHAYTOR, Q.C.:
Q. How valuable -- from a technologist point of view, how valuable is that to you?
MR. GREEN:
A. It's very valuable because you will get instant feedback. Ordinarily you will do IHC stains, send them out to the pathologists. They may or may get back to you on the quality, depending on how difficult the case is to interpret, but if you sit around the multi-headed scope, you get difference of opinions from different pathologists, and if a stain is not what they're looking for, they can tell you right there, "maybe this is over-stained, maybe it's under-stained, you know, it's not doing what we need it to do".

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CHAYTOR, Q.C.:
Q. Okay. Other than Dr. Elms then -- how often does that take place? How often does the CAP external process --
MR. GREEN:
A. Probably about the same frequency as the UK.
CHAYTOR, Q.C.:
Q. So about three times a year?
MR. GREEN:
A. About three times a year.
CHAYTOR, Q.C.:
Q. And other than Dr. Elms, who else has participated in that process?
MR. GREEN:
A. Dr. Lynn Morris-Larkin has participated, and Dr. Dan Fontaine.
CHAYTOR, Q.C.:
Q. That's it?
MR. GREEN:
A. On a regular basis, yeah.
CHAYTOR, Q.C.:
Q. And I take it -- maybe this is more of a question for Dr. Denic, but there's been no schedule set up so that a different pathologist would participate at least once a

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year?
MR. GREEN:
A. No, not to my knowledge. It's only when -- at first when we started the external quality assurance, it was just another job to do. It was more work, but as we got into using it, we found that it was very valuable. Actually it helped -- it was an educational tool and it helped.
CHAYTOR, Q.C.:
Q. And do all of the -- are all of the technologists expected to take part in the process?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And all three of you -- is it three of you now?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. You do. How is your work currently divided up? We've heard about the rotation that you used to go through. When did the rotation stop and how is your work now divided amongst

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the three of you?
MR. GREEN:
A. The rotation -- we don't rotate through general lab any more. We don't do gross. We're dedicated to IHC. We have three people in IH -- well, one person just retired, another person is in the process of retiring.
CHAYTOR, Q.C.:
Q. I understand Mr. Simms has retired?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And Ms. Butler is in the process of retiring?
MR. GREEN:
A. She'll be retiring at the end of this month. So basically that will leave me, plus we have two other people who are training.
CHAYTOR, Q.C.:
Q. And how long have those two people been with you?
MR. GREEN:
A. One person has been there since probably October/November of last year, and the other person is coming on board now.
CHAYTOR, Q.C.:

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Q. Okay, and so you're all in the same area now in terms of the IHC lab, and are there -- how does your day normally work, though, in terms of divvying up the tasks that have to take place?
MR. GREEN:
A. I usually take -- I'm usually the "go to" person in that department now, and the other person that we have there, we split up the work into one week you are actually running the slides, and the other week you're preparing to run the slides, cutting the sections, organizing the work.
CHAYTOR, Q.C.:
Q. Do you know whether or not through the CAP program any issues have been identified or any recommendations made with respect to ER and PR?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. Do the results -- do you see the results when they come back?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. And nothing has been brought to your attention?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. How long does it take the CAP program where you would be looking through the microscope with the pathologist? How long a process is it to do that assessment?
MR. GREEN:
A. With the CAP program, depending on the number of case studies and the number of slides, you have five--it's typically five case studies, probably ten to twelve slides on each one. You're probably talking fifty to sixty slides. It's not uncommon to spend a couple of hours under the microscope.
CHAYTOR, Q.C.:
Q. And I take it that, is that a couple of hours for the whole five case studies?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And is there--can you do a case study or one

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or two at a time, is there any necessity to do them all in the same sitting?

MR. GREEN:

A. You could, but logistics of getting everybody together, again, once you got everybody in that room, there's a tendency to lock the door.

CHAYTOR, Q.C.:

Q. And you find two hours straight, than a half hour here or there.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, I hear what you're saying. And again, though, there's no requirement for anybody to attend in the way of pathologists?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And if we could look, please, at P-0050? And are the technologists required to attend?

MR. GREEN:

A. Yes, they have to attend, unless for some reason that there is an urgent case that has to be done and they can't leave the IHC lab,

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everybody will go down.

CHAYTOR, Q.C.:

Q. And has there been a good turn out of the technologists?

MR. GREEN:

A. Yes, they look forward to--well, it's a learning tool and it's an opportunity to learn.

CHAYTOR, Q.C.:

Q. Now, Mr. Green, this is a spreadsheet of recommendations and there is a number of versions, it's updated from time to time and this is the most recently updated that we've had, April 26, 2007. And there is, I think, 52 recommendations altogether and you will see the recommendations by either Trish Wegrynowski for the most part or Dr. Banerjee and/or Dr. Banerjee. Have you seen this document before?

MR. GREEN:

A. Yes, it may not be the same version, but most of the--I'm familiar with the recommendations.

CHAYTOR, Q.C.:

Q. Okay, and when did you first see this document or a version of it?

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MR. GREEN:

A. My recollection, it would probably be November of 2007.

CHAYTOR, Q.C.:

Q. November, 2007, so around the time that you did the interview with myself and Mr. Coffey?

MR. GREEN:

A. Yes, probably around then, shortly before that.

CHAYTOR, Q.C.:

Q. So in starting up the process in February, 2007, you weren't provided with a copy of the recommendations?

MR. GREEN:

A. No. Some of them may have been verbally--the first time I saw the document itself, not the spreadsheet, was when it was released by the Commission.

CHAYTOR, Q.C.:

Q. And so in terms of 52 recommendations, were these otherwise communicated to you, and in particular in the timeframe and your work getting ready for starting up the process again in February, 2007?

MR. GREEN:

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A. Some of the, like the external quality assurance, I know that one is December, 2005. I wasn't sure it was on the list, but I had figured that it was on the list.

CHAYTOR, Q.C.:

Q. Because it was taking place.

MR. GREEN:

A. And a lot of things were taking place, I didn't necessarily know that there was a structured list, but it wasn't hard to figure out that these were things that had to be done and that they needed to be done, documentation took on a much more of a priority, standard operating practices were starting to be written, pHing of the buffers -

CHAYTOR, Q.C.:

Q. So you were figuring out what must have come out of the external reviews based on the changes that were happening?

MR. GREEN:

A. Based on the changes that were happening and the recording of temperatures on the water batch, recording temperatures of the refrigerator, all these things now had to be done, done daily, so even though no one told

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me exactly that they had to be done, it wasn't hard to figure out that these were recommendations.

CHAYTOR, Q.C.:

Q. So nobody actually sat you and the other technologists down and gave you a briefing as to what needed to be done and why it needed to be done?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And who was it that was telling you, though, that things like temperature and the pH being checked, who was telling you that those things would now be necessary?

MR. GREEN:

A. Barry would tell us, you know, make sure we're recording temperatures.

CHAYTOR, Q.C.:

Q. And Mr. Green, in terms of--and just looking down through some of this, and you've seen, of course, the external reviews now, you've since seen the external review, in particular, Trish Wegrynowski. How useful would that have been to you, to have seen prior to November of

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2007?

MR. GREEN:

A. Well it's very difficult to do things if you don't know--if you don't have a copy or you're not told exactly what to do. If you had a clear list of things to do, it's much easier to implement.

CHAYTOR, Q.C.:

Q. And you were involved in the implementation of some of these recommendations?

MR. GREEN:

A. Almost all of them.

CHAYTOR, Q.C.:

Q. Almost all of them. If we could look, please, at P-0114? And, Mr. Green, this is a document of notes and I'm not really sure of the author, it may be Heather Predham, but it's regarding a meeting or some feedback received from immunohistochemistry technologists, so yourself and, I take it, others, on May 29th, 2007. Do you remember a meeting on May 29th, 2007 in which feedback was provided?

MR. GREEN:

A. It doesn't ring a bell with me.

CHAYTOR, Q.C.:

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Q. Do you remember any meeting with Ms. Predham to discuss any issues? For example, it says here "Expressed concerns related to co-ordination of quality assurance activities for entire immunohistochemical service. Vast majority of IHC SOP's not signed off. ER/PR have been completed, no knowledge or feedback re: external proficiency testing." Any of those things sound familiar to you?

MR. GREEN:

A. Generally familiar, but on the external proficiency testing, I would have been aware of that.

CHAYTOR, Q.C.:

Q. You would have been?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So I'm just trying to get a sense if you were in attendance or had any discussions, whether it's a meeting or individually checking with you, whether or not you recall this being raised around May, 2007, those issues that are listed here? Also says, "No knowledge of overall action plan or status of same." Would

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that have been a concern of yours at that time period?

MR. GREEN:

A. It probably would have been a concern.

CHAYTOR, Q.C.:

Q. "Recommended training for technologists to read controls has not occurred as of May 29th, 2007."

MR. GREEN:

A. Yeah, we had no formal training to read controls.

CHAYTOR, Q.C.:

Q. Has that since happened?

MR. GREEN:

A. Yes, we now--every day Dr. Ford Elms comes over and we review all controls before they leave.

CHAYTOR, Q.C.:

Q. And Dr. Elms does that with you?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And in February, 2007 when the ER/PR started up, did he do that? Was that going on throughout 2007?

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MR. GREEN:
A. Not on a regular basis, no.
CHAYTOR, Q.C.:
Q. So when did it start on a regular basis that he now attends daily?
MR. GREEN:
A. Dr. Ford Elms started to spend a lot more time in the lab within the last year, within the last few weeks we are looking, specifically looking at the controls, but once the breast group took over the ER/PR, they kind of took control of the controls on those. We would read the controls and make sure that they worked, that the ERs and Prs, the positive controls worked before we sent them over to the breast group and they would check them again when they received them over there.
CHAYTOR, Q.C.:
Q. Okay, so the training right now, in the last few weeks with Dr. Elms, that's not involving ER/PR?
MR. GREEN:
A. No, that's all the antibodies.
CHAYTOR, Q.C.:
Q. Oh, all right. And what training have you

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had, if any, to read the controls for ER/PR?
MR. GREEN:
A. The training that we received was from Dr. Ejeckam when he was here. He taught us how to read the external controls, to recognize if the stain worked. We weren't required to report on controls and internal controls is not in our area of expertise, although he did show us--Dr. Ejeckam did show us internal controls for our own knowledge, but it wasn't--it's not part of our scope of duties.
CHAYTOR, Q.C.:
Q. Okay, but Dr. Ejeckam did take the time to show you what an internal control is and how to look for it?
MR. GREEN:
A. He taught us how to read the external controls, how to look for variability in the controls. He taught us how to--different types of breast cancer, the internal controls in a normal ductal epithelium, as just for general knowledge, he just wanted us to be knowledgeable about it, even though it wasn't part of our job.
CHAYTOR, Q.C.:

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Q. And did that happen prior to August, 2005?
MR. GREEN:
A. That would have, it probably happened around that time, I'm not sure when Dr. Ejeckam left.
CHAYTOR, Q.C.:
Q. He would have still been there in August, September, 2005, on in through.
MR. GREEN:
A. It would have been happening then.
CHAYTOR, Q.C.:
Q. So was it after this issue of ER/PR arose that Dr. Ejeckam showed you how to read the controls for ER/PR?
MR. GREEN:
A. Probably would have been after that time, yes.
CHAYTOR, Q.C.:
Q. Bearing in mind that you were continuing to run the slides for ER/PR, although they weren't being read at the time, after August, 2005?
MR. GREEN:
A. Yes, that's true.
CHAYTOR, Q.C.:
Q. So it was around that time?
MR. GREEN:

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

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A. That's true.
CHAYTOR, Q.C.:
Q. And were you aware of that, that it had resumed without Mr. Dyer being aware?
MR. GREEN:
A. I knew that we were doing it, I didn't necessarily know that--I wouldn't have known that Barry didn't know. I would have assumed that he had been told, it would have been the normal course of events for the manager to be informed.
CHAYTOR, Q.C.:
Q. Okay, and in terms of the current situation, are you--do you have any concerns regarding communication now in the lab?
MR. GREEN:
A. No, communications have improved a lot since we had--there was a time when we didn't have a designated pathologist for IHC, but now that we have a designated pathologist for IHC, communication is much better.
CHAYTOR, Q.C.:
Q. And, I take it, that's Dr. Elms?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. And so any questions that you have or any feedback that you have, Dr. Elms is readily available to you and the other technologists?
MR. GREEN:
A. Yes, if he's not on site, we can get hold to him by phone.
CHAYTOR, Q.C.:
Q. Were you also involved in, there was a review carried out by QMPLS in December, 2007?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And what was your involvement in that?
MR. GREEN:
A. Before those people came down, I saw a list of, a spreadsheet with all those recommendations. We worked on a lot of those recommendations to make sure they were in order.
CHAYTOR, Q.C.:
Q. So that's around the time you were shown the recommendations' list.
MR. GREEN:
A. Yes, I think they came on December 7th, QMPLS.

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

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with SP1, so we were working on that one. Dedicated pathologists, that was--technologists already in place.
CHAYTOR, Q.C.:
Q. When did that happen? When did you stop rotating and the three of you become assigned to the IHC lab?
MR. GREEN:
A. I don't know exactly, but by this point it had been happening for quite awhile. Education conferences, that was ongoing.
CHAYTOR, Q.C.:
Q. How about number seven, implement Tissue-Tek X-Press?
MR. GREEN:
A. That's not happening.
CHAYTOR, Q.C.:
Q. That's not happening, okay.
MR. GREEN:
A. Re-institute ER/PR service, that was done.
CHAYTOR, Q.C.:
Q. In February.
MR. GREEN:
A. External quality assurance was done.
CHAYTOR, Q.C.:

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Q. What about No. 16, "Procedure manual outlining the SOP's to be created for all IHC antibodies and methods including the Ventana operator's manual"?
MR. GREEN:
A. We did a lot on the manual before the QMPLS people came down.
CHAYTOR, Q.C.:
Q. And have you done work on it since?
MR. GREEN:
A. It's ongoing. The SOP's will never be completed, they are living documents, they will change from year to year, even some of the new ones that we have in place now, after they are used, they'll have to be amended and changed.
CHAYTOR, Q.C.:
Q. So what was the status as of December, 2007 when you started working on it, the status of the SOP's?
MR. GREEN:
A. They had been started. I had worked with Dr. Ford Elms and I did a lot of the ones for the IHC lab, in particular, the ones that were specific to IHC. I had written them out,

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handwritten those, gave them to him, he had dictated those onto tape and I think he was working on secretarial help to put those into the format that, formalized format for SOP's.
CHAYTOR, Q.C.:
Q. And so that was ongoing then after the QMPLS people came as well?
MR. GREEN:
A. Yeah, before, during and after.
CHAYTOR, Q.C.:
Q. And I'm going to take you through a manual that we now have, a lot of the work appears to be 2008 work, so I take it was the vast majority of your work done in 2008?
MR. GREEN:
A. Probably not the vast majority, but some of it was ongoing.
CHAYTOR, Q.C.:
Q. And you started the process when, December 2007?
MR. GREEN:
A. Around there, I would imagine, yes.
CHAYTOR, Q.C.:
Q. 18. "Routine equipment maintenance performed and documented as per company protocols." And

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that was completed as of April?
MR. GREEN:
A. We now keep those documents, copies on the walls.
CHAYTOR, Q.C.:
Q. "Documented evaluation of IHC antibodies to ensure sensitivity and specificity of results".
MR. GREEN:
A. That is part and parcel with antibody validations. We had a lot of antibody validations going on at the one time. So, there was a lot of activity in that regard.
CHAYTOR, Q.C.:
Q. Okay. Number 29 refers to "laboratory to send out up to ten cases per month for correlation of results". Is that to an external lab?
MR. GREEN:
A. That is done by the pathologists and for--they pick ten cases at random. Well, they may not even pick the cases. I think the QA person would pick those cases and send them out. I had no part in that, that would be handled by the pathologist and the QA.
CHAYTOR, Q.C.:

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Q. Okay. And then number 31 refers to further SOPs. Did you also work on those for accessioning, grossing and fixation?
MR. GREEN:
A. I didn't work on those, no.
CHAYTOR, Q.C.:
Q. Okay. And 35, "SOPs for tissue processor and embedding", did you work on those?
MR. GREEN:
A. No, the SOPs which I worked on would be IHC specific.
CHAYTOR, Q.C.:
Q. Okay. And so then 37, "SOPs for IHC in compliance with the clinical and laboratory standards institute". I take it you worked on those?
MR. GREEN:
A. I worked on those.
CHAYTOR, Q.C.:
Q. Okay. And "compilation of antibody specification sheets".
MR. GREEN:
A. I worked on those.
CHAYTOR, Q.C.:
Q. "Pipette accuracy and calibration

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documentation", number 40, that was in progress.
MR. GREEN:
A. Yes, I was working on those too.
CHAYTOR, Q.C.:
Q. So, you worked on that as well?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So, those are some of the things on the list that you worked on gearing up for QMPLS to come in.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. And then the last page, I don't know if there's anything else there that you can see. So, when Brian Hewlett came in December 2007, did you meet with Mr. Hewlett?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And what was the purpose of your discussions with Mr. Hewlett?
MR. GREEN:

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

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MR. GREEN:
A. We were, yes.
CHAYTOR, Q.C.:
Q. You were, after that?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. Mr. Green, we understand there was a visual imaging machine also in the lab or brought into the lab at one point.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Was that--do you know who brought it in? Who was instrumental in having it come in?
MR. GREEN:
A. Dr. Ejeckam was instrumental in approaching the sales people from Ventana to bring it in for a in-house education and demonstration.
CHAYTOR, Q.C.:
Q. And what was the purpose of that machine? What could it be used for?
MR. GREEN:
A. The VIAS is used to--it takes a mathematicl logarithm and the pathologist will view a

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piece of tissue on a microscope and there's a screen set up. He will pick an appropriate number of screens, probably eight to ten screens which are suspect. And the machine will scan those slides and it will give you a result. And it will take out the human factor, the variability factor in the reading of the slides.
CHAYTOR, Q.C.:
Q. And is that machine still at the laboratory?
MR. GREEN:
A. No, it was removed.
CHAYTOR, Q.C.:
Q. And do you know why that--was it ever used while it was there?
MR. GREEN:
A. It had minimal usage. The reason we know because the way the system works is it's like a debit system, a card system with the machine. And that's how you pay for the machine. Every time you use the machine, you debit time from the machine. And when the debit card is used up, you had to buy a new debit card. That's how the machine is paid for. And when the representative came in to

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take the machine back, he wasn't very happy because he said he never this machine a fair evaluation because there was basically no usage on your debit card. It was minimal usage.

CHAYTOR, Q.C.:

Q. Mr. Green, you're aware, of course, about the issues which arose regarding ER/PR in 2005 and the number of patients who ultimately had changed results upon retesting at Mount Sinai. From a technical point of view, do you have any opinion as to what may have caused those changed results?

MR. GREEN:

A. From a technical--I thought about it a lot.

CHAYTOR, Q.C.:

Q. I would think you had a lot of time to think about it.

MR. GREEN:

A. I've had a lot of time to think about it and I can give you my thoughts on it. Is that what you want?

CHAYTOR, Q.C.:

Q. Sure.

MR. GREEN:

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A. Okay. These are what I think are possible contributing factors; fixation, handling of the surgical specimen from the OR before it reaches the lab; breast tissue grossing from bread loafing to the actual size of the representative block that is submitted and the fixation required.

From a processing perspective, probably compromised by large fatty blocks in large numbers. When you consider that a lot of specimens are processed at the same time, but you basically had no problem with all the other specimens.

From a cutting perspective, breast tissue being difficult to cut and difficult to adhere to the slide.

If any of the above are compromised, the cutting will be compromised and the tissue specimen will be compromised. So, if the handling, the grossing, the processing and an optimal--cutting won't be optimal. Blocks selection by the pathologist for ER/PR testing. Blocks should have normal epithelium and tumour tissue.

Interpretation is a subjective process,

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with a 30 percent cutoff point. And a cutoff point which most people think of positives as being positives and negative as being negative. Where in this particular test, if you had a 30 percent or less positivity, you would be considered negative. That would be a factor.

No standardized reporting criteria where internal controls could be documented or no statistical correlation to go along with it.

CHAYTOR, Q.C.:

Q. I'm sorry, can you just explain that again or say that again.

MR. GREEN:

A. Okay. Most statistical or historical database.

CHAYTOR, Q.C.:

Q. And what do you mean by that?

MR. GREEN:

A. So, if there are statistics that are out there that a certain percentage of cases in certain types of cancers should be positive and they weren't, we had no documentation, no statistics -

CHAYTOR, Q.C.:

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Q. You weren't keeping track of your numbers?

MR. GREEN:

A. Weren't keeping track of those numbers.

CHAYTOR, Q.C.:

Q. And are you doing that now?

MR. GREEN:

A. I'm not sure. I'm not, but it's not in my area of expertise.

CHAYTOR, Q.C.:

Q. So, the pathologists would be able to answer that or Barry Dyer?

MR. GREEN:

A. Probably or probably the IT department. I'm not really sure.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. Dedicated technologists in IHC and dedicated pathologists to oversee it. The need for continuing education is ongoing; keep current with the changes and the methodology and theory. Like antigen retrieval methodology which had changed from the DAKO system to the Ventana system was a major difference which in hindsight, that we saw. Quality -

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CHAYTOR, Q.C.:
Q. So, what do you think from the antigen retrieval point of view, could have been an issue with the DAKO system?
MR. GREEN:
A. Well, when we switched over from DAKO to Ventana, we were right in the middle of the ER/PR episode. And when we started running the ER/PRs on the Ventana system, some people thought that Ventana system was too sensitive. My interpretation is that the Ventana system wasn't too sensitive, it was working the way it should have worked. It seemed to pick up a lot of the specimens that weren't picked up on the old system. And when you compare both systems, the biggest difference was antigen retrieval. The DAKO system having the 20 minutes in citrate buffer with a pH 6 and the Ventana system having a standard antigen retrieval which was 60 minutes in a Ph 8.
CHAYTOR, Q.C.:
Q. Sorry, when you say you switched over to the Ventana, you were right in the middle of the ER/Pr episode.
MR. GREEN:

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A. Well, I'm not exactly sure of the dates, but I know that -
CHAYTOR, Q.C.:
Q. You would have switched to the Ventana in April 2004. Was there anything going on with ER/PR at that time?
MR. GREEN:
A. Not that I know of. I'm looking at it in hindsight, at the systems.
CHAYTOR, Q.C.:
Q. Okay. So, the issues were going on, is what you're saying, regarding ER/PR, but not detected at that point.
MR. GREEN:
A. We didn't know and the thing is we didn't know we had a problem until after.
CHAYTOR, Q.C.:
Q. And in terms of the antigen retrieval, when it was done in the DAKO system, I think you told us before in terms of how that happened and the temperature, the water bath and the length of time for it. How stringent was that in terms of the timing and the temperature for the water bath? How stringent was that and was that something that was really drilled

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into you that was a key requirement?
MR. GREEN:
A. It wasn't stringent in the fact that it was recorded every time, but it was 20 minutes in the antigen retrieval. We didn't vary from that. Now, like, you had to time it with a timer and you had to physically be there when the timer went off. So, there is a possibility for error.
CHAYTOR, Q.C.:
Q. Yes. And there was a timer and you would have to be there, as you say. Back in your rotation days which you would have been when DAKO machine was there and the more manual process of antigen retrieval, if you weren't there, if you were otherwise engaged, you wouldn't know that the timer went off?
MR. GREEN:
A. No. The only problem with that is that it would have stayed in antigen retrieval longer than it should have which wouldn't necessarily be a bad thing, in hindsight.
CHAYTOR, Q.C.:
Q. Yes. It's the under -
MR. GREEN:

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A. It's the under which would -
MR. GREEN:
A. Yes, and in terms of gauging the timer or maintenance on the timer or on that equipment, do you know if there was maintenance taking place back in those days?
MR. GREEN:
A. I don't know, by the time I had--St. Clare's to the Health Science, all the protocols and procedures and validation of those antibodies would have taken place years ahead.
CHAYTOR, Q.C.:
Q. Yes, but the actual checks on the equipment, ongoing checks on the equipment to make sure that the timers are working, that the temperature is accurate, was any of that taking place?
MR. GREEN:
A. The only temperature check that we had was a thermometer which we physically put in the solution.
CHAYTOR, Q.C.:
Q. What if the temperature was too high? Would that have an effect on the tissue or on the antigen retrieval process?

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MR. GREEN:
A. No. From my knowledge that I have, knowing that Mount Sinai now uses a pressure cooker at 121 degrees, a higher temperature probably may have been an advantage.
CHAYTOR, Q.C.:
Q. Okay. So, a lower temperature -
MR. GREEN:
A. A lower temperature would -
CHAYTOR, Q.C.:
Q. - would be more of a concern.
MR. GREEN:
A. - be more detrimental than a higher temperature.
CHAYTOR, Q.C.:
Q. And if the heating wasn't long enough?
MR. GREEN:
A. If the heating was too short, it would have more of an impact than if the temperature had been too long. If it had been a little bit longer, you would have more antigen retrieval time. So, it probably wouldn't have hurt.
CHAYTOR, Q.C.:
Q. Okay. And in those days too, of course, you would have been diluting your own antibodies?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. ER/PR. And if your dilution was too high or too low, what effect might that have?
MR. GREEN:
A. The stronger the antibody, the more chance of getting of more intense reaction. Usually stronger is better.
CHAYTOR, Q.C.:
Q. And do you remember any discussion about PR along the way and the PR antibody being too strong?
MR. GREEN:
A. PR antibody had traditionally been more intense than the ER antibody.
CHAYTOR, Q.C.:
Q. Okay. I'm sorry, you were giving me a list then and I stopped you at the antigen retrieval.
MR. GREEN:
A. These are my observations, yes.
CHAYTOR, Q.C.:
Q. Yes, I understand.
MR. GREEN:

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A. Quality assurance program which will be full time and dedicated would help to attract trends and keep current information and to monitor with a technical and a diagnostic parameters, like a dedicated quality assurance program which we now have would have helped back then.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. And technology itself, the new technology should be embraced to improve and enhance the science.
One of the workshops that I attended back in 2005, they were discussing about ER/PR and the problems with it generally and the consensus then was that within five years, the ER/PR technology which we were using would be obsolete and they would have a new technology.
THE COMMISSIONER:
Q. Sorry, I didn't hear that part, Mr. Green. You said -
MR. GREEN:
A. Back in 2004/2005 the consensus was that the technology that we were using then, it would

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

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there are a fair number that you were involved in the drafting of. So, I'd like to spend a bit of time on this. It takes a while for it to come up. Perhaps you can tell us the volume, the physical copy that I have here is about an inch and a half thick, say, is there a book of this nature kept in the laboratory?

MR. GREEN:

A. There's a master copy in the IHC lab.

CHAYTOR, Q.C.:

Q. Okay. And how long has that been the case?

MR. GREEN:

A. It's been there--it had started before the QMPLS people came down which would be December of '07 and it's been constantly added to and updated since then.

