COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

June 25, 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. . . . . Members of the Breast Cancer
. . . . . Testing Class Action
Mark Pike . . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Stacey O'Dea. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities
Simon Clements . . Drs. O'Malley, Pritzker, Wegrynowski & Mullen

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Certificate

COMMISSIONER:
Q. Please be seated. Ms. Chaytor.
MS. PATRICIA WEGRYNOWSKI, EXAMINATION BY SANDRA CHAYTOR, Q.C. (CONTINUED)
CHAYTOR, Q.C.:
Q. Thank you. Good morning, Commissioner. Good morning, Ms. Wegrynowski.
MS. WEGRYNOWSKI:
A. Good morning, Ms. Chaytor.
CHAYTOR, Q.C.:
Q. I think when we left last day we were on your second report. And if we could have--thank you, Registrar, you already had it up on the screen. So for everybody else then it's P-0048, page 10. And we're down to the recommendations that you made, No. 10. Again you're talking about the need for a procedure manual outlining all standard operating procedures. No. 11, on the top of page 11 is about the "Antibody specification sheets have been compiled in alphabetical order." And "Formal documented validation sheets needed for each working antibody detailing its specific requirements for use, including the appropriate control tissue and staining

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pattern." And "Any change in lot number requires verification." So this is more detail in terms of what you were looking for in terms of the organization of the antibody specification sheets?

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And then again you have the fact that the microscope maintenance and documentation had not been addressed since your last assessment, No. 12. No. 13 then again you pick up on this whole issue about documentation guaranteeing the pipette accuracy and calibration and you note that that had not been addressed since your last assessment?

MS. WEGRYNOWSKI:

A. Correct.

CHAYTOR, Q.C.:

Q. Ms. Wegrynowski you took us through a demonstration, thank you, yesterday, regarding that. Did you have any sense at all how old the pipettes were at the Eastern Health lab?

MS. WEGRYNOWSKI:

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A. No, I never saw any documentation as to when those pipettes had been purchased.

CHAYTOR, Q.C.:

Q. Okay. And you were told by the people in the lab that they had never been calibrated?

MS. WEGRYNOWSKI:

A. That is correct.

CHAYTOR, Q.C.:

Q. How important are pipettes to what you do, how important is that to your job?

MS. WEGRYNOWSKI:

A. The pipettes are a critical tool to what we do in immunohistochemistry. When you're using concentrated primary antibodies, you need to guard against the accuracy of the dilution of which you validate it to. So without those pipettes ever being calibrated, you could never be assured that the dilution that you had that day was the same as what you had validated, nor could you be assured that the dilution that you did today would be the same as tomorrow.

CHAYTOR, Q.C.:

Q. And what are the potential consequences to, for example, an ER/PR test?

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MS. WEGRYNOWSKI:

A. To any test if you were to make a dilution and it did not draw enough of the primary antibody, you would be under diluting, you would have a lower concentration.

CHAYTOR, Q.C.:

Q. Okay. And in terms then of the outcome of the test, how would that be affected?

MS. WEGRYNOWSKI:

A. You would have a weaker response signal.

CHAYTOR, Q.C.:

Q. And No. 14 then you refer again to the digital temperature readings "do not suffice and thermometer readings are to be recorded" and that had been brought up in your first assessment, you note. And "The refrigerator which contains all the antibodies and detection system does not have a thermometer in it for daily readings." And you note that that had also been brought up the first time around?

MS. WEGRYNOWSKI:

A. Correct.

CHAYTOR, Q.C.:

Q. You note that "The refrigerator containing the

Page 8

antibodies and detection systems is not on an alarm. An alarm system should be considered."

MS. WEGRYNOWSKI:

A. Correct.

CHAYTOR, Q.C.:

Q. Okay. Now, there was a refrigerator that you indicated yesterday that was alarmed?

MS. WEGRYNOWSKI:

A. Correct. Upon reflection of that I have to--I think what I was thinking when I wrote this is that the alarm system is a little bit more than just being on or off, that it would alarm in case the temperature, going without a standard set. So if you wanted it to sit between four and eight degrees, it should notify the user.

CHAYTOR, Q.C.:

Q. Okay. And the documented evaluation, No. 15, "Documented evaluation performed to ensure the sensitivity and specificity of all tests has been commenced. The validation documentation must be stringent." And you go on to note, "The procedure manual should contain the processes that are in place to ensure that all reagents used are appropriately controlled.

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Parallel testing of old versus new reagents is acceptable."

MS. WEGRYNOWSKI:

A. Correct.

CHAYTOR, Q.C.:

Q. And you indicate that "Alternate protocols should be included in the procedure manual." And "The pH is now verified with all pH dependent reagents." So that had been a recommendation?

MS. WEGRYNOWSKI:

A. Yes, they had done that.

CHAYTOR, Q.C.:

Q. Okay. "There must also be a process in place in procedure manual for those instances where the pH is outside the acceptable limits." Regarding "New equipment, instrument selection criteria to be documented." You indicate that "No evidence of a new equipment selection criteria document was provided" despite your previous recommendation. And again, you talk about evidence needed of training and competency of the staff and competency and training on the Ventana benchmark has been completed at that point?

Page 10

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. And No. 17 regards the corrective action log, which we discussed yesterday.

MS. WEGRYNOWSKI:

A. Um-hm.

CHAYTOR, Q.C.:

Q. To be maintained, to record all issues and concerns. And finally, 18 is "A policy must be established relating to the non-specific false positive staining associated with staining from endogenous biotin. This is critical." And "Testing which requires pretreatments and heat-induced epitope retrieval should be routinely blocked with avidin and biotin to avoid this issue." With respect to the issues that had been identified in your first assessment such as, for example, the pipette calibration, which I'm gathering from you is an important issue, was there any indication given to you as to why six months later those things had not yet been implemented?

MS. WEGRYNOWSKI:

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A. No.

CHAYTOR, Q.C.:

Q. If we continue on then, please, at page 14 again deals with immunofluorescent staining. And then at page--and I shouldn't skip that, if there's anything there that you wanted to point out?

MS. WEGRYNOWSKI:

A. Just I was surprised that none of this had been implemented.

CHAYTOR, Q.C.:

Q. So it's still the same recommendations that you had put forward six months prior?

MS. WEGRYNOWSKI:

A. Yes. They still were not using controls.

CHAYTOR, Q.C.:

Q. Okay. And you indicate, "Cover slipping of the slides is performed in a lit environment."

MS. WEGRYNOWSKI:

A. Yes. And then on page 15 of the exhibit is the discussion again regarding the controls. And "Negative controls are still not used" as suggested in your original recommendations. Was there any explanation give as to why that was the case?

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MS. WEGRYNOWSKI:

A. No.

CHAYTOR, Q.C.:

Q. "Daily assessment of the external positive controls and documentation are not performed in the immunohistochemistry laboratory. Without assessing the controls internal daily troubleshooting of the procedure is no occuring in the immunohistochemistry laboratory." And of course, that's something, as well, that you had brought up in your prior assessment. Was there any indication given as to why that was not yet happening?

MS. WEGRYNOWSKI:

A. No. I think they were, if I'm not mistaken, I have a section written below that a multi-header has been purchased and had not arrived yet, so that would be the tool that they would use to enable them to learn and assess.

CHAYTOR, Q.C.:

Q. So they didn't yet have the microscope that they -

MS. WEGRYNOWSKI:

A. Correct.

CHAYTOR, Q.C.:

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Q. - would need to be able to learn to do this?
MS. WEGRYNOWSKI:
A. As a group, yes.
CHAYTOR, Q.C.:
Q. Okay. And then No. 22 of your recommendations speaks again about the negative controls to be assessed, "should be assessed by the registered technologist prior to the slides leaving the laboratory." And again, that hadn't been addressed since your first assessment?
MS. WEGRYNOWSKI:
A. No.
CHAYTOR, Q.C.:
Q. "The negative tissue control blocks to be run for every antibody. A multi-tissue or sausage block will serve this purpose." What do you mean by "sausage block"?
MS. WEGRYNOWSKI:
A. It's not unusual to take a block comprised of different body tissue types, liver, spleen, tonsil, just to get just a composition of different tissues so that when you're running it against your control block when you're first validating it, that you know it's

Page 14

negative, that it's not staining anything that you were not expecting.
CHAYTOR, Q.C.:
Q. Okay. And then No. 24, "Immunohistochemistry registered technologist to be trained to assess the quality of the external positive and negative patient controls tested daily." And "Signed documentation of this must be retained." And again, I take it then they were waiting on the microscope in order to be able to start to -
MS. WEGRYNOWSKI:
A. I believe so.
CHAYTOR, Q.C.:
Q. - learn how to do that? "The pathology laboratory" No. 25, "is intending to change their processing equipment." And this is the issue about the X-press tissue processor that we discussed yesterday?
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. And the importance of making sure your controls, you're comparing control tissue to tissue that has been handled in the same

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manner as the patient tissue?
MS. WEGRYNOWSKI:
A. Correct.
CHAYTOR, Q.C.:
Q. Okay. And on the fourth section of your report you talk again about the surgical reports and those three recommendations, 26, 27 and 28 were all at your--they were all part of your previous report?
MS. WEGRYNOWSKI:
A. Correct.
CHAYTOR, Q.C.:
Q. And they had yet to be implemented. No. 28 here, the "Results regarding immunohistochemistry testing providing predictive/prognostic information must include information in the surgical report regarding the specimen processing, antibody clone and the scoring method used." I take it that would be the pathologists would record that information?
MS. WEGRYNOWSKI:
A. Correct.
CHAYTOR, Q.C.:
Q. Was there any reason give or explanation as to

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why moving towards the standardized template of reporting had yet to take place?
MS. WEGRYNOWSKI:
A. I think the pathologists were having some discussions surrounding that.
CHAYTOR, Q.C.:
Q. And what did you understand that to mean, discussions?
MS. WEGRYNOWSKI:
A. They were trying to determine what terminology they were going to use for their headers. Other than that, I don't know.
CHAYTOR, Q.C.:
Q. Okay. And then under "Quality Assurance" part 5 you note that "Great improvements have been made in this area." And you note that they've become involved in the external quality assurance programs with both College of American Pathologists and the UK NEQAS program. And I take it you were pleased to see that?
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. And you write that "Senior administration has

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given approval and support for a total quality management program." So in addition to that there was to be a quality management program had been approved and was getting support from senior management. And "The quality management system will encompass all processes relating to quality assurance with a major focus of continual improvement." And you indicate "There must be standards of performance. A goal of the program is to provide a system which is as failure resistant as possible." And "The quality management program for the laboratory will have representation for both technical and professional staff. A fulltime equivalent registered technologist has been assigned to this position." And I take it that was -

MS. WEGRYNOWSKI:

A. Catherine Parnell.

CHAYTOR, Q.C.:

Q. Yes. And you spoke with Ms. Parnell?

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And then you had a number of

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recommendations flowing from that, including No. 29, "The quality management initiative by the Eastern Regional Integrated Health Authority be shared with the other regions of Newfoundland to ensure best medicines practices." And you had mentioned something along those lines, too, in your last report?

MS. WEGRYNOWSKI:

A. Yes, I did.

CHAYTOR, Q.C.:

Q. Months prior. Why is that important, why is it important that that be shared with the other regions?

MS. WEGRYNOWSKI:

A. One of--if I understood correctly how the work was coming into Eastern Health and how it was authority for a particular portion of the province, I felt that it was important that everyone handle their tissues the same way and they have the same control management system, that it would guard against error, it would assist them in that. It's like being on the same page.

CHAYTOR, Q.C.:

Q. And you go on to say "The quality management

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team should be involved in the quality improvement activities within the organization and with the user physicians." Can you just explain what that means?

MS. WEGRYNOWSKI:

A. That you don't work in isolation, that you're part of a team.

CHAYTOR, Q.C.:

Q. Okay. And No. 30 says, "The laboratory is to establish quality indicators to monitor the laboratory's contribution to patient care." What would you be contemplating in terms of quality indicators in that context?

MS. WEGRYNOWSKI:

A. If I could just, their benchmarking tools. For example, if we go back to fixation, we would then start tracking what are the number of reprocessing, what are the issues that are coined in where are the problems that we're having so that you benchmark, you see what the numbers are and you try to narrow the gap.

CHAYTOR, Q.C.:

Q. Okay. And again you speak of, "For a successful quality management team, the laboratory management shall ensure that

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opportunities identified for improvement are dealt with." And what did you have in mind there?

MS. WEGRYNOWSKI:

A. That once a benchmark or once something is identified that there are processes in place to correct them.

CHAYTOR, Q.C.:

Q. And the "Corrective action logs should be assessed from each area and include an investigation to determine the underlying root causes. The results of the corrective action should be monitored to ensure they were effective in solving the original problem. Trends may also be identified which will aid in the development of policies and/or procedures." Can you just explain what you're referring to here and what kind of investigation would you contemplate to determine underlying root causes?

MS. WEGRYNOWSKI:

A. Okay. If I could just give you a very simple one. If you receive specimens to the laboratory and they're from a particular unit and you find consistently that there's patient

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information missing, it's that sort of information that you can compile because there needs to be then a learning tool to that particular unit. So by tracking that information then you could go back to them and say, this is what we're finding and this is what we need and this is why we need it, how can we work together to ensure that this is completed. And then you would then continue tracking to ensure that there's--it's been corrected.

CHAYTOR, Q.C.:

Q. Okay. And in this situation we understand and blocks were sent up to Mount Sinai from Newfoundland in the retesting process, that the blocks that were sent were the original blocks processed here in Newfoundland and then forwarded to Mount Sinai and Mount Sinai produced their own slides, and ultimately, as I'm sure you're aware, there were a number of conversions. What, from a technical point of view could be the cause of those conversions?

MS. WEGRYNOWSKI:

A. The way that the protocols and procedures that were in place at Eastern Health at the time

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they were using the DAKO autostainer were very different than what we use presently at Mount Sinai. They had validated their antibody--they were using their antibody with a pretreatment with the steam method and at Mount Sinai we do not use that particular method. We use a method to expose the epitope which is on a microwave and it's not like a home-based microwave. We use a particular piece of equipment that is NIST traceable, so again, the National Institute of Standardized Technology has this equipment where we can monitor the time at temperature so that we can guard against any irregularities, we can ensure that every single slide is treated at the same time at the same temperature, and I believe that was a crucial part of it. Our pipettes are guarded against, so we can guarantee that our dilutions are the same every day. And I'm not sure of what the detection system was for sensitivity at Eastern Health, but those I would think are reasonable parameters for change.

CHAYTOR, Q.C.:

Q. Okay. And then your report ends with a

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conclusion which basically, I believe, is a summary of everything that I've taken you through in terms of your recommendations, unless there's something in there that you would like to point out or emphasize? I'll just ask you to have a quick review of that?

MS. WEGRYNOWSKI:

A. No, I think it's a summation. I think it's just to bear in mind that the second paragraph on the last page, which reads "the stringency required to ensure the reproducibility of all immunohistochemistry testing is paramount. No antibody should be used on patients until after documented validation is completed," is probably one of the strongest paragraphs I wrote.

CHAYTOR, Q.C.:

Q. That probably sums it all, from your perspective?

MS. WEGRYNOWSKI:

A. I believe so.

CHAYTOR, Q.C.:

Q. So Ms. Wegrynowski, if we could have P-1757, please, Registrar? And this was the document I took you to yesterday which you believe to

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be the spreadsheet that you were provided before you came for your visit, the March 10th, 2006 spreadsheet, which had 30 recommendations on it from yourself or Dr. Banerjee and two--actually 28 of those and two at the bottom appear to be Dr. Cook and internal, so 28 from yourself and/or Dr. Banerjee, and if we could have then, please, P-0277? That was as of March 10th 2006.

MS. WEGRYNOWSKI:

A. Okay.

CHAYTOR, Q.C.:

Q. And you were here the end of March 2006, and this was the document that I meant to bring your attention to yesterday, after you left, after you left Eastern Health. I brought up the 2007 document, but this is actually updated April 25th, 2006.

MS. WEGRYNOWSKI:

A. Okay.

CHAYTOR, Q.C.:

Q. So this is the updated document, within a month or three weeks of your visit again, and this one is up to 30 recommendations here. I'm sorry, up to--and then we have June 30th,

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2006, and you'll see, at that point in time, the recommendations are then up to 52. So by June of 2006 and all of those recommendations are attributed to yourself and/or Dr. Banerjee. So certainly on the spreadsheet, the number of recommendations, some of which were no doubt from your initial assessment, but not recorded on the first spreadsheet.

MS. WEGRYNOWSKI:

A. Okay.

CHAYTOR, Q.C.:

Q. But by June 2006, it appears that any new recommendations that you came up with, as well as all your original, appear to now be on the spreadsheet.

MS. WEGRYNOWSKI:

A. Okay.

CHAYTOR, Q.C.:

Q. And if we could go back for a moment, please, to--I'm sorry, if there's anything there that you wanted to -

MS. WEGRYNOWSKI:

A. May I just -

CHAYTOR, Q.C.:

Q. Sure, take your time.

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MS. WEGRYNOWSKI:

A. When did you say this was written?

CHAYTOR, Q.C.:

Q. This one is indicated to be updated June, this particular version is June 30th, 2006. You see the date here in the top.

MS. WEGRYNOWSKI:

A. Okay, right.

CHAYTOR, Q.C.:

Q. Okay, and we get the current status, what's in progress or completed in this column and expected completion date in this column.

MS. WEGRYNOWSKI:

A. What does number 40 mean, when you're talking about pipette accuracy and calibration, that it's in progress? Why would it not be completed and ongoing?

CHAYTOR, Q.C.:

Q. And this is in--so that's as of June 2006, yes, okay, and I certainly don't know the answer, but I can appreciate you asking the question. If we could go back, please, to P-0048? And you indicate here, "the stringency required to ensure the reproducibility of all immunohistochemistry testing is paramount. No

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antibody should be used on patients until after documented validation is completed." In late March 2006, when you were in St. John's, was there any such documented validation?

MS. WEGRYNOWSKI:

A. Not on every antibody. I believe it was in progress. That would be earlier in the report, I believe.

CHAYTOR, Q.C.:

Q. Overall then, from your perspective, Ms. Wegrynowski, as of the time of your second review at the end of March 2006, how much progress had been made?

MS. WEGRYNOWSKI:

A. They had begun to look at the process. The procedure manuals were nowhere near where I thought they might have been. Some of the basics, I felt were still missing, refrigerators, pipettes. They had a long, long way to go. They had started on the external quality assurance programs, but in my humble opinion, if you don't start at the bottom, you can only take the top up so far.

CHAYTOR, Q.C.:

Q. And if we could look, please, at P-0314, page

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three? This is not a document I would expect you to be familiar with. It's a question and answer briefing note.

MS. WEGRYNOWSKI:

A. Okay.

CHAYTOR, Q.C.:

Q. It's a Government document, and it's dated May 2nd 2006, and what we understand is that this is what's prepared to provide information, for example, to the Minister and question and answer briefing notes often for heading into the House of Assembly, and this was Minister Osborne at the time and it refers to, under key messages, the third bullet, "a quality review began immediately when the problem was discovered. Eastern Health has had the method of testing for ER/PR receptors reviewed by external consultants," and we understand that to be certainly yourself and Dr. Banerjee. "Their recommendations have been implemented and the consultants returned to Eastern Health in early April to assess" and it says "of progress."

MS. WEGRYNOWSKI:

A. Okay.

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CHAYTOR, Q.C.:
Q. "Eastern Health expects to begin testing of new patients in St. John's once the consultants' final report has been received and reviewed, likely in late May" and the idea of "their recommendations being implemented and consultants returned in early April to assess progress," and we understand it was late April that Dr. Banerjee was in and you were in in late March, and this is underlined and a note made over here and there's been evidence that this is from Minister Osborne, and he recorded that he was told that the consultants were very pleased with the progress/results.

In terms of what you've personally, your opinion as to the progress of the results, would it be fair to say that you were very pleased with the progress and the results, upon your second visit?

MS. WEGRYNOWSKI:
A. I think the word "very" is an overstatement. I think they had made some start. You would have to speak to the person that gave Minister Osborne that information.

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CHAYTOR, Q.C.:
Q. Yes. I'm just wondering though how that--if that is being reported as your assessment or that you were--your opinion is that you were very pleased, what is your response to that?

MS. WEGRYNOWSKI:
A. I did not get a sense from my report that I was very pleased.

CHAYTOR, Q.C.:
Q. So Ms. Wegrynowski, you sent your report on in May of 2006. Did you receive any feedback from that report?

MS. WEGRYNOWSKI:
A. No, just a letter.

CHAYTOR, Q.C.:
Q. And the letter thanking you, I take it, for your services?

MS. WEGRYNOWSKI:
A. Correct.

CHAYTOR, Q.C.:
Q. Did anyone ever discuss with you the possibility of coming here to do a seminar or a discussion on quality assurance?

MS. WEGRYNOWSKI:
A. They had spoken to me briefly at my meeting with the pathologists, that they were looking at doing a day with QA and whatever lectures and asked me if I'd be interested in participating in that, but I never heard anything back.

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CHAYTOR, Q.C.:
Q. Okay. You said that in your exit interview, I believe, with Dr. Williams, he asked you some questions about the difference between CAP and UK NEQAS?

MS. WEGRYNOWSKI:
A. Yes.

CHAYTOR, Q.C.:
Q. What are the differences between those two programs?

MS. WEGRYNOWSKI:
A. Okay. The College of American Pathologists for immunohistochemistry, what happens is that you will receive your survey, they will send you the slides. They will tell you what markers they would like you to stain. You provide them with the information of what clone you're using and the manufacturer. You stain the slides with your own in-house controls and your negative controls, and the

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pathologists will then read them. It is set up so that the pathologist has--they're able to select from a list what the responses would be, whether it's one plus, two plus, three plus or whatever it is. They are given a very short history of the patient, and at the end, there are different diagnosis and they select what that is. The slides are retained in the laboratory and the paperwork is then sent off to CAP. They then which compile it and then you're rated against your peers. How many came up with this for a response signal? How many came up with this for a diagnosis? And that's--and then you also know who's using what clone in the marketplace. So it can be used in a variety of ways.

With the UK NEQAS, it's a little bit different. They send you the slides. You then stain the slides in-house. You provide them with your protocols. You then evaluate the slides with your pathologist, so you provide a technical mark and the pathologist provides a mark as well. You send it off to them and then they return the paperwork and slides to you and with their mark by four

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assessors.
CHAYTOR, Q.C.:
Q. And you compare then yours to theirs?
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. And is there any particular benefit to one program as opposed to the other?
MS. WEGRYNOWSKI:
A. They both have their own pros and cons.
CHAYTOR, Q.C.:
Q. And I take it in some respects, they complement one another?
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. I'd just like to explore with you a little bit about the training of technologists for IHC, and you indicated that when you were trained, that it was not part of the--the actual IHC was not part of your training at that point in time. Is it currently part of the curriculum for technologists?
MS. WEGRYNOWSKI:
A. No, it is not, unfortunately.

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CHAYTOR, Q.C.:
Q. Okay, and so then bringing a technologist into your IHC lab at Mount Sinai, how is that person trained to do their job?
MS. WEGRYNOWSKI:
A. We start off at the ground. The microtomy that is used in IHC is very different than what you would use in the routine histology laboratory. One of the reasons are that the block has already been given an HNE. So you want to ensure that the tissue is never removed. You don't want to lose any of the tumor tissue. So the way that we even perform the microtomy is very different.

Going forward from that, the way we handle our slides are different. Some slides are heated. Some slides are kept in the cold. So there's different parameters with that that they need to learn. We do it on a very, very slow basis. It's rather overwhelming to say to someone, here, just sit and do this. One of the things they must always do is they must read our standard operating procedures and our manual. They learn from the very beginning that when inventory comes in, how they are to

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handle it. It's all the lot information. It sounds rather dry, but it's done in a very, very systematic order.

Once the technologist is comfortable with the microtomy, and it's not just the microtomy, they're learning and they're understanding. It's a different nomenclature. The names that I used today probably don't make much sense to many people. If you can imagine if you have 300 different antibodies that they sound so alien. So it's an opportunity for a technologist to start understanding the verbiage that we use and how we handle them. There are many different pre-treatments associated with the antibodies and that becomes all marked on the slides for them. So they start understanding a little bit about the work flow. They are always given the opportunity to review the antibody specification sheets and all validation slides that are held with them. All the slides that we are presently using now for validation are all marked with the validation date and the lot number down the slide and they are always kept by our microscope. Even when reviewing

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positive control ourselves, we go back and we look at them. We don't--people don't use antibodies every single day. Some are very specialized, and if we ourselves are not sure, we're more than happy to include them and give them to the pathologist, who will get back to us, and we can view them again at the multi-header at a later date.

So that's just part--just of that portion, and then the technologist would start moving on to what we call the sort and handling desk, which is if you have 400 slides looking at you, you have to find a way to put them in some semblance of order and that is based very much on the pre-treatment and the detection system that we use. So that when we set up for a day's run, when our machines are only holding 50, how do you accommodate four or five hundred slides a day in a very streamlined fashion and provide a turnaround time that is expected from your department?

At that point, again, there is the review of the slides. There is the review of the controls and no one is ever left alone to do a task. From there, we move on to start

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bringing people in and they will start setting up in the morning. So it's at that point, they start learning about the pre-treatments, how we do the pre-treatments, how do we ensure that the consistency of the pre-treatments. But all the way along, they're learning, they're making up the buffers. So they're pHing the buffers. They're becoming part of the integral part of the department. They recognize--many of them will start--actually I should backtrack.

Many of them will start with very simple techniques, which is a kidney biopsy. It comes in, it's cut on a microtome--a cryostatic, excuse me, so it's frozen. It's a one-step immunohistochemistry technique. So you put on that antibody. They learned how to dilute the antibody. They learn to work within the dark and they learn how to take it forward. Keep it in the fridge, sign it up to the pathologist. So very rudimentary steps there introduced.