CHAYTOR, Q.C.:

Q. Yes. And if it's been revised, does that appear on the policy, that it's a revised version.

MR. GREEN:

A. Some of the SOPs will be in draft, will be stamped "draft", others will be signed off.

CHAYTOR, Q.C.:

Q. Okay. Yes, and a number of those towards the

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back are still indicated to be in draft, there's a number in the back.

MR. GREEN:

A. Yes, that's correct.

CHAYTOR, Q.C.:

Q. Okay. If we could go then to page nine, please, Registrar? And this is the fixation policy and I don't think you were involved or were you in this? It's indicated to have been Dr. Denic and Mr. Gulliver. And authored by Catherine Parnell. Were you involved in the drafting of this?

MR. GREEN:

A. Catherine may have called over and asked questions from time to time. It was quite common when she was working on these that if she wanted something checked, she'd call and I would check it out for her.

CHAYTOR, Q.C.:

Q. Okay. And this, the original approval date is indicated to be February 4th, 2008. And it's to be reviewed February 4th, 2009. So, I take it there's to be an annual review of the various policies?

MR. GREEN:

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A. Yearly review, yes.

CHAYTOR, Q.C.:

Q. Okay. And the approval date being February 4th, 2008, when the ER/PR testing resumed in 2007, was there a fixation policy in effect and approved at that point in time?

MR. GREEN:

A. Not to my knowledge.

CHAYTOR, Q.C.:

Q. Currently, I understand that ER/PR is being sent out again now to Mount Sinai?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So, it continued up until a few weeks ago, from February 2007 up until a few weeks ago though it was taking place in the lab.

MR. GREEN:

A. We still cut the slide sin duplicate and do the ER/PRs on them before they're sent out.

CHAYTOR, Q.C.:

Q. Okay. So, you're still running a parallel process in St. John's.

MR. GREEN:

A. Yes. The problem is that we don't have a

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breast group anymore.

CHAYTOR, Q.C.:

Q. To read the slides.

MR. GREEN:

A. To read the slides, because one of the suggestions was we sub-specialize and get a breast group, but since then, the people who were involved, one of the pathologists is on sick leave and the other pathologists has resigned. So, there is not breast group. We have to send them out for interpretation.

CHAYTOR, Q.C.:

Q. What's the purpose of running the slides in St. John's, continuing to do that while they're being done as well as Mount Sinai.

MR. GREEN:

A. What it does is it keeps our skill up, keep on doing the slides, when we finally get results back, we can check those results against the ones we were sending out to make sure that our process is still working the way it should work.

CHAYTOR, Q.C.:

Q. Okay. So, to keep up the technological side of the skills and then there'd be some

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comparison done when the slides come back.
MR. GREEN:
A. Because you don't want to stop and have to start all over again. At least this way there's a continuity in the service and there are duplicate slides there. So, there's no problem to check those against the ones that are already done.
CHAYTOR, Q.C.:
Q. And has Dr. Elms or any other pathologist involved in reading the slides now?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So, there's nobody checking the slides as they're done now?
MR. GREEN:
A. The ER/PR slides?
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. Are not checked, no.
CHAYTOR, Q.C.:
Q. Okay. And if we could have page 17, please. This is handling sub-optimal specimens in

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

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

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

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bench.
CHAYTOR, Q.C.:
Q. And is there a requirement now that the type of fixative be recorded?
MR. GREEN:
A. It should be recorded on the specimen bottle and on the requisition.
CHAYTOR, Q.C.:
Q. And specimens cut by the surgeon in such a way interfere with the gross or microscopic evaluation or resection or other clinically relevant pathological information. That's something, I take it, the pathologist -
MR. GREEN:
A. You'll have to ask the pathologist about that one.
CHAYTOR, Q.C.:
Q. Yes, okay. And it says all pathology specimens are considered precious as sub-optimal pathology specimen will not be disguarded. Number three says, "any problems with fixation, handling, transport, processing will be addressed as soon as the problem is identified. Appropriate corrective action will be taken and the specimen will be

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processed as usual. The original problem will be documented in an occurrence report". So, I take it, if you know the problem, then an occurrence report is now required.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And that's new?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And what would an appropriate corrective action be?
MR. GREEN:
A. Corrective action would be to document it so that we would take that specimen and we would process it as usual, so that when it went out to the pathologist, at least they would have some indication that the specimen they have may not be optimal, but they will know a reason why it's not optimal. So, that when they report it, they can take that into consideration.
CHAYTOR, Q.C.:
Q. Okay. And if there's a problem with the

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

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no diagnostic value.
CHAYTOR, Q.C.:
Q. Okay. And is there currently any reprocessing of specimens taking place?
MR. GREEN:
A. Not that I'm aware of. Now since I' dedicated to IHC, I have very little contact with the gross bench any more.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. But I'm not aware of any.
CHAYTOR, Q.C.:
Q. So what happens on that end now you're not familiar with?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. If we could have page 27, please, and this one is monitoring temperature dependent equipment, and the author is Lynn Wade, and original approval date is February 29th, 2008, effective date, same date, and review date, well, we hope not, February 29th, 2009.
MR. GREEN:

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A. There might be a problem there.
CHAYTOR, Q.C.:
Q. That's right, and Terry Gulliver is the issuing authority.
MR. GREEN:
A. We had a lot of SOPs which are being tackled all at the one time. That's why those dates are --
CHAYTOR, Q.C.:
Q. Yes, yes. "All pathology laboratory temperature dependent equipment must be monitored and the documentation of all checks and corrective actions must be retained". Now for ER/PR testing, what equipment would that be?
MR. GREEN:
A. The ER/PR would be no different than any of the other antibodies for IHC. We would record the temperature of the water baths, we float the sections, the temperature of the oven which we place the sections in before staining, the temperature of the refrigerator where the antibodies are stored. That should do it.
CHAYTOR, Q.C.:

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

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A. Yes, we've been recording those temperatures for quite some time, probably 2005.
CHAYTOR, Q.C.:
Q. And in the manner that's indicated in this particular policy?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So that's been going on since the issue of ER/PR arose?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Do you know in drafting the policies and procedures that you were involved with, do you know whether or not there was any assistance sought from external agencies or external laboratories?
MR. GREEN:
A. I know when I drafted the ones that I drafted, we had some templates from different places to go by. I wasn't concerned about the template business. I wanted to get the information down, so I used the manuals and the procedures -- manuals that we had there.

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

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from the body, and at most within 30 minutes", and it goes on with four steps there. Was there a procedure -- a written procedure in place -- this one is dated March 17th, 2008. Was there a written procedure prior to March 17th, 2008?

MR. GREEN:

A. Not that -- I wasn't aware of a written procedure, but the unwritten rule from everybody in pathology was that the specimen had to go in 10 percent buffered formalin as soon as possible because everybody knew that fixation was the only process that couldn't be reversed, so -- even though it may not have been written, everybody was aware of the importance of putting a specimen into formaldehyde.

CHAYTOR, Q.C.:

Q. If we could look at page 48, please, and again this is a procedure and this one is for pathology tissue, handling breast specimen, needle localization, and there's special precautions in bold capital letters, "Needle localization breast specimens must not be placed in formalin or any other fixative at

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the time of collection. The specimen must be given directly to a laboratory technologist or pathologist when it is taken to the biology lab", and then number two under procedure in bold, "Do not add formalin or any fixative". Do you know was that happening, were they being placed in formalin or other fixative?

MR. GREEN:

A. I'm not aware -- I would assume that if the surgeons were going to do this, they would have notified the pathologist and it would be treated like a frozen section. The pathologist would be notified upon the procurement of the specimen.

CHAYTOR, Q.C.:

Q. So you're not aware of whether or not -- I'm just wondering, the necessity to have this procedure, you're not aware whether or not this arose from difficulties of that nature?

MR. GREEN:

A. I'm not aware, no.

CHAYTOR, Q.C.:

Q. Number seven says, "Give the specimen to a technologist or pathologist. Do not leave a dry specimen on the bench". Are you aware

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whether or not dry specimens were being left on the bench?

MR. GREEN:

A. Not to my knowledge, and the only reason it would be given to technologist would be to bring it directly to the pathologist so they can handle it.

CHAYTOR, Q.C.:

Q. If we could have page 64, please. This is effective May 22nd, 2008, and it's called "Pathology specimen reception", and this procedure provides instructions for handling pathology specimens after arrival in the lab, and there's a detailed list here in terms of checking the specimen and checking the requisition. Then coming under -- there's numbers here up to number 15. Number five says, "Check the label on the specimen container and requisition against the information in the pathology specimen book". Number 10 is, "Check off each entry individually and tear off and retain top white sheet from book. The book itself goes back to the originating department". Where does the top -- you retain the top right sheet from the

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book. What happens to that?

MR. GREEN:

A. That would be stored in the area where the specimens are delivered to a lab across from the gross lab. So what would happen if a specimen were brought down to the lab and the label on the specimen did not correspond with the label on the requisition, whoever is the data entry person would call back up to the OR or to the floor and one of those people would have to come down and they would have to make the necessary changes.

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. If they couldn't make it themselves, they would have to take the specimen back and make sure that somebody, whoever filled it out to make those changes.

CHAYTOR, Q.C.:

Q. And it says under four, roman numeral IV, "If not corrected within 24 hours, refer case to lab manager, clinical chief, site chief or his or her pathologist designate". What happens to the specimen in the meantime?

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

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

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A. That's true.
CHAYTOR, Q.C.:
Q. And did you have any similar policy in place for you at that time?
MR. GREEN:
A. No written policies.
CHAYTOR, Q.C.:
Q. Or procedure, I should say, policy or procedure.
MR. GREEN:
A. And the specimens -- the scope of training for the pathology assistants is much greater than the specimens we handled as part of our grossing duties. They would be handling larger specimens like breasts, bowel, lungs. We didn't --
CHAYTOR, Q.C.:
Q. You never grossed breasts?
MR. GREEN:
A. We never grossed large specimens.
CHAYTOR, Q.C.:
Q. If we could have, please, page 115. This is a procedure for the Tissue TEK VIP5 Tissue Processor, and is that the tissue processor used for ER/PR, for the breast tissue?

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

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machine, a list of the solutions that were used on the machine, capacity, and troubleshooting.

CHAYTOR, Q.C.:

Q. Okay, and this says, "In the case of a power failure, the VIP5 has a battery back up which would hold the computer memory as to the station processor was in at the time of the failure. On power restoration, the processing cycle is continued". Has that always been the case, has it always had --

MR. GREEN:

A. It has. That's part of the system that's built into the VIP, so that if the -- if the power were to go or if somebody were to unplug the machine and move it, when you plugged it back in, all the protocols that you had put in there, they would be kept in memory. So you wouldn't have to reprogram the machine again.

CHAYTOR, Q.C.:

Q. And is there any concern if, for example, the power interruption is for a number of hours? Is that of any concern to your processing?

MR. GREEN:

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A. No, the way the VIP System is set up, it's a closed system, so the blocks would be in one of the solutions, either in alcohol or xylene or wax, and fixation is the first -- the two first -- the first and second solution on that machine, formaldehyde. That's where additional fixation would take place. Even if the machine malfunctioned in one of those stations, so long as it was in formaldehyde, it wouldn't be a problem. The biggest problem would be your day's work would be delayed.

CHAYTOR, Q.C.:

Q. But it shouldn't cause any problem to the tissue --

MR. GREEN:

A. Tissue itself.

CHAYTOR, Q.C.:

Q. Including the fixation stage?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And the function of the tissue processor then is indicated to be to fix, dehydrate, clear, and wax?

MR. GREEN:

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A. Infiltrate with wax, yes.

CHAYTOR, Q.C.:

Q. Okay. Then the instrument itself, and there are four major components identified to the instrument; the control panel, the retort, the paraffin oven, and the reagent cabinet. Perhaps you could just explain how this -- those different components and how it actually works?

MR. GREEN:

A. The control panel is the computer part of the instrument that will hold the protocols if you're going to use for processing. The retort actually is a chamber where you will place your baskets. The solutions will be pumped in and out of the retort during the process. The paraffin ovens are ovens which maintain the wax. So at the last stage of the processing, these tissues are subject to paraffin wax which impregnates the tissue, and the reagent cabinet below will hold all the reagents which are pumped in and out of the retort on the top.

CHAYTOR, Q.C.:

Q. Okay, and the next on 119, there's a procedure

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here for the VIP5 processing schedules, and it has a difference between overnight and weekend schedule and a long weekend schedule. What difference would it make? Why is there a necessity to have this for overnight, weekend, and long weekend?

MR. GREEN:

A. The pathology lab doesn't operate -- they don't usually operate after hours, so it's usually a nine to five, Monday to Friday operation. On Monday the specimens are put in the processor and we have a protocol set up so that the machine takes approximately 11 hours, 11.5 hours, to go through the full cycle. So the way the machine works, you program in the end -- you program in the end time, the time that you want to take your blocks off. The machine will calculate backwards and tell you the time you have to start the machine. Monday, Tuesday, Wednesday, and Thursday, not a problem, the same protocol. It'll be the same protocol for the weekend or long weekend, with the exception that you set up the machine on a timer delay and you also put in the time that you want the machine to finish. So then

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it will start off in formalins, and that's where it'll be kept. It'll go through formalin, be kept in alcohol until -- it sits in one of those solutions until the start up time. Like, on a weekend, it will start sometime early -- late Sunday, finish 11 hours later, and end up around 5:30 or 6:00 o'clock on Monday. If it was a long weekend and nobody was available on Monday, it would be an extra 24 hour delay set on the machine. So there's three different protocols set up.

CHAYTOR, Q.C.:

Q. So it's set up so that it wouldn't--the process wouldn't actually finish until Monday? Is that the idea?

MR. GREEN:

A. Yeah, it will hold the process from starting so it will finish on--it would finish, on a long weekend, it would finish on a Tuesday morning. On a regular weekend, it would finish on a Monday morning.

CHAYTOR, Q.C.:

Q. So same amount of times for each of these steps?

MR. GREEN:

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A. Yes, it's the -

CHAYTOR, Q.C.:

Q. But the machine is programmed -

MR. GREEN:

A. The end time is how the--you work backwards, so you program in the time you want it to finish and the machine does the rest.

CHAYTOR, Q.C.:

Q. Yes, that's what I was curious about because when I looked at it, I couldn't see--it would seem to be the same amounts of time.

MR. GREEN:

A. All the times are the same. It's timed. The only difference is that the--when you set up the machine on a Friday, you put all the specimens in the retort and press delay. It goes into the formalin and goes through the fixation stage. Then it will hold it into the alcohol stage and will pick up from there and process.

CHAYTOR, Q.C.:

Q. Okay, and is that written in here somewhere? Because when I looked at these graphs, they all appeared to be the same.

MR. GREEN:

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A. Yeah, they are all the same. The only difference is in the -

CHAYTOR, Q.C.:

Q. When you would actually start the process?

MR. GREEN:

A. When you would tell the machine when to finish.

CHAYTOR, Q.C.:

Q. Okay, but that's not written in here?

MR. GREEN:

A. No.

THE COMMISSIONER:

Q. Sorry, I just want to make sure I understood that point. So are you saying that the specimens from Friday would get to stage three on Friday. Then there would be a pause?

MR. GREEN:

A. Yeah.

THE COMMISSIONER:

Q. Until some point on Sunday evening, so that, in the case of a regular weekend, so that they would be held in alcohol at stage three until that point on Friday evening and they would finish in the normal course for the Monday morning operation?

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MR. GREEN:

A. Yes, exactly.

THE COMMISSIONER:

Q. All right, thank you.

CHAYTOR, Q.C.:

Q. Thank you. And the last graph in this policy, page six of eight, I'll just bring you down to that. It's reprocessing schedule number ten. What's that about?

MR. GREEN:

A. That's if you were to have a specimen and for some reason it didn't reprocess properly, you could -

CHAYTOR, Q.C.:

Q. Sorry, it didn't process properly?

MR. GREEN:

A. Didn't process properly, you could start off and use this protocol and basically since it wasn't a fixation problem, since it was already fixed in formalin, you could skip the--and alcohols on the machine, although they are--their main purpose is to remove the water, ethanol is also a fixative. So you wouldn't be necessary to give it extra fixation, so you would jump the program and

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start off in ethanol and -
CHAYTOR, Q.C.:
Q. Start in step five?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and is that--was that the process being used before, if reprocessing had to take place?
MR. GREEN:
A. That would be--that's not the reprocessing schedule that I'm familiar with. The one at St. Clare's that we use, we would take the specimens, particularly breast specimens had to be reprocessed and we would put them--we would remove the wax, put them in formalin and go through the whole process again.
CHAYTOR, Q.C.:
Q. So you would have done the whole thing again?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And are you aware of any particular danger in doing that now?
MR. GREEN:

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

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MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And the procedure provides a list of potential processing problems and their possible causes and solutions and then there's a chart which gives a problem, cause and solution. Was there anything similar in effect for you when you were involved in the processing phase?
MR. GREEN:
A. I would say most of these were taken right from the manufacturer's manual.
CHAYTOR, Q.C.:
Q. So there would be the manufacturer's manual -
MR. GREEN:
A. It would have been in the manual, which would be in the room with the processor.
CHAYTOR, Q.C.:
Q. Okay, and this appears to be very similar to the manufacturer's manual?
MR. GREEN:
A. They look very similar to the manufacturer's. I don't know the reference on the bottom, but I would be surprised if it wasn't.
CHAYTOR, Q.C.:

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

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CHAYTOR, Q.C.:
Q. Okay, and the next one is still in keeping with processing. It's troubleshooting, Tissue Tek VIP5 processor troubleshooting, in effect May 22nd, 2008, and it provides instructions for dealing with problems that can occur with the processor. And again, was there such a policy in place or is this something new?
MR. GREEN:
A. This looks like it came from the manual. I would say the processor is probably alarmed to the switchboard at the Health Science, so if it were to malfunction during the middle of the night, the person on the switchboard would call the on-call person.
CHAYTOR, Q.C.:
Q. Okay, and has that always been the case, that it's connected to the switchboard?
MR. GREEN:
A. It hasn't always been the case, but it's been like it for a few years. Not exactly sure what time it was set up.
CHAYTOR, Q.C.:
Q. So this says "when an error is detected, an alarm sounds for about ten seconds, repeating

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every minute until the error is cleared. The error number warning message is to flash repeatedly on the warning line. To stop the internal alarm, you press the alarm off. If the instrument is left unattended for longer than five minutes after the internal alarm sounds, an external alarm, if connected, is activated. Slide the retort bar to the left and then to the right to turn off the external alarm." So the external alarm would be the switchboard?
MR. GREEN:
A. Switchboard.
CHAYTOR, Q.C.:
Q. Okay, and if -
MR. GREEN:
A. If it was -
CHAYTOR, Q.C.:
Q. - if connected.
MR. GREEN:
A. The reason for the hook up to the switchboard, because since there's nobody there after hours, nobody would--and this happens overnight.
CHAYTOR, Q.C.:

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Q. And the tissue processing, of course, does take place overnight?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Did you ever know for the external alarm not to be connected?
MR. GREEN:
A. After it's been--after it was put in place, I have not been aware of any problems with the external alarm.
CHAYTOR, Q.C.:
Q. And number nine talks about if a problem had occurred, then ensure the tissue blocks are not adversely affected. How would you know if the tissue blocks had been adversely affected?
MR. GREEN:
A. I think you'd have to go to the next line that says "if you're unable to start the processor." So you have to--there are--you got two options at that point. You can leave the blocks in whatever station they are or you can manually process those blocks, which means that you'd have to take the blocks and put them in individual--the same solutions that

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were on the machine and you can have--you could carry them through by hand. But it's not a very practical solution because you're dealing with a large number of blocks and it's time consuming. So you're better off either getting that machine fixed or sending the blocks to your other machine, because we have two machines and starting up the processing and going on from there.
CHAYTOR, Q.C.:
Q. So to determine--my question being whether or not the tissue blocks are adversely affected, is there anything that you would look for? How would you be able to make that determination?
MR. GREEN:
A. At that stage, I'm not aware of any way that you could tell.
CHAYTOR, Q.C.:
Q. Okay, and number ten says "if tissues are in absolute alcohol or xylene when the processor stops, check the length of time the tissues were in that solution. Do not allow the tissues to stay in either absolute alcohol or xylene for an extended period of time, more

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than the allotted times on the processors. The tissues may be irreparably damaged if left too long in either one."

MR. GREEN:

A. Yeah, what would happen, if they were left in alcohol, alcohol is a fixative and the tissues would become harder than they usually would need to be.

CHAYTOR, Q.C.:

Q. So if the problem did occur with the processor over night, then it could cause damage to the tissue if they're left in the absolute alcohol or xylene?

MR. GREEN:

A. Absolute alcohol, it would have to be there a long time for to be damaged that would be irreparable.

CHAYTOR, Q.C.:

Q. And were you aware of that when you were running the tissue processor?

MR. GREEN:

A. I've never had an experience where they were left in alcohol.

CHAYTOR, Q.C.:

Q. But were you aware that that could case

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irreparable damage?

MR. GREEN:

A. I was aware of the fact that the only stage that was irreversible would be fixation. If it was adequately fixed, we were under the impression that we could repair the damage to any tissues.

CHAYTOR, Q.C.:

Q. And this now requires--this policy requires that an occurrence report be completed. Was that the case prior to May of 2008?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. If we look then, the next policy at 139, you are the author, and this is a policy for accommodating longer fixation time on the processor, and why would this procedure be necessary?

MR. GREEN:

A. It would probably be necessary if the tissue--if from the gross room, from the gross bench that you saw that the tissues were not fixed at that point and that if you were to put those on the machine with the regular

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processing schedule that they would not--because on the regular processing schedule, I think there's maybe one-two hours maximum fixation and that will not be enough.

CHAYTOR, Q.C.:

Q. Okay. So this allows extra fixation time if tissues come to you which have not been adequately--or have not fixed long enough?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. This allows extra fixation time to take place within the processor?

MR. GREEN:

A. You would have to--with this program here, you would have to process those tissues alone on the processor, not with the regular blocks on the processing schedule.

CHAYTOR, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. Ms. Chaytor, wherever you can find a good time, we'll take the break.

CHAYTOR, Q.C.:

Q. Thank you. And again, how would you know? I

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take it the times are now documented. Is that how you would know?

MR. GREEN:

A. If--how would I know if sections needed longer fixation times?

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. That would have--now, that would either have to come from the pathologist or the pathologist assistant. They would be handling that, and these would be--have to be larger specimens.

CHAYTOR, Q.C.:

Q. Okay, and if we look then at the next page, 141, the next procedure, it's the manual deparaffinization of tissue blocks and reprocessing, and then on--and I realize you're not the author of these. Then on 143, it's a procedure for handling tissue blocks which were not dehydrated processed properly on the tissue processor. So it's reprocessing tissue blocks not properly dehydrated. The first one is a manual process.

MR. GREEN:

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

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performed with the standard overnight process typically used with fresh tissue. The extent of chemical exposure renders the specimens dangerously over-dehydrated to the point that they may become unsuitable for diagnosis. The shorter program should be used with immersion times at least half the original ones." Would that apply in any way to breast tissue?
MR. GREEN:
A. That would--I would imagine that would apply to any tissue, regardless of what type of tissue it would be.
CHAYTOR, Q.C.:
Q. Okay, and were you aware of that?
MR. GREEN:
A. No, it's not the reprocessing that we had used at St. Clare's.
CHAYTOR, Q.C.:
Q. I'm sorry, it wasn't the process you used, the reprocess?
MR. GREEN:
A. It's not the reprocessing schedule that we used at St. Clare's.
CHAYTOR, Q.C.:
Q. Okay. This is a good place, please,

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Commissioner.
THE COMMISSIONER:
Q. We'll take the morning break.
(RECESS)
THE COMMISSIONER:
Q. Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. Page 145, please, Registrar? Mr. Green, this is a procedure regarding the use of B-5 fixative in pathology and it provides instructions for the use of B-5 fixative. When would -
THE COMMISSIONER:
Q. (Inaudible) communicating with him to turn down some of that equipment.
CHAYTOR, Q.C.:
Q. Thank you.
THE COMMISSIONER:
Q. Thank you. There we go. That's better.
CHAYTOR, Q.C.:
Q. Much better, thank you. When would B-5 fixative be used? It says here it's routinely used for bone marrow biopsies and some lymph nodes when lymphomas are suspected and may be used for other--with other tissues, at the

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discretion of the pathologist or pathologist's assistant. Is it ever used in breast tissue?
MR. GREEN:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. And had it ever been in any involvement you've had? You've never--it's never been used in breast tissue?
MR. GREEN:
A. It's possible to have a specimen fixed in B-5 if it was a--if they did a mastectomy and they were checking lymph nodes with the same specimen, that it could be a B-5 fixed specimen. It's not the optimum choice for IHC studies.
CHAYTOR, Q.C.:
Q. And why is that?
MR. GREEN:
A. Because of the fixative. It's a bit harsher than formaldehyde. It's used for nuclear detail and the -
CHAYTOR, Q.C.:
Q. I'm sorry, I didn't hear you.
MR. GREEN:
A. B-5 fixative is used for nuclear detail on

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some of the lymphomas and on bone marrows. It's quite commonly used on bone marrows, but I think they have rethought their policy now. Most bone marrows are not fixed in B-5 any more. So if you did IHC on a B-5 fixed block, it should be noted that it's B-5.

CHAYTOR, Q.C.:

Q. Okay, and why is that? Why would you note it?

MR. GREEN:

A. You may not get optimal results from B5 fixative, as opposed to formaldehyde because your protocols are set up and your controls are used on formalin fixed tissue.

CHAYTOR, Q.C.:

Q. If we could have, please, page 161? And this you are the author of and this says, "Effective this procedure as of May 22nd, 2008 and its pH meter daily calibration and use." And it provides instructions for the daily calibration and use of the pH meter. And it's written here, "The pH of the solution will affect its reactivity, some stains and reactions will only occur if the solution is at the correct pH. A pH meter is used to accurately measure pH." And I realize now

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this procedure only came into effect in May of 2008, this written procedure.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Was this happening in any event prior to May 22nd, 2008, what we see written here?

MR. GREEN:

A. That is the normal procedure for standardizing the pH meter, using the pH meter, if you were the first one to use it in the day, you would standardize it using those three buffers that are there, pH 4,7 and 10. That would be the standard practice.

CHAYTOR, Q.C.:

Q. And was that happening prior to May of 2008?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And was, for example, it goes on in terms of there's ten steps to the procedure and--sorry, 17 steps to the procedure and then another eight steps to use pH meter to measure pH of the solution and there's eight more steps there. Was there anything similar written

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down for anybody to use, there's 17 steps and then another eight steps, was there anything in writing prior to May of 2008?