And from there, in a very slow, organized fashion, then we move on to being able to work on the equipment, understanding the equipment,

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what the alarms mean, if there's a problem with set up, how do we change drops, and that is gone over in a very slow fashion. From there, we'll start working on getting the slides out and then sitting down together and finally reading the controls together.

CHAYTOR, Q.C.:

Q. Ms. Wegrynowski, how long does all take? How long a process is it before that technologist is then actually left on their own to do their job in the IHC lab?

MS. WEGRYNOWSKI:

A. About a year into it.

CHAYTOR, Q.C.:

Q. I'm sorry?

MS. WEGRYNOWSKI:

A. About a year.

CHAYTOR, Q.C.:

Q. About a year before they're left to do their job on their own?

MS. WEGRYNOWSKI:

A. Depending on what part it is. Some parts, you're certainly comfortable with in six months, but we're talking the full gamete, I would say easily a year, and even then, it's

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not unusual to come in in the morning and say "I didn't hand this out because I'm not quite sure," and we'll go over that together.

CHAYTOR, Q.C.:

Q. And if that, if it's a technologist who otherwise had years of training in other parts of the pathology lab, would that time period be abbreviated?

MS. WEGRYNOWSKI:

A. Yes, it would be, because my expectations are, at that point, that they understand microtomy. They would understand the issues with that. They would still certainly have to spend time on that bench understanding the differences between the different antibodies and how the slides have to be handled. It would be an abbreviated version, but it still wouldn't be--it would still be six to nine months. It's not routine histology. It's very, very different. So we spend a lot of time going over troubleshooting issues.

CHAYTOR, Q.C.:

Q. Ms. Wegrynowski, if there were to be any suggestion that what happened in the lab here in St. John's might not be different than

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what's happening in other labs across the nation, that this in fact could be a national issue because of the test being finicky or probabilistic, based on your review of the lab in St. John's, do you agree with that assessment or suggestion?

MS. WEGRYNOWSKI:

A. The word "finicky" no. Capricious perhaps. If it is done in a very stringent manner and you have all guards against it, then I'm not sure I agree with that comment.

CHAYTOR, Q.C.:

Q. Just have a general question for you, in terms of a process that we heard at least in mid to late January of this year, and I'm not sure that this process is still being carried out, but I would just ask whether or not there's any concerns regarding this. There's some suggestion that when the ER/PR tests resumed here in St. John's that all the breast tissue was being grossed at St. Clare's Hospital. So if the breast surgery occurred at the Health Sciences -

MS. WEGRYNOWSKI:

A. Yes.

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CHAYTOR, Q.C.:
Q. - the specimen would be placed in formalin in the OR, sent down to the lab, before it then gets transferred over to St. Clare's to have-- to be grossed, the formalin was drained off the specimen, packed in a bag, sealed in a container and sent over, that could take anywhere from half hour to forty-five minutes. The specimen then is grossed at St. Clare's, the block sent back--block produced, block sent back to Health Science, the slides are made there and stained, then the slides were sent back to St. Clare's to be interpreted by the two pathologists over there. Could you provide any comment on, please, whether or not you have any concerns about that as a process.
MS. WEGRYNOWSKI:
A. I think you lost me halfway through.
CHAYTOR, Q.C.:
Q. I'm sorry.
MS. WEGRYNOWSKI:
A. Sorry.
CHAYTOR, Q.C.:
Q. Okay, well it's a good thing I have notes, I'll try again. Okay, so the surgery taking

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place at--the breast surgery taking place at Health Sciences.
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, all the grossing is taking place at St. Clare's, so the specimen is then sent over to St. Clare's to be grossed.
MS. WEGRYNOWSKI:
A. Okay.
CHAYTOR, Q.C.:
Q. In order for that to happen, the formalin being--drained off the breast tissue, packed in a bag, sealed in a container, sent across town, might take half hour to forty five minutes.
MS. WEGRYNOWSKI:
A. At what temperature?
CHAYTOR, Q.C.:
Q. I don't know, and we understand it was being sent by courier.
MS. WEGRYNOWSKI:
A. Okay.
CHAYTOR, Q.C.:
Q. The idea of the formalin being drained off, is

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that of any concern?
MS. WEGRYNOWSKI:
A. I'm not familiar with that procedure.
CHAYTOR, Q.C.:
Q. Have you ever heard of that happening?
MS. WEGRYNOWSKI:
A. No.
CHAYTOR, Q.C.:
Q. And the specimen is then--the blocks are then sent back to the Health Science and the slides made and then the slides sent back. You indicated that Mount Sinai does this testing for other centres?
MS. WEGRYNOWSKI:
A. Yes, we do.
CHAYTOR, Q.C.:
Q. And in terms of receiving the samples into Mount Sinai, I take it the specimen doesn't come in a bag without formalin?
MS. WEGRYNOWSKI:
A. No, and the work that I receive always comes in blocks. I wouldn't receive fresh specimens.
CHAYTOR, Q.C.:
Q. So the blocks are done in the site and then

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sent on to Mount Sinai and then you make your slides?
MS. WEGRYNOWSKI:
A. Yes, yes.
CHAYTOR, Q.C.:
Q. If we could look at P-0764 please? And this is a draft fixation policy and as of the last evidence we've had from Eastern Health on it, it had not yet been implemented but there's certainly a good draft made here and if you could just have a look at this document and -
MS. WEGRYNOWSKI:
A. Right.
CHAYTOR, Q.C.:
Q. - tell me your thoughts and any comments you may have on this document?
MS. WEGRYNOWSKI:
A. All right. I agree with her overview. Three hours is rather short for fixation on a biopsy, but if that's--there are no national standards on that, but -
CHAYTOR, Q.C.:
Q. So the three hours on the biopsy is short, in your opinion.
MS. WEGRYNOWSKI:

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A. But there are no national standards, so - I definitely agree with the statement that "if the appropriate fixation time is not met, the following statement will be attached to the final specimen report. Pathology results may be adversely affected due to improper tissue fixation." I concur. Yes.

CHAYTOR, Q.C.:

Q. Okay, so I take it for an SOP, at least for the fixation, that this would pretty well cover what you had in mind?

MS. WEGRYNOWSKI:

A. Yes. They would also have to include in their standard operating procedures for when they're doing their grossing, what their expectations were, is that for handling of the larger specimens.

CHAYTOR, Q.C.:

Q. Okay, can you give us an example of that?

MS. WEGRYNOWSKI:

A. If something came in, what's your expectation times, how it was going to be blocked--bread loafed, whatever and the whole bit and how long it was going to be sitting in formalin prior to it being grossed. Because you would

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bread loaf it, if you got a piece of breast, you would bread loaf it, you wouldn't necessarily make your blocks that day, it would then sit in a container and then your blocks would be made the following day.

CHAYTOR, Q.C.:

Q. Okay, and it does indicate here the date and time of fixation must be documented on the requisition.

MS. WEGRYNOWSKI:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And there are other linkages cross referenced, I'm not sure though, we've been through this before, whether or not any of them--we have breast specimen, needle localization -

MS. WEGRYNOWSKI:

A. That may very well then be speaking to what I just mentioned.

CHAYTOR, Q.C.:

Q. Yeah, not sure of that right now but we can certainly have a look at that. Is there anything else included in there or not included in there that you would like to see or is this pretty well--pretty well does it?

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MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. So Ms. Wegrynowski, after submitting your second report in May of 2006, were you ever contacted by Eastern Health for any further advice or assistance on this matter?

MS. WEGRYNOWSKI:

A. No, I was not.

CHAYTOR, Q.C.:

Q. Have you ever had any further contact from Eastern Health regarding your two reviews and the reports that you produced?

MS. WEGRYNOWSKI:

A. I've had two phone calls subsequent to my last visit at Eastern Health.

CHAYTOR, Q.C.:

Q. And when did those phone calls take place?

MS. WEGRYNOWSKI:

A. One was last spring and one was later--one followed that, I couldn't give you the dates, the exact dates.

CHAYTOR, Q.C.:

Q. So spring meaning spring 2007?

MS. WEGRYNOWSKI:

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A. Yes.

CHAYTOR, Q.C.:

Q. And who was that phone call from?

MS. WEGRYNOWSKI:

A. That phone call was from Mr. Barry Dyer.

CHAYTOR, Q.C.:

Q. And what was the purpose of Mr. Dyer's phone call in the spring of 2007?

MS. WEGRYNOWSKI:

A. He called to let me know that the Premier would be reading my report that afternoon.

CHAYTOR, Q.C.:

Q. That the Premier would be reading your report?

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. Was anything else discussed with Mr. Dyer?

MS. WEGRYNOWSKI:

A. I don't recall.

CHAYTOR, Q.C.:

Q. What was your reaction to that?

MS. WEGRYNOWSKI:

A. Put the phone down and said, "Oh".

CHAYTOR, Q.C.:

Q. Okay, if we could look, please, at P-0455?

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And this is e-mail exchanges which start on May 23rd, 2007 from Barry Dyer to Terry Gulliver. This is within Eastern Health, Ms. Wegrynowski, and the importance is indicated, there's no subject indicated but importance is high. And it's "Hi, Terry! Trish was notified on Wednesday, May 23rd at 1240 hours"--so the time and date is recorded. "She does not want the report to go public." Was there any discussion about your report going public?

MS. WEGRYNOWSKI:

A. I don't remember that, I think the first comment kind of negated anything after that.

CHAYTOR, Q.C.:

Q. Then that e-mail gets, the line, as we will, from Terry then, Terry Gulliver passes that on to Nash Denic. Subject is forwarding the e-mail, importance is high. Dr. Denic then passes that up the line, same date at 3: 45 p.m. to Dr. Howell. The subject is T. Wegrynowski's report, importance high. "Hi Oscar, Trish Wegrynowski, the lab reviewer, doesn't want her report to go public." And then Dr. Howell passes that, the next day, up

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to the CEO, George Tilley and the subject is forward T. Wegrynowski's report, importance high. "FYI, for what it's worth, Oscar." So is this, May 23rd, is that time consistent with your recollection of when you received that phone call?

MS. WEGRYNOWSKI:

A. I couldn't give you the exact date, but it certainly happened in the morning before lunch and as far as the report going public, I never assumed it would go public because it was a peer review and they had told me I was covered under the Evidence Act.

CHAYTOR, Q.C.:

Q. And what Mr. Dyer indicated to you was that the Premier would be reading your report that day?

MS. WEGRYNOWSKI:

A. That's what I heard.

CHAYTOR, Q.C.:

Q. Ms. Wegrynowski, the second phone call you received was from whom?

MS. WEGRYNOWSKI:

A. Pat Pilgrim.

CHAYTOR, Q.C.:

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Q. And what was the purpose of Ms. Pilgrim's call?

MS. WEGRYNOWSKI:

A. To tell me that the report that was written under the Evidence Act, that there was discussions going on in the legislature about that.

CHAYTOR, Q.C.:

Q. I'm sorry, discussions?

MS. WEGRYNOWSKI:

A. Concerning--from what I recall, concerning how this, how my report was being--how the Evidence Act was reflected upon my report and that seems right.

CHAYTOR, Q.C.:

Q. I'm sorry, I didn't mean to cut you off.

MS. WEGRYNOWSKI:

A. I said maybe I'm not explaining it correctly, I don't know enough about the Evidence Act, myself, but I got the sense that what I had originally signed up for was the parameters were now changing.

CHAYTOR, Q.C.:

Q. So at that point in time there was discussion that your report may not be protected under

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the Evidence Act any more?

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. And I take it that phone call happened sometime after Mr. Dyer's phone call to you?

MS. WEGRYNOWSKI:

A. Yes.

CHAYTOR, Q.C.:

Q. Was it a matter of months later, weeks later?

MS. WEGRYNOWSKI:

A. I don't have a sense of time on that.

CHAYTOR, Q.C.:

Q. Okay. And I take it no further contact after that?

MS. WEGRYNOWSKI:

A. None.

CHAYTOR, Q.C.:

Q. Were you contacted to be advised that your reports, that in fact there had been an application to the Court and that your reports, pursuant to Judge Dymond's decision could be used by this Commission. Was there any contact made to advise you of that?

MS. WEGRYNOWSKI:

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A. I only heard from my own in-house people.
CHAYTOR, Q.C.:
Q. Okay. Ms. Wegrynowski, I'll just take a moment here, but I believe those are all my questions for you. There was one issue, I'm not sure if this came out, how many ER/PR tests currently are carried out in your lab at Mount Sinai?
MS. WEGRYNOWSKI:
A. Oh I don't know, I think I gave this number somewhere along the line to someone, I don't know, a thousand tests a year, easily, I don't know. I could get back to you on that if you need a firm number.
CHAYTOR, Q.C.:
Q. Okay, that's fine, thank you. Is there anything else that I have not covered with you that you think would be important for the Commissioner to know or that you would otherwise like to share with the Commissioner?
MS. WEGRYNOWSKI:
A. If I may make some closing remarks? This process has been weighing heavily on my mind for nearly two years. If I may, Madam Commissioner, I would like to make some

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closing remarks for your consideration. First and foremost, I think that not many are aware that up to 85 percent of decisions concerning diagnosis and treatment are based on laboratory test results. Medical laboratory technologists are one of the largest groups in the medical community, yet we are the least recognized. When the general public thinks of health care professionals, doctors and nurses immediately come to mind. We struggle with our low profile because we perform our roles behind the scenes. Laboratories are a critical component of the health care system. Because of the demand for resources in other areas of health care, our visibility is further diminished. It is time that the importance of medical laboratory technologists is recognized.