MR. GREEN:

A. No, there was no written protocol, just the manufacturer's instructions.

CHAYTOR, Q.C.:

Q. And was, in fact, the pH being checked, the pH meter being calibrated each day?

MR. GREEN:

A. Each day it was used. If you didn't use the pH meter that day, there was no need to calibrate it, but you always calibrate it before use.

CHAYTOR, Q.C.:

Q. And that was the practice for how long?

MR. GREEN:

A. Since I had moved to the Health Science, that was the practice set over there.

CHAYTOR, Q.C.:

Q. In 2002?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And was there any way of--was it required that

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it be recorded that you in fact had done such calibration?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. If we could look then, please, at 167, page 167? And this is a procedure, the author is Catherine Parnell and it's a procedure for paraffin tissue embedding, "All routine tissue sections must be correctly oriented and embedded in wax after processing." And then there's a number of steps, all the way up to 21, as to how that is to happen. And this is March 17th, 2008. Was this procedure written down anywhere prior to March of 2008?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. No. 18 says, "incorrectly embedded paraffin blocks, such as floating sections, air bubbles or cracked blocks should be melted down by leaving the blocks in a metal mould inside the warming chamber of the embedding centre. When melted re-embed, carefully following any instructions exactly. For example, turn 90

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degrees or place on edge." Is that something you would have been aware of?

MR. GREEN:

A. Yeah, that's the normal practice. Some specimens had to be embedded in a certain--most specimens are embedded in a--the way they are put into a cassette. The are specimens like vas deferens sections or tubaligation sections, which had to be embedded so that you get a cross section or you can see a lumen in the tissue. So if you were embedding a fallopian tube and it happened to fall down on its side, you would have to re-embed it and stand it up, so that when it was cut, you would see a whole in the centre, or a lumen.

CHAYTOR, Q.C.:

Q. And if we could have, please, 173? This refers to a QC number. Can you tell us what's the QC number?

MR. GREEN:

A. QC is a quality control number. In this reference here, it's for H&E stain slides, H&E is the routine slide on all pathology specimens, QC number we apply every day, that's in the routine lab which I usually

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don't have much dealing with anymore.

CHAYTOR, Q.C.:

Q. And there's a QC number in the IHC lab?

MR. GREEN:

A. We apply a QC number at the end of the process, but with the H&E slides, they have one slide for the whole day. In the IHC lab, we have control on each slide, so each slide has its own quality control.

CHAYTOR, Q.C.:

Q. That's the process now.

MR. GREEN:

A. Yeah, that's the process now.

CHAYTOR, Q.C.:

Q. So I just want to be clear, what--before that, before you actually had your control slide, what's the purpose of a--sorry, the control on your patient slide, what was the purpose of your QC number? What purpose would that -

MR. GREEN:

A. The QC number, that was applied in, not in IHC but general pathology, that was assigned to that day, so that you know that all slides that you ran a particular slide and checked the slide and checked that the H&E stain was

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working properly and all slides that came out on that day were assigned that QC number.

CHAYTOR, Q.C.:

Q. All slides, so regardless of patient, they all have -

MR. GREEN:

A. Yeah, all patients ran that day would have the same QC number.

CHAYTOR, Q.C.:

Q. Would have the same QC number. And was there a similar practice in place in the IHC lab so that all tests that were run in a particular batch would all have the same QC number?

MR. GREEN:

A. No, in the IHC lab, when we had batch controls, like in the case of ER when there was one batch ran, the only thing that was done was the date was written on the slide, but there was no QC number assigned to it.

CHAYTOR, Q.C.:

Q. So you couldn't try and track patients who had their tests done in the same batch through a QC number in IHC?

MR. GREEN:

A. No.

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CHAYTOR, Q.C.:

Q. And is that still the case, is there any QC number used in the IHC lab?

MR. GREEN:

A. No, what we have now is since we have a control on every slide, that is our quality control for that patient.

CHAYTOR, Q.C.:

Q. But if something else happened in the process along the way and you wanted to be able to determine which patients were also put through the same process, there's no common QC number?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And what's the purpose of having a QC number?

MR. GREEN:

A. A QC number in general pathology, what it does is it's a reference so that what you will do, you will look at the H&E stain and if there's a problem with the staining, you won't run your slides, rather than run all your slides and find out that there's a problem with the hematoxylin eosin stain. So the QC slide is run first and checked, and if that checks out,

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then you can run your whole day slides to be confident that your solutions are working the way they are working. And you can keep that QC slide and you can compare yesterday's slide with today's and you will also have that slide there for tomorrow when you run your slides--run a comparison to see if there are subtle differences in your stain.

THE COMMISSIONER:

Q. I guess I missed something, you're saying the QC slide is run first?

MR. GREEN:

A. The QC slide is--in the routine pathology lab, you will run one--you will take a slide--probably a piece of appendix and you will run a H&E on that slide and check it under the scope.

THE COMMISSIONER:

Q. Uh-hm.

MR. GREEN:

A. If your blues and your pinks and everything work out fine, then you can go ahead with your day's work and run all those through.

THE COMMISSIONER:

Q. All right.

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CHAYTOR, Q.C.:

Q. And if we could have then, please, page 177? And this is a policy entitled "Corrective Action for IHC Occurrences" and again, the approval date is February 29th, '08. And a review date that I'm sure will be revised. And the policy, "all issues regarding quality of IHC staining and all corrective actions undertaken must be documented." And this is going to laboratory technologists, as well as pathologists. And the policy is intended to provide guidance for the reporting and documentation of sub-optimal staining and corrective actions undertaken. And then there's a list of steps to take, three steps to take, including entering the issue into, onto the record of quality issue's form in the Corrective Actions Log Book. The idea of a Corrective Action Log Book, when did that first come into being?

MR. GREEN:

A. That would have taken place after Trish had come down to the lab, it was one of her recommendations, so we probably started around the same time that we started keeping a log of

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all the temperatures. And the purpose of the Corrective Action Log is that if you make a mistake there, at least you've shown that you've done troubleshooting and you know how to fix the error and if the error happens again, you can pick up trends and also it brings the technologists and the technologists together, so that if there's a problem, they can work out any problems.

CHAYTOR, Q.C.:

Q. So when in fact did the IHC lab get a Corrective Action Log Book? I understand the idea arose out of Trish Wegrynowski's review, when did this become--the policy is dated just February of '08, but when did this actually become in practice?

MR. GREEN:

A. It's probably been into effect, we've had that log maybe since 2005, early '2006 probably.

CHAYTOR, Q.C.:

Q. And is this, to your knowledge, is this actually taking place when there's an issue?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

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Q. And the Corrective Action Log Book is being filled out?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And is it being reviewed at least monthly by the clinical director?

MR. GREEN:

A. Yes, Dr. Elms.

CHAYTOR, Q.C.:

Q. Sorry?

MR. GREEN:

A. Dr. Ford Elms is reviewing it. And then on page 181, we have the external controls for immunohistochemistry staining policy. And this one also came into effect on February 29th, 2008. And this one, the testing though resumed, the ER/PR testing resumed a year before that, so was there policy in effect when the testing resumed in February, 2007?

MR. GREEN:

A. This policy here wasn't into effect then.

CHAYTOR, Q.C.:

Q. This wasn't?

MR. GREEN:

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A. No.
CHAYTOR, Q.C.:
Q. And so in terms of external controls, what was the policy at that point in time?
MR. GREEN:
A. External controls are run on all IHC slides.
CHAYTOR, Q.C.:
Q. Okay, so it was just that, the policy was that an external control was run for each antibody?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. The policy says that "appropriate external controls will be run with all batches of slides for immunohistochemistry staining." And who determines what is appropriate external controls? How many and which controls?
MR. GREEN:
A. Which controls? We've got a manufacturer's recommended control, in the case of an ER positive is a known positive ER case; in the case of lymphomas, most of them would be tonsils. The manufacturer supplies the antibody, lists a control, a recommended

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control. We will use that control for our tests and the pathologist, in this case Dr. Ford Elms, he will check the control and if he's satisfied that it's demonstrating what we want to demonstrate, well that's the control that we'll use. And that's the way we set up our control bank.
CHAYTOR, Q.C.:
Q. Okay, and on to page 182, it talks about positive controls and negative controls and each antibody, with the exception of the quantitative antibodies listed below, will have a negative control run on a regular basis. But then under quantitative antibodies, it refers to a negative control will be run with each case for quantitative antibodies, and that includes the HER2/neu and the ER/PR. So a negative control is now run.
MR. GREEN:
A. Routinely run on every patient.
CHAYTOR, Q.C.:
Q. And was that the case in February, 2007, when the testing resumed?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. And that continues, well I know you're not doing ER/PR now, although you're doing ER/PR, but it's not being read.
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. So that continues to be your practice.
MR. GREEN:
A. Even the ones that we're doing in duplicate now, we run negative controls on those and batch controls and positive controls.
CHAYTOR, Q.C.:
Q. And do you follow all of the procedures and policies for the ER/PR that you're doing now, even though it's not going to be read, I take it you still follow your policies and procedures?
MR. GREEN:
A. We don't deviate from the policy at all.
CHAYTOR, Q.C.:
Q. Okay. And this talks about batch controls "sausage". "For ER/PR purposes, a batch control consisting of three resulted tissues, multi-tissue block and known positive and

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known negative and a known weak expressor tissue are placed on a separate slide and run in duplicate. One batch slide is sent to the breast tissue group and one remains in the lab for reference."
MR. GREEN:
A. That's the triple control which I referred to before.
CHAYTOR, Q.C.:
Q. Right, but it is contained, your triple control is contained on the same slide as your patient tissue?
MR. GREEN:
A. No, triple control is run with a batch of all the ER patients. Each patient has its own positive control and each patient has its own negative control and the batch control, the triple control is for the whole run.
CHAYTOR, Q.C.:
Q. Okay, so right now in running an ER test, you would have the patient's tissue and a positive control and a negative control, so it's three pieces of tissue on that slide, on the patient slide, is that right?
MR. GREEN:

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A. Yes, we'll have a -
CHAYTOR, Q.C.:
Q. The patient tissue, and then the positive tissue and your negative.
MR. GREEN:
A. Patient tissue, and on top of that was positive control.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. We'll have a patient tissue alone, which would be a negative control.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And we'll have one triple control which would be run with our--two triple controls. One that we ran with our batch, one is sent over to the breast group and the other is kept in our lab. So we can compare the next batch be run to that one.
CHAYTOR, Q.C.:
Q. So the only thing contained on the patient tissue slide, other than the patient tissue, is the positive -

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MR. GREEN:
A. The positive control.
CHAYTOR, Q.C.:
Q. Okay, and is that a weak positive, a strong positive, what is that?
MR. GREEN:
A. That would be a strong positive.
CHAYTOR, Q.C.:
Q. That's a strong positive. And then there's a separate slide which contains your triple control and that's run for the entire batch.
MR. GREEN:
A. Yeah, and that would contain a negative which is, that's a breast case which there are no ER reaction, an intermediate which is weaker than the strong positive and the strong positive.
CHAYTOR, Q.C.:
Q. Okay, and there's two batch slides, and one is sent to -
MR. GREEN:
A. One is sent to the breast group.
CHAYTOR, Q.C.:
Q. Okay, where does it go now?
MR. GREEN:
A. Well right now we file them at St. Clare's.

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CHAYTOR, Q.C.:
Q. So it's all just being filed right now.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And one remains in the lab then for reference?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And where is it kept in the lab?
MR. GREEN:
A. The reference, we--what we do after the run is complete, from the Ventana system, we'll print of a, what we call a run report. Print off two copies of the run report, we'll keep one run report on file and we'll write the run number on our triple control. We'll send the other copy to St. Clare's with the ER/PR slides when the breast group starts--when the breast group is functioning, we sent a copy to them, had all those patients and a run number of it and a run control.
CHAYTOR, Q.C.:
Q. So if you wanted to go and find the control slides that were run with a particular batch

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last month, how would you go about doing that?
MR. GREEN:
A. We've got a file set up at St. Clare's and we would look up the date that we ran on the machine. We know the run number. We can go in on the machine and print off that particular run and that will give us a list of all the patients, or we can just flip through out file that we have there. All patients we run, we keep a copy of the runs too now.
CHAYTOR, Q.C.:
Q. So it's now in the computer that you can put in the run number and get all the patients that day?
MR. GREEN:
A. That ran that day.
CHAYTOR, Q.C.:
Q. And you would also be given the --
MR. GREEN:
A. We've got a hard copy also there.
CHAYTOR, Q.C.:
Q. But also in terms of the control slide or the batch slide that was run with the batch, that would also be inputted into the computer?
MR. GREEN:

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A. Yes.
CHAYTOR, Q.C.:
Q. And whose responsibility is it to do that?
MR. GREEN:
A. It would be the technologist who runs the ER/PR.
CHAYTOR, Q.C.:
Q. And your reference for this was David Dabbs?
MR. GREEN:
A. Dabbs.
CHAYTOR, Q.C.:
Q. Your supporting document, David Dabbs. The policy for appropriate handling and optimal fixation of tissue specimens that ensure optimal results is communicated to those sites that refer tissues to this centre, and is that happening?
MR. GREEN:
A. I would assume that all the -- since we're a reference centre for the island and we get slides -- blocks/slides from all over, I would assume these copies have been sent to those hospitals, but it would not be my responsibility to do that.
CHAYTOR, Q.C.:

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Q. Okay. We have a list here with key words; negative control, positive control, in-house control. What do you mean by the in-house control?
MR. GREEN:
A. The in-house control is the positive control which is put on every patient's slide.
CHAYTOR, Q.C.:
Q. That's the one on the patient's slide?
MR. GREEN:
A. Yeah, and the in-house control is a control that's treated in exactly the same way as your patient's tissue.
CHAYTOR, Q.C.:
Q. And, of course, batch control we just spoke about. Key words -- so could you go in then on the -- what's the purpose of key words? Can I go -- can you go in and do a search of these key words?
MR. GREEN:
A. I'm not familiar with recovering the information using those key words on the Meditec System.
CHAYTOR, Q.C.:
Q. Okay. And there it is, there's your

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definition of in-house control.
COMMISSIONER:
Q. What's the difference between in-house control and what used to be called an external control?
MR. GREEN:
A. The same -- there is no difference.
COMMISSIONER:
Q. Just new phraseology, but the same thing?
MR. GREEN:
A. Yeah. In-house is a term we picked up from NEQAS when doing the external QA.
COMMISSIONER:
Q. All right, thank you.
CHAYTOR, Q.C.:
Q. And the next, page 185, is selection of external controls for ER/PR and Her-2-neu immunohistochemistry. So there's a specific policy geared towards ER/PR and Her-2-neu?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And this is brought into effect again February 29th, 2008?
MR. GREEN:

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A. Yes.
CHAYTOR, Q.C.:
Q. Was there any policy in place in February, 2007, when testing for ER/PR resumed?
MR. GREEN:
A. Yeah, this -- the ER/PR policy that I referred to with the negative controls and the triple control, and each patient control, that was all into effect at that time.
CHAYTOR, Q.C.:
Q. Was it reduced to writing at that time?
MR. GREEN:
A. Pardon?
CHAYTOR, Q.C.:
Q. Was it in writing?
MR. GREEN:
A. No, not in the -- only probably would have been in my handwriting, written writing, not in the format that we have here.
CHAYTOR, Q.C.:
Q. So I take it the practice was adhered to, but there was no written policy as such?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:

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Q. And this talks about positive and negative and weak expresser control tissues must be processed on runs with patient tissue for ER/PR and Her-2-neu. Control tissues are selected from archive patient tissue. All cases for ER/PR and Her-2-neu receptor antibodies must contain known positive and known negative.

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. And that's what we discussed?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And the purpose being to ensure that appropriate controls are identified and run with each ER/PR and Her-2-neu case, and then the procedure to follow, there are six steps. The first being that the assigned technologist will search Meditec for known cases for ER and PR. So this is looking for, I take it, in order for you to be able to identify and prepare controls?

MR. GREEN:

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A. Yes.

CHAYTOR, Q.C.:

Q. And the pathologist director of the IHC laboratory will review the identified cases and select the appropriate tissue. So I take it, you or one of your colleagues would search to try and find a known case and then you bring it to Dr. Elms, and he decides if it's suitable, is that correct?

MR. GREEN:

A. You may do a search and you may find several cases there. We would do an ER/PR on those cases and Dr. Ford Elms would look at the cases and say -- we may have a half dozen. He may say, well, three or four of these are good to use, and then we'll use those blocks. Those will be our -- part of our inventory for controls.

CHAYTOR, Q.C.:

Q. And the rest, I think, is self-explanatory there. Number six says, "When an in-house control". So that's the control that -- that's not the in-house control.

MR. GREEN:

A. Yeah.

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CHAYTOR, Q.C.:

Q. That's just a control meaning within your own institution.

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So when an in-house control is not available from the laboratory tissue supply, efforts will be made to purchase a commercial control or the tissue will be sent to a reference laboratory for testing. So if you're not able to come up with a suitable control, is there any criteria then in coming up with what would be an appropriate control from a commercial control or from another laboratory?

MR. GREEN:

A. Commercial controls are usually what we call cell line controls in that those controls are cells which are grown for that particular purpose and use. They're a -- they're a good test of your system to see that your system is working, but it's not the optimal test because you do not have tissues which are fixed and processed in the same manner as the patient's tissue. So wherever possible, you would

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endeavour to use your own in-house controls.

CHAYTOR, Q.C.:

Q. And in terms of your own process in terms of looking back within your own institution for controls, do you only use tissue which has been processed according to current standards?

MR. GREEN:

A. Yes, according to the -- which is fixed and processed in the same way as the patient's tissue, yes.

CHAYTOR, Q.C.:

Q. As the patient's tissue.

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So in terms of any changes that has happened to the process in the past few months or year, you can't go back beyond that to find --

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. So it's very recent tissue that has been processed in the past year that you would use for your controls?

MR. GREEN:

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A. Well, we're -- with a control bank, you're always updating your controls. So you're always looking for new blocks to try -- like, each time you try a new batch, the pathologist will look at them and check them out.

CHAYTOR, Q.C.:

Q. And is that -- is that limitation expressed anywhere in your policy?

MR. GREEN:

A. Not that I'm aware of.

CHAYTOR, Q.C.:

Q. The importance for the patient tissue or the control tissue to be processed and fixed in the same manner as the patient tissue?

MR. GREEN:

A. I'm sure it's written down here somewhere, but an in-house control, by definition, I think -- I think the definition of the in-house control probably says that it's fixed and processed in the same.

CHAYTOR, Q.C.:

Q. And we had that on the last page, page 184, there was in-house control.

MR. GREEN:

A. Yeah.

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CHAYTOR, Q.C.:

Q. So known positive tissue that has been subjected to the same fixation processing as the test specimen?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So that is for finding any external control to be used in the process?

MR. GREEN:

A. Any external control, yeah.

CHAYTOR, Q.C.:

Q. And not just the one that goes on the patient tissue? The positive control that's put on the patient tissue --

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Has to be treated in the same manner as the patient's tissue?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. What about your batch controls?

MR. GREEN:

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A. The same -- same conditions apply.

CHAYTOR, Q.C.:

Q. Right,okay. So the same condition applies whether it's your batch control or --

MR. GREEN:

A. Or the positive, yes.

CHAYTOR, Q.C.:

Q. Right. So this definition here of in-house control means any external control?

MR. GREEN:

A. Any control -- any external control.

CHAYTOR, Q.C.:

Q. That's the one I just took you to. So page 189, investigating false positive and false negative immunohistochemistry staining, and this came into effect on February 29th, 2008. It says, "In the event of a suspected false positive or false negative result, all investigative and corrective actions must be documented", and the purpose is to ensure appropriate follow-up and corrective actions are undertaken when IHC staining errors are suspected. Then the procedure has eight steps, and the following steps -- follow the steps below to investigate and document false

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positive or false negative IHC staining. Number one is the pathologist will identify suspected staining error on an IHC slide. Two, the pathologist must report the situation to the staff of the immunohistochemistry lab. Mr. Green, in looking back on what happened in 2005, and there were a number of retests run in-house in 2005 after the index case, did any pathologist report that situation to the staff of the immunohistochemistry lab?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. "The cases documented and the reviews undertaken by an IHC technologist and the director of IHC laboratory". Fourthly, "evaluate the immunohistochemical staining run in which the slide staining was generated". Do you know to your knowledge whether or not the immunohistochemical staining run which generated the slide was investigated in 2005?

MR. GREEN:

A. Not that I'm aware of.

CHAYTOR, Q.C.:

Q. "Review controls for the identified run". Six,

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"Review the documented staining protocol for the slide in question on the day in which it was tested". Are you aware of whether or not that happened?

MR. GREEN:

A. Staining protocol would not have changed. Once we set a staining protocol number, we don't vary from that protocol.

CHAYTOR, Q.C.:

Q. And I believe you've told us that your protocol is basically the same now with some adjustment basically to the incubation period? It's the same as what you had in place in April of 2004, in any event?

MR. GREEN:

A. When we do -- now when we do ER/PRs, the protocol number that we are using will be the same on all patient slides from week to week, month to month.

CHAYTOR, Q.C.:

Q. Okay, and then seven, "If the issue is not resolved, review all documentation about the slide, including excisioning of the sample and the identification of the tissue block from which the slide was cut, and then document in

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the corrective action logbook all actions undertaken, results of review, and any corrective actions taken", and the supporting documents for that include CCHSA, Ventana operators manual, and David Dabbs".

MR. GREEN:

A. David Dabbs.

CHAYTOR, Q.C.:

Q. The Ventana's operators manual, to your knowledge in 2005, did the Ventana operators manual have a procedure for investigating suspected false positive or false negative stains?

MR. GREEN:

A. There was a troubleshooting section in there which would have included those, which are basically general guidelines which means that you go backward and check your protocol, check your slides that were run, check your controls.

CHAYTOR, Q.C.:

Q. Okay, and in terms of there now being a corrective action logbook, from the time the testing resumed in February, 2007, up until it stopped just this spring or summer of 2008,

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are you aware of whether or not there has been any investigations for false positive or false negative IHC stains?

MR. GREEN:

A. For ER/PR or in general?

CHAYTOR, Q.C.:

Q. ER/PR is what started since February of '07.

MR. GREEN:

A. No. There will be slides from time to time which you won't get the expected result, and then the usual practise is to repeat that test, and if then you have a problem, then you will start backtracking and try to find out problems somewhere back in the system, but that would be the -- we repeat the test, and if the test the second time was fine, your problem would be solved and you just record that in your corrective action, specimen number whatever repeated.

CHAYTOR, Q.C.:

Q. So you haven't had the occasion to have to go through this procedure for ER/PR?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

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Q. Have you had to go through it for other IHC stains?

MR. GREEN:

A. There have been stains which we've had problems with which we have to go back and repeat the test and try different protocols to optimize the antibodies.

CHAYTOR, Q.C.:

Q. Attached here is definitions of false positive and false negative, and a negative immunohistochemistry result for an antigen in a tissue in which that antigen exists. So I take it the definition of negative is -- and positive then, an appropriately intense positive stain for antigen in a tissue in which that antigen does not exist.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Who decides what's an appropriately intense positive stain?

MR. GREEN:

A. That would be the pathologist.

CHAYTOR, Q.C.:

Q. In terms of negative, I take it there's no

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

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external control on --
MR. GREEN:
A. External control on the slide.
CHAYTOR, Q.C.:
Q. Okay, and then what's your QC check, okay? What's that?
MR. GREEN:
A. After the slides are stained, we will check to make sure that that positive control works, that it's positive. if it doesn't work, we repeat it, we won't send it out. We won't send it from the lab. If it works, it goes to the pathologist for interpretation, and once it goes to the pathologist, it's signed out -- read and signed out by the pathologist.
CHAYTOR, Q.C.:
Q. So the technologist checking the external controls, is it just the external controls you check?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. You don't check the internal control?
MR. GREEN:
A. No, that's the domain of the pathologist.

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CHAYTOR, Q.C.:
Q. So you check the external control, and if it doesn't -- if you're not satisfied, then you go in this direction in quality control review and corrective actions take place?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And when did it become the process or the procedure for the technologist to check the external controls prior to sending out to the technologist?
MR. GREEN:
A. It probably happened when Dr. Ejeckam was in charge and he started teaching us to check the controls, how to check the controls, and by that time we were putting positive controls on each patient, so it would have happened around then.
CHAYTOR, Q.C.:
Q. So when you get down to this block here, QC check, okay, do you document in any way that you've looked at the external control and it is, in fact, okay?
MR. GREEN:

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A. On the original requisition that comes from the pathologist, the technologist will sign that requisition. When they send that requisition, they say they have completed the work and checked the controls.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. External controls.
CHAYTOR, Q.C.:
Q. Does it say that anywhere in your policy or your procedure here?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And is there anywhere on the form where it would be indicated that you have to sign off?
MR. GREEN:
A. On the bottom of the form, it says technologist signature and the date.
CHAYTOR, Q.C.:
Q. And that's been the case for some time, though?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. So by signing it, it now means that you've checked. Not only did you do the process, you are the technologist responsible for the process, but you also checked the external controls?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But how does the pathologist know that or the person reading the slides?
MR. GREEN:
A. When the pathologist gets those slides and the requisition and it's signed, it means that we've done the work and they would assume that we would not have sent the control out to them if the control didn't work.
CHAYTOR, Q.C.:
Q. So there's nothing written anywhere to document that?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. To make sure that new people coming in are of that understanding; for example, new

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pathologists coming. How would they then know -- without it being a written policy, how would they know that that, in fact, is the practise at the Health Sciences IHC lab?
MR. GREEN:
A. They probably wouldn't know unless we told them or another pathologist told them.
COMMISSIONER:
Q. The external control you check before it goes out and that is the external control on the patient's slide?
MR. GREEN:
A. Yes.
COMMISSIONER:
Q. Do you have any role in respect of the batch slides?
MR. GREEN:
A. We don't do batch slides any more. The only batch slides that we do are the ones with the ER/PR triple controls.
COMMISSIONER:
Q. Yes. Do you have any role with those?
MR. GREEN:
A. We will check those to make sure that they -- the staining works on those before we send

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them to the breast group, but the breast group has the final responsibility. They will not accept those slides if the controls don't work.
COMMISSIONER:
Q. So when you're sending them to the breast group, you in addition to sending -- you send that slide as well?
MR. GREEN:
A. Yes.
COMMISSIONER:
Q. Although you will have been expected to check yourself?
MR. GREEN:
A. Yes.
COMMISSIONER:
Q. In a preliminary way in respect of that slide before you send it out to them, but they get the final call?
MR. GREEN:
A. That's true.
COMMISSIONER:
Q. Have I got that right?
MR. GREEN:
A. Yes.