In the past, medical laboratory technologists were excluded from important public policy decision-making. It has only been recently that health care leaders and government officials have asked for our professional input. Our input is vital for successful patient care at a national level.

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It is well documented that a shortage of medical laboratory technologists will occur within the next decade. The paucity will have a significant detrimental impact on the Canadian health care system. In my opinion, it is imperative that requirements for entry into the profession, as well as our standards of practice, are not eased. Core competencies must continuously be upgraded to reflect evolving medical advancements. It is the obligation of the medical laboratory technologist to be responsible and accountable for their professional acts and practices. There are discreet and well-defined standards of practice, as well as laws and regulations governing our profession. The onus is in all in the profession to maintain and improve their skills and knowledge and to keep current with our changing scientific advances through continuous learning.

Immunohistochemistry medical technologists are integral members of the health care team. We share knowledge which is essential to the diagnosis and treatment of disease. In the pathology setting, the

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pathologist and the medical laboratory technologist work in tandem. The technologist must perform reproducible tests in a stringent manner and the pathologist must interpret technically complex results; thus together providing effective patient care.

Although each of our professions have defined scopes of practice, they are interdependent. Due to complex and highly interpretative nature of immunohistochemistry testing, effective interaction between the pathologist and the medical laboratory technologist is a necessity. Immunohistochemistry has a direct and immediate impact on patient diagnosis and therapies. Historically, immunohistochemistry has been a satellite laboratory to histology. Immunohistochemistry and histology are two different entities and should be treated as thus. Recognized subspecialties include electron microscopy and cytogenics. In my opinion the dynamic and complex nature of immunohistochemistry warrants specialized training at the academic level, as well as stringent adherence to practice, as it is a

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dynamic and not a static laboratory.

I would like to thank you for your time today and for giving me the opportunity to offer my opinion to this process.

CHAYTOR, Q.C.:

Q. Thank you, Ms. Wegrynowski.

MS. WEGRYNOWSKI:

A. You're welcome.

THE COMMISSIONER:

Q. Some of the other counsel here may have some questions for you. Mr. Pritchard?

MS. PATRICIA WEGRYNOWSKI, EXAMINATION BY MR. ROLF PRITCHARD.

MR. PRITCHARD:

Q. Thank you, Commissioner. Good morning, Ms. Wegrynowski. My name is Rolf Pritchard and I'm here representing Her Majesty in Right of Newfoundland and Labrador. I just have one or two questions for you this morning.

Ms. Wegrynowski, you mentioned that you received a phone call, I think you said in the spring of 2007 from Mr. Dyer.

MS. WEGRYNOWSKI:

A. Yes.

MR. PRITCHARD:

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Q. And he advised you that the Premier was going to read your report. Is that correct?

MS. WEGRYNOWSKI:

A. Correct.

MR. PRITCHARD:

Q. And do you have any knowledge of whether or not the Premier ever did read your report around about that time?

MS. WEGRYNOWSKI:

A. I have no knowledge.

MR. PRITCHARD:

Q. No, all right. Thank you very much.

MS. WEGRYNOWSKI:

A. You're welcome.

THE COMMISSIONER:

Q. Thank you. Mr. Simmons?

MS. PATRICIA WEGRYNOWSKI, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Thank you, Commissioner. Good morning, Ms. Wegrynowski, we've met before and as you know I'm here representing Eastern Health. So, I do have some questions for you coming out of the evidence that you've given so far. And some of it is background and things we're

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interested in in relation to the way you do things at Mount Sinai and some other things are more specific to what you done for Eastern Health.

First of all, I just want to pick up on a point you've just made in your statement. And you said, if I can get this right, that one of the things that's needed in immunohistochemistry in Canada, I take it, is that there needs to be specialized training at an academic level for people involved in immunohistochemistry. And I wonder if you can tell me a little bit more about what you foresee there? What type of academic training you think should be available and whether you know if that type of academic training for immunohistochemistry is currently available anywhere in the country?

MS. WEGRYNOWSKI:

A. I don't believe it's available anywhere in the country, but I would like to see that immunohistochemistry is, at least, provided a part of the pathology modules when medical laboratory technologists are being training, at the very least.

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MR. SIMMONS:

Q. So, at the very least, it should be something that would be added to the training programs for the technologists. And if you had your druthers, as they say, where would you see it? How far would you see it going?

MS. WEGRYNOWSKI:

A. It could certainly be done as a speciality advancement.

MR. SIMMONS:

Q. Okay.

MS. WEGRYNOWSKI:

A. But the same being said as well as for residency programs, pathology residents need the same sort of experience and expertise as well.

MR. SIMMONS:

Q. Yes. And from your knowledge, do they receive that type of focus in their residency training?

MS. WEGRYNOWSKI:

A. Not to my--but I can't comment on that. It's just something that I would be aware of.

MR. SIMMONS:

Q. Okay. So, in the absence of that type of

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academic level training for technologists. I take it what has happened in your laboratory is that you wanted to take fairly extensive orientation and training program yourself that you described for us earlier.

MS. WEGRYNOWSKI:

A. Correct.

MR. SIMMONS:

Q. Yes, okay. Now, in your laboratory, I believe you've told us that you have five technologists who are dedicated to full time work in the immunohistochemistry.

MS. WEGRYNOWSKI:

A. Correct.

MR. SIMMONS:

Q. And your position is as--I mightn't get the title right--but lead technologist for those five.

MS. WEGRYNOWSKI:

A. That would be fair.

MR. SIMMONS:

Q. And as the lead technologist, is part of you role then to bring a higher level of knowledge and expertise to the work than the other five may have. So that if there are more

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complicated things to do or difficult troubleshooting to do, that you would become involved in it.

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. Is that part of what you do?

MS. WEGRYNOWSKI:

A. That's part of what I do.

MR. SIMMONS:

Q. Okay. So, would it be fair for me to expect then that the other five technologists wouldn't be expected to necessarily have the same in-depth understanding of IHC that you've been able to demonstrate for us here?

MS. WEGRYNOWSKI:

A. My expectation is that they would understand that theory and be able to participate in the troubleshooting.

MR. SIMMONS:

Q. Right, okay. How often is--I know you've described IHC as complex, there are many different antibodies and many different purposes, how common is it for troubleshooting to be required when these tests are being

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performed?

MS. WEGRYNOWSKI:

A. That would depend on circumstances.

MR. SIMMONS:

Q. Sure. In your experience, is it something that comes up daily, weekly, once a month?

MS. WEGRYNOWSKI:

A. Any of the above.

MR. SIMMONS:

Q. And of the above, it depends. You do, but it's not uncommon for troubleshooting to be required in one type of test or another, is it?

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. Okay. And how--what are the different ways that it might be recognized that troubleshooting in a test is needed? How does it bubble up to the surface? Who brings it up to someone's attention that we have a problem that we need to deal with?

MS. WEGRYNOWSKI:

A. Your controls would fail, you would have non-specific staining.

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MR. SIMMONS:

Q. Um-hm, okay. So, are there situations where the technologists, the five technologists who work for you would recognize that there's been an issue with a test and we need to troubleshoot it?

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. Okay. Are there cases where your technologists would not be the ones to recognize it, but someone else in the chain?

MS. WEGRYNOWSKI:

A. It can happen.

MR. SIMMONS:

Q. Yes. Are there cases where it would be the pathologists who review the results of the work would come back and say, we have an issue that needs troubleshooting?

MS. WEGRYNOWSKI:

A. Yes, they can come back. They most certainly do.

MR. SIMMONS:

Q. Okay. So, in your experience, both of those are potential sources of recognition that

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there's an issue that needs troubleshooting?
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. Yes. And I expect that there's different levels of involvement that the people in your lab and the pathologists have when it comes to actually doing the troubleshooting in a test. Are there things that the technologists can look after themselves, problems that they solve on their own?
MS. WEGRYNOWSKI:
A. Could you give me an--I'm not sure what you're asking.
MR. SIMMONS:
Q. Well, if you've got an external control that's failed and the technologist look at it and they can tell that the control didn't stain at all when it's supposed to. Is that the sort of thing that they would tackle--a problem they would tackle solving on their own or would they immediately bring someone else in to help them?
MS. WEGRYNOWSKI:
A. No, we would take care of that ourselves. We

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would stop it and say "this didn't work. Okay, what do we need to do?" and start forward the following day.
MR. SIMMONS:
Q. Right. Are there situations where you have a troubleshooting to be done where you would have to involve expertise beyond your own technologists in order to solve the problems?
MS. WEGRYNOWSKI:
A. Could you provide me with an example of that, please?
MR. SIMMONS:
Q. Not very well, because I don't understand the details of it well enough to give you a specific example, but are there situations where if a pathologist has recognized a problem, that you've got pathologists in your laboratory medicine program who you can turn to for assistance in troubleshooting problems?
MS. WEGRYNOWSKI:
A. My pathologists, do they help me troubleshoot? Well, we can certainly have a dialogue about it.
MR. SIMMONS:
Q. Yes. Are there pathologists at Mount Sinai

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who are sub-specialized in the sense that they are particularly interested or particularly work in areas that involved one set of testing, like the ER/PR testing, for example?
MS. WEGRYNOWSKI:
A. Absolutely. Mount Sinai is, that's what we are compromised of.
MR. SIMMONS:
Q. Right, and at Mount Sinai, those are Dr. O'Malley and Dr. Mullen, I believe?
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. So do you ever have occasion where you have to involve people like them in issues to do with troubleshooting the results of tests?
MS. WEGRYNOWSKI:
A. Not necessarily troubleshooting, but there's certainly a dialogue if somebody wanted to come back to you about something. When it comes to our breast work, most of our work is outside consult work, so--and I go back to our client satisfaction forms, that this is what -
MR. SIMMONS:
Q. Yes.

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MS. WEGRYNOWSKI:
A. So if they're not seeing something at their end, they'll come back. They have no problems coming back and asking questions. The same is true of all the pathologists.
MR. SIMMONS:
Q. Yes. So the outside pathologists who send in the consults will come back to you with questions as well? Is that what you're saying?
MS. WEGRYNOWSKI:
A. I have not ever had that.
MR. SIMMONS:
Q. Okay, sorry, misunderstood that. You had told us, going back sometime, to when you first were first involved in ER/PR testing being instituted by the IHC method. I think you were at was it Women's College Hospital?
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. And that was a transition from what we've heard described as the ligand binding assay or LBA method?
MS. WEGRYNOWSKI:

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A. Correct, yes, the DCC method, yes.
MR. SIMMONS:
Q. We've also heard it referred to as a bioassay?
MS. WEGRYNOWSKI:
A. That's correct.
MR. SIMMONS:
Q. Is that another term for it?
MS. WEGRYNOWSKI:
A. Yes, it gave a quantitative number, yes.
MR. SIMMONS:
Q. And you were involved, I think, in that at the time when that was done at the lab where you worked, were you?
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. And did I understand you to say that the validation process used then was to compare the IHC results against the ligand binding assay results?
MS. WEGRYNOWSKI:
A. That was part of that premise, yes. They wanted to assure the specificity and accuracy, that's correct.
MR. SIMMONS:

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Q. Right, right, so it wasn't--and we've also heard mention of gold standards here in testing, and some of us lay people have had conceptions about what that means, but I'm not sure if we're right. Is there, in laboratory medicine, a technical use to the term "gold standard"? When you speak of there being a gold standard for a test, what is that?
MS. WEGRYNOWSKI:
A. I'm not sure I've used that term myself, but -
MR. SIMMONS:
Q. Well, I think in relation to the FISH comparison for HER2. I'm not sure if you did or if one of the witnesses earlier used that.
MS. WEGRYNOWSKI:
A. I did not refer to it that way, but I can speak to you how the comparative is derived.
MR. SIMMONS:
Q. Yes, sure.
MS. WEGRYNOWSKI:
A. When the DCC method could give a quantitative response to the amount of estrogen and progesterone in the tumor, you were able to get a succinct number. Much pathology, you must understand, although it is rather

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quantitative, it is rather--it's qualitative quantitative because we do not put in a piece of whatever and come out with a number, and so when you're talking about comparing FISH to HER2/neu or the DCC to estrogen and progesterone, if that's what you're going--if that's what I'm understanding the question, then that's how it is done.
MR. SIMMONS:
Q. Okay, and because another way, I would understand, to validate a test like ER/PR would be to compare your test results to a clinical outcome with a patient, and eventually, I think, there was research done which -
MS. WEGRYNOWSKI:
A. Done to ensure that that -
MR. SIMMONS:
Q. - approached it that way, so that you know that your test result matches something that provides a benefit to a patient.
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. But when ER/PR was instituted by the IHC

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method, the validation process was to compare it to the previous test?
MS. WEGRYNOWSKI:
A. You'd need to speak to Dr. Frances O'Malley or Brendan Mullen about this.
MR. SIMMONS:
Q. Okay, but at the time that you were involved in it, that was, I presume, considered an appropriate way to validate ER/PR by IHC was to have a process of comparing it to the ligand binding assay?
MS. WEGRYNOWSKI:
A. At a technical level, that's what I was asked to do.
MR. SIMMONS:
Q. Yes, and at the technical level, would that involve running parallel tests, a test of a sample on ligand binding assay and test the same sample on ER/PR -
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. - and see what the results were, okay. So if that was the approach that had been used here in St. John's, that was what was then the

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Health Care Corporation prior to Eastern Health, when the ER/PR test was instituted, that wouldn't surprise you that that same process would have been adopted for the initial validation of it?