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COMMISSIONER:
Q. Okay, thank you.
CHAYTOR, Q.C.:
Q. So the external batch control, that actually goes to the pathologist as well?
MR. GREEN:
A. Yes, for ER/PR.
CHAYTOR, Q.C.:
Q. So the pathologist reads IHC slides. So that is intended to include the batch control slide as well as the patient slide?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Then there's just a number of others that you're involved in, you're the author of them. This one is ancillary products records and it's keeping track of information on ancillary products.
MR. GREEN:
A. All this information, although it's -- with the system that we have now, the Ventana System, it's electronically stored. This is a backup manual paper record.
CHAYTOR, Q.C.:

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Q. Okay, so this is a backup manual -- paper record for in case it's lost on the system, on the Ventana System?
MR. GREEN:
A. Yes, and the system itself electronically back up the system itself by using zip disk. Once a year we'll download all the information on the Ventana System and that's stored.
CHAYTOR, Q.C.:
Q. And I take it there hasn't been any problem with the system or loss of any information?
MR. GREEN:
A. We have never lost any information.
CHAYTOR, Q.C.:
Q. And then there's ordering glass slides procedure, there's EZ prep dilution, and you have a procedure for -- on page 209, reaction buffer dilution for benchmark?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And that procedure provides instructions for reaction buffer dilution?
MR. GREEN:
A. That's correct.

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CHAYTOR, Q.C.:
Q. And was this procedure in writing prior to March of 2008?
MR. GREEN:
A. Only in the Ventana Manual, but not as a separate standalone document.
CHAYTOR, Q.C.:
Q. Okay. Then on page 211, there's a procedure dealing with bar code labels, and then on 213, we have antibody protocols, and you are the author of this as well, and it's in effect as of March 19, 2008, and each antibody has it own specific protocol which is optimized and customized through our laboratory conditions and environment, and it's strictly followed. The protocol is used to demonstrate a specific antigen and specific tissue elements. I take it, Mr. Green, this is new?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. As of March of 2008?
MR. GREEN:
A. It's been into effect for quite some while.
CHAYTOR, Q.C.:

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Q. And as of when, as of March of 2008? Is that when this came into effect or into use?
MR. GREEN:
A. It's probably been into effect before that. That's when it finally got typed and put into the format.
CHAYTOR, Q.C.:
Q. And do you know whether or not it was in effect in February, 2007, when testing resumed?
MR. GREEN:
A. It was.
CHAYTOR, Q.C.:
Q. So it's been in effect for over a year?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But reduced to writing in March of this year, okay. The idea of optimizing and customizing each antibody or the protocol for each antibody to your own lab and environment, that's something that came about, I take it, the realization of that came about and the actual practice of doing that came about after the issues arose in 2005?

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

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

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

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antibody, incubation time and all the particulars of that particular protocol, so that if you wanted to go back and look at--if you had patients that were stained with that antibody a year ago, you could go back and find out the information that you used and protocols that you used.
CHAYTOR, Q.C.:
Q. And we could go back for up to two years?
MR. GREEN:
A. Two years.
CHAYTOR, Q.C.:
Q. And what about we needed, for example, what happened with the retesting process here, went back several years, what happens if you need to go back more than two years? Is that information otherwise recorded anywhere?
MR. GREEN:
A. This policy wasn't into effect at that time and there was no policy for retired antibodies.
CHAYTOR, Q.C.:
Q. I realize that, but was there any consideration--why the two years now in bringing in this procedure, why two years?

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MR. GREEN:
A. I think that that documentation for retired antibodies, in the literature it says must be kept for a minimum of two years. You can keep it for as long as you wish.
CHAYTOR, Q.C.:
Q. And the operating manual Ventana system, it was used as a reference, so was this part of the operating manual for Ventana system, that such information would be kept for two years?
MR. GREEN:
A. I'm not exactly sure on that, but I could check it out for you.
CHAYTOR, Q.C.:
Q. Okay, and the idea of the type of antibodies and incubation period that the antigen retrieval process, is that recorded on the patients record anywhere?
MR. GREEN:
A. If the patients--any slide that's run on the Ventana system will have a bar code on that slide and a protocol number. By referring to that protocol number, if it was a retired antibody, we could check and see which protocol was used. As long as you have the

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patient's slide with that bar code on the top.
CHAYTOR, Q.C.:
Q. And that's for anything done on Ventana?
MR. GREEN:
A. Yes, because in order for the slide to be run on the Ventana, it has to be bar coded.
CHAYTOR, Q.C.:
Q. And the current process, you'd be able to go back and check for two years, according to this protocol?
MR. GREEN:
A. On retired antibodies, yes.
CHAYTOR, Q.C.:
Q. Yes, on retired antibodies, and Dr. Ford Elms brought in page 221 as the issuing authority and you're the author, and this is request for immunohistochemistry staining, and I take it it's query diagnosis. Is that -
MR. GREEN:
A. That means query diagnosis, yes.
CHAYTOR, Q.C.:
Q. Okay, so, and then on the--sorry, 223, we have cutting of immunohistochemistry slides and this procedure is to provide instructions for the cutting of the slides and there's seven

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

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

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

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

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Q. Okay, and it's indicated here to be the Ventana Benchmark troubleshooting guide?
MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. Okay, and was that happening, a technologist working in the IHC area, was this happening that -
MR. GREEN:
A. That would be the normal course of events to follow when you had trouble with a stain, and if all--if you went through all these steps here and you didn't find a resolution, you would call Ventana and ask for their customer technical department.
CHAYTOR, Q.C.:
Q. And it says here "non-staining of particular antibody referred to the Ventana Benchmark troubleshooting guide." Why wouldn't the steps or the information from the Ventana Benchmark be--why wouldn't it just be included here along with the other information?
MR. GREEN:
A. Well, I guess, it would be--these steps that you see, these are for under staining and over

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staining.
CHAYTOR, Q.C.:
Q. Right, so we have -
MR. GREEN:
A. And like if you had non-staining -
CHAYTOR, Q.C.:
Q. - over staining, under staining and non-staining of a particular antibody and then non-staining of all antibodies in the run.
MR. GREEN:
A. When you have non-staining of all antibodies, usually you got a--if you got non-staining of all antibodies, there's probably a problem with not a particular antibody, but with the detection system or with the equipment itself. Then you would have a series of checks to go through to check out the equipment. That's when you would call in the Ventana technical people.
CHAYTOR, Q.C.:
Q. Right, but the non-staining of a particular antibody, so for example, if you have your ER and you check your external control and it hasn't worked, there hasn't been any staining, what--it says here "refer to the Ventana

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Benchmark troubleshooting guide." So what would that tell me? What would I find out?
MR. GREEN:
A. If you had non-staining of one particular antibody?
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. Well then, you would go through the steps to see if your--first thing you would check is your antibody itself to see if you had enough volume of antibody. That would be the most obvious check to make, because even though these antibodies come predilute from the manufacturer, then they may come with enough antibody to do 250 tests, but the onus is still on the operator to check and make sure that there is sufficient volume in that to do those tests.
CHAYTOR, Q.C.:
Q. So if you went looking to the Ventana Benchmark troubleshooting guide, would you find specific information to help you with a particular antibody?
MR. GREEN:

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

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

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procedure for managing Ventana Benchmark electronic data includes "the Ventana Benchmark computer will electronically store the run data on the hard drive." So what would the run data include?
MR. GREEN:
A. The run data will include everything, every patient that has been run on that system. It will include all the reagents that had been used on that system, expiry dates and lot numbers, plus every patient that has been run on the system.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. Every antibody that's been run.
CHAYTOR, Q.C.:
Q. Okay, and then the Ventana has an archive electronic data binder that the disk is stored in?
MR. GREEN:
A. Yes, that's correct.
CHAYTOR, Q.C.:
Q. So do you know whether or not there was any check of the run data which was being archived

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by the Ventana system? I guess that went back to April 2004 when the Ventana came in operation. Do you know if there was any check for any run data which may have been archived back to April 2004 with respect to the ER/PR tests that were found to be necessary to rerun?
MR. GREEN:
A. I gave that zip disk to Barry who brought it to our IT department to duplicate that.
CHAYTOR, Q.C.:
Q. So you did do that? You brought the disk to Barry Dyer?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And that was given, to your knowledge, to the IT department?
MR. GREEN:
A. Who were going to--they were supposed to print out a hard copy of all the information which would have been--which would have reported all the information from the first day that the system went into operation.
CHAYTOR, Q.C.:

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

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whose responsibility is it to ensure or what checks and balances are built into the system to ensure that the policies and procedures are, in fact, followed?
MR. GREEN:
A. We have a QA department now which are basically responsible for making sure that these standard operating procedures are in place. It is the manager's responsibility to--I guess it's the QA's responsibility to make sure that they are delivered to the lab and it's probably the manager's responsibility to make sure that everybody has read and signed off on the--read the procedure.
CHAYTOR, Q.C.:
Q. So, for example, you've had a new person start and you have someone else who's just recently started. You had somebody start last fall and have you been involved in the training of those people at all?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and what do you do to ensure that they are familiar with the procedures?

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

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

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CHAYTOR, Q.C.:
Q. And Mr. Green, I appreciate you've done a lot of work on these procedures, and from what you've told us, it appears you became involved in December 2007, shortly before QMPLS came in. Do you know why it took so long to create and bring into effect these policies and procedures?
MR. GREEN:
A. I would guess because we didn't have a dedicated person on staff who could handle the workload.
CHAYTOR, Q.C.:
Q. Thank you for your time. Those are my questions, and I'm sure some of the other lawyers may have questions for you.
MR. GREEN:
A. Thank you.
THE COMMISSIONER:
Q. Mr. Pritchard?
MR. PRITCHARD:
Q. Thank you, Commissioner. I don't have any questions for Mr. Green. Thank you very much.
THE COMMISSIONER:
Q. Mr. Browne?

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MR. BROWNE:
Q. I do have some questions, Commissioner.
THE COMMISSIONER:
Q. Do you want to take the luncheon break first? If you want to do that, I'm quite happy to accommodate--it's the normal point.
MR. BROWNE:
Q. Sure. That's what I'm just wondering, whether it would be -
THE COMMISSIONER:
Q. Well, it's probably easier on Mr. Green if we gave him lunch before he had to -
MR. BROWNE:
Q. I would think that would be fair.
THE COMMISSIONER:
Q. All right then. Can we do the rounds of the room and see how much time we're going to require this afternoon?
MR. BROWNE:
Q. I anticipate I'll be about 20-25 minutes.
THE COMMISSIONER:
Q. All right. Mr. Pritchett?
MR. PRITCHETT:
Q. We don't anticipate any questions, Commissioner.

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THE COMMISSIONER:
Q. Ms. Newbury?
MS. NEWBURY:
Q. About ten minutes or so.
THE COMMISSIONER:
Q. Mr. Pike?
MR. PIKE:
Q. No questions.
THE COMMISSIONER:
Q. Mr. Simmons, do you want to weigh in?
MR. SIMMONS:
Q. I'll probably be no more than five minutes, depending on what happens.
THE COMMISSIONER:
Q. All right, then I guess we can schedule the next witness with that in mind, and we'll start at two. Thank you all.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Mr. Browne.
MR. KENNETH GREEN, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Good afternoon, Mr. Green.
MR. GREEN:
A. Good afternoon.

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MR. BROWNE:
Q. I'm Peter Browne. I think we've met previously. I represent a number of the individual physicians who've been asked to give evidence here for the Commission, and there's a couple of areas I want to cover with you, and before I begin, if there's some redundancy here, I apologize. I understand in your profession or at least in the medical profession, redundancy is not a bad thing. In our profession, it's kind of frowned upon. So I apologize if I am redundant.
I want to begin with your training in 2002. We heard from Ms. Welsh, who I understood you confirmed that she was the person who trained you into the job in 2002, and Ms. Welsh, in giving her testimony to the Commissioner, remarked, I think, that during the time she was at the Health Sciences, it was common knowledge not to go looking for continuing education funding because the money wasn't there. Now you were both at St. Clare's and at Health Sciences Centre. What's your impressions about the time, I guess let's look at the '90s and into the point of 2005,

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we'll use it as a cut off--what's your impressions with regard to Mrs. Welsh's comments?

MR. GREEN:

A. I would agree with that statement. There wasn't a lot of extra money for educational purposes or any other purpose for that matter.

MR. BROWNE:

Q. Okay, and that was both your experience at St. Clare's and Health Sciences?

MR. GREEN:

A. It would be the same for both. You would get--you were afforded money for local conferences for registration at those conferences, but anything else, hotel accommodations, anything else, you would have to cover on your own expense.

MR. BROWNE:

Q. And did you ever make inquiries about why the money wasn't there or go looking for money for these conferences and get, you know, refused or anything like that?

MR. GREEN:

A. It was just that the money wasn't there.

MR. BROWNE:

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Q. Okay, and that was--that sort of, it was made known to all and sundry that this was the case. Is that right?

MR. GREEN:

A. It was common knowledge.

MR. BROWNE:

Q. Okay. What about opportunities to--when you came over to the Health Sciences in 2002 and started doing immunohistochemistry, did you realize that that was sort of quite a different field from what you'd been doing previously at St. Clare's?

MR. GREEN:

A. It was all new.

MR. BROWNE:

Q. Okay. Were you ever given the opportunity to read about the subject, either around the time Ms. Welsh was training you or afterwards?

MR. GREEN:

A. There was never any free time to read or there wasn't any time set specifically for reading or study.

MR. BROWNE:

Q. Now we've heard the notion of protected time. Is that something you've heard about as well,

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is that a term--and let me ask you, as the technologist who's now sort of overseeing this, the most senior technologist, the notion of getting people such as yourself and your colleagues protected time, do you have any thoughts on that subject?

MR. GREEN:

A. It would be invaluable. It probably would be the only opportunity that some people will get to get additional information, to study theory and to check out articles, you know. With being so busy and just trying to get the day's work done, if you could take an hour and have a designated time, it would be invaluable.

MR. BROWNE:

Q. And I guess that potential is there with the Health Sciences library nearby that if there are textbooks or whatever that are not necessarily in the lab, that those could be available, journals could be available through the Health Sciences Centre as well?

MR. GREEN:

A. That's true.

MR. BROWNE:

Q. Now pathologists have been, I think, at some

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point given a period of time for continuing medical education. One point is one week, I think we've heard from some pathologists. Do you have an equivalent period of time where you can go off and do -

MR. GREEN:

A. There's no designated time.

MR. BROWNE:

Q. Okay. Again, is that something that would be worthwhile?

MR. GREEN:

A. It would be invaluable.

MR. BROWNE:

Q. In terms of your--and just staying with your knowledge base and how it has changed since 2002, reflecting back on your evidence the other day, am I correct in stating that, I guess, the main sources of your increased knowledge since that time were Dr. Ejeckam in 2003 onward?

MR. GREEN:

A. That's true.

MR. BROWNE:

Q. Your Ventana training in 2004 in Arizona?

MR. GREEN:

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A. True.
MR. BROWNE:
Q. Your IHC conferences in 2005, 2006?
MR. GREEN:
A. That's true.
MR. BROWNE:
Q. And then Montreal Jewish General, your time you spent there. So that would be sort of the major sort of knowledge base?
MR. GREEN:
A. Yes.
MR. BROWNE:
Q. Now the time you spent in Arizona in 2004, I think you had commented, and I'm not sure, and I apologize if this was canvassed by Ms. Chaytor, but you learnt about the theory of antigen retrieval. Is that right?
MR. GREEN:
A. We learnt about the theory of IHC in general.
MR. BROWNE:
Q. Okay, sorry, and was there anything in particular about antigen retrieval that you learned there in 2004?
MR. GREEN:
A. Not specifically, but generally.

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MR. BROWNE:
Q. Okay, and the person who taught you this course and gave you this information was a technologist? Is that right?
MR. GREEN:
A. I'm not sure if it was a technologist, but that's what I assumed.
MR. BROWNE:
Q. And in terms of learning about internal controls, that's not something you learned until 2005, did I understand that today?
MR. GREEN:
A. I would have no knowledge of internal controls until Dr. Ejeckam showed me.
MR. BROWNE:
Q. And that was in 2005?
MR. GREEN:
A. Yeah.
MR. BROWNE:
Q. Okay. Now you also mentioned, I think the other day, your experience at Montreal Jewish General that the technologists or at least the technologist who you interacted with was trained to look at both external internal controls?

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

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before sending it out? Is that right?
MR. GREEN:
A. To see that there was a reaction.
MR. BROWNE:
Q. See there was a reaction, and then you would then show the controls to pathologists before sending them out?
MR. GREEN:
A. Show the controls -
MR. BROWNE:
Q. The external control?
MR. GREEN:
A. Out-of-town cases or -
MR. BROWNE:
Q. Well, let's--the in-town cases, you would just put in -
MR. GREEN:
A. Put in their mail box in the reading room.
MR. BROWNE:
Q. And the out-of-town cases, you would do what?
MR. GREEN:
A. We would check with one of the pathologists before we sent them out.
MR. BROWNE:
Q. Right, okay, and I think there was some--at

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some point, you mentioned that that wouldn't always be the case. Is that right? Did I understand you that sometimes it's possible you may have sent it out without checking it with a pathologist?

MR. GREEN:

A. Probably not likely. Most likely I would check with the pathologist.

MR. BROWNE:

Q. Okay, and just if you were asked again the other day by Ms. Chaytor, if a pathologist had a problem with an external control not working, the process you would go through--again now, this is between 2002-2005, you would repeat the test?

MR. GREEN:

A. That would be the most obvious step.

MR. BROWNE:

Q. Okay. I think you also mentioned troubleshoot to find out what the problem was.

MR. GREEN:

A. Yes.

MR. BROWNE:

Q. Okay. Did you ever do that under the DAKO regime? I'll use the term DAKO--distinguish

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between DAKO and Ventana for the moment.

MR. GREEN:

A. The initial repeat, it would be the same on either system.

MR. BROWNE:

Q. Okay, no, the troubleshooting.

MR. GREEN:

A. And the troubleshooting wouldn't be so easy on the DAKO system because I was not as familiar with the DAKO system. At that time, I probably would have only had one year's experience and out of that, one-third of the time was actually spent on the machine. But most of my knowledge was developed on the Ventana system.

MR. BROWNE:

Q. Do you recall ever having an instance where you were required to troubleshoot on the DAKO machine?

MR. GREEN:

A. Nothing in particular, but I'm sure there have been cases where we would have had to have repeats.

MR. BROWNE:

Q. Okay, and was there--you mentioned today that

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the Ventana had a guide on troubleshooting. Was there an equivalent guide under the DAKO?

MR. GREEN:

A. I have never seen it.

MR. BROWNE:

Q. Okay, and I think you mentioned as well that if it was brought to your attention an external control failed, there was no--and this is again in answer to a question from Ms. Chaytor the other day, no automatic policy to rerun all the slides for that batch?

MR. GREEN:

A. That's correct.

MR. BROWNE:

Q. And I think you said as part of that answer, because it was the pathologist's responsibility to pick up appropriate--to pick the appropriate block with the appropriate internal control, that they would read the internal control?

MR. GREEN:

A. Yes.

MR. BROWNE:

Q. But you wouldn't have known about internal controls until 2005.

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MR. GREEN:

A. That's true.

MR. BROWNE:

Q. So you wouldn't have known that piece of information?

MR. GREEN:

A. No, I would not, that's true.

MR. BROWNE:

Q. Okay, and when you trained with Ms. Welsh, there was no discussion about the notion, at least for ER/PR, and I guess so I'm clear on this, when you were trained by Ms. Welsh, you were trained generally in IHC? Is that right?

MR. GREEN:

A. Yes.

MR. BROWNE:

Q. Would that training period have included potentially ER and PR, do you know?

MR. GREEN:

A. ER/PR would have been run during that period, along with all the other antibodies. I'm sure it would be.

MR. BROWNE:

Q. And the notion of the nuclear staining, importance of nuclear staining, was that ever

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discussed between you and Ms. Welsh?
MR. GREEN:
A. No, at that stage, the basic training was on running the equipment.
MR. BROWNE:
Q. Okay. Now in terms of showing the external controls to a pathologist, would you just walk through that process with me, if you could for a minute. You'd show the slide, the external control slide. Is that right?
MR. GREEN:
A. Are we talking DAKO or Ventana?
MR. BROWNE:
Q. Again, let's stay with DAKO for the time being, pre--yes, because I keep forgetting between--let's use the--let me rephrase this. Instead of using 2005, let's go 2004, pre 2004.
MR. GREEN:
A. Okay.
MR. BROWNE:
Q. The external control under DAKO, when you went to a pathologist with the external control, would you bring any other documentation with you?

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MR. GREEN:
A. No. Now there was a time at the Health Science where the controls were all put in the reading room for a pathologist to check. So when that occurred, you would not go to a particular pathologist. You know, you would not have any interaction with them at all. You would just put the controls out in the reading room.
MR. BROWNE:
Q. Okay, but the times where you did go to pathologists and ask a pathologist to check the external controls, can you tell me would you--besides giving the slide to the pathologist, would you give him any other documentation?
MR. GREEN:
A. Not that--I can't remember doing so.
MR. BROWNE:
Q. What would you tell the pathologist?
MR. GREEN:
A. You'd be telling him that--depending on which antibody you were running, you could ask him to check the control, because sometimes not all controls are of equal value. They'll ask

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him a control--if this was a good control, and if it wasn't a good control, they would say "well, it could be better" or could have that conversation.
MR. BROWNE:
Q. Would that be your practice every time you spoke to a pathologist?
MR. GREEN:
A. No, not--no, a lot of controls worked regularly all the time and you would just say "can you check this for me?"
MR. BROWNE:
Q. Okay, and would there be anything else, but just say "just check this"?
MR. GREEN:
A. Yeah.
MR. BROWNE:
Q. That would be -
MR. GREEN:
A. You might ask them for their opinion and they would say it's fine.
MR. BROWNE:
Q. Okay, what about on reruns, would you let the pathologist know that this was rerun?
MR. GREEN:

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A. On a rerun, you mean a repeat?
MR. BROWNE:
Q. Yes.
MR. GREEN:
A. Usually the pathologist would--we would--unless there was something obviously wrong, the pathologist would get the slides and they would be the one to request a repeat.
MR. BROWNE:
Q. Right, but if you were--if it was somebody outside the Health Sciences asking for a repeat, would the pathologist--would you check that with the pathologist before sending it out to the outside, if it was a repeat?
MR. GREEN:
A. Not necessarily, no more than checking with a normal--a repeat wouldn't be--wouldn't necessarily send up a flag or anything.
MR. BROWNE:
Q. But would you tell the pathologist that it was a repeat and the reasons for the repeat?
MR. GREEN:
A. You may, depending on what the circumstances were.
MR. BROWNE:

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Q. Now antigen retrieval, again, I want to just be clear on a point. Did you--when you were testifying the other day, was the control slide exposed to the same antigen retrieval technique as all the other slides? Again, DAKO, so we're clear on this.
MR. GREEN:
A. DAKO control slides, yes, it would, because if you're using an ER, the protocol for that ER would have to be the same as the protocol for the -
THE COMMISSIONER:
Q. Are you talking about a separate control slide?
MR. BROWNE:
Q. Yes, separate control slide.
MR. GREEN:
A. Yes, it would have to be treated the same way.
MR. BROWNE:
Q. Okay, and are they done--just so--we heard about batches. Is the antigen retrieval process for each patient slide, again under the DAKO system, done at the same time as the control slide?
MR. GREEN:

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A. Yes.
MR. BROWNE:
Q. Okay, and you'd mentioned there was some occasions where the robotic arm on the DAKO machine, there was some difficulties with it. Were these ever reported to your superiors at all or would you just--the responsibility would be with you to contact maintenance or DAKO?
MR. GREEN:
A. If we had a problem, we would contact--usually contact the biomedical department and they would send somebody down to do the necessary repairs.
MR. BROWNE:
Q. So there was no sort of reporting mechanism to your superiors about problems or anything like that?
MR. GREEN:
A. No.
MR. BROWNE:
Q. Now tissue processing, Mr. Green, I just want to go over that for a minute, just so I'm clear on a couple of points. If a block was reprocessed, it would not be distinguishable

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from an ordinary block that wasn't? Is that right?
MR. GREEN:
A. Not normally, no.
MR. BROWNE:
Q. Okay, and that sometime in the '80s, while you were at St. Clare's, a particular pathologist, I think it's Dr. Tadross, is that -
MR. GREEN:
A. That's correct.
MR. BROWNE:
Q. - mentioned about reprocessing blocks?
MR. GREEN:
A. That's true.
MR. BROWNE:
Q. And I think you said it became policy after that?
MR. GREEN:
A. After that, it was common practice.
MR. BROWNE:
Q. Common practice, it wasn't a policy?
MR. GREEN:
A. No.
MR. BROWNE:
Q. There was no written policy?

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MR. GREEN:
A. No.
MR. BROWNE:
Q. Okay, and was that made known to every pathologist that came through St. Clare's?
MR. GREEN:
A. They would have known if their breast specimen, if they were waiting on their breast specimen and it was delayed, but they would not necessarily be notified otherwise.
MR. BROWNE:
Q. So how would -- so they -- you're saying the inference would be that if it was delayed, that would mean it was reprocessed?
MR. GREEN:
A. That would be one of the reasons for it being reprocessed.
MR. BROWNE:
Q. Would that be communicated?
MR. GREEN:
A. Not necessarily. No, you would not -- a pathologist if he or she had a busy workload and there were a lot of cases, he may not be expecting to get to a case for a couple of days, so he may never know it was reprocessed.

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

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somebody sent in a slide from out of town and they wanted that slide -- an ER/PR done on that slide, chances are it wouldn't be an histogrip slide and it wouldn't be a positive charged slide. So you would go ahead and do that. The chances would increase that you would lose tissue on a slide.
MR. BROWNE:
Q. And in terms of Eastern Health and its predecessor, Health Care Corporation, who would be in charge of ordering slides for a lab?
MR. GREEN:
A. Ordering slides for the lab?
MR. BROWNE:
Q. Yeah, and the positively charged slides and so on, whose responsibility is that?
MR. GREEN:
A. The positively charged slides right now we would just set up so we order them every couple of months, but back then I'm not really sure who was responsible.
MR. BROWNE:
Q. And the notion of having positively charged slides, when was that brought to your

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

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Corner Brook -- most outside hospitals would send in the blocks and we would cut the blocks, so it wasn't a problem.
MR. BROWNE:
Q. Okay.
MR. GREEN:
A. But Western Memorial, they would send in slides of their own because I guess when they cut the slides, they wanted to make sure that if they didn't have a lot of tissue, it was easier for them to cut those slides and send them in. When they first started to send them in, they were on regular slides. So we mentioned it to the -- I guess we mentioned it to the manager and they probably called them or sent them a memo, and we sent out samples of slides that we were using and asked them to order their own.
MR. BROWNE:
Q. Would that have been in 2004 after the Ventana came on line?
MR. GREEN:
A. It would have been after Ventana came on line because that's the only time it was an issue.
MR. BROWNE:

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Q. And just going back, you mentioned as well the histogrip, and you found out about the histogrip slides when you came over to the Health Science?
MR. GREEN:
A. Over to the Health Science. We didn't use them at St. Clare's.
MR. BROWNE:
Q. Was that ever communicated back to St. Clare's, do you know?
MR. GREEN:
A. Not that I'm aware of.
MR. BROWNE:
Q. Is there any reason why that wasn't communicated back to St. Clare's?
MR. GREEN:
A. In the beginning, St. Clare's would cut their own slides and send over, but somewhere along the process the policy changed and the blocks were sent to the Health Sciences, so that the issue probably took care of itself.
COMMISSIONER:
Q. Mr. Green, are you saying that the positively charged slides were a requirement for the use of the Ventana machine?