MS. WEGRYNOWSKI:

A. That would be fair.

MR. SIMMONS:

Q. Okay. I have some questions about the machinery used in IHC testing.

MS. WEGRYNOWSKI:

A. All right.

MR. SIMMONS:

Q. And I've heard references to open systems and closed systems, and my understanding, which might not be correct, is that the DAKO semi-automated system used in your lab and previously used here is what's called an open system because there's the ability to vary things like antibody dilutions and antigen retrieval methods and timing. And that the Ventana benchmark system now in use here is considered a closed system because you don't have the same ability to vary those types of things. Am I on the right track with that?

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MS. WEGRYNOWSKI:

A. I think that's fair.

MR. SIMMONS:

Q. Okay. And are there any--and both types of systems are in use across the country in labs now, I believe?

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. Yes, they are. And are there any particular pros and cons to taking one approach, the open system approach or the closed system approach?

MS. WEGRYNOWSKI:

A. It needs to fit the needs of your organization?

MR. SIMMONS:

Q. Yes. What sort of needs would suggest that the open system or the closed system might be a better fit?

MS. WEGRYNOWSKI:

A. Again, it would depend on the needs of your organization, volume, cost. There are many factors.

MR. SIMMONS:

Q. Um-hm, right. At Mount Sinai, we understand

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that you work in what I think you call the service lab.

MS. WEGRYNOWSKI:

A. Yes, I do.

MR. SIMMONS:

Q. Which provides testing for clinical reasons for patients.

MS. WEGRYNOWSKI:

A. Correct.

MR. SIMMONS:

Q. And Ms. Mendas is she kind of your counterpart in the research lab?

MS. WEGRYNOWSKI:

A. No, she's the manager of the research lab.

MR. SIMMONS:

Q. Oh, she's the manager, okay.

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. So, there's the separate research lab as well?

MS. WEGRYNOWSKI:

A. Yes, there is.

MR. SIMMONS:

Q. Both use the open system.

MS. WEGRYNOWSKI:

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A. Yes.

MR. SIMMONS:

Q. Is there any particular advantage to the open system in the research environment, in the research lab.

MS. WEGRYNOWSKI:

A. Again -

MR. SIMMONS:

Q. You can't say, okay. You suggested that there are actually some variations in protocol between the research lab and the service lab in your institution, between the protocols that are used. You don't have the same set of written protocols for performance of IHC testing in both labs, do you?

MS. WEGRYNOWSKI:

A. No, I have my own set. They have their own set, but they do mirror each other I understand.

MR. SIMMONS:

Q. Sure, yes. But it hasn't been determined that there needed to be a single set of protocols that were exactly the same in both labs?

MS. WEGRYNOWSKI:

A. That is no in part of my decision making.

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MR. SIMMONS:
Q. Okay. You had mentioned that there's a college in Ontario that medical laboratory technologists are members of. That's a licensing body, is it?
MS. WEGRYNOWSKI:
A. Yes, it is.
MR. SIMMONS:
Q. And is that licensing mandatory in the province of Ontario?
MS. WEGRYNOWSKI:
A. To work in the province of Ontario, we must be members of CMLTO.
MR. SIMMONS:
Q. How long has that been in effect roughly?
MS. WEGRYNOWSKI:
A. I know that's on my CV.
MR. SIMMONS:
Q. It hasn't been 20 or 30 years? It's relatively recent, isn't it?
MS. WEGRYNOWSKI:
A. It took a number of years for us to get to that point.
MR. SIMMONS:
Q. Yes. Have you seen any particular value or

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advantages come out of having a college in place that licenses and presumably carries out some other functions in Ontario?
MS. WEGRYNOWSKI:
A. Yes. I believe that because--I think the technologist has to understand more about their scopes of practice. And we have our focus magazines, opportunities for learning. As I say, I've worked on the practice guidelines so we were able to guide what are the expectations of the histology in the province of Ontario. So, there's a wealth of information that we can get out for the college, but most importantly, the public is protected. College is for the public, not necessarily for the technologists.
MR. SIMMONS:
Q. Right. Well, it enables the technologists, I presume, to deliver a more standardized and perhaps better approach in product, in -
MS. WEGRYNOWSKI:
A. Well, that QMPLS.
MR. SIMMONS:
Q. Okay. Well, in the college then, you've said that you've worked for the college on practice

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guidelines?
MS. WEGRYNOWSKI:
A. Yes, I have.
MR. SIMMONS:
Q. Okay. Were those sorts of things in existence and in place in Ontario prior to the college being there to do them?
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. Mount Sinai laboratory, I expect you'll agree with me probably that it's one of the foremost and more stringent IHC laboratories in the country. Would that be a fair statement?
MS. WEGRYNOWSKI:
A. I would assume stringency would be in all IHC laboratories.
MR. SIMMONS:
Q. Yes, okay. Does something like having a college and practice guidelines make it easier to share the knowledge that's been gained in the laboratory like yours with others in your province who now have to be licensed and have to meet those same sorts of practice guidelines?

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MS. WEGRYNOWSKI:
A. I'm not sure about sharing the information, not from the college.
MR. SIMMONS:
Q. Okay. Well, what do the practice guidelines address then?
MS. WEGRYNOWSKI:
A. The practice guidelines of?
MR. SIMMONS:
Q. Yes, what--the college. You referred to the college has practice guidelines and you've been involved in the development of them.
MS. WEGRYNOWSKI:
A. The practice guidelines that I'm referring to were as for the area of histology. So, the expectations were there that we determined how many slides a technologist should be able to cut depending on the composition, whether they were biopsies or large specimens, the amount of work flow ergonomics. It was that sort of information that we working on.
MR. SIMMONS:
Q. Okay.
MS. WEGRYNOWSKI:
A. We did not do the area of IHC.

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MR. SIMMONS:
Q. Oh, I see, okay.
MS. WEGRYNOWSKI:
A. We did histology.
MR. SIMMONS:
Q. Sorry about that.
MS. WEGRYNOWSKI:
A. That's okay.
THE COMMISSIONER:
Q. And these guidelines, are they directed more to the kind of work that one can be expected to do as opposed necessarily to the steps involved in doing the work?
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. Now, in Ontario as well, aside from the technologists, the laboratories have a level of regulation and accreditation. I've heard you mentioned both OLA and QMPLS.
MS. WEGRYNOWSKI:
A. QMPLS is a portion of OLA.
MR. SIMMONS:
Q. This was my next question, OLA stands for what?

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MS. WEGRYNOWSKI:
A. Ontario Lab Accreditation.
MR. SIMMONS:
Q. Okay. And what kind of an organization is that? Is that one of these voluntary organizations or is this something mandated by the province?
MS. WEGRYNOWSKI:
A. It's mandated.
MR. SIMMONS:
Q. So, I presume there's legislation somewhere in the background that has created it?
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. And can you tell me something, what its role is?
MS. WEGRYNOWSKI:
A. I'm not sure that I'm the authority to speak to you on the role of -
MR. SIMMONS:
Q. Well, you've got a perspective because you're working in an important in Ontario and I presume you have a perspective on how you see the role that -

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MS. WEGRYNOWSKI:
A. I can tell you what my role is with--I can tell you what I do.
MR. SIMMONS:
Q. Please, yes.
MS. WEGRYNOWSKI:
A. We are sent surveys several times a year, not unlike what you already know with your laboratory. And they will send us the slides, they will tell us what they would like us to stain. We will use our in-house controls and we will use their slides. We will provide them with all our protocols and the negative. It all gets shipped back off to them. And they will send everything back to us with a critique.
MR. SIMMONS:
Q. Okay. And how long has that service been available in Ontario?
MS. WEGRYNOWSKI:
A. It's been a couple of years. I can't recall the exact start date.
MR. SIMMONS:
Q. Within the last couple of years?
MS. WEGRYNOWSKI:

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A. Don't quote me on that.
MR. SIMMONS:
Q. Okay, no, but it hasn't been ten years ago?
MS. WEGRYNOWSKI:
A. I don't think OLA has been in existence for ten years.
MR. SIMMONS:
Q. Okay. And what QMPLS does is that something different than that as well or is it part of it?
MS. WEGRYNOWSKI:
A. It's an overseeing body.
MR. SIMMONS:
Q. Yes. And the QMPLS role in Ontario, what do they do for your lab?
MS. WEGRYNOWSKI:
A. My goodness, I'm not sure I'm the best person to answer this question for you. Brendan Mullen might be able to -
MR. SIMMONS:
Q. Do they accredit your lab?
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. They do? So, you've participated in the

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accreditations when they come in?
MS. WEGRYNOWSKI:
A. Yes, they do.
MR. SIMMONS:
Q. So, like accreditations generally, there'll be reviewers who will come in -
MS. WEGRYNOWSKI:
A. Yes, they do.
MR. SIMMONS:
Q. - with some set of standards that -
MS. WEGRYNOWSKI:
A. Absolutely.
MR. SIMMONS:
Q. - they're going to take and prepare your -
MS. WEGRYNOWSKI:
A. Absolutely, that's right and our manuals have to reflect this.
MR. SIMMONS:
Q. Right, okay. And that happens how often?
MS. WEGRYNOWSKI:
A. Hm?
MR. SIMMONS:
Q. That's fine, if you don't know, that's fine. It's probably every two or three years, something in that area, it is?

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MS. WEGRYNOWSKI:
A. Yes, It is not annually.
MR. SIMMONS:
Q. Okay. And that's something different than the Canadian American Pathologist review that you referred to as well.
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. It's an additional one. There's been some reference to synoptic reporting by pathologists. I believe we heard from a previous witness that that was implemented in your facility in about 2005, does that sound about right?
MS. WEGRYNOWSKI:
A. That would be correct; that is right.
MR. SIMMONS:
Q. Okay. So, prior to 2005, were you familiar with the type of mechanisms used for reporting by pathologists of the ER/PR results?
MS. WEGRYNOWSKI:
A. You need to speak to Frances O'Malley or Brendan Mullen about that.
MR. SIMMONS:

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Q. Okay. Have you played any role in your lab in monitoring of rates of positivity of ER/PR testing over the years?
MS. WEGRYNOWSKI:
A. Not me, no.
MR. SIMMONS:
Q. Do you know if it's been done?
MS. WEGRYNOWSKI:
A. I know that they have been working on a program and I know that Brendan Mullen--you can speak to Brendan Mullen about that.
MR. SIMMONS:
Q. So, we can ask Dr. Mullen about it?
MS. WEGRYNOWSKI:
A. Yes. He -
MR. SIMMONS:
Q. You haven't had any involvement in any monitoring of positivity rates.
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. Has anything been reported to you over the years, in your position to say that 2003, we're at the end of 2003, here is our rate of positives and negatives?

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MS. WEGRYNOWSKI:
A. In passing we might have discussed it, but I couldn't comment on it, being formal.
MR. SIMMONS:
Q. Okay. When you were asked to come here to St. John's and do you initial review, you've described it to us as being--you've use the term peer review. And although you weren't actually reviewing the work of technologists when you came, but we've also heard the term quality review, that's been used here. But in any event your expectation was that it was a review that would have an element of confidentiality and an element of legal protection?
MS. WEGRYNOWSKI:
A. Absolutely.
MR. SIMMONS:
Q. Right, okay. Were you asked to do what you would have considered and investigation into the cause of the change in test results?
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. Was the process that you planned to use when

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you came here one that you would have adopted if you had been asked to come in and do an investigation?
MS. WEGRYNOWSKI:
A. Not necessarily.
MR. SIMMONS:
Q. No. And once you got here, your process changed once you came and saw what the level of documentation and operating procedures and so on was and you changed into a more of an educational type of mode, I understand.
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. And that's not something, is it, that would have been directed towards an investigation into cause?
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. Was your report intended to be a report on investigation into cause of the test changes?
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:

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Q. Now, you did identify a significant number of deficiencies that you found at the IHC laboratory when you conducted you review and you've reported on those in both of your reports. And would it be fair to say that many of those deficiencies could have been factors that would contribute to an original test not having worked?
MS. WEGRYNOWSKI:
A. Could you rephrase that for me, please?
MR. SIMMONS:
Q. Would it be fair to say that many of the factors that you identified could have been ones that contributed to why an original test didn't work?
MS. WEGRYNOWSKI:
A. They were definitely factors that contributed, yes.
MR. SIMMONS:
Q. Okay. And did your work--your work didn't go so far though as to isolate any particular factors in any particular cases?
MS. WEGRYNOWSKI:
A. I think I gave a very broad based--I had two and a half days.