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MR. GREEN:
A. It is, yes.
COMMISSIONER:
Q. As opposed to somebody saying really you ought not use a ordinary slide when you're doing antigen retrieval?
MR. GREEN:
A. No, the --
COMMISSIONER:
Q. Do you get my difference?
MR. GREEN:
A. The Ventana system required it. You didn't run regular slides.
COMMISSIONER:
Q. Okay, thank you.
MR. BROWNE:
Q. Again I apologize for going back to antigen retrieval on the DAKO System. What was the method that you employed at the Health Sciences for antigen retrieval?
MR. GREEN:
A. Antigen retrieval was performed in the water bath.
MR. BROWNE:
Q. Water bath?

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MR. GREEN:
A. We had a water bath which was set up which was heated to between 95 and 100 degrees. In that water bath we would put a glass dish and the antigen retrieval solution was in the glass dish, and then used a thermometer to check the temperature of the antigen retrieval, not of the water.
MR. BROWNE:
Q. Okay.
MR. GREEN:
A. So then you would put the slides that you had for antigen retrieval into the coplin jar inside the water bath and set your timer for 20 minutes.
MR. BROWNE:
Q. And this was big enough to, I guess, hold the whole batch, was it?
MR. GREEN:
A. It was big enough to hold a rack of slides.
MR. BROWNE:
Q. Okay. Now just on that point -- and you found out subsequent through Mount Sinai that they use a different method, they use the pressure cooker?

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MR. GREEN:
A. Yes.
MR. BROWNE:
Q. Can we just -- Registrar, can I have Exhibit P-2155, please. Do you see the ER/PR section here. This is for the DAKO machine, is it, Mr. Green?
MR. GREEN:
A. Yes.
MR. BROWNE:
Q. It mentions somewhere here Visionware boiling method. Is that what you were using? Do you see that there, third line?
MR. GREEN:
A. I would assume that it's the boiling method that we were using at the Health Science, yes.
MR. BROWNE:
Q. But you're not certain of that, are you?
MR. GREEN:
A. I'm not certain. I wouldn't -- no, I'm not certain.
MR. BROWNE:
Q. Do you know what it was called, the particular water bath? Did it have a -- did it have a --
MR. GREEN:

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A. It was always referred to as the water bath method.
MR. BROWNE:
Q. And when you talked about -- I think it was the other day when Ms. Chaytor was asking you some questions about a run. That would be the whole process, would it be?
MR. GREEN:
A. A run would be all the slides.
MR. BROWNE:
Q. From start to finish --
MR. GREEN:
A. From start to finish.
MR. BROWNE:
Q. Through the whole process.
MR. GREEN:
A. A run could be 48 slides or it may be 10 slides.
MR. BROWNE:
Q. Fair enough, but it would be -- so I'm clear as to what you're saying, that would mean the whole antibody -- employment of the primary and secondary antibody?
MR. GREEN:
A. Yes.

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MR. BROWNE:
Q. The antigen retrieval?
MR. GREEN:
A. Yeah, start to --
MR. BROWNE:
Q. Start to finish?
MR. GREEN:
A. Correct.
MR. BROWNE:
Q. Okay, thanks, and that usually took about three hours?
MR. GREEN:
A. Depending on the number of slides, around three to three and a half hours.
MR. BROWNE:
Q. Were there various points where you would have to intervene in that process and you would have to time and so on?
MR. GREEN:
A. Once the system is set up and you had your antigen retrieval slides, the slides -- when you set up your run, you divide it into what we call AR slides and non AR slides. The non AR slides didn't have anything to -- we just took those from the oven, dehydrated those,

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took the -- removed the wax from them, brought them to water (phonetic). They're ready to go on the machine, they're kept in water, and then we would do the antigen retrieval slides which means that they had to be dehydrated, wax removed, brought to water. They'd be -- you do the antigen retrieval process and take those -- then you would catch up all your slides, then load them all on the machine, and then your run would start.
MR. BROWNE:
Q. I guess what I'm unclear on is were there points in there where you had to be in the room at all times?
MR. GREEN:
A. No, the only point that you wanted to monitor was when you put the slides for antigen retrieval in the antigen retrieval solution and then you set a clock for twenty minutes.
MR. BROWNE:
Q. So that's the one where you had to be there?
MR. GREEN:
A. That's the point where you would want to remove your slides from antigen retrieval.
MR. BROWNE:

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Q. Thank you. When you started in 2002, as well -- and prior to that time over at St. Clare's, formalin was made in-house, I think, up until about 2003, is that right?
MR. GREEN:
A. That's true.
MR. BROWNE:
Q. Were you following -- and you had a crossover period both at Health Sciences and at St. Clare's?
MR. GREEN:
A. True.
MR. BROWNE:
Q. Were you involved in performing the preparation at both institutions?
MR. GREEN:
A. Not at the Health Science at all. That wasn't part of my job over there. At St. Clare's, it was very infrequently. The lab assistant's job was to make up the formalin.
MR. BROWNE:
Q. Was there a particular protocol in place at St. Clare's, do you know, for --
MR. GREEN:
A. There was a recipe to follow.

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MR. BROWNE:
Q. I'm almost there. Just a few more questions. Now antigen retrieval, that was the responsibility of the technologist to do?
MR. GREEN:
A. It was.
MR. BROWNE:
Q. And I think you answered to Ms. Chaytor the other day that there was no pathologist suggested any changes to antigen retrieval. Why would a pathologist suggest changes to antigen retrieval?
MR. GREEN:
A. If a particular pathologist was fairly familiar with an antibody and it probably wasn't performing to what they expected it to perform, especially on a particular patient, they would probably suggest something different, but not -- most of the pathologists would not have that knowledge. It would be only someone like Dr. Ejeckam who would.
MR. BROWNE:
Q. Would a pathologist, in fact, be able by looking at the slide determine antigen retrieval?

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

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

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same one again, but there were definitely more technologists there than me.
MR. BROWNE:
Q. And then it mentions in the last sentence, "A logbook is available in the reporting room to record all problems". This is what we saw -- is that similar to the document we saw in the current policies in terms of reporting difficulties with slides, because if you look at top of this, it's talking about reporting the technical quality of slides, error of labelling, and so on? Is that notion --
MR. GREEN:
A. This logbook that we're referring to here is not the same logbook. The logbook here was a logbook which the pathologists would record defects and stuff like that.
MR. BROWNE:
Q. Right, so the pathologists were writing this information in?
MR. GREEN:
A. Yes.
MR. BROWNE:
Q. Presumably to get that back to technologists?
MR. GREEN:

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A. Yes.
MR. BROWNE:
Q. Okay. Were you aware of that logbook and was that information getting back to you?
MR. GREEN:
A. I became aware of the logbook at some point in time, but unless you went and physically looked at the book and looked for problems, you may not know.
MR. BROWNE:
Q. Was there anybody on the technical side in charge of looking at that and communicating that information back to technologists or was that the responsibility of the technologists to go look?
MR. GREEN:
A. Probably the responsibility of all the technologists because the -- the issues in this logbook may not necessarily refer to IHC. They would be anything from what we call floaters -- that means that a piece of tissue appears on the slide that doesn't belong on the slide, or it could be a fold in the tissue, or it could be a surgical number that went out and instead of saying 1234, it might

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

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

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MR. GREEN:
A. Thank you.
MR. BROWNE:
Q. Thank you, Commissioner.
COMMISSIONER:
Q. Thank you, Mr. Browne. Ms. Newbury.
MR. KENNETH GREEN, EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good afternoon, Mr. Green.
MR. GREEN:
A. Good afternoon.
MS. NEWBURY:
Q. Jennifer Newbury for the Canadian Cancer Society. I just have a few questions for you this morning, and I want to start first with the alarm on the DAKO System. You'd mentioned that there was an alarm that sounded when there was a problem with the reagent volume?
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. Were there any other alarms on this equipment that you're aware of?
MR. GREEN:
A. Not that I'm aware of.

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MS. NEWBURY:
Q. Okay.
MR. GREEN:
A. I had very little experience with the DAKO System, and probably Mary Butler will probably be able to answer that question better than I.
MS. NEWBURY:
Q. And do you know if there had been any policies and procedures in place that required that this machine be attended throughout the three and a half hour run or the three hour run?
MR. GREEN:
A. No, there was no requirement to stand and watch the machine or anything; it was set and once it was set to go, you could do other duties.
MS. NEWBURY:
Q. Okay, and was there any practice of trying to stay, at least, you know, in close proximity to the machine, even if you are doing other activities?
MR. GREEN:
A. No, it was never an issue.
MS. NEWBURY:
Q. So it's possible then that the alarm might

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sound and a technologist may not be there to hear it?
MR. GREEN:
A. During regular work hours with most of the IHC, if the alarm sounded, it was quite likely that somebody would be there to get the person who was doing the immunoperoxidase that week.
MS. NEWBURY:
Q. Okay. And in terms of the prospective testing after August, 2005, you had indicated that the technologists in the IHC lab continued to prepare slides for all prospective patients.
MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. Do you know if any of the pathologists were made aware that you were continuing to prepare these slides?
MR. GREEN:
A. Not that I'm aware of, we continued on doing the slides as normal, just that they weren't sent to St. Clare's.
MS. NEWBURY:
Q. Okay. And what was the purpose of continuing to do those slides?

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MR. GREEN:
A. We wanted to compare the results, when the Mount Sinai results came back with our slides that we were running, which would give us some measure of confidence in our system.
MS. NEWBURY:
Q. Okay, and that wasn't done under the guidance of any pathologist?
MR. GREEN:
A. No.
MS. NEWBURY:
Q. And you had mentioned that on occasion a pathologist would request a repeat of an ER/PR test because different results had been received than what had been expected by the pathologist?
MR. GREEN:
A. It's possible.
MS. NEWBURY:
Q. Is it possible or do you actually recall that that happened?
MR. GREEN:
A. I don't really recall specifically, no.
MS. NEWBURY:
Q. Okay, so you can't recall a pathologist ever

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elaborating on that with you, saying I expected different results for some reason or another?
MR. GREEN:
A. No. Can you ever recall a situation where there was a third request for an ER/PR test, a third repeat, I guess?
MR. GREEN:
A. Not to my knowledge.
MS. NEWBURY:
Q. Okay. You've mentioned that after the flood that occurred in the lab at Eastern Health, the medical school lab was used by the technologists from the IHC lab.
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. Do you know if the medical school has its own equipment, any of its own equipment to use for IHC testing?
MR. GREEN:
A. Not that I'm aware of.
MS. NEWBURY:
Q. Okay, so you don't know if they do any of their own testing for research purposes?

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MR. GREEN:
A. They do research at the medical school, yes.
MS. NEWBURY:
Q. Okay, but you have no idea what type of equipment, whether they use a manual process?
MR. GREEN:
A. No, I don't think it's an automated equipment.
MS. NEWBURY:
Q. Okay. Is there ever any collaboration with the medical school for any reason in relation to immunohistochemical testing?
MR. GREEN:
A. We run the--since we have an automated system, from time to time we will do research work for those people and we will run some of their antibodies.
MS. NEWBURY:
Q. Okay, and so it's done for research purposes, but it's all done by the same technologist within the IHC lab?
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. So you never have someone from the medical school coming over to use your equipment?

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MR. GREEN:
A. Never, they don't operate our equipment.
MS. NEWBURY:
Q. Is there ever any sharing of educational resources or anything of that sort for immunohistochemical testing? Do you ever attend seminars together with anyone at the medical school?
MR. GREEN:
A. Not since I've been involved?
MS. NEWBURY:
Q. And you had indicated that Dr. Robb had been doing a lot of work with respect to ER/PR testing and do you know what the purpose of this work was?
MR. GREEN:
A. No, I don't.
MS. NEWBURY:
Q. Okay, so you don't know if it was for a validation of any of your procedures or research or -
MR. GREEN:
A. I assumed it was research, one of his research projects that he had on the go.
MS. NEWBURY:

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

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MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. Would you consider that program that Eastern Health is participating in to be an external proficiency program?
MR. GREEN:
A. It is an external proficiency program, but the emphasis would be on educational content.
MS. NEWBURY:
Q. Okay, and is that educational content both for the benefit of technologists and pathologists?
MR. GREEN:
A. It is, yes.
MS. NEWBURY:
Q. And does it have any means of evaluating the technical skills of a technologist involved in immunohistochemical testing?
MR. GREEN:
A. Only from the aspect where you've got a round table-type discussion where you're comparing the results of the particular antibody and getting some various opinions on it, but it's not an independent arm's length unbiased look at the slides.

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MS. NEWBURY:
Q. Okay, so it's a group activity, first of all.
MR. GREEN:
A. Yes, exactly.
MS. NEWBURY:
Q. And when Eastern Health receives the slides that are sent from CAP, do the technologist do anything with those slides?
MR. GREEN:
A. We received the slides from CAP and then we--there is a list of antibodies that goes with each case study. The technologist job is to run those slides and what we will do, we will run some of our own--those slides don't have controls, so we run our set of controls again with those slides and they will review it with the pathologist and the technologist.
MS. NEWBURY:
Q. So are these antibodies that are currently being used by Eastern Health?
MR. GREEN:
A. Yes, they're normal every day antibodies.
MS. NEWBURY:
Q. Okay, so they are the normal antibodies that you use.

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MR. GREEN:
A. Yes, normal protocols.
MS. NEWBURY:
Q. So the technologist's role then would be to test the slides from CAP with the antibodies that you have in your lab.
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. And also to prepare your own external control slides.
MR. GREEN:
A. Controls to go with those slides.
MS. NEWBURY:
Q. Okay. And then rather than sending them off to be tested, getting a score card like with the NEQAS program, you have a system of self-assessment by comparing the results from your test -
MR. GREEN:
A. What, the way the package works, when the, you'll do a work up and do all the case studies and when we go down underneath the scope, we will look at each case study and there will be a list of--each antibody that's

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in that list will be recorded as reactive and non-reactive or any comments. At the end of the list, there are favourite interpretations. The pathologist will pick a favourite interpretation, depending on after reading the slides, depending on--they're basically diagnosed from each patient from the information that's there, and the slides themselves are not sent out. The slides themselves are kept, but the information is sent out and at the end of the day, well the end of the week when this process is over, the report will come back and you can compare your institution to the responses of all the other institutions.
MS. NEWBURY:
Q. Okay, so you run comparison, although you do send the information to the College of American Pathologists?
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. So they can check that as well?
MR. GREEN:
A. Yes, they check the information, but not

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physically the slides.
MS. NEWBURY:
Q. Okay. And with the CAP program, would there be any role in evaluating any pre-analytical work for ER/PR testing?
MR. GREEN:
A. Only if one of the cases happened to be a case study that involved doing ER/PR, which has been known to, depending upon which case studies are requested.
MS. NEWBURY:
Q. Okay.
MR. GREEN:
A. But you couldn't specifically say that, request an ER/PR case study, they determine which case studies you could do.
MS. NEWBURY:
Q. Okay, so you have no idea what's coming.
MR. GREEN:
A. No.
MS. NEWBURY:
Q. Until you receive it.
MR. GREEN:
A. That's true.
MS. NEWBURY:

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Q. And the other program that your lab participates in is the QMPLS and now I understand that that organization has an external quality assurance program, as well as the laboratory accreditation division?
MR. GREEN:
A. True.
MS. NEWBURY:
Q. Now, I understand that in 2007, you had your lab reviewed by this organization?
MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. Has your lab ever participated in any external proficiency testing programs offered under their quality assurance division?
MR. GREEN:
A. We are starting to do that now.
MS. NEWBURY:
Q. Okay, and that's with respect to ER/PR testing, specifically or IHC testing?
MR. GREEN:
A. IHC testing in general.
MS. NEWBURY:
Q. Will it include ER/PR do you know?

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MR. GREEN:
A. I would assume that will be one of the antibodies, but I am not totally sure.
MS. NEWBURY:
Q. Okay.
MR. GREEN:
A. When you talk to Dr. Ford Elms, he will be able to tell you that.
MS. NEWBURY:
Q. Okay, so he's the one that's in charge of starting that new external proficiency.
MR. GREEN:
A. He set up that one, yes.
MS. NEWBURY:
Q. And do you have any idea when that is supposed to commence?
MR. GREEN:
A. I think we've already done one test, one pilot program with those already.
MS. NEWBURY:
Q. And when was that done?
MR. GREEN:
A. Probably earlier this year.
MS. NEWBURY:
Q. Back to the College of American Pathologists,

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one quick question I overlooked. Do each of the technologists get involved in preparing the slides that are, not only the slides that are sent from CAP, but also in preparing the external control slides?
MR. GREEN:
A. That would be my--upon 'til now, that was my responsibility.
MS. NEWBURY:
Q. So you are the only technologist that has done anything with the external control slides.
MR. GREEN:
A. So far, yes.
MS. NEWBURY:
Q. So far, okay, and have any of the other technologists prepared any of the slides that are sent from CAP, in terms of applying the antibodies, or is that something that you have only done to date?
MR. GREEN:
A. When the slides are ready to be stained, whatever technologist is using the machine at that time, I just passed the slides over, say if you've got room, put these on with your regular slides and they'll be run, there's

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nothing--there's no special run or anything, they're treated the same as all other slides.
MS. NEWBURY:
Q. And is there any reason why you're the only technologist to date that has been involved in doing the external control slides for that program?
MR. GREEN:
A. When we started the program, I was given the responsibility to do that. One technologist has retired, the other technologist retiring this month and so far, I'm training in a new technologist, so it's just -
MS. NEWBURY:
Q. The timing, okay.
MR. GREEN:
A. Yes,
MS. NEWBURY:
Q. And do you know if there are plans to--when the new technologists are trained and read to go, that they will also be involved in preparing the external control slides for -
MR. GREEN:
A. They will probably be involved, but most likely we've just acquired a new position,

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Ph.D position and that person will be responsible for external quality assurance and for antibody validation.

MS. NEWBURY:

Q. Okay.

THE COMMISSIONER:

Q. I'm sorry, a new what kind of position?

MR. GREEN:

A. A Ph.D.

THE COMMISSIONER:

Q. Thank you. That person is not on board yet, is -

MR. GREEN:

A. Yes, she is, yes.

THE COMMISSIONER:

Q. Oh, okay.

MS. NEWBURY:

Q. Will there ever be a situation where there are technologists who are in the day-to-day testing, IHC testing, preparing external control slides, but not participating in the CAP program?

MR. GREEN:

A. Not in our department, now everybody will be versed on everything.

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MS. NEWBURY:

Q. Everything, okay.

MR. GREEN:

A. From all aspects.

MS. NEWBURY:

Q. And in the NEQAS program that has been used by the immunohistochemical lab, are each of the technologists also involved in the external proficiency testing offered by that program?

MR. GREEN:

A. Right now the bulk of it is handled by myself.

MS. NEWBURY:

Q. Okay, and it's the same timing issue.

MR. GREEN:

A. Same timing issue.

MS. NEWBURY:

Q. And once the new technologists come on board, do you think they will, too, be participating -

MR. GREEN:

A. They will all be versed and incorporated into the system.

MS. NEWBURY:

Q. And I understand under that program that the skills of technologists are evaluated through

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a couple of means, number one by the staining of the slides that are sent by the UK to Eastern Health.

MR. GREEN:

A. Yes.

MS. NEWBURY:

Q. And they ultimately get evaluated because they do get sent back to the UK, and then the preparation and staining of in-house external controls, which originate from Eastern Health and are also sent to the UK for evaluation.

MR. GREEN:

A. That's true.

MS. NEWBURY:

Q. Okay, and are the in-house external controls used for this external proficiency testing always used specifically for that purpose?

MR. GREEN:

A. They are the regular controls that we run every day with everything else, they're no different.

MS. NEWBURY:

Q. And are older control slides ever used for the NEQAS external proficiency testing? Do you ever go back into your bank of controls and

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look for something?

MR. GREEN:

A. No, we'll use current slides.

MS. NEWBURY:

Q. And there's just one more area, I just wanted to make sure that I understand the controls that are currently being used because I got a little confused between last week and today. As I understand your evidence, there are currently four patient specific slides being used for ER and PR testing, two for ER and two for PR testing and these are specific to the patient?

MR. GREEN:

A. That's true.

MS. NEWBURY:

Q. And also there are two triple batch control slides used, run with each batch of tests?

MR. GREEN:

A. That's true.

MS. NEWBURY:

Q. Okay, and on one of the patient specific slides for ER testing, that slide would contain patient tissue, which includes the tumour, plus normal epithelial tissue which

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acts as an internal positive control?
MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. That's one of the specimens on, one of the patient specific slides. And on that same slide, is there an external positive control, which is a strong positive control?
MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. Okay, and then the second patient specific slide for the ER test contains a patient tissue without the primary antibody applied?
MR. GREEN:
A. That's true, that's the negative control.
MS. NEWBURY:
Q. And that's the negative internal control?
MR. GREEN:
A. That's the negative patient control.
MS. NEWBURY:
Q. Okay.
MR. GREEN:
A. It's a negative patient reagent control.
MS. NEWBURY:

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Q. Okay. And it is a piece of tissue from that very same patient.
MR. GREEN:
A. Yes, when the block is cut, one piece is put on a tissue by, a slide by itself and the very next piece is put on--or they put the positive control.
MS. NEWBURY:
Q. And the reason why a separate slide is used for the negative internal control is because you don't apply the primary antibody -
MR. GREEN:
A. Primary antibody, there's no primary antibodies applied, there should be no antigen antibody reaction.
MS. NEWBURY:
Q. Okay, and is this normal patient tissue that's used for that negative control?
MR. GREEN:
A. It's the same block that we're testing for ER/PR.
MS. NEWBURY:
Q. So is there a need to make sure that it has tumour and normal tissue or one or the other?
MR. GREEN:

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A. The pathologists would choose a block that we would run on ER/PR, so they would know that from looking at their H&E slide, they would submit the appropriate block.
MS. NEWBURY:
Q. Okay, so they pick then, the piece of tissue that acts as the negative internal control, which is placed on the separate slide.
MR. GREEN:
A. Yes, that's run by the pathologist.
MS. NEWBURY:
Q. And then the triple batch control would be used for a number of patients who are all being tested at the same time?
MR. GREEN:
A. For all the patients that are run that week.
MS. NEWBURY:
Q. And that slide would contain three external controls, the one which is ER negative.
MR. GREEN:
A. True.
MS. NEWBURY:
Q. One which is ER intermediate.
MR. GREEN:
A. True.

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MS. NEWBURY:
Q. And the third is ER positive?
MR. GREEN:
A. That's correct.
MS. NEWBURY:
Q. That's a strong positive, I take it?
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. And then the PR slides is basically the same as with the ER -
MR. GREEN:
A. Same thing, yeah.
MS. NEWBURY:
Q. Just that you use a PR antibody, an antibody for PR testing?
MR. GREEN:
A. That's true.
MS. NEWBURY:
Q. And you use PR positive specimens as external controls, is that -
MR. GREEN:
A. Yes.
MS. NEWBURY:
Q. Thank you, I just wanted to be clear on that.

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Those are all the questions I have, thank you very much.

MR. GREEN:

A. Thank you.

THE COMMISSIONER:

Q. Mr. Pritchett, have you changed your mind or are you still not wishing to question?

MR. PRITCHETT:

Q. I have no questions, Commissioner.

THE COMMISSIONER:

Q. Mr. Crosbie, do you have any questions for this witness?

CROSBIE, Q.C.:

Q. No questions, thank you.

THE COMMISSIONER:

Q. Are you still of the same view, Mr. Pike?

MR. PIKE:

Q. I stand firm on my (unintelligible).

THE COMMISSIONER:

Q. All right.

MR. SIMMONS:

Q. Thank you, Commissioner.

MR. KENNETH GREEN, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Good afternoon, Mr. Green. I have just a few

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things for you.

MR. GREEN:

A. Good afternoon.

MR. SIMMONS:

Q. First of all, can we have Exhibit P-0113, please? Mr. Green, Ms. Chaytor showed you this exhibit which has a number of memos on it. And the first two she showed you were ones from Dr. Ejeckam on April 4th, 2003 and May 2nd, 2003 and I believe you told us you hadn't seen either of those before.

MR. GREEN:

A. That's correct.

MR. SIMMONS:

Q. There is a third memo and it is here on page five and it's dated June 19th, 2003. Now, I have had an opportunity to show you this memo prior to your coming here to give evidence. And can you tell me whether you recognize that memo, having seen it on any previous occasion?

MR. GREEN:

A. I have seen this memo.

MR. SIMMONS:

Q. Can you tell me the circumstances under which you saw it, please?

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MR. GREEN:

A. I've had occasion to go to Dr. Ejeckam's office to bring some IHC slides for him to look at and he was in one of his moods that day, which was kind of agitated. So, after he looked at the slides and a conversation ensued and he goes to this filing cabinet and he shows me this memo. And he was kind of upset because there were things he wanted done and they didn't seem to be happening as fast he'd like them to happen. So -

MR. SIMMONS:

Q. Do you know what sort of things he wanted done?

MR. GREEN:

A. He wanted a separate IHC lab. He wanted dedicated technologists for the area and those were the type of things he was looking for.

MR. SIMMONS:

Q. Okay. Was this the first you'd heard of him speak about wanting those things done or was that an issue that you'd know he had -

MR. GREEN:

A. I was aware that those were his feelings.

MR. SIMMONS:

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Q. Okay. This memo is dated June, 2003. Do you know how close it was to that time that he showed you the memo?

MR. GREEN:

A. I don't know exactly because at the time I saw the memo, the time didn't make a difference to me, you know.

MR. SIMMONS:

Q. Did you see it before the IHC operation was moved into the separate space that it occupies now?

MR. GREEN:

A. I don't think we were separate at that time.

MR. SIMMONS:

Q. Okay. So, that would have been before the Ventana machine was acquired, in that case, would it have been?

MR. GREEN:

A. June 19th, 2003, probably.

MR. SIMMONS:

Q. Okay. Now, when Dr. Ejeckam showed you the memo under those circumstances, did you have any discussion or did he give you any explanation of the circumstances that led to him writing that memo?

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MR. GREEN:
A. He was probably upset and probably went to administration or to management and there probably weren't funds there and he wanted this stuff done and they seemed to be dragging their heels. And the might have wanted to light a fire under them to get them to move ahead.
MR. SIMMONS:
Q. Did he tell you anything about having any concerns or not about any of the testing that had been done previously in the lab?
MR. GREEN:
A. No, he was concerned about changes, the physical location and stuff like the, he wanted done.
MR. SIMMONS:
Q. Did he tell you anything about having suspended any of the testing at any point prior to this?
MR. GREEN:
A. No.
MR. SIMMONS:
Q. Okay. Exhibit P-2149, please, page 24. Ms. Chaytor showed you this requisition also.