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MR. SIMMONS:
Q. Right. Would it be fair to say that the focus of what you were doing was to assess the lab as it existed in order to make those recommendations so that appropriate changes could be implemented on a go forward basis?
MS. WEGRYNOWSKI:
A. I thought I was there to do a peer review, but that is what I ended up doing.
MR. SIMMONS:
Q. Okay. So, you ended up doing what I just described?
MS. WEGRYNOWSKI:
A. Yes, not what I originally thought I was going to do.
MR. SIMMONS:
Q. Okay. I'll refer you to just one document.
MS. WEGRYNOWSKI:
A. Okay.
MR. SIMMONS:
Q. This is a picky question. P-1743, please?
MS. WEGRYNOWSKI:
A. A what question?
MR. SIMMONS:
Q. This is a picky question.

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MS. WEGRYNOWSKI:
A. Oh, picky question, oh boy.
MR. SIMMONS:
Q. One little curiosity point. This was your early e-mail, July 28, 2005. So, this was at the very beginning when you were first contacted about coming here, I think.
MS. WEGRYNOWSKI:
A. Um-hm.
MR. SIMMONS:
Q. And if you look down through your e-mail message to Dr. Carter, you've listed five questions there and the fourth one was a question as to whether the MLTs, the technologists, were dedicated or rotating staff.
MS. WEGRYNOWSKI:
A. Okay.
MR. SIMMONS:
Q. Now, at this very early point had you already had any indication or any -
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. - as to whether they were dedicated or

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rotating?
MS. WEGRYNOWSKI:
A. No.
MR. SIMMONS:
Q. But I was curious as to why it would be a question that you would even think to ask, as to whether they were dedicated or rotating?
MS. WEGRYNOWSKI:
A. Oh, because in a histology setting, that is not unusual to have people dedicated to an area or rotate doing different benches all the time.
MR. SIMMONS:
Q. Okay.
MS. WEGRYNOWSKI:
A. And I had no idea whether immunohistochemist--how immunohistochemistry was perceived or set up at this organization. So, that's why I asked the question.
MR. SIMMONS:
Q. Right. So, it was something that you recognized at the outset that it could be done one way or the other, either dedicated or rotating and this was an important point for you to know.

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MS. WEGRYNOWSKI:
A. I'm not sure about doing it one way or the other in immunohistochemistry, but the question was there because I knew nothing. So, it was, I'm trying to gather as much information before I come on site so that I don't waste the time on site.
MR. SIMMONS:
Q. Okay. I have some questions for you now about the types of personnel and staffing that you can have in this area. Now, there's been some discussion of pathology assistants.
MS. WEGRYNOWSKI:
A. Okay.
MR. SIMMONS:
Q. Now I know I expect in your role in the--you've confined to immunohistochemistry, you probably don't have a lot of interaction with pathology assistants at your institution, do you?
MS. WEGRYNOWSKI:
A. Daily, but not--I speak to them usually daily, but not necessarily about what they do and how they do it.
MR. SIMMONS:

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Q. Okay. Do you--and when you came here to Newfoundland, there were no pathology assistants in place?
MS. WEGRYNOWSKI:
A. Correct.
MR. SIMMONS:
Q. And the pathologists were doing the grossing of the specimens with the senior technologists carrying out some grossing duties, you probably understood that to be the case?
MS. WEGRYNOWSKI:
A. Yes, I did.
MR. SIMMONS:
Q. And I believe included in your recommendations was a recommendation that pathology assistants would be of advantage?
MS. WEGRYNOWSKI:
A. Yes.
MR. SIMMONS:
Q. Okay. What sort of advantages would you see flowing from including pathology assistants in the process?
MS. WEGRYNOWSKI:
A. Continuity of how the specimens were going to be handled.

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MR. SIMMONS:
Q. Um-hm.
MS. WEGRYNOWSKI:
A. The pathologists assistant never works along, they always work under a pathologist, so they would always be the daily interaction rounds or whatever you would like to discuss with that. It provides the pathologists with an opportunity to spend less time in actually doing grossing and allows them to do their own reading. I'm not sure what your residency program is here, but they can also work with that. Is that something that you're looking for?
MR. SIMMONS:
Q. Well, no, I'm not looking for anything in particular other than just your views as to what to inform us about, what you perceive the advantages being of having pathology assistants available. Now the consistency, how does the consistency play into the work that's done in the immunohistochemistry lab?
MS. WEGRYNOWSKI:
A. The consistency would then be how the specimens were handled, how they were once

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excised from the body, we could streamline the transition getting it into the lab. The grossing would be done in a very similar manner. You would have your documentation however it was going to be set up by your pathologist and the size of the sections are extremely critical.

MR. SIMMONS:

Q. Um-hm, okay. So when you look at some of the technical things that you can have trouble with in doing an IHC test, it's helpful to have that kind of consistency in the processing of the specimen before it reaches your lab?

MS. WEGRYNOWSKI:

A. Consistency is very important in pathology, yes.

MR. SIMMONS:

Q. It will reduce the range of things maybe that can be difficult to deal with in performing an IHC test, can it?

MS. WEGRYNOWSKI:

A. They can ensure that your proper fixation is in place.

MR. SIMMONS:

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Q. Yes, okay. So instituting pathology assistants at Eastern Health would be certainly viewed by you as having been a big advantage?

MS. WEGRYNOWSKI:

A. As an asset, yes.

MR. SIMMONS:

Q. A step forward, okay. Now, recommendations coming out of your review and of Dr. Banerjee's, as well, included designating a pathologist as a position like a director of immunohistochemistry. What sort of advantages do you see coming out of that kind of a move, designating a pathologist to be the person responsible for IHC testing?

MS. WEGRYNOWSKI:

A. That would be the person in my laboratory who signs off on my manuals, they are the person that I go to when I have the external quality that I need to do. The only codicil to that is, and this is his choice, you'd have to speak to him to verify it, but if it's breast pathology, if we get a case of a breast, then Frances or Brendan will go ahead and read it.

MR. SIMMONS:

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Q. Right, okay. So you have a pathologist who's not only charged with that kind of responsibility but presumably has an interest and develops an expertise in carrying out that role in relation to immunohistochemistry, as well?

MS. WEGRYNOWSKI:

A. Yes.

MR. SIMMONS:

Q. The first question I asked you about was your recommendation about academic training for immunohistochemistry to understand, presumably to understand the science, so the people doing the work understand and scientific basis for the work that they're doing, help them understand what it is they're doing and why. And you wouldn't have been familiar with this when you were here, because this is a development that's more recent at Eastern Health, but there's been a position added in the immunohistochemistry service to, for someone maybe equivalent to a lead tech who has a PhD science background who will be charged with the responsibility for things like the validation. How would you see that

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kind of a move in relation to addressing some of the underlying concerns that you had when you reviewed the labs?

MS. WEGRYNOWSKI:

A. Are they medical laboratory technologists?

MR. SIMMONS:

Q. Yes.

MS. WEGRYNOWSKI:

A. I think that role would be up for Eastern Health to decide how best to carry it out.

MR. SIMMONS:

Q. Okay. Thank you, very much. That's all the questions I have for you.

MS. WEGRYNOWSKI:

A. Thank you.

COMMISSIONER:

Q. Mr. Browne, do you have any questions? I'm just wondering whether you want us to take the morning break before you start or after?

MR. BROWNE:

Q. Probably be better to take the morning break.

COMMISSIONER:

Q. Well why don't we take the morning break and then you can have your opportunity to cross-examine.

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(RECESS)

MS. TRISH WEGRYNOWSKI, EXAMINATION BY MR. PETER BROWNE

MR. BROWNE:

Q. Good morning, Ms. Wegrynowski. My name is Peter Browne. I represent a number of the individual physicians who have been asked to testify before the Commission. Mr. Simmons said he had a picky question. I have a curious question, actually, to begin with. And that is in relation to an item in your curriculum vitae, and actually, the last item on page 4. And it mentions that you attended the Biological Stain Commission annual meeting. can you just give some more information around that? That is a U.S. body that's been in existence for a number of years, I understand. Could you explain the purpose of that body?

MS. WEGRYNOWSKI:

A. The Biological Stain Commission -

MR. BROWNE:

Q. Yes.

MS. WEGRYNOWSKI:

A. It was derived originally, they were the ones that took care of all the stains. All the

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stains have particular codes, so they were ensuring the certification of the stains. It was a very--it was an enlightening meeting for me to attend because there were also members there of the National Institute of Standardized Testing and we had dialogues going on even just about the calibre of the slides that we are using in immunohistochemistry.

MR. BROWNE:

Q. Now, the Biological Stain Commission, is that part of also a regulatory agency in the United States?

MS. WEGRYNOWSKI:

A. I couldn't speak to that.

MR. BROWNE:

Q. Okay. And I'm assuming that the Biological Staining Commission also looks after IHC stains?

MS. WEGRYNOWSKI:

A. I'm not sure they do. You know, it's dyes, they take care of dyes.

MR. BROWNE:

Q. Simply dyes, okay, thank you. You spoke yesterday about the Sakura Express and we've

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heard some evidence previous to that here in relation to this machine being purchased by Eastern Health. And did I understand your evidence correctly that this particular machine uses alcohol as oppose to formalin as a fixative?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. And that is problematic when it comes to immunohistochemistry because most of the immunohistochemistry is based on formalin-fixed tissues, is that correct?

MS. WEGRYNOWSKI:

A. It's not as much as it is a problem as that you need to ensure that your controls are handled in the same manner as what your tests are.

MR. BROWNE:

Q. Okay.

MS. WEGRYNOWSKI:

A. So if that's what they were going to proceed with, that was one of the codicils they needed to keep in mind.

MR. BROWNE:

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Q. Okay. And do you have any--well, does your institution have a similar machine?

MS. WEGRYNOWSKI:

A. We do not use that machine.

MR. BROWNE:

Q. Okay. Are you familiar with this particular machine and its usage?

MS. WEGRYNOWSKI:

A. I've seen it at conventions, but I don't have any -

MR. BROWNE:

Q. Now, you mentioned, as well, just along that topic, that at your institution you have equipment purchase protocol?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. Is there a committee that is around that protocol, are there certain individuals who, I guess, develop the protocol?

MS. WEGRYNOWSKI:

A. I can speak to it in my involvement in it. We, ourselves, have been looking to purchase more stainers for the immunohistochemistry department and we needed to look at several

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different companies, and it was my technical director, the charge technologist and myself who did this.

MR. BROWNE:

Q. Okay. Are pathologists involved in, I guess, the decision around the purchasing of equipment?

MS. WEGRYNOWSKI:

A. They can be.

MR. BROWNE:

Q. There was some evidence and you were referenced to this point yesterday, as well, about in-house formalin. I take it does Mount Sinai or has Mount Sinai ever made in-house formalin?

MS. WEGRYNOWSKI:

A. I believe they did a long time ago.

MR. BROWNE:

Q. And did you have or are you aware of whether or not they had standard operating procedures with regard to in-house formalin?

MS. WEGRYNOWSKI:

A. It's well before my time.

MR. BROWNE:

Q. Okay. Is there, from your knowledge base, are

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there particular problems with making in-house formalin versus commercially prepared formalin?

MS. WEGRYNOWSKI:

A. Myself, my personal opinion is safety.

MR. BROWNE:

Q. Safety in terms of safety to the -

MS. WEGRYNOWSKI:

A. Individual -

MR. BROWNE:

Q. - individual.

MS. WEGRYNOWSKI:

A. Making it, yes.

MR. BROWNE:

Q. Is there, I guess is there any particular risk that if not prepared or diluted properly that it may lead to under or over fixation of tissue?

MS. WEGRYNOWSKI:

A. It would change your percentages. I can't speak to the under, over.

MR. BROWNE:

Q. Okay. At Mount Sinai what type of slides are used or are there particular slides used for IHC interpretation? I'm referring in

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particular to positively charged slides. Can you explain what that is and does your institution use such a slide?

MS. WEGRYNOWSKI:

A. Yes, we do. We use them to ensure that the sections do not fall off a slide. So you use deionized water so that there's absolutely, there's no charge in the water with a negatively charged tissue, will attach the positively charged slide. So it's just to adherence of the tissue so that it does not come off during some of the procedure. It's a long procedure, and in our particular case we microwave which can be--it's going up to 115, 120 degrees celsius.

MR. BROWNE:

Q. So it's to protect tissue coming off during the whole, I guess, detection, antigen retrieval detection process that the slide goes through?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. Okay. And as well you mentioned yesterday that I think you used the term "standard

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operating procedures are living and breathing documents"?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. Over the time period that you have been with Mount Sinai how often have you changed, for instance, your standard operating procedures for antibodies, detection systems and so on?