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It's dated June 21st, 2002. This would have been how long after you moved from St. Clare's to the Health Science Centre?
MR. GREEN:
A. I moved over in April of 2002.
MR. SIMMONS:
Q. So, this would have been within a couple of months of you first beginning to do IHC testing.
MR. GREEN:
A. Yes.
MR. SIMMONS:
Q. The pathologist there is Dr. Dalton. Do you know where Dr. Dalton practised medicine?
MR. GREEN:
A. Central Newfoundland.
MR. SIMMONS:
Q. And when you go down to the side, there's the notation that you were referred to that says controls checked, KG. And I believe you identified that as being your initials.
MR. GREEN:
A. That would be mine.
MR. SIMMONS:
Q. Okay. And I think you identified earlier that

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that would mean that you looked at the positive control slide before returning this requisition with slides to Dr. Dalton.
MR. GREEN:
A. That would be the most likely prospect.
MR. SIMMONS:
Q. Okay. Now, does this mean that you looked at the control slide and kept it in St. John's or does it mean you looked at the control slide before sending it to Dr. Dalton with slides for the patient sample?
MR. GREEN:
A. Looking at the time on that requisition being over there only probably two months, I don't think I would have had the knowledge or the expertise to check it myself. I probably sent it off with the surgical.
MR. SIMMONS:
Q. Okay. So, you're saying it's most likely that the control slide went to Dr. Dalton despite the fact that you've noted "checked controls" -
MR. GREEN:
A. Yes, I probably--yes. That's the most likely case.

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MR. SIMMONS:
Q. Yes. Now, can you recall, on any occasion, ever checking a control yourself for an out-of-town test and not having it also checked by a pathologist?
MR. GREEN:
A. No.
THE COMMISSIONER:
Q. Sorry, can you run that by me again? I thought we were saying originally that when you said controls checked, KG, that was indicating that I could conclude that only you had checked them within the St. John's.
MR. GREEN:
A. Within town.
THE COMMISSIONER:
Q. Okay.
MR. GREEN:
A. Out-of-town, we always ran them by a pathologist.
MR. SIMMONS:
Q. And the difference -
THE COMMISSIONER:
Q. So, I guess that's my question back again. When it says "controls checked, KG", does that

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mean that you checked them or that somebody else checked them and you wrote your initials there?

MR. GREEN:

A. It could have been someone could have checked them, I could have checked them to make sure there was brown staining and send them off with the surgical -

THE COMMISSIONER:

Q. The writing under that where it says, "slides and block returned".

MR. GREEN:

A. Yes.

THE COMMISSIONER:

Q. Is that yours?

MR. GREEN:

A. Yes.

THE COMMISSIONER:

Q. So, why wouldn't you write slides and block and control returned or is slides meant to include control?

MR. GREEN:

A. Well, when we wrote slides and blocks returned, we would send the slides and block back to whatever institution sent them in.

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Sometimes you would hold the blocks for a week or so, or sometimes we would send the slides and blocks out. If they wanted more work, they'd have to send the slides, blocks back in. So, that would expedite it. And sometimes they would call looking for their slides and blocks. And if we didn't write down that we sent them back, sometimes they would blame us for not sending them back.

THE COMMISSIONER:

Q. Okay. When you write "slides and block", is the word "slides" large enough to encompass the controls or if you had sent controls separately, would you note that as "controls, slides and block"?

MR. GREEN:

A. I can't be sure if it's--I can't be specific either way.

THE COMMISSIONER:

Q. All right. Thank you.

MR. SIMMONS:

Q. And just to be clear, can you recall ever sending slides with patient tissue results on it to an out-of-town pathologist with either, without sending the controls or without having

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a St. John's pathologist check the controls?

MR. GREEN:

A. We have sent them out after we started using the Ventana system and putting controls on the slides.

MR. SIMMONS:

Q. And that's the only circumstance?

MR. GREEN:

A. Yes. It would be routinely--after we start putting controls on the slides, we would send them out to those out-of-town hospitals.

MR. SIMMONS:

Q. Okay. You told us about the training you received when you moved from St. Clare's to the General Hospital site, from Ms. Welsh and that was, I guess, essentially on-the-job training.

MR. GREEN:

A. That's true.

MR. SIMMONS:

Q. Now, at that point you had considerable experience as a laboratory technologist. I believe you'd also had ten years involved in the provincial association -

MR. GREEN:

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A. That's true.

MR. SIMMONS:

Q. - as well, on the executive and as president. At that time, do you know if there were any educational institutions, any schools, colleges or otherwise where a person could go for a course of IHC training?

MR. GREEN:

A. To my knowledge, there was no formal training available for IHC.

MR. SIMMONS:

Q. Right. So, was there any alternative available other than on-the-job training in order to learn to do IHC?

MR. GREEN:

A. Not that I'm aware of.

MR. SIMMONS:

Q. Okay. And the opportunity that you had eventually to go to Jewish General and observe their immunohistochemistry laboratory there, was there anything really different about that or was that really an opportunity for on-the-job training, but at a different institution other than your own.

MR. GREEN:

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A. On-the-job training at a different institution who use the same equipment as we did.

MR. SIMMONS:

Q. Okay. Now, there's two new technologists now in your laboratory; one has been there for six months and one who's fairly new. Is there anywhere else you can turn now to send them, either than for annual conventions, such as NSH, or perhaps to a manufacturers facility. Is there anywhere else you can send them, to a school, for them to learn IHC training or is the on-the-job training -

MR. GREEN:

A. The on-the-training is the only training available. There's no formal training in IHC.

MR. SIMMONS:

Q. Thank you, very much, Mr. Green. I don't know if you have anything else that you'd like to add yourself or if there is any other statement that you'd like to make -

MR. GREEN:

A. Well, just -

MR. SIMMONS:

Q. - a chance to say enough already.

MR. GREEN:

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A. Well, I just got a couple of comments. They are going to be very brief. I would like to reiterate the issue of training. All our laboratory technologists are trained and qualified to work in our laboratories. They have all completed the required education and have passed national exams the same as our counterparts throughout Canada. The training we receive on the job and on new equipment is the same in every laboratory. People are trained and they train their colleagues. There are no formal training institutions for IHC. We, who work in pathology are reminded every day with every specimen, the importance of doing our work to the best of our ability. For we all have families who are affected by cancer, by sickness and disease.

I would like to thank the Commission for giving me the opportunity to give some insight into the day-to-day workings of the pathology lab. Thank you.

MR. SIMMONS:

Q. Thank you very much, Mr. Green.

THE COMMISSIONER:

Q. Ms. Chaytor, is anything arising?

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CHAYTOR, Q.C.:

Q. Just a couple of points.

MR. KENNETH GREEN, RE-EXAMINATION BY SANDRA CHAYTOR, Q.C.

CHAYTOR, Q.C.:

Q. Mr. Green, you indicated that Western would send in their own slides to be stained.

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. And was that throughout the whole time that you were there from 2002, when you first went there, I mean?

MR. GREEN:

A. Probably more closely to recent--I've noticed it more recently than previously.

CHAYTOR, Q.C.:

Q. Okay. And so up until the time that it shut down--well, you weren't doing it since 2007, they didn't resume with you in 2007. So, when you say more recently, you mean 2005, back in 2005, back August -

MR. GREEN:

A. Not back that far.

CHAYTOR, Q.C.:

Q. Not back that far. So, when is it that

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Western would send in their own slides for staining?

MR. GREEN:

A. When?

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. I'm not sure specifically what date. We would have a problem with staining slides that weren't on plus slides because chances are we would lose some of the tissue. So, we made a point of sending out a package of our slides for them to use with the information where they could order their own and that's what they do to this day.

CHAYTOR, Q.C.:

Q. Okay, but they don't -

THE COMMISSIONER:

Q. Is this for IHC generally?

MR. GREEN:

A. For IHC only.

CHAYTOR, Q.C.:

Q. Were they doing that then for ER/PR tests, including ER/PR tests?

MR. GREEN:

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A. Not usually. They would usually send their own blocks.
CHAYTOR, Q.C.:
Q. They'd send blocks--that's what I'm trying to figure out, if there were certain hospitals which were sending actual slides to you to be stained as opposed to the blocks for you to create the slides, for ER/PR testing in particular?
MR. GREEN:
A. Western Memorial is the only one that comes to mind. Sometimes they would have a particular piece of tissue and the only slides they would have would probably be the ones that were already on slides. So, then you would have to try to do a IHC stain on some of those.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. So, I can't specifically say that there were any ER/PR slides that we handled that way.
CHAYTOR, Q.C.:
Q. Okay. So, you're not saying that Western ever sent slides for ER/PR testing, you created the slides for Western.

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MR. GREEN:
A. Usually, yes.
CHAYTOR, Q.C.:
Q. For ER/PR?
MR. GREEN:
A. That would be the norm.
CHAYTOR, Q.C.:
Q. Now, you also said in the beginning, St. Clare's would also send their slides. When you're back at St. Clare's, before 2002, and ordering ER/PR testing or arranging for that to happen for the pathologists at St. Clare's, were you sending slides to the Health Science to be stained or were you sending blocks?
MR. GREEN:
A. In the beginning we would send slides, sometime during the course of events, we stopped sending slides and sent the tissue over there.
CHAYTOR, Q.C.:
Q. Okay. And how close to when you left in 2002--I take it when you left in 2002, the practice was to send blocks?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. Okay. And how long have that practice been going on that it was blocks, not slides?
MR. GREEN:
A. I'm not exactly sure. You could probably check with Les on that; Les will probably know more about that.
CHAYTOR, Q.C.:
Q. Okay. You mentioned that Dr. Ejeckam--this was a question Mr. Browne asked you about antigen retrieval and you said someone like Dr. Ejeckam would have the knowledged base to be able to determine if you should be changing or tweaking your antigen retrieval times.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. What were you able to tell or what do you know about that level of knowledge of other pathologists and why is it that you think they might not have that knowledge base?
MR. GREEN:
A. Unless they had the technical background in IHC, they probably wouldn't know the day-to-day operations which they would not know which

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antibody required antigen retrieval unless they specifically looked it up. It would not be in their area of expertise.
CHAYTOR, Q.C.:
Q. But have you had enough interaction with them to be able to make that determination?
MR. GREEN:
A. Are you asking for my opinion?
CHAYTOR, Q.C.:
Q. Yes. You said that it depends on their knowledge base. And I would take it that you know Dr. Ejeckam well enough to say it.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So, I'm just wondering well what's your source of knowledge as to the knowledge base of other pathologists with respect to IHC?
MR. GREEN:
A. I wouldn't know the knowledge base of any pathologists.
CHAYTOR, Q.C.:
Q. Okay. And I take it now you would have some familiarity with Dr. Elms however, and his knowledge base?

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MR. GREEN:
A. Yes.
THE COMMISSIONER:
Q. So, that's a question of somebody really turning up in the lab and demonstrating and their interest in IHC, is it?
MR. GREEN:
A. Yes, they would have to ask a particular question, be specific enough to ask that question about an antibody.
CHAYTOR, Q.C.:
Q. And if we could have please, P-1576. Mr. Browne, I believe it was also took you to this document, page three, the reference to "a log book is available in the reporting room to record all problems". And you became aware, you said, at some point that such a log book existed. Was that a log book only for pathologists to record issues in or was that also a log book for technologists to record -
MR. GREEN:
A. Technologists would not record in that book.
CHAYTOR, Q.C.:
Q. Okay. So, this was left in the reporting room. And if the pathologist had an issue,

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

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MR. GREEN:
A. I'm not sure whose responsibility it was to check it and relay it back to the staff.
CHAYTOR, Q.C.:
Q. Okay. And did that happen? Did you get any feedback back from this logbook? Was anybody checking it and letting the technologists know what was written?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. And are you aware whether or not any problems with respect to the IHC was recorded in this book?
MR. GREEN:
A. I'm not aware of any.
CHAYTOR, Q.C.:
Q. Do you know if these--it's probably books at this point--do you know if this logbook or books still exists?
MR. GREEN:
A. I don't--I haven't seen it. I don't think it exists.
CHAYTOR, Q.C.:
Q. Why is that? Have you made inquiries about

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it?
MR. GREEN:
A. \No, I haven't seen it in the recording room.
CHAYTOR, Q.C.:
Q. And is there any similar book or any similar system now for pathologists to relay concerns to the technologists?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. So, if they have any complaints today, how is that handled?
MR. GREEN:
A. If there's a--if a pathologist has a complaint about the quality of a slide, they will usually ask for a re-cut which means that they will submit a form and sometimes in that form they will put on it, query floater or something like that.
CHAYTOR, Q.C.:
Q. Okay. The issue with respect to--and this was a question through Ms. Newbury, the issue of continuing to prepare slides beyond August 2005 for the prospective slides that went on to Mount Sinai for the prospective testing.

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You've indicated that that wasn't done under the guidance of any pathologists. Did anyone ask you to do that?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So, this is something the technologists took on themselves to do?
MR. GREEN:
A. We only received one memo. And the memo said that there would be a hold on reporting. So, nobody ever told us to stop staining the slides.
CHAYTOR, Q.C.:
Q. So, that's how you interpreted Dr. Cook's August 8th memo, that you would continue to prepare the slides, but that the pathologists wouldn't be reporting?
MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. And there was no communication to the contrary to the technical staff. So, you kept preparing the slides.
MR. GREEN:

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

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Ejeckam?
MR. GREEN:
A. I don't necessarily think that it wasn't serious. Does this memo have two pages?
CHAYTOR, Q.C.:
Q. This memo has at least two, let's just see, three pages.
MR. GREEN:
A. I think the third page is the most -
CHAYTOR, Q.C.:
Q. This is the third page here.
MR. GREEN:
A. Yes. This was the area that he seemed to concentrate on.
CHAYTOR, Q.C.:
Q. On the third page?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay. So, this page here, for example, number six, he says "it is pertinent to mention that results of immuno stains are extremely important in histopathologic diagnosis, especially where classification of lymphomas and determination of benign or malignancy of

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

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Q. Okay. So, you saw Dr. Ejeckam with the memo.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And he read out portions of this to you?
MR. GREEN:
A. He read out bits and pieces of it.
CHAYTOR, Q.C.:
Q. And through that encounter with Dr. Ejeckam, were you concerned about the product that your laboratory was producing?
MR. GREEN:
A. I didn't get that impression from him. I got the impression from him that he was frustrated at the lack of, at the speed at which the things that he wanted, if at all, were being performed.
CHAYTOR, Q.C.:
Q. Did you, after speaking with Dr. Ejeckam that day, relay that information to anybody else?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So you didn't speak to your manager, Mr. Dyer about it?

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MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And you didn't tell any of the other the lab technologists what Dr. Ejeckam had just told you?
MR. GREEN:
A. No, because I didn't know if he showed me that letter in confidence because I knew who the letter was addressed to and so, I didn't discuss it with anybody.
CHAYTOR, Q.C.:
Q. Those are my questions, Commissioner, thank you very much.
THE COMMISSIONER:
Q. Mr. Green, thank you very much for assisting us in this process.
MR. GREEN:
A. Thank you.
CHAYTOR, Q.C.:
Q. Thank you, Mr. Green.
MR. GREEN:
A. Thank you.
THE COMMISSIONER:
Q. Why don't we take the afternoon break and then

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we can proceed with the next witness.
(RECESS)
THE COMMISSIONER:
Q. Ms. Chaytor?
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. The next witness is Mr. Les Simms.
MR. LESLIE SIMMS, SWORN, EXAMINATION BY SANDRA CHAYTOR, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
MR. SIMMS:
A. Leslie Simms, L-E-S-L-I-E, Simms, S-I-M-M-S.
REGISTRAR:
Q. Thank you.
MR. SIMMS:
A. Thank you.
CHAYTOR, Q.C.:
Q. Good afternoon, Mr. Simms.
MR. SIMMS:
A. Good afternoon, Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Commissioner, there's one new exhibit that I would ask, please, to have entered through

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

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Came to St. John's, worked at the Grace for a while in physiotherapy, then went into the nursing assistant program at the Grace, and that's where I was introduced to the laboratory, and always having a fascination with science, I thought this would be interesting, so I applied to CONA, College of Trades and Technology at that time, where there was a three-year program, a six-semester program being offered, and I applied and met the requirements, did that program, graduated in 1972, and after writing the provincial and national examinations, which qualified me to work anywhere in Canada, some parts of the U.S.A. and the United Kingdom. Took a job back to St. Anthony and mainly to get some experience in all departments, because in the smaller hospitals, a new technologist coming out would practice in all departments. I worked mainly in hematology, but continued to do all departments and cover call.

Job opening at--always was mostly interested in pathology. St. Clare's had an opening in 1977 that I applied for and got that position. So I moved in December of '77,

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

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new, and the IHC. And I stayed at the Health Science until I retired, May the 30th this year.

CHAYTOR, Q.C.:

Q. Okay, so just this past six weeks?

MR. SIMMS:

A. Right.

CHAYTOR, Q.C.:

Q. Okay. Mr. Simms, you indicated that you were most interested in pathology and when you saw the opening then, I believe you said it was 1977, you applied and was successful in getting the position at St. Clare's. In your course of studies, did you concentrate at all in pathology? Was there any such thing as a concentration?

MR. SIMMS:

A. No, there was no concentration in particular in pathology, but no more than any of the other departments, in the other disciplines.

CHAYTOR, Q.C.:

Q. And your program back then was a three-year program?

MR. SIMMS:

A. Three-year program, full three years. There

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was six semesters.

CHAYTOR, Q.C.:

Q. Okay, and you wrote both a provincial and a national exam?

MR. SIMMS:

A. I did.

CHAYTOR, Q.C.:

Q. And the national exam entitled you, I take it, to work wherever in the country?

MR. SIMMS:

A. Wherever in the country.

CHAYTOR, Q.C.:

Q. Okay, and you were persuaded, you said, to move after over 25 years at St. Clare's. You were persuaded to move to the Health Sciences, and who persuaded you to do that?

MR. SIMMS:

A. Barry Dyer.

CHAYTOR, Q.C.:

Q. Barry Dyer, okay.

MR. SIMMS:

A. Who was the manager at the Health Science at that time.

CHAYTOR, Q.C.:

Q. And was there any particular reason why you

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were targeted for that position?
MR. SIMMS:
A. Because I was the most senior person around in pathology at that time.
CHAYTOR, Q.C.:
Q. Okay, and I take it in terms of looking for someone who would have experience in IHC, those technologists would be few and far between?
MR. SIMMS:
A. There were none.
CHAYTOR, Q.C.:
Q. There were none, okay. So you were senior and it's not like there was anyone else out there that could have had IHC experience?
MR. SIMMS:
A. Right.
CHAYTOR, Q.C.:
Q. Okay. Now I understand there had been a brief period of time at St. Clare's when IHC was introduced there. What do you recall about those days and what experience or exposure did you have to IHC at that point in time?
MR. SIMMS:
A. There was very little exposure. We decided--

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

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anybody showing the lead?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. And you say the little bit that you did learn about it was self taught through reading whatever was involved. Was it done through kits at that point in time?
MR. SIMMS:
A. It was kits at that time.
CHAYTOR, Q.C.:
Q. And so you read whatever instructions came with the kits?
MR. SIMMS:
A. The spec sheets were invaluable.
CHAYTOR, Q.C.:
Q. Okay, and I take it nobody else had had any experience with IHC, none of the other technical staff?
MR. SIMMS:
A. At St. Clare's?
CHAYTOR, Q.C.:
Q. At St. Clare's, at that time?
MR. SIMMS:
A. No.

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CHAYTOR, Q.C.:
Q. Okay, and was there any learnings from--Health Science, I guess, was already doing the IHC. Was there any communication with the Health Sciences to try and assist St. Clare's in that?
MR. SIMMS:
A. We would talk to Peggy and Mary. When I say "we" I mean Ken and I, right, we would talk to Mary and Peggy if we had any questions that we thought, you know, they could help us with.
CHAYTOR, Q.C.:
Q. And when you were at St. Clare's, your position there, other than IHC, that was only a six-month--were you assigned specifically to IHC or that was just part of your overall duties?
MR. SIMMS:
A. That was part of our overall duties, Ken and myself.
CHAYTOR, Q.C.:
Q. And -
MR. SIMMS:
A. Because at that time, around that time, Ken and I worked together for 30 plus years and

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even at St. Clare's, there was basically, you know, most of the time, only two of us. So we sort of shared--we sort of did whatever.

CHAYTOR, Q.C.:

Q. So two of you in the pathology lab?

MR. SIMMS:

A. Yes, but there was assistants and so on, but there was two technologists.

CHAYTOR, Q.C.:

Q. Okay. There were pathology assistants?

MR. SIMMS:

A. No, no, laboratory assistants.

CHAYTOR, Q.C.:

Q. Okay, and did you--you indicated coming over to the Health Sciences, you had to also then gross. So there wasn't--grossing wasn't part of your duties at St. Clare's, I take it?

MR. SIMMS:

A. Not at St. Clare's. I assisted with the gross, but that was only to put specimens in cassettes and label cassettes, etcetera, but no direct involvement with the gross, no.

CHAYTOR, Q.C.:

Q. So at St. Clare's, in the pathology department, you'd be responsible though for

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doing blocks, slides, special stains, H & E slides, all of that would have been part of your regular duties?

MR. SIMMS:

A. Everything that was involved in pathology.

CHAYTOR, Q.C.:

Q. Okay, all right. And you retired. Did you eventually become a laboratory technician two?

MR. SIMMS:

A. That came about--it's ironic because that was--part of getting that reclassification was the fact that I was a senior tech at the time at St. Clare's and when we introduced the immunohisto--the immunoperoxidase, it was called then, staining, that was added to my duties, so that I was upgraded to a technologist two.

CHAYTOR, Q.C.:

Q. And what did it mean to be a technologist two?

MR. SIMMS:

A. You would do more of the specialized area. More of the general work would be left for other people to do.

CHAYTOR, Q.C.:

Q. So in reality, did--how did your job change?

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MR. SIMMS:

A. Not a great deal.

CHAYTOR, Q.C.:

Q. Okay. So after St. Clare's stopped doing IHC or I take it that St. Clare's continued to use the Health Sciences for most, if not all, of its IHC requirements?

MR. SIMMS:

A. All of it, yes.

CHAYTOR, Q.C.:

Q. Okay, and would you be involved in arranging that, arranging for slides to be sent over?

MR. SIMMS:

A. For, and I can't remember how long, we were sending slides over and I would be involved in that too, along with Ken, and then somewhere along the line, we just sent blocks. I think because the Health Science, Peggy and Mary, I think, wanted to keep everything in line so that they would cut the blocks along with their own. They went on their own slides and so on. So we would--at the point, we were only sending blocks.

CHAYTOR, Q.C.:

Q. Yes, so that came up while you were here today

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with Mr. Green's evidence, that at some point, St. Clare's was actually--you were still producing your own slides and just sending the slides for IHC staining?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

Q. And are you able to shed any light on when that practice stopped and you started actually sending blocks over to be processed?

MR. SIMMS:

A. Period of time wise you mean?

CHAYTOR, Q.C.:

Q. Yes.

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and you, yourself, moved in 2003?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

Q. So it had stopped before that?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

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Q. When you arrived at the Health Science in 2003, St. Clare's was then sending blocks, I take it?
MR. SIMMS:
A. Um-hm. We were only sending slides for a short period of time. I don't remember when we actually--when we started sending to the Health Science. I gather it was the--I don't know when we started sending, but it was only a short period of time we were sending slides.
CHAYTOR, Q.C.:
Q. Okay. When did you actually start--what was your start date at the Health Sciences Centre?
MR. SIMMS:
A. Paddy's Day, that's why I remember. March the 18th, 2003.
CHAYTOR, Q.C.:
Q. March 18th, 2003?
MR. SIMMS:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, and so when you went there, what training did you then receive in IHC?
MR. SIMMS:
A. My training then was--Peggy was the lead tech

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there, that was my understanding from when I moved in, and I was--the first week I was there, I don't think I was on IHC the first week I was there. I think it was the second week, and I followed Peggy around while she actually did the stains. I made my own notes and followed there and for that week and the following week, if I remember correctly, then I did them and Peggy kept an eye on what I was doing.
CHAYTOR, Q.C.:
Q. Okay. So your first week, you think you were doing something other than IHC?
MR. SIMMS:
A. Probably just getting orientated into the laboratory.
CHAYTOR, Q.C.:
Q. Into the lab, yes, okay, and the second week then, you job shadowed, for lack of a better term, you job shadowed Peggy Welsh during the IHC procedures?
MR. SIMMS:
A. That's right.
CHAYTOR, Q.C.:
Q. And then the week after, you went back to the

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

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or Mary.
CHAYTOR, Q.C.:
Q. Okay, and so they were nearby?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. Even though they weren't in the rotation, you were in there by yourself, you could check with them?
MR. SIMMS:
A. They were in shouting distance.
CHAYTOR, Q.C.:
Q. Okay, and did you frequently then have to consult with them or ask them questions?
MR. SIMMS:
A. No, not often, because what I did first, I remember taking--setting up my run for the next day or whatever, I would take my work home with me and go over it three or four times to make sure that the dilutions were correct and I had everything lined up properly and so on.
CHAYTOR, Q.C.:
Q. Okay, and using the DAKO machine, I take it, would that have been the first time you used

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such a machine?
MR. SIMMS:
A. Yes, it was.
CHAYTOR, Q.C.:
Q. Okay, and Peggy taught you to use that, I take it?
MR. SIMMS:
A. She did.
CHAYTOR, Q.C.:
Q. Okay, and other than actually using the machine, what else were you--what other instruction, in terms of IHC, were you given or was the focus mostly on the operation of the machine or were you given anything in terms of the theory, for example, of IHC?
MR. SIMMS:
A. The focus was mainly on the machine, the operation of the machine. It was my own, my responsibility to find textbooks and so on and the theory, if I was so interested, you know, in the theory at that time, I would focus--it was my responsibility to go, find textbooks and journals and whatever else.
CHAYTOR, Q.C.:
Q. And did you do that?