MS. WEGRYNOWSKI:

A. It can happen. It's not on a regular basis. Your procedure would change if you received a new lot of antibody and the concentration had changed, which would then result in a different dilution, your procedure manual would change, as well.

MR. BROWNE:

Q. And I believe, as well, you mentioned that they are reviewed on an annual basis, is that right?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. Okay. And you have indicated to the Commissioner during your evidence that your

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institution uses the DAKO semi-automated stainer, is that correct?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. And that particular machine uses a pump that applies stain to the slide, is that right?

MS. WEGRYNOWSKI:

A. Yes, it does.

MR. BROWNE:

Q. Okay. Has your institution ever had any problems with that particular, the pump that applies the stain?

MS. WEGRYNOWSKI:

A. Yes, we have.

MR. BROWNE:

Q. Is that a regular occurrence or is there just an isolated event?

MS. WEGRYNOWSKI:

A. I couldn't speak to that, but as a user of it you recognize that the pumps are taking longer and longer and it is my responsibility then to get in touch with the manufacturer who will come in and do service calls on that.

MR. BROWNE:

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Q. But as a technologist you should be in a position to recognize difficulties with a particular pump if it is not applying the stain correctly?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. Now, you were asked both yesterday and today about the microtome?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. And I believe this morning, in fact, you when asked about teaching technologists, sort of walking through the understanding of immunohistochemistry you would start with the microtome as sort of the ground level, is that--did I understand you to be correct in saying that this morning?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. Okay. So obviously that's a very important mechanical instrument?

MS. WEGRYNOWSKI:

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A. Yes.

MR. BROWNE:

Q. In terms of as it relates to IHC as well as the whole lab?

MS. WEGRYNOWSKI:

A. Yes.

MR. BROWNE:

Q. Okay. And that--so I am correct, that is the mechanical instrument that is used to cut the specimens from blocks into thin transparent slices to be put on a slide?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. Okay. And I think if I got your statement correct, you made this morning, was you don't want to lose tissue when you're using this machine?

MS. WEGRYNOWSKI:

A. Correct.

MR. BROWNE:

Q. Can you explain that a bit further, please?

MS. WEGRYNOWSKI:

A. Every block that comes in--okay, I have to think how to put this. If the block isn't

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always on the same angle, there are centring screws that the technologist would use to make the section or make the block come up directly to the blade so that when they started to come down with the section onto the blade, that they wouldn't be then going into the section.

MR. BROWNE:

Q. Right.

MS. WEGRYNOWSKI:

A. So they use something called centring screws so that the best of their ability they're lining up that block so that when it hits the blade, that you're not losing as--you don't want to lose any tissue.

MR. BROWNE:

Q. Right. When you say "tissue", you're talking normal epithelium, for instance, if -

MS. WEGRYNOWSKI:

A. I'm talking about whatever is embedded in that block.

MR. BROWNE:

Q. Right. Well, that would include in relation to, for instance, ER/PR, would that be normal epithelium that may be affected by or lost by that process?

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MS. WEGRYNOWSKI:
A. Correct.
MR. BROWNE:
Q. Okay. And I think you testified earlier, as well, that that may in terms of pathology, normal epithelium is used as an internal control?
MS. WEGRYNOWSKI:
A. The ductal epithelium, yes.
MR. BROWNE:
Q. Okay. You were shown--if we may, Registrar, P-0101? This letter you were shown yesterday, Ms. Wegrynowski, and that's the letter by Dr. Carter. And I think your evidence was as follows, and I want to be clear on this point, that the content of this letter encapsulate your concerns and your recommendations that were in your report. Is that a fair statement?
MS. WEGRYNOWSKI:
A. That's what I took away after reading that letter for the first time yesterday.
MR. BROWNE:
Q. Okay. Are you aware or was it brought to your attention whether or not this was ever

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protected by the Evidence Act or any other legal process?
MS. WEGRYNOWSKI:
A. This letter?
MR. BROWNE:
Q. Yes.
MS. WEGRYNOWSKI:
A. I didn't even know the letter until yesterday, so, no.
MR. BROWNE:
Q. Right. But has anybody brought it to your attention that this, in fact, was not protected in any fashion?
MS. WEGRYNOWSKI:
A. No.
MR. BROWNE:
Q. You spoke extensively both yesterday and today about the importance of pipettes and the calibration of pipettes in relation to the immunohistochemistry process. And if I captured your evidence correctly, if they're not calibrated properly, they cannot or they can cause improper dilution?
MS. WEGRYNOWSKI:
A. Correct.

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MR. BROWNE:
Q. Is that in relation to the antigen retrieval process?
MS. WEGRYNOWSKI:
A. No, that is in relation to making up the primary antibody.
MR. BROWNE:
Q. Okay. And sorry, and the primary antibody which leads to the amount of signal that is brought out through, I guess, the whole process?
MS. WEGRYNOWSKI:
A. Correct.
MR. BROWNE:
Q. So and the amount of signal is what the pathologist looks for when trying to determine in relation to ER/PR the percentage of ER positivity, PR positivity?
MS. WEGRYNOWSKI:
A. Correct.
MR. BROWNE:
Q. Mr. Simmons asked you this morning about the pathologist's role in troubleshooting. They are the end-product users of this process in terms of they're most involved in the post-

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analytical phase of the immunohistochemistry, is that correct?
MS. WEGRYNOWSKI:
A. Yes.
MR. BROWNE:
Q. And would you expect primarily that it's their job to look at the quality of the slide and relate any concerns back to the technologist and once those concerns are related back to the technologist that the technologist will take steps to try and troubleshoot and address what the quality issues may be?
MS. WEGRYNOWSKI:
A. Yes, as a team.
MR. BROWNE:
Q. Thank you. That's all the questions I have, Commissioner.
COMMISSIONER:
Q. Thank you, Mr. Browne. Ms. O'Dea?
MS. TRISH WEGRYNOWSKI, EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good morning, Ms. Wegrynowski, my name is Jennifer Newbury and I represent the Canadian Cancer Society, Newfoundland and Labrador

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Division. I have a few questions for you this morning. And I want to start off just to get you to explain a little bit more about the issue or the topic of sensitivity and specificity. And I want to make sure I understand it first. Is sensitivity the proportion of actual positives that are correctly identified as such?

MS. WEGRYNOWSKI:

A. Yes, if you're taking that out of the Roche Manual, that's exactly what they wrote.

MS. NEWBURY:

Q. Okay. And specificity is the proportion of actual negatives that are correctly identified as such?

MS. WEGRYNOWSKI:

A. Correct.

MS. NEWBURY:

Q. Okay. And what stages of immunohistochemical testing can impact sensitivity and specificity and perhaps if you can relate that to pre-analytic, analytic and post-analytic stages?

MS. WEGRYNOWSKI:

A. In the pre-analytic it's most definitely formalin fixation and processing.

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MS. NEWBURY:

Q. Yeah.

MS. WEGRYNOWSKI:

A. If that protein is not captured right from the beginning, that can lead to a negative result.

MS. NEWBURY:

Q. Okay.

MS. WEGRYNOWSKI:

A. Or hollow nuclei or however it's described. Again, in the laboratory setting in the analytical stage it's extrinsicies to protocols, it's ensuring that the buffers, that everything is done in a very stringent manner, and post-analytically that would be the pathologists and their interpretation.

MS. NEWBURY:

Q. Okay. So in the pre-analytic stage then if, I guess the key thing is the fixation in formalin and if that's not done properly, then would the concern be with regard to the sensitivity of the test or the specificity or both?

MS. WEGRYNOWSKI:

A. To the positives.

MS. NEWBURY:

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Q. Okay. And so that would be missing positive tests?

MS. WEGRYNOWSKI:

A. Reducing the amount, yes, because they wouldn't be fixed to get the signal.

MS. NEWBURY:

Q. Okay. And at the analytic stage would any difficulties, I guess, or improper procedures applied, would that lead to problems with both specificity and sensitivity or is one more likely to occur than the other?

MS. WEGRYNOWSKI:

A. I can't see one occuring more than the other, but you could get more of a false negative than you could to do with sensitivity or specificity.

MS. NEWBURY:

Q. Okay. And can you comment on any concerns at the post-analytic stage or is that the pathologists?

MS. WEGRYNOWSKI:

A. The pathologists.

MS. NEWBURY:

Q. And is there any correlation between sensitivity and specificity if you have a test

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that's run in a uniform manner, would you have, if you have greater sensitivity does that mean that you have a loss of specificity or is there -

MS. WEGRYNOWSKI:

A. No.

MS. NEWBURY:

Q. There's no correlation between those two at all?

MS. WEGRYNOWSKI:

A. Not that I'm aware of.

MS. NEWBURY:

Q. Based upon your review of testing procedures at Eastern Health, do you have any observations about the likely sensitivity of ER/PR testing?

MS. WEGRYNOWSKI:

A. I didn't look at their actual testing. I just did a broad-based assessment of the institution.

MS. NEWBURY:

Q. But just generally speaking, based on what you saw, would you be able to say, you know, you may have concerns with one--with sensitivity of your ER/PR testing? You can't comment?

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MS. WEGRYNOWSKI:
A. No, I can't.
MS. NEWBURY:
Q. And you can't comment on any predictions or observations about specificity either?
MS. WEGRYNOWSKI:
A. No, I cannot.
MS. NEWBURY:
Q. Okay. Would you have had enough information, based on what you observed during your assessment of the lab, about whether or not ER positive test results were likely to be valid?
MS. WEGRYNOWSKI:
A. Could you please rephrase that for me?
MS. NEWBURY:
Q. I'm just wondering, based on what you observed when you did the review of the lab, would you have any concerns about ER positive test results that had been developed through those procedures?
MS. WEGRYNOWSKI:
A. I can't comment directly to that. I would say that one would need to go back and look at the original validation process and ensure that every--that all procedures were handled in the

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same manner.
MS. NEWBURY:
Q. Okay. So you would not--I'll just rephrase the question this way. Would you have been able to give anyone assurances that ER/PR positive test results should be okay, based upon what you observed in the lab?
MS. WEGRYNOWSKI:
A. I can't make that comment.
MS. NEWBURY:
Q. Okay. Did you ever have any discussions with anyone at Eastern Health regarding ER positive test results?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. And do you know if any of your colleagues would have had any dealings with this ER positive results?
MS. WEGRYNOWSKI:
A. My colleagues have never mentioned anything like that to me.
MS. NEWBURY:
Q. And what is the impact of the absence of negative controls? And you've mentioned in

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your most recent report that there was still no negative controls in place. What is the impact of that?
MS. WEGRYNOWSKI:
A. For example, if there was some non-specific staining or cross-reactivity with that particular control slide, then you would recognize that as a negative. So if there was some staining in that negative, I mean, there shouldn't be, but it can occur, if you're not blocking for Avidin and Biotin, it would be the difference between what was staining in the negative control or the negative tissue compared to the positive tissue.
MS. NEWBURY:
Q. So in the absence of the negative control, would it be possible that a test is incorrectly identified as being ER positive?
MS. WEGRYNOWSKI:
A. Not necessarily.
MS. NEWBURY:
Q. Okay, and -
MS. WEGRYNOWSKI:
A. Not necessarily because if you have your internal controls and your internal controls

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are working -
MS. NEWBURY:
Q. Okay, and which internal controls are those?
MS. WEGRYNOWSKI:
A. In the breast tissue, the ductal epithelium.
MS. NEWBURY:
Q. Okay. You were asked this morning about whether or not you or your lab monitors for positivity of ER and PR results.
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And I'm not sure if that question was directed at you or the lab. You indicated that you don't monitor for -
MS. WEGRYNOWSKI:
A. I personally don't. I believe it's being done. Perhaps you would like to ask Brendan Mullen about that.
MS. NEWBURY:
Q. Okay. Are you personally involved in any other type of monitoring of test results at Mount Sinai, and I'll give you some examples? Do you ever--are you personally involved in monitoring by a type of cancer or grade of

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cancer or stage of cancer?
MS. WEGRYNOWSKI:
A. Myself, no.
MS. NEWBURY:
Q. No, okay, and the reason I ask, I had mentioned to Dr. O'Malley, I'd asked whether she was familiar with any procedures for monitoring, and she believed that there are standard operating procedures in place and she thought that you would probably be able to go into detail on that, but that's not in your area, is it?
MS. WEGRYNOWSKI:
A. I take care of the standard operating procedures on how to perform the immunohistochemistry.
MS. NEWBURY:
Q. Okay.
MS. WEGRYNOWSKI:
A. But as far as grading of the tumors, no, I do not do that.
MS. NEWBURY:
Q. Okay, but even monitoring some of your results, looking for trends in, you know, whether you get ER/PR positive results in

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certain types of cancer or certain grades of cancer?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. That's not your area?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. Okay, and would it be Dr. Mullen who would know about that or who would know?
MS. WEGRYNOWSKI:
A. Perhaps you could ask him, yes.
MS. NEWBURY:
Q. Okay, thank you. I noticed in your curriculum vitae that you--and I'll refer to page three of that. Actually, I forget the exhibit number. That's 1730. And page three, you were an invited lecturer at the NSH convention Toronto?
MS. WEGRYNOWSKI:
A. Um-hm.
MS. NEWBURY:
Q. First of all, what is that convention? What does that stand for?