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MR. SIMMS:
A. Yes, I did.
CHAYTOR, Q.C.:
Q. So you sought out extra information?
MR. SIMMS:
A. I sought out extra reading material, yes.
CHAYTOR, Q.C.:
Q. And when you began then in March of 2003, how many antibodies were there approximately?
MR. SIMMS:
A. Between 70 and 80.
CHAYTOR, Q.C.:
Q. And what documentation--you say you took your own notes. Were you provided any documentation as to how to do the procedures and the protocols for the 70 to 80 antibodies?
MR. SIMMS:
A. Only on the technical manual. There was no written policy or written procedure that you could go and pick up and say, you know, that I could--that I knew of anyway, so I made my own notes in conjunction with what Peggy would state.
CHAYTOR, Q.C.:
Q. Okay, and what was the technical manual? What

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was that?
MR. SIMMS:
A. The machine, the manual that came with the machine, you know, troubleshooting the machine and operating the machine and what everything was used for, basically the technical manual.
CHAYTOR, Q.C.:
Q. Okay, and how about the actual protocols for the antibodies, where were those?
MR. SIMMS:
A. They were all fit in--they were in the machine. I can't even--I can never remember. Remember, see, for one thing that now we're talking about a very short period of time, I was involved in the DAKO bit, right. I mean, you're only talking eight to ten months.
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. So it was very quick and I was just getting my feet wet.
CHAYTOR, Q.C.:
Q. So it's eight to ten months from March 2003 for the rest of 2003.
MR. SIMMS:

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A. Until we got into the Ventana.
CHAYTOR, Q.C.:
Q. It's almost a year. It's April '04 then before the Ventana comes on.
MR. SIMMS:
A. Yeah, and in that year, I would only do it every third week.
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. So I probably only did anywhere from 12 to 15 runs.
CHAYTOR, Q.C.:
Q. Right, and I take it in that, the week that you watched Ms. Welsh and then a week that you did the work and she watched, you would not have processed all 70 or 80 antibodies in those two weeks?
MR. SIMMS:
A. Oh no, absolutely not.
CHAYTOR, Q.C.:
Q. Okay, and so in terms of how you would know to do the other--how to do the other antibodies, those protocols, you're saying would have been put into the computer of the machine?

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MR. SIMMS:
A. They're all put into the computer and basically the protocols for most of the antibodies are pretty well all the same, except for antigen retrieval.
CHAYTOR, Q.C.:
Q. Okay, and what were you taught about antigen retrieval? Had you been involved for--first of all, had you been involved for--first of all, had you been involved in antigen retrieval prior to 2003?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and what did you--what did Ms. Welsh then teach you about antigen retrieval?
MR. SIMMS:
A. We had a water bath and I called it the boiling technique, where we boil it in a buffer, in a buffer for--citrate buffer for 20 minutes and then let it cool off to room temperature.
CHAYTOR, Q.C.:
Q. And then you let it cool to room temperature?
MR. SIMMS:

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A. Yes.
CHAYTOR, Q.C.:
Q. And 20 minutes at what temperature?
MR. SIMMS:
A. 97 to 100.
CHAYTOR, Q.C.:
Q. And how stringent were you or how religious were you in terms of did you understand the timing and the temperature had to be strictly adhered to?
MR. SIMMS:
A. Very stringent.
CHAYTOR, Q.C.:
Q. And you understood that from Ms. Welsh?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. And what if -- was there any alarm system that would let you know when your twenty minutes were up or how would you do that? Was there a timer?
MR. SIMMS:
A. We had timers. We had timers in the lab, and being we had a timer, I would always check. I would always wear a watch as well, right. So

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there was a couple of checks that I did. I would note the time -- what I would usually do is note the time on a piece of paper or on my sheet that I was -- the day's log. I would note the time that I put them in, plus set the clock, or the timer.
CHAYTOR, Q.C.:
Q. And the ER and PR, of course, are two antibodies that require antigen retrieval?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. And while watching Ms. Welsh that first week, do you know whether or not she did any ER or PRs?
MR. SIMMS:
A. I couldn't tell because ER/PR at that time was just another -- you know, to me, it was just another antibody. There was nothing specific, nothing different about the ER/PR at that point in time.
CHAYTOR, Q.C.:
Q. So there were others, I take it, that also required antigen retrieval besides ER/PR?
MR. SIMMS:

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A. Yes.
CHAYTOR, Q.C.:
Q. So you don't know whether or not the first time you did ER or PR tests, that you were on your own doing it, or whether or not it was done alongside Ms. Welsh?
MR. SIMMS:
A. I couldn't recall that.
CHAYTOR, Q.C.:
Q. Okay. You said that you set a timer for doing your antigen retrieval, and what if you weren't in the general area when the twenty minutes were up?
MR. SIMMS:
A. I never knew of any time -- if I was responsible for the DAKO machine, I never knew of any time I wasn't in the area. I was never out of hearing shot of the timer if I was responsible for the IHC.
CHAYTOR, Q.C.:
Q. How much time did you overlap then with Ms. Welsh? She left at, I believe, in --
MR. SIMMS:
A. Five weeks.
CHAYTOR, Q.C.:

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Q. And this whole process of the antigen retrieval, what was your impression at the time of coming over from St. Clare's? What was your impression of the method of antigen retrieval at the Health Science?
MR. SIMMS:
A. I don't understand what you mean by "my impression of it".
CHAYTOR, Q.C.:
Q. What did you think of the technique that was being used or did you have any impression of the technique?
MR. SIMMS:
A. I just thought it was very aggressive, aggressive, the boiling and that, right. It was very hard on the tissue, which is sometimes why we would get pieces of tissue floating off or some tissue floating off altogether because it was exposed to this boiling technique and you would lose tissue.
CHAYTOR, Q.C.:
Q. And you were --
MR. SIMMS:
A. So it's a very aggressive technique.
CHAYTOR, Q.C.:

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Q. It was an aggressive technique, and did you have reason to read up on other methods of antigen retrieval?
MR. SIMMS:
A. I did not.
CHAYTOR, Q.C.:
Q. You did not, and you weren't otherwise aware of any through your own personal experience, other methods of antigen retrieval?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Now we also have heard that while the DAKO machine was in operation, the antibodies, ER and PR, were not pre-diluted. So what were you taught in terms of how to dilute the antibodies?
MR. SIMMS:
A. I knew -- from general practice, I knew how to make dilutions. So those dilutions were no different than any other dilutions that I would make in the laboratory, which is just another dilution. You make a dilution. If it's 1 in 50, you do 1 in 50. If it's --
CHAYTOR, Q.C.:

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

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was new there. I didn't know much about it, so I -- from my understanding, it was Mary and Barry did that, and if I remember correctly, that was the only thing that changed was the ER dilution.
CHAYTOR, Q.C.:
Q. The ER dilution, okay, and did you even understand that that had to be done from time to time or that there would be validation from time to time of the antibody?
MR. SIMMS:
A. Not at the beginning.
CHAYTOR, Q.C.:
Q. Okay.
MR. SIMMS:
A. Right. That wasn't taught to me at the beginning, but after a couple of three months into it, then I started -- you know, I was made aware that, you know.
CHAYTOR, Q.C.:
Q. And --
MR. SIMMS:
A. But that would be the responsibility of the lead tech.
CHAYTOR, Q.C.:

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Q. Okay, and after Ms. Welsh left, who was that?
MR. SIMMS:
A. Mary.
CHAYTOR, Q.C.:
Q. Ms. Butler, Mary Butler?
MR. SIMMS:
A. Uh-hm, sorry.
CHAYTOR, Q.C.:
Q. And at the end then of your couple of weeks with Ms. Welsh, how comfortable did you feel in your training in IHC?
MR. SIMMS:
A. Not comfortable at all.
CHAYTOR, Q.C.:
Q. And at any point in time, did your comfort level increase, and if so, how -- how is it that you became more comfortable in doing what you were doing?
MR. SIMMS:
A. My comfort level increased and I became more aware of what I was doing was when I got involved with Ventana.
CHAYTOR, Q.C.:
Q. And that's in 2004?
MR. SIMMS:

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A. That began -- I think December of 2003 probably, but it was into 2004 before we actually started using it, but in preparation for the Ventana System coming, of course, we had reading material, we had documentation -- you know, we had various things to read, and Barry was very good at that, supplying information that way. Then I was -- it was new to everyone, so I didn't feel out of place. You know, I was learning the same thing as everybody else was learning with the Ventana, "this is a new system, this is the way we do it, and this is why we do it, this is how we do it".
CHAYTOR, Q.C.:
Q. Okay, and why is it that then you felt more comfortable? Is it because everybody was starting off at the same base?
MR. SIMMS:
A. Same level, yes.
CHAYTOR, Q.C.:
Q. Same knowledge level?
MR. SIMMS:
A. Yes, yes.
CHAYTOR, Q.C.:

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Q. So it wasn't necessarily the system itself, it was just that you felt you're getting in at the ground level with everyone else in trying to learn the new system?
MR. SIMMS:
A. That's right.
CHAYTOR, Q.C.:
Q. Okay, and --
MR. SIMMS:
A. And basically the procedures never changed -- the procedure don't change, anyway. We're doing the same procedure I was doing with the KIT method back in the early 90s, basically the same as when we started running the Ventana, the actual procedure itself, you know, the antibody -- primary antibody, tertiary, you know, these were pretty much the same.
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. With just a few technological developments, but basically the procedure remained the same.
CHAYTOR, Q.C.:
Q. And do you recall the first time that you ran

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out of an antibody and you had to actually be involved in validating a new batch or bringing a new batch on?
MR. SIMMS:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And do you recall how far into the process were you at that point?
MR. SIMMS:
A. I was into Ventana before I did that. I never did that with DAKO.
CHAYTOR, Q.C.:
Q. Okay, and I take it, was there someone who assisted you then to be able to do that?
MR. SIMMS:
A. With the first validation I did?
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. Yes, absolutely.
CHAYTOR, Q.C.:
Q. And who was that?
MR. SIMMS:
A. Ken Green.
CHAYTOR, Q.C.:

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Q. Do you recall were there expiry dates on the vials of antibodies?
MR. SIMMS:
A. There were.
CHAYTOR, Q.C.:
Q. And did you ever have a difference of opinion with anyone over the significance of expiry dates?
MR. SIMMS:
A. Most of the antibodies, it did not reach the expiry date because they were used before -- they were used up before the expiry date came about. There were a couple of them that was done very -- not very often, and -- yeah, I can remember a couple being used with the expiry date, not ER/PR.
CHAYTOR, Q.C.:
Q. And what do you recall about that? What discussion did you have around that?
MR. SIMMS:
A. I thought it was unusual, but it was a -- these things are really very expensive, and the cost savings -- you know, it was a cost saving measure because -- now don't get me wrong. If we did do a run with an expired

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date, say, we did, we always made sure that the control was the same as it was prior to before.
CHAYTOR, Q.C.:
Q. And so you are aware of a couple of times when antibodies that were expired were used, but they weren't ER/PR?
MR. SIMMS:
A. If I remember correctly.
CHAYTOR, Q.C.:
Q. And whether or not that ever happened with ER and PR as well, you're not aware?
MR. SIMMS:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. Okay.
MR. SIMMS:
A. And on the Ventana, that never happened at all. There was never any expiry date problem.
CHAYTOR, Q.C.:
Q. Okay, and who was it that indicated to you about the cost and expensive the antibodies?
MR. SIMMS:
A. I can't recall specifically who, but most likely Peggy.

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CHAYTOR, Q.C.:
Q. Did you have in that first year or so, your first year, say, because then the Ventana is brought on, how much interaction would you have in that time period with pathologists?
MR. SIMMS:
A. Not a great deal the first year I was there, not a great deal, because that was -- again like I said, I was new, so I didn't -- they didn't come to me.
CHAYTOR, Q.C.:
Q. Okay, and how frequent would it be for pathologists to come to the pathology lab, other than Dr. Ejeckam? We'll talk about him in a minute, but was it a common occurrence to have pathologists in the pathology lab?
MR. SIMMS:
A. Yeah, they would -- yes, yeah.
CHAYTOR, Q.C.:
Q. And if they came looking for anything or talking or with any questions, you didn't tend to be the one in the early days that they approached, I take it?
MR. SIMMS:
A. That's right.

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CHAYTOR, Q.C.:
Q. And how about -- your manager, I guess, would have been Barry Dyer at the time?
MR. SIMMS:
A. It was.
CHAYTOR, Q.C.:
Q. And how much contact would you have had with Mr. Dyer?
MR. SIMMS:
A. A good amount of contact, daily contact.
CHAYTOR, Q.C.:
Q. So he was there frequently, there on a daily basis?
MR. SIMMS:
A. Absolutely.
CHAYTOR, Q.C.:
Q. During the DAKO days then, what was the -- what was taught to you about external controls?
MR. SIMMS:
A. External controls back then, and from the DAKO days especially, right, all that I understood of external controls was you look at a slide under the microscope and you get a chemical reaction, a brown reaction. That was it. I

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had no specific details as to which cells were staining or anything else, it was just the reaction.

CHAYTOR, Q.C.:

Q. So you were taught that you would look at the control slides after you run a batch to see whether or not there has been any reaction, and you were just taught to look for brown staining?

MR. SIMMS:

A. That's it.

CHAYTOR, Q.C.:

Q. But not in any particular areas?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and who taught you that?

MR. SIMMS:

A. Peggy.

CHAYTOR, Q.C.:

Q. That was Peggy?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

Q. And how many controls were run per batch? If

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you have, say, five different antibodies on a batch, how many controls were run?

MR. SIMMS:

A. There would be five controls run.

CHAYTOR, Q.C.:

Q. So there was one control run for each batch?

MR. SIMMS:

A. For each antibody.

CHAYTOR, Q.C.:

Q. Sorry, for each antibody, yes. Was there ever a time period when there was only one control run -- one control run per batch?

MR. SIMMS:

A. I don't understand the question.

CHAYTOR, Q.C.:

Q. Do you recall ever having a time or a concern that there was only one control run per batch irregardless of how many antibodies were on the machine?

MR. SIMMS:

A. Not that I recall. I had some problem with that question back when it was first asked of me, right, and I couldn't recall if I did or not, but thinking about it, I don't think so. I think it was run -- the control was run with

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every batch for every antibody.

CHAYTOR, Q.C.:

Q. So every antibody that was on the machine had a control for that antibody, and sometimes, I take it, there might be more than one control, is that right?

MR. SIMMS:

A. Yeah, it depends on the case too. You may have one antibody there, you may have five, but it was from five -- there was one control run with every antibody, but not necessarily every case.

CHAYTOR, Q.C.:

Q. Right.

MR. SIMMS:

A. There was one control run per antibody, yes.

CHAYTOR, Q.C.:

Q. And you might have more than one control depending on where -- who had ordered the test?

MR. SIMMS:

A. If it was from out of town, yes, you would run an extra one. I don't think we ran an extra one if it was from St. Clare's, if I remember correctly.

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CHAYTOR, Q.C.:

Q. I'm sorry?

MR. SIMMS:

A. I don't think we ran an extra one if it was from St. Clare's.

CHAYTOR, Q.C.:

Q. So what would happen in that case, how would the pathologist at St. Clare's become informed about the external controls?

MR. SIMMS:

A. We would -- I would mark on the requisition, right, that we had the controls, and somebody had another case -- usually if I didn't send over the control, somebody else had another case. If I just had that antibody and no other person had this particular antibody ordered in the hospital, then I would send it over to St. Clare's, but if -- if there was another pathologist that ordered it at the Health Science, it would stay at the Health Science and I would inform on the requisition -- usually on the requisition who they were to call at the Health Science and say, you know, who checked the control.

CHAYTOR, Q.C.:

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Q. So your practice was to mark on the requisition that was going back to St. Clare's that Dr. so and so had the controls, so that then the pathologist at St. Clare's could contact that physician and talk about the controls?
MR. SIMMS:
A. I did.
CHAYTOR, Q.C.:
Q. And so you didn't have a pathologist read the control before you sent off the patient's slides to St. Clare's?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. While you were at St. Clare's and involved in ordering ER/PR tests for the pathologists there or arranging that, did you have occasion to request that controls be sent over?
MR. SIMMS:
A. Not that I recall.
CHAYTOR, Q.C.:
Q. Did any pathologist there ever express any concern that they were receiving patient slides without the controls?

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MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Do you recall having any discussions with Ms. Welsh then around that issue while you were still at St. Clare's and discussing with her whether or not there were -- you were going to receive the external controls?
MR. SIMMS:
A. Sometimes, right, a couple of times I remember calling and asking Peggy if she would send over the controls, yes.
CHAYTOR, Q.C.:
Q. So that was on your own initiative.
MR. SIMMS:
A. My own initiative.
CHAYTOR, Q.C.:
Q. Not because any pathologist asked for it.
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and what was Ms. Welsh's response to your inquiries in that regard?
MR. SIMMS:
A. If the pathologist needs them, I'll send them over, but only if the pathologist needs it. She wasn't going to send them over to me.
CHAYTOR, Q.C.:
Q. Okay, and in that context, did she ever mention internal controls to you?
MR. SIMMS:
A. I've wracked my brain around this issue too for internal controls because I know it's come up so often. I know I became aware of or more aware of internal controls when Dr. Ejeckam came on the scene, but I seem to recall Peggy telling me at certain points in time, you know, well, we may not have a good external control for this particular antibody, we're still working on it, but if I'm doing a piece of bowel or a piece of lung, it's okay because there is a built in control. A built in control, she called it, right. Now whether or not she meant that to be an internal control, I don't know, but she said it's okay sometimes because there's a built in control in this particular tissue.
CHAYTOR, Q.C.:
Q. Okay, and this is while you're still at St. Clare's and you're having a phone

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conversation, I take it, with Ms. Welsh?
MR. SIMMS:
A. No, this was when -
CHAYTOR, Q.C.:
Q. Oh, this is after you're moved over, okay.
MR. SIMMS:
A. Having a discussion with Peggy concerning internal controls at St. Clare's.
CHAYTOR, Q.C.:
Q. So on occasions when there may have been some concern that the external control wasn't that good, she was saying that there's a built in control?
MR. SIMMS:
A. That's what I would recall.
CHAYTOR, Q.C.:
Q. Which could be the internal control and so the pathologist would have that safeguard, is that what you took that to mean?
MR. SIMMS:
A. That was my understanding, right, but I had no idea what an internal control looked like, again, I would probably have just looked down to see if there was any reaction. But I couldn't speak on internal controls at that

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point in time.
CHAYTOR, Q.C.:
Q. And was there any rule or did you understand that you weren't supposed to send the tests out to the pathologists unless you, yourself, had checked the external controls, was there any rule or any guidelines along that?
MR. SIMMS:
A. There was no set rule for that. We checked, you know, I checked the external controls just to see if the test procedure was working, that was my only reason for checking external controls and if there was any reaction, it was working, it there wasn't, it wasn't working. And if it wasn't working, if there was no, if there was no staining in the control at all, then I would go to Ken or Mary or Barry, whoever, and say, you know, there's no point--is there any point in sending this out, there's no reaction here, right.
CHAYTOR, Q.C.:
Q. And did that happen from time to time?
MR. SIMMS:
A. Very seldom, no, once or twice probably in the whole time.

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CHAYTOR, Q.C.:
Q. And what would happen in that case?
MR. SIMMS:
A. And then we would do a repeat, right, and see if you would get the same result as you got.
CHAYTOR, Q.C.:
Q. And was there any investigation carried out to try and back track to find out why it hadn't worked the first time?
MR. SIMMS:
A. There would be. If it worked the second time, right, yes, you would go back and try to find out what happened.
CHAYTOR, Q.C.:
Q. And do you recall ever detecting any problems? Ever figuring out why something, why an external control had never stained?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. You indicated that you only knew to look for brown staining and later on Dr. Ejeckam, I believe you said, taught you what exactly to look for.
MR. SIMMS:

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A. That's right.
CHAYTOR, Q.C.:
Q. When did Dr. Ejeckam do that? Was that before everything happened in 2005 or after?
MR. SIMMS:
A. After.
CHAYTOR, Q.C.:
Q. It was after, okay. And what did Dr. Ejeckam teach you then to look for?
MR. SIMMS:
A. To be more specific in external controls, which cells were staining, which independent cells were staining--or which were supposed to stain. And that was a very brief teaching as well. You know, he tried his best but he didn't have too long to do it and we were much too busy to really take the time out to be taught, unfortunately, right. Where I learned most of my knowledge on external controls, now we're talking Ventana now.
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. Is the Ventana is a catalogue of their antibodies which has a coloured photograph of

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a certain piece of tissue and the way it should look as an explanation of the antibody that's used, the clone, a brief statement on what is stained and in which cancers it stains in, right, and so that's where I developed most of my knowledge or a fair amount of my knowledge for external controls, was there, and if you could reproduce the same picture, day after day, after day, well you sort of got used to it after awhile and you would notice any slightest change, you would pick it up.
CHAYTOR, Q.C.:
Q. And when did you start doing that? Was that also after everything happened in 2005?
MR. SIMMS:
A. That's when we started the Ventana.
CHAYTOR, Q.C.:
Q. So that was in April, 2004, around then? So early in 2004?
MR. SIMMS:
A. Right, so prior to Dr. Ejeckam attempting to teach us, we were still at that for the year before.
CHAYTOR, Q.C.:
Q. And you would study the pictures that were

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provided by Ventana?
MR. SIMMS:
A. Yes, and Ventana also supplied a great technical support, you could pick up the phone any time and call Ventana, they had technical people on hand all the time.
CHAYTOR, Q.C.:
Q. And was there usually one person that you would contact at Ventana or was it someone different?
MR. SIMMS:
A. There was two that I recall.
CHAYTOR, Q.C.:
Q. Okay, and who were they?
MR. SIMMS:
A. I can't remember their names.
CHAYTOR, Q.C.:
Q. And we've heard the name Carol Quevillon?
MR. SIMMS:
A. That was the lady who would come in, yeah, she was a representative from Ventana, come in from Montreal to assist us in setting up the machine.
CHAYTOR, Q.C.:
Q. And was she someone that you could also

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contact if you had any questions?
MR. SIMMS:
A. If necessary.
CHAYTOR, Q.C.:
Q. You have, so you indicate that there may have been a couple of occasions where there was an issue with the controls not staining. Do you recall whether or not that was ever ER/PR?
MR. SIMMS:
A. No, it wasn't ER/PR.
CHAYTOR, Q.C.:
Q. It wasn't ER/PR.
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Do you ever recall anyone complaining to you about the quality of ER/PR slides?
MR. SIMMS:
A. In--what are we talking DAKO or Ventana?
CHAYTOR, Q.C.:
Q. At any point in time prior to everything happening in 2005?
MR. SIMMS:
A. Quality of the slides, oh yes, oh yes.
CHAYTOR, Q.C.:

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Q. And specifically about ER/PR?
MR. SIMMS:
A. Not specifically.
CHAYTOR, Q.C.:
Q. That's what I'm wondering, whether or not there was any--so you had concerns expressed about the quality of IHC slides.
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. But not necessarily or not specifically ER/PR/
MR. SIMMS:
A. Not necessarily ER/PR, but ER/PR were included in some of these statements.
CHAYTOR, Q.C.:
Q. And who raised those concerns and what were the concerns?
MR. SIMMS:
A. Different pathologists and the concerns were that the tissues were washing, you know, may have washed off the slide or all the tissue wasn't present, no--at that point they didn't look at internal controls, but no, just tumour tissue, no normal tissue around to compare with the tumour.

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CHAYTOR, Q.C.:
Q. And a pathologist would raise that as a concern?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. And what would cause the tissue to wash off the slide from a technical point of view?
MR. SIMMS:
A. Because, well from fixation and processing because if you're cutting breast tissue, if you don't get a proper sample, if you don't get a fairly thin smaller sample of tissue with tumour and normal tissue attached to it, you get a lot of fatty tissue, and fatty tissue is very difficult to fix, very difficult to process and very difficult to cut.
CHAYTOR, Q.C.:
Q. So I take it in the discussions of it being brought to your attention that there is issue with the tissue coming off the slides, there would be a discussion about the poor fixation or the poor processing of the tissue?
MR. SIMMS:

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A. Or possibly that that's what was causing it, because, as you know, we weren't involved in the fixation. All we got was a paraffin block to work with and sometimes we would cut it, we would know immediately this is going to be trouble because you could see the tissue was fatty and not fixed properly or not processed properly and you knew it was going to give you trouble and many times, not many times, but at times we would actually mark on the requisition itself, when it went back, you know, suboptimal tissue, right. Sometimes we would call the pathologist. I've called over to Bev Carter, Don Cook. I've called several people and said, look, this particular block here is not very good quality, can we try another block.

CHAYTOR, Q.C.:

Q. Okay, and that was particularly true of breast tissue, I take it?

MR. SIMMS:

A. Yes, and it would be mostly breast tissue. Most of the other specimens, most all the other antibodies or the tissue we did was fine, right, but ER/PR and being the type of

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tissue it was, it would cause some concern.

CHAYTOR, Q.C.:

Q. And that was subject of discussion amongst the technologists.

MR. SIMMS:

A. Oh absolutely.

CHAYTOR, Q.C.:

Q. And also amongst technologists and pathologists that there was issues regarding fixation with, in particular, the breast tissue?

MR. SIMMS:

A. Yeah, or Ken and I would often say to each other, look, you know, we're wasting our time by supplying this slide to them.

CHAYTOR, Q.C.:

Q. And, Mr. Simms, to your knowledge was anything done about it?

MR. SIMMS:

A. Not up to the point that I left.

CHAYTOR, Q.C.:

Q. Up until you left this year?

MR. SIMMS:

A. Uh-hm.

CHAYTOR, Q.C.:

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Q. Nothing done to address -

MR. SIMMS:

A. Not really, they tried various things, but they're still getting suboptimal tissue, whether it's from the fixation or not acquiring a proper technique for a proper piece of tissue or tissue too big or too thick, you know, but now they have PAs now who are supposedly being trained to cut, give the proper tissue to us or to the IHC lab for cutting.

CHAYTOR, Q.C.:

Q. So up until you left your job in May of 2008, you still had concern about the quality of tissue that you were seeing?

MR. SIMMS:

A. It had improved but it still wasn't up to where we wanted it.

CHAYTOR, Q.C.:

Q. And back in the pre-2005 days, before all this came to light, so pre to mid 2005 anyhow, when issues of fixation were discussed or raised about the suboptimal quality of the tissue, do you know if there was any efforts back in those days to try and address the issue?

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MR. SIMMS:

A. If there was an effort, it was made on us, we would suggest, keep suggesting to the residents or whoever is cutting the particular piece of tissue, you know, we would say can you make it this size, can you make sure you got a piece of tumour and normal tissue? We would suggest to them that, you know, look, if you keep giving us these huge chunks of material, we're going to have problems.

CHAYTOR, Q.C.:

Q. And was there ever any record kept of that?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. And we've heard reference here today of Mr. Green, the issue of a log book in the reporting room, did you ever see that log book?

MR. SIMMS:

A. Never saw it.

CHAYTOR, Q.C.:

Q. Okay.

MR. SIMMS:

A. Now also bearing in mind too that that was a

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log book for the general lab, that wasn't specific for IHC, the log book that was the pathology reporting.

CHAYTOR, Q.C.:

Q. No, we understood that was for any issues.

MR. SIMMS:

A. For any issue. I never seen it, no.

CHAYTOR, Q.C.:

Q. And did you know it exists or that it existed and perhaps you should look through it to see whether or not any issues were coming up?

MR. SIMMS:

A. I knew it existed from the fact that Barry, who had a meeting with the general staff, had suggested that this was what he was going to try, because there was some issues in the general lab, so I'm going to try putting a log book in and they can write their complaints in it. And from my understanding, it was Barry who was going to check it, you know, being the manager.

CHAYTOR, Q.C.:

Q. Okay, so you didn't understand that there was any responsibility on the technologists to check it?

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MR. SIMMS:

A. No, I did not.

CHAYTOR, Q.C.:

Q. And was there ever any issues brought forward to you from that log book?

MR. SIMMS:

A. Not to my knowledge.

CHAYTOR, Q.C.:

Q. Okay, and now, of course, there are policies in place and that's most of which appears to be around the time you were leaving or after you left.

MR. SIMMS:

A. That's right.

CHAYTOR, Q.C.:

Q. - at those with Mr. Green this morning and there is policies to actually keep track of any occurrences or any issues that may arise and in particular with respect to suboptimal tissues. I take it there was no policy or procedure in place in your day for that to happen?

MR. SIMMS:

A. No, there was not.

CHAYTOR, Q.C.:

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Q. Okay. Do you recall any particular difficulties with the DAKO machine?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Did it always seem to operate properly? Do you recall any times when it wasn't operating?

MR. SIMMS:

A. The runs that I did, the ten--like I said, the 12, 14, 15 runs that I did on it, it never failed, it never malfunctioned.

CHAYTOR, Q.C.:

Q. It never caused you any problem. And Mr. Green mentioned some issues with the robotic arm. Were you aware of any issues with the robotic arm?

MR. SIMMS:

A. I was aware of that.

CHAYTOR, Q.C.:

Q. You were?

MR. SIMMS:

A. I was made aware by Ken, probably.

CHAYTOR, Q.C.:

Q. So you never had the experience yourself of a run being interrupted because of difficulty

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with the robotic arm?

MR. SIMMS:

A. No, I did not.

CHAYTOR, Q.C.:

Q. And other than that, you weren't aware of any issues with the machine?

MR. SIMMS:

A. The machine ran very well, if you maintained it properly, but I never had any issues with that particular machine, no.

CHAYTOR, Q.C.:

Q. Was it your practice to always place the control slides in a particular area on the machine?

MR. SIMMS:

A. Personally, I would always place them at the end, I would have my run log, number one to 48 and usually the last six or eight, however many was at the end, I would have them at the end.

CHAYTOR, Q.C.:

Q. So I take it if you do that and there's a problem with the robotic arm or a glitch in it and then it continues on, you would know if there were a problem and it didn't get to the

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end because your control slides wouldn't stain.

MR. SIMMS:

A. Right, wouldn't stain properly. But it was very--even if you had an interruption like that with a robotic arm, if I was running the IHCs for them, it wouldn't go undetected. I'm not that far out, no, it wouldn't go undetected. You would pay more attention than that to it.

CHAYTOR, Q.C.:

Q. Yes, you didn't leave the machine?

MR. SIMMS:

A. No, not really.

CHAYTOR, Q.C.:

Q. So how long would it take to run the machine in a regular batch?

MR. SIMMS:

A. The procedure itself?

CHAYTOR, Q.C.:

Q. Yes, if there's 48 slides.

MR. SIMMS:

A. Three to three and a half hours.

CHAYTOR, Q.C.:

Q. And what would you do while the machine is

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running?

MR. SIMMS:

A. I may do some cutting, I don't know, I don't know what my duties would be, it was various things, right.

CHAYTOR, Q.C.:

Q. And if you had other duties though to do, or carry out, would they be done in the vicinity of that machine?

MR. SIMMS:

A. If I was on the IHC machine, if I was on that particular week, that was my job. I may have done other things around, I may have went up around the corner of the bench and cut some, you know, help with some cutting or whatever and that stuff, right, but running the IHC machine took all your time anyway. It's easy to say--or not easy to say, but I can understand people thinking, okay, this thing is on there now for three hours, right, what do you do in the meantime? The other things is you get ready for the next day, for one thing, you get, you know, see what you got for the next day and so there's always preparation to be done. And I would never, like I said,

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if I went out to help, I would never roam far from the machine.

CHAYTOR, Q.C.:

Q. Were there any alarms on the machine?

MR. SIMMS:

A. I'm told there was; I never heard one.

CHAYTOR, Q.C.:

Q. Okay, and what do you know, it was equipped for an alarm in what event?

MR. SIMMS:

A. I don't know that either, I just know that sometimes there was an alarm that would go off. My understanding was there was an alarm that would go off if there was insufficient solution.

CHAYTOR, Q.C.:

Q. And when did you learn that?

MR. SIMMS:

A. Couldn't tell you, Ken might have mentioned it somewhere along the line.

CHAYTOR, Q.C.:

Q. Is it since all of this issue arose or did you know that at the time you were operating -

MR. SIMMS:

A. No, he probably told me back then.

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CHAYTOR, Q.C.:

Q. You knew it when you were operating the DAKO machine?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

Q. Was the machine ever allowed to run overnight?

MR. SIMMS:

A. I never did an overnight run.

CHAYTOR, Q.C.:

Q. Are you aware that there were overnight runs?

MR. SIMMS:

A. There were overnight runs because I remember we had to put two waste baskets because we found out quite clearly that, did an overnight run and it overflowed, so we needed another waste container.

CHAYTOR, Q.C.:

Q. What does that mean, I haven't heard that before.

MR. SIMMS:

A. A waste container is when the rinse is off, one that keeps the specimens wet during the night, right, during the whole process, it takes more solution to keep, you know, because

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you don't want your slides to dry out, so you just keep continuously wetting -

CHAYTOR, Q.C.:

Q. And you learned at some point that you needed two waste baskets for that?

MR. SIMMS:

A. Yeah, I can remember that.

CHAYTOR, Q.C.:

Q. And I'm sorry, what is the waste basket doing, what was it used for?

MR. SIMMS:

A. Just collecting the waste reagents, it has got to go somewhere, these things that are washed and the solutions that are used, once they're used, they run down into the machine and run out into a waste, right.

CHAYTOR, Q.C.:

Q. And I take it at some point you realized one wasn't enough, so you came in, in the morning, and there's a mess.

MR. SIMMS:

A. Yes, if you're doing an overnight run, but I personally can't recall, like I said, I didn't do all that many runs on the DAKO and I can't remember doing an overnight run to be honest

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with you. I may have, but I don't recall it.

CHAYTOR, Q.C.:

Q. Okay, but you recall someone else doing an overnight run with -

MR. SIMMS:

A. I can remember Mary mentioning it.

CHAYTOR, Q.C.:

Q. And other than the issue of needing an extra waste basket, do you recall any other problems or concerns about doing overnight runs?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Other than the fixation then that we've spoken about, do you recall any other issues about IHC testing or any concerns about IHC testing and the quality of the slides being brought to your attention?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. No other difficulties in relation to the process itself?

MR. SIMMS:

A. No.

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CHAYTOR, Q.C.:

Q. What about any difficulties with respect to the tissue processor?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. And when you first realized when you finished your career, you were dedicated to the IHC lab, but I take it in 2003 when you first went there, you would also have to operate the tissue processor?

MR. SIMMS:

A. I didn't operate a tissue processor.

CHAYTOR, Q.C.:

Q. At the Health Science at all?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Okay.

MR. SIMMS:

A. I did at the Health Science, I did the gross, did some general cutting, some special stains; the IHC, kidney biopsies, frozen sections, all that stuff, but I didn't do the processor because, you know, are you talking about in

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the filling of it and changing it and -

CHAYTOR, Q.C.:

Q. Yes.

MR. SIMMS:

A. No, I didn't do that.

CHAYTOR, Q.C.:

Q. You weren't involved.

MR. SIMMS:

A. No, there was a person there who did that.

CHAYTOR, Q.C.:

Q. Okay, and the times in which, you said there were times when tests had to be repeated, the communication from the pathologists on that, were there ever any reasons told to you as to why repeats were necessary or were there inquiries made of you as to why the test needed to be repeated?

MR. SIMMS:

A. At the beginning 'til at least until I became more knowledgeable in the IHC, I was--we need this repeated, it doesn't work, that was the extent.

CHAYTOR, Q.C.:

Q. And meaning it doesn't work, meaning the controls didn't work?

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MR. SIMMS:
A. No, meaning the procedure didn't work.
CHAYTOR, Q.C.:
Q. And how would the, how would anyone know that if the procedure hadn't worked? Wouldn't it have to be the controls?
MR. SIMMS:
A. Because the picture didn't fit what they thought it should be.
CHAYTOR, Q.C.:
Q. So pathologists were bringing to your attention that they wanted a test repeated because the outcome of the test wasn't in keeping what they felt it should have been.
MR. SIMMS:
A. Expected, yes.
CHAYTOR, Q.C.:
Q. And do you recall that ever being true of ER/PR tests?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. And how is it that, is it that it wasn't or you don't recall which test it was?
MR. SIMMS:

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

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MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and so you satisfy yourself that the procedure was working because the external control had worked.
MR. SIMMS:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Okay.
MR. SIMMS:
A. And I was happy to rerun it or redo it because I knew if the procedure was working, I would get the same result or I had better get the same result, so that was a test for us as well. We rerun it, you should, if your external control is working properly at the first run, well, why wouldn't you get the exact same picture in the second run.
CHAYTOR, Q.C.:
Q. And Mr. Simms, do you recall on those occasions rerunning the test and being told the outcome of the repeat?
MR. SIMMS:
A. No.

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

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IHC tests?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. You indicated that fixation, of course, was more of an issue with breast tissue.
MR. SIMMS:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. But it didn't stand out in your mind that ER/PR are being asked to be repeated more often?
MR. SIMMS:
A. They seem to accept the poor quality stains.
CHAYTOR, Q.C.:
Q. Who is "they"?
MR. SIMMS:
A. Poor quality slides. The pathologists seem to accept that this is a poor quality slide, but this is the best I can get.
CHAYTOR, Q.C.:
Q. How were the relations between the technical staff and the medical staff at the Health Sciences?
MR. SIMMS:

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A. Good. I had no problem with it.
CHAYTOR, Q.C.:
Q. And did you notice any difference between the working atmosphere between the two at the Health Sciences from the St. Clare's?
MR. SIMMS:
A. St. Clare's was a different atmosphere working, it was a smaller unit, so it was more of a--I had to use this term, but more of a family unit, everybody worked, you know, were together; whereas at the Health Science there were many more pathologists and they were scattered all over the place. At St. Clare's we were all in close proximity to each other, we could just--if you thought there was a problem, we could just dart across the hall and they would do the same for us, right.
CHAYTOR, Q.C.:
Q. So there was more opportunity to interact in the smaller atmosphere?
MR. SIMMS:
A. Absolutely.
CHAYTOR, Q.C.:
Q. Okay. Were you aware of any tension between the technical staff and the medical staff, the

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pathologists?
MR. SIMMS:
A. No tension, there may be times when there was various discussions on various things, but it wasn't such tension, they were--both groups were professionals, so there was, no. But we all have our days.
CHAYTOR, Q.C.:
Q. Yes. Did you feel that your advice or feedback was welcomed by pathologists?
MR. SIMMS:
A. I don't know how to answer that one because, there was no feedback. If I took the opportunity of telling someone, well I think this such and such and such and such, right, whatever, I think this may have happened or that may have happened, the usual answer was okay, that's okay, I'll take care of it.
CHAYTOR, Q.C.:
Q. So did you sense that there was any issue as to you trying to offer your opinion as to what may have caused the problem?
MR. SIMMS:
A. Again, I don't know, rephrase the question.
CHAYTOR, Q.C.:

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Q. Okay, well did you sense any attitude towards you that that perhaps wasn't your territory, that that was better left to pathologists to determine?
MR. SIMMS:
A. Yes, but that could have been just my way of thinking. I can't speak for anybody else, but sometimes I did feel that way, yes.
CHAYTOR, Q.C.:
Q. You felt that way.
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. And so it may have been something that you perceived as opposed to it being someone's actual attitude?
MR. SIMMS:
A. Absolutely.
THE COMMISSIONER:
Q. Mr. Simms, what about the other way around, were there pathologists who encouraged you to make comments about the slides or the quality of what you saw or problems that you might have observed as a technology within the laboratory?

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MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. And is that also true of Dr. Ejeckam?
MR. SIMMS:
A. Dr. Ejeckam, that's a different story. He was very encouraging, very helpful. I was only speaking to the point in time--I didn't think we had gotten to Ejeckam yet, that was that period of time.
CHAYTOR, Q.C.:
Q. Yes, so he was an exception to the rule?
MR. SIMMS:
A. Yes, he was, big exception to the rule.
CHAYTOR, Q.C.:
Q. Did you feel at the Health Sciences then if you had a problem or an issue or a concern about, other than Dr. Ejeckam, that there was a pathologist that you could go to or that the pathologist would be approachable to your issues?
MR. SIMMS:
A. Most of them were approachable. I had no trouble approaching any of them, believe me, I'd approach any of them, just got different

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

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

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

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

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

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blocks.
MR. SIMMS:
A. Let me back up a little, it wasn't so much as being asked to do things, it was projects to be done that they were coming directly to us, rather than going to the proper structure and letting somebody organize this. We were becoming disorganized, we had, you know, ten, twelve different things going on. We were working ten and twelve hours a day.
CHAYTOR, Q.C.:
Q. So individual pathologists were coming to you instead of it being streamlined through the normal process?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. So this wasn't -- for example, this wasn't Dr. Carter or Dr. Cook asking you to do a batch of retests?
MR. SIMMS:
A. That included too. That was part of it too.
CHAYTOR, Q.C.:
Q. That was part of it?
MR. SIMMS:

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A. That was part of it.
CHAYTOR, Q.C.:
Q. But this is something over and above that, individual pathologists were coming to you?
MR. SIMMS:
A. Right.
CHAYTOR, Q.C.:
Q. With requests for retest on older blocks?
MR. SIMMS:
A. Right, yes, and saying these particular stains weren't working. If they had a problem with their everyday cases -- we were still doing everyday cases, so we would still get pathologists coming in concerned with a particular case, current cases.
CHAYTOR, Q.C.:
Q. Their current cases?
MR. SIMMS:
A. Not necessarily ER/PR.
CHAYTOR, Q.C.:
Q. Okay, and the request, though, on the older blocks, were they for ER/PR tests?
MR. SIMMS:
A. From what I recall, yes, some of them were.
CHAYTOR, Q.C.:

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Q. Okay.
MR. SIMMS:
A. But I can't speak for the reason. You would have to ask the particular pathologist that.
CHAYTOR, Q.C.:
Q. Yes, but there were requests -- well, who are they then, who are the particular pathologists who asked you to do retests on older blocks in that time period?
MR. SIMMS:
A. Nash - Dr. Denic, Dr. Cook, and Dr. Carter.
CHAYTOR, Q.C.:
Q. Okay, and in through -- I'll talk to you a little more about what happened in 2005 and what you were aware of was happening, and what you may not have been aware of was happening, and we'll come to that. If we could just stick to the issue of before all of that happened, the relations between the pathologists and the technologists. Do you recall any issue between any particular technologist and technologist?
COMMISSIONER:
Q. Technologist and --
CHAYTOR, Q.C.:

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Q. I'm sorry, did I say technologist and technologist? It's getting late, isn't it? Technologist and pathologist, sorry. Do you recall any issue between, for example, Ms. Butler and Dr. Carter?
MR. SIMMS:
A. Ms. Butler will have to speak to that. I will not speak to any --
CHAYTOR, Q.C.:
Q. And whether or not you were involved in that, and do you have anything to say about that?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. You had no involvement?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Okay, you have knowledge of that?
MR. SIMMS:
A. I have knowledge of that, yes, but you'll have to speak to Ms. Butler on that.
CHAYTOR, Q.C.:
Q. Yes, and we will indeed, but you in terms of -- was there ever a period of time when you

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refused to do certain work for Ms. Carter in backing up her -- for lack of a better word, backing up Ms. Butler with her issues?
MR. SIMMS:
A. Absolutely not, never refused to do any work for any pathologist that was ever requested. I may have referred her to the manager, but I never refused any work.
CHAYTOR, Q.C.:
Q. May have referred the pathologist to the manager?
MR. SIMMS:
A. May have been referred, yeah, referred to the manager, you know, or if it was -- any pathologist, if they wanted some certain project done or whatever, okay, well, go to Barry and if he ok's it, I'll gladly do it for you.
CHAYTOR, Q.C.:
Q. And was that in the context of the issue that Ms. Butler was having?
MR. SIMMS:
A. I can't comment on that either. I don't know.
CHAYTOR, Q.C.:
Q. Why? You don't know?

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MR. SIMMS:
A. No, I don't know.
CHAYTOR, Q.C.:
Q. So you don't know -- you don't know what I'm speaking of in terms of --
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. You being involved in any issue?
MR. SIMMS:
A. No.
COMMISSIONER:
Q. Mr. Simms, could you be a little more specific about this business of the organization and people coming directly to you as opposed to through the manager? What was your view of how it was supposed to work during that time frame? If a pathologist wanted something done, were you preferring that they go via Mr. Dyer or was it just that there got to be so many individual requests that nobody was giving it priority? What was the problem here?
MR. SIMMS:
A. In my 35 years of service, right, as a bench

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technologist, all my direction came from the manager.

COMMISSIONER:

Q. Okay.

MR. SIMMS:

A. Right. So if I got a request or if someone came in, again for lack of a better term, complaining about certain issues, I would point them in the direction of the manager.

COMMISSIONER:

Q. So in your view, there was an order to things and that the lab would work better if everybody kept to the order that it was supposed to be in?

MR. SIMMS:

A. Absolutely, because we had -- we had the everyday work to do and we had various projects to do, and it was no point in coming to us and saying can you fit this in for me, this is only going to take ten minutes, can you do this, can you do that. So, no, there was no point in doing that because then everybody would get less. So my - I always stuck to the idea if you want something done, if you want me to do it, I'll gladly do it for

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you, but it'll have to go through the proper channels.

CHAYTOR, Q.C.:

Q. I just want to ask you then about Dr. Ejeckam, and I take it he took a particular interest in the technologists and in teaching you various things?

MR. SIMMS:

A. He did.

CHAYTOR, Q.C.:

Q. Did he seem knowledgeable to you in IHC?

MR. SIMMS:

A. He seemed very knowledgeable in IHC.

CHAYTOR, Q.C.:

Q. And was there a point in time where both Dr. Ejeckam and Dr. Carter were trying to teach the technologists?

MR. SIMMS:

A. There was a point in time when both of them were trying to teach, yes.

CHAYTOR, Q.C.:

Q. And perhaps you could tell the Commissioner about that?

MR. SIMMS:

A. I don't know how to go at that one. There was

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various times we were sitting around the table and, you know, teaching us and it was a great idea, but -- and he would be showing us specific things, but Dr. Ejeckam and Dr. Carter tended to disagree on what they were looking at, right. They were trying to teach us -- or he was trying to teach us, and they would have disagreements. So it came to the point we're saying this is pointless, all right; if you're telling me this is this, and Dr. Carter is there questioning it, well, how am I supposed to learn or whose word am I supposed to take. So that was -- the teaching area, that was for a very short period of time. It was a great idea, it just didn't work.

CHAYTOR, Q.C.:

Q. Okay. At that time, do you remember what time period was that? Was that before everything arose in 2005?

MR. SIMMS:

A. Before that?

CHAYTOR, Q.C.:

Q. It was before 2005?

MR. SIMMS:

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A. Yeah.

CHAYTOR, Q.C.:

Q. And what were you concentrating on in that time period? Was that ER and PR that was being looked at?

MR. SIMMS:

A. ER/PR.

CHAYTOR, Q.C.:

Q. Okay. So it was a teaching exercise for ER and PR?

MR. SIMMS:

A. It was.

CHAYTOR, Q.C.:

Q. And that predated the 2005 issue?

MR. SIMMS:

A. Yes.

CHAYTOR, Q.C.:

Q. And overall, as you've described, it didn't turn out -- while it was a great idea, it didn't turn out to be a valuable learning experience to you?

MR. SIMMS:

A. Right.

CHAYTOR, Q.C.:

Q. Were the other techs involved in that as well?

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MR. SIMMS:
A. Yeah, Ken and Mary. Yes, they were.
CHAYTOR, Q.C.:
Q. Okay.
MR. SIMMS:
A. And there is a -- I don't know if the Commission has it or not, there is a logbook available where we had various teachings. It's a teaching logbook where we would write in because Ejeckam was a stickler on documentation, and he made me -- not made me, but asked me to get a book and we would write in the case number and any comments that him or Bev made would be written in it, and I would write down what we were supposed to look at and what we were supposed to see. So there is a --
CHAYTOR, Q.C.:
Q. A teaching log book?
MR. SIMMS:
A. A teaching log book somewhere around, yes.
CHAYTOR, Q.C.:
Q. Do we have that? No, I don't think we have that. Perhaps we could ask Mr. Simmons, if he can make inquiries about that.

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MR. SIMMS:
A. With various comments in it.
CHAYTOR, Q.C.:
Q. Okay, and that would also tell us the time frame that this was happening?
MR. SIMMS:
A. Yes.
CHAYTOR, Q.C.:
Q. Yes, okay.
MR. SIMMS:
A. It will, it's all dated.
CHAYTOR, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. Ms. Chaytor, wherever you want to find a spot, we'll break for the day.
CHAYTOR, Q.C.:
Q. Sure. Okay, did Dr. Ejeckam continue on then with his efforts to try and instruct and teach the lab technologists?
MR. SIMMS:
A. As much as he could, for the time that we had, yes, and we could always--and I found with Dr. Ejeckam, we could always go to him, if we came up with something, if we wanted to know

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something, we could go to him and he would only be too happy to -
CHAYTOR, Q.C.:
Q. To help you?
MR. SIMMS:
A. - to help us.
CHAYTOR, Q.C.:
Q. Okay, and was Dr. Ejeckam trying to invoke certain changes in the IHC process or in the IHC portion of the lab?
MR. SIMMS:
A. Certain changes?
CHAYTOR, Q.C.:
Q. Yes.
MR. SIMMS:
A. In which?
CHAYTOR, Q.C.:
Q. Do you recall whether or not--did he discuss with you anything that he was trying to see happen with respect to IHC?
MR. SIMMS:
A. Oh yes, he wanted--he was quite specific and he told everyone in ear shot that he wanted its own department and its own dedicated staff. That was his two main objectives in

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life.
CHAYTOR, Q.C.:
Q. And did you ever sense that Dr. Ejeckam was becoming frustrated in his goals?
MR. SIMMS:
A. Oh yes.
CHAYTOR, Q.C.:
Q. And did he speak to you about that? What did you understand -
MR. SIMMS:
A. Various times.
CHAYTOR, Q.C.:
Q. And what did you understand the source of his frustration to be?
MR. SIMMS:
A. That he couldn't get moving fast enough, that he couldn't get the powers to be to move to do anything. He would write letters. He would talk to them. He would write letters. He would make suggestions, but they--you know, he just couldn't get people to move. Now at least not in the--as fast as he wanted them to.
CHAYTOR, Q.C.:
Q. Okay, and we've had here, if we could just

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bring up P-0113, please? There's a series of three memos that Dr. Ejeckam wrote back in April of 2003.

MR. SIMMS:

A. Um-hm.

CHAYTOR, Q.C.:

Q. Did you ever--were you aware that these memos had been written?

MR. SIMMS:

A. Which one? This one first?

CHAYTOR, Q.C.:

Q. This one here, April 4th, 2003, and this one is actually suspending certain stains which included ER and PR.

MR. SIMMS:

A. This one, no, and I can understand this one not coming to my knowledge because I was only--that was only like a month after I got there, so I wouldn't have been involved in -

CHAYTOR, Q.C.:

Q. So this one is indicated to be copied though to Barry Dyer and all technical staff on immunohistochemistry.

MR. SIMMS:

A. Um-hm, yeah.

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CHAYTOR, Q.C.:

Q. But you didn't receive that?

MR. SIMMS:

A. Being a rookie, I wouldn't have had a whole lot to do with this one.

CHAYTOR, Q.C.:

Q. Okay. So you think you were overlooked in this distribution because you were the new person on the block?

MR. SIMMS:

A. Yeah.

CHAYTOR, Q.C.:

Q. Okay. The other one is dated May 2nd, 2003, and it's not indicated that it would have gone to you. It's pathologists, Health Science, St. Clare's, out of town, and this is a three-page memo. Oh, I'm sorry, it is. Yes, it is, all technical staff in immunohistochemistry and Barry Dyer, and the site chief at both Health Science and St. Clare's. So did you receive this memo?

MR. SIMMS:

A. Didn't see that memo either.

CHAYTOR, Q.C.:

Q. You didn't see this memo?

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MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. This one is May 2nd, 2003. Didn't receive that?

MR. SIMMS:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and then the last one is dated June 19th, 2003 and this one is just to Mr. Gulliver and, sorry, it's copied to a number of doctors and Mr. Dyer. Did you receive a copy of this memo?

MR. SIMMS:

A. I didn't receive or see a copy of this memo. However, I was read various parts of it when it was in its handwritten form.

CHAYTOR, Q.C.:

Q. When it was in its handwritten form?

MR. SIMMS:

A. Um-hm.

CHAYTOR, Q.C.:

Q. Okay, and who read that out to you?

MR. SIMMS:

A. Dr. Ejeckam.

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CHAYTOR, Q.C.:

Q. Okay, and this is dated June 19th, 2003.

MR. SIMMS:

A. Um-hm.

CHAYTOR, Q.C.:

Q. So I take it that was prior--that was sometime prior or around about June 19th, 2003 or before June 19th, 2003?

MR. SIMMS:

A. Yes, around there, might have been only a couple, a day or a couple of days before.

CHAYTOR, Q.C.:

Q. And how did that come to be that Dr. Ejeckam read out portions to you?

MR. SIMMS:

A. I was--because he was--you know, he used to keep saying this every other day about this, you needed to--we need our own department, we need this, we need that, and I don't know, I carried--I guess I carried some slides over to him, you know, and he said "Les, what do you think of this?" and then he proceeded to read a few things, right, and my comment was "they should stand up and listen to that."

CHAYTOR, Q.C.:

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Q. Okay, and the idea that he's saying "following persistent erratic results of immunostains in our laboratory, I accepted to work closely with the technical staff in order to rectify these problems."
MR. SIMMS:
A. He didn't read me that part. He used to remind me of that part every day.
CHAYTOR, Q.C.:
Q. He would remind you that -
MR. SIMMS:
A. That we needed--he wanted to work closely with the technical staff.
CHAYTOR, Q.C.:
Q. Did he also inform you that he perceived there to be persistent erratic results of the immunostains?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:
Q. Were you aware that there was any such concern regarding the product coming out of the lab?
MR. SIMMS:
A. No.
CHAYTOR, Q.C.:

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

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

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 15th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.
Dated at St. John's, Newfoundland and Labrador this 15th day of July, A.D., 2008
Judy Moss

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