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MS. WEGRYNOWSKI:
A. It's the National Society of Histotechnology.
MS. NEWBURY:
Q. Okay, and you participated in a lecture, "Mapping the Molecular Pathways of Cancer: The Role of IHC and the Importance of Tumor Registries."
MS. WEGRYNOWSKI:
A. Um-hm.
MS. NEWBURY:
Q. Can you explain a little bit about that particular lecture?
MS. WEGRYNOWSKI:
A. In that particular lecture, I presented it with Dr. Aaron Pollett. So he took care of all the pathologist's scope of practice and I took care of the technological scope of practice. In that particular lecture, one of the challenges that we had faced was that we had received slides from Europe and they had not put the slides on a correct slide, and so what we had done in that particular case was that we had actually stripped the sections from the slides and applied them to the correct slide and then were able to go forward with the

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staining process. So rather complicated, but that was part of my -
MS. NEWBURY:
Q. Okay, and how does the tumor registry and the importance of tumor registries tie into that particular lecture?
MS. WEGRYNOWSKI:
A. That was how we got--we would not have been able to perform that particular testing had I not done what I have done, so it was a combination of how we used it on the technological side and took it to the pathology side.
MS. NEWBURY:
Q. Okay. So did you personally have any views on the importance of tumor registries?
MS. WEGRYNOWSKI:
A. That was done by Dr. Aaron Pollett.
MS. NEWBURY:
Q. Okay, thank you. I just want to explore with you a little bit about the role of technologists in maintaining best practices in a laboratory, and I guess the time and resource commitment that's required of a technologist to maintain those best practices,

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what can you say about, you know, what you need to do or what other technologists in your lab have to do to maintain best practices? What sort of time commitment, what sort of resource commitment is required for that?

MS. WEGRYNOWSKI:

A. It's a lot of paperwork. It's ensuring that all the documentation is maintained. It's ensuring that every single one of us are aware of it. It comes right back down to the very basis, ensuring those lots are in, ensuring that we're stringent, ensuring that each of us are doing it in the exact same manner. So when we start getting to the EQA testing, it's compiling all that information and it's keeping current with our antibody data sheets. It's recognizing that when you open up a new vial, you must stop. You must go back to the data sheets, ensure that that lot is there, sign off on the open date of that. It's all those intricacies that must be maintained.

MS. NEWBURY:

Q. Okay, and aside from what you do in the lab, in terms of the documentation and all of those procedures, what about the time commitment and

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resource commitment outside of the laboratory setting, and I give, as an example, conducting any of your reading. You mentioned that you do a lot of reading.

MS. WEGRYNOWSKI:

A. I do.

MS. NEWBURY:

Q. Attending conferences, you know, reading journals, that type of thing, continuing medical education, what sort of a time commitment would be involved with that?

MS. WEGRYNOWSKI:

A. I spend several hours a month doing that myself.

MS. NEWBURY:

Q. Okay, and in terms of your ability to find the time to do that, and I'm focusing not just on your external activities, but your internal lab activities, is there protected time for technologists? When you walk in the door and you've got a new procedure you need to, you know, revise or update a standard operating procedures manual or you need to validate something because you have a new antibody that you have to work with, do you have protected

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time as a technologist to do that or are you expected to come in on the weekends or do this -

MS. WEGRYNOWSKI:

A. It's part of my day-to-day activities.

MS. NEWBURY:

Q. And how do you handle that, in terms of, you know, if you have so many tests that come through your lab in the day time? I'm just wondering, you know, really down to the mechanics of how does that work. How do you make sure that you're not being asked to do, you know, 100 tests that day as well as do your validation procedures and update your -

MS. WEGRYNOWSKI:

A. The validation procedures would be done with the 100 tests that day, and validating the procedures, it's like many of our jobs, we juggle and we do the best that we can.

MS. NEWBURY:

Q. Okay. So there's no sort of routine practice that you--you know, if you need to do something, you'll have a half a day set aside for that and shift the burden of -

MS. WEGRYNOWSKI:

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A. I try.

MS. NEWBURY:

Q. - some of the routine testing, okay. So you just manage to do what you can with the time that you have?

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. Okay, and in terms of developing the standard operating procedures, I take it there's some team work involved in doing that?

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. Okay, and who would be--who would take the lead for developing standard operating procedures, particularly as it relates to ER/PR testing, as an example?

MS. WEGRYNOWSKI:

A. We have a quality manager and Gaman Modi would be the person. There are very specific guidelines written out by OLA and by CAP and that is what we follow. We have our processes all documented and the processes are all there for our standard operating procedures.

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MS. NEWBURY:
Q. Okay. So you have procedures as to how to develop your standard operating procedures within the lab and you follow that?
MS. WEGRYNOWSKI:
A. Yes, and I believe that's what I used when I gave my report. I gave, I think it's MCCLS, whatever.
MS. NEWBURY:
Q. Okay, and in terms of the actual sort of mechanics of validating a test or the mechanics of putting together your manual, is that primarily done, the actual work itself, done by technologists or does the quality manager get involved in that or are they just overseeing the process?
MS. WEGRYNOWSKI:
A. It's done by the technologists.
MS. NEWBURY:
Q. Okay, and to what extent do pathologists or pathologists assistants get involved, get engaged in that process? Are they there to help with any of the heavy lifting for that or are they there to provide input or feedback at the end of the day? How does that work?

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MS. WEGRYNOWSKI:
A. Perhaps I misunderstood your question. You said pathologists and pathologists assistants?
MS. NEWBURY:
Q. Yes, do they have any role at all in the standard operating procedures? Do they assist with helping to develop it or do they just provide feedback at the end of the day or do they perhaps not even provide feedback?
MS. WEGRYNOWSKI:
A. The pathologists assistants have their own manuals.
MS. NEWBURY:
Q. Okay.
MS. WEGRYNOWSKI:
A. And those manuals are a complete compilation of how every single body type is used and they have their own manuals for that.
MS. NEWBURY:
Q. Okay, so they have nothing to do with the technologists' standard operating procedures?
MS. WEGRYNOWSKI:
A. No, we all have our own.
MS. NEWBURY:
Q. Okay, and pathologists have their own as well, do they?
MS. WEGRYNOWSKI:
A. Yes, they do.
MS. NEWBURY:
Q. Okay, but do pathologists get involved at all in the technologists--do they have to approve it or provide feedback in terms of -
MS. WEGRYNOWSKI:
A. They do.
MS. NEWBURY:
Q. They do, okay, and that's at the end of your-- I guess, your first draft of your manual?
MS. WEGRYNOWSKI:
A. When we're ready to sign off, they'll do-- they'll look back and they need to sign off on it.
MS. NEWBURY:
Q. Okay, and who is able to initiate implementing a new procedure? Is that done solely by technologists or solely by pathologists or a bit of both?
MS. WEGRYNOWSKI:
A. Collaborative.
MS. NEWBURY:
Q. Okay, and in terms of the quality assurance

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and quality control, are they prepared as separate standard operating procedure manuals or are they incorporated into manuals that you do yourself?
MS. WEGRYNOWSKI:
A. They're incorporated into the one manual.
MS. NEWBURY:
Q. Okay, and would the quality manager be involved in writing that or is that still the responsibility of the technologist to prepare that portion of the manual?
MS. WEGRYNOWSKI:
A. In my--what I've dealt with, it's been myself, but the quality manager is always there if you have any questions.
MS. NEWBURY:
Q. Okay. They're there as a resource?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And do they have to sign off on the procedures at the end of the day?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:

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Q. And would you also be involved in determining any applicable external quality assurance procedures or quality control procedures? External proficiency testing, is that part of your manual?
MS. WEGRYNOWSKI:
A. How we do it?
MS. NEWBURY:
Q. Yes.
MS. WEGRYNOWSKI:
A. Yes, and we have a manual that holds our EQA.
MS. NEWBURY:
Q. Okay, and that's something that you do yourself, is it, or is that -
MS. WEGRYNOWSKI:
A. Yes, it comes in through the quality manager. He will gather the documentation and it'll come through me and then when the results come, I will send the results out or my findings out. The results, the information will come back through him, back through me, to me.
MS. NEWBURY:
Q. You've mentioned that a lot of your early learning after you became a medical laboratory

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technologist came through workshops offered by manufacturers?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And is that something that's still present today? Are manufacturers still out there offering workshops?
MS. WEGRYNOWSKI:
A. I couldn't comment.
MS. NEWBURY:
Q. Okay. It's been mentioned a few times, and you've referred to it yourself, that there are no national standards as such applicable to ER/PR testing and one example that you gave this morning was the fixation.
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. Three hours had been put into the fixation policy document by Eastern Health, the draft document that you were shown this morning, and you thought that might be a little low, but you commented that there are no national standards in place, and I understand that

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there might be some work, some movement in Canada to implement national standards. I'm just wondering if you are aware of any activity in that regard?
MS. WEGRYNOWSKI:
A. I've heard that that may be something that's being looked at, yes.
MS. NEWBURY:
Q. And would you know any detail as to what types of things might be standardized, if that were to happen?
MS. WEGRYNOWSKI:
A. I don't know at this point.
MS. NEWBURY:
Q. Okay, and if there were national standards put in place, and I guess it would depend on what types of standards were there, do you know how this would impact your work as a technologist? I mean, would you still go through the things that you've mentioned this morning about validation of antibodies? Would you still be involved in developing standard operating procedures, notwithstanding, for example, a new standardized procedure for ER/PR testing?
MS. WEGRYNOWSKI:

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A. If I understand your question correctly, if there was standards that were required of us from across the nation, then those standards would put in place first. However, we would continue to validate, maintaining the stringencies of whatever were put in place for the nation.
MS. NEWBURY:
Q. Okay, so is it fair to say that many of the things that you would do would not necessarily be standardized or is that too difficult for you to predict?
MS. WEGRYNOWSKI:
A. I think I'm misunderstanding the question.
MS. NEWBURY:
Q. I guess what I'm trying to get at is what types of things would you anticipate would be standardized if national standards were to be put in place, and how would that impact upon what is left for you to do as a technologist?
MS. WEGRYNOWSKI:
A. I wouldn't want to speculate.
MS. NEWBURY:
Q. Okay. If a technologist is fully versed and skilled at developing standard operating

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procedures and to conduct validation, which I understand is something that you're fully capable of doing, based on your experience and your education. Does that help you as a technologist in troubleshooting problems?

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. The fact that you're so well versed in developing standard operating procedures, the fact that you have experience in validating test procedures, that helps you with troubleshooting?

MS. WEGRYNOWSKI:

A. It's the validation that assists with the troubleshooting, yes.

MS. NEWBURY:

Q. Okay, it's the validation and not so much the standard operating procedures.

MS. WEGRYNOWSKI:

A. Correct.

MS. NEWBURY:

Q. And would you expect that all technologists would have capability of validating tests, validating equipment, validating antibodies

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that are being used, is that something that you would expect of each and every technologist or is it left to someone in charge of that division?

MS. WEGRYNOWSKI:

A. I couldn't speak for all technologists.

MS. NEWBURY:

Q. But just from your expectation, what would you like to see happen in your own lab?

MS. WEGRYNOWSKI:

A. I think that that certainly could fit under the scope of practice.

MS. NEWBURY:

Q. Okay. You had indicated yesterday that Mary Butler seemed uncomfortable with the task of developing standard operating procedures, did I capture that correctly?

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. Okay, and again, that's your observations and that's understandable. Do you know, based on your discussions with her, whether she was aware, prior to arriving at Mount Sinai, that this was an activity expected of her while she

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was there?

MS. WEGRYNOWSKI:

A. I couldn't speak to what Mary Butler was told.

MS. NEWBURY:

Q. Okay, she didn't mention anything to you that she was taken off guard with that or any comment of that type?

MS. WEGRYNOWSKI:

A. No.

MS. NEWBURY:

Q. And is there anything that you would expect in the background of a technologist that would enable that individual to develop standard operating procedures? I mean, how does someone--how is someone trained to develop a standard operating procedure?

MS. WEGRYNOWSKI:

A. Well there are guidelines out there on how a standard operating procedure can be written and I provided that documentation to them. The standard operating procedures is simply what you are doing, so if you were versed in what--if you knew -

MS. NEWBURY:

Q. Do you ever run across a situation where

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someone knows what they're doing, but sort of getting it down on paper in a format that's understandable by their peers or colleagues, you know, is a little bit of a different skill or separate art that they may not be comfortable with, I mean, just the writing skills alone, for example.

MS. WEGRYNOWSKI:

A. Right. Mary was not comfortable with using the computer.

MS. NEWBURY:

Q. Okay, thank you.

MS. WEGRYNOWSKI:

A. You're welcome.

MS. NEWBURY:

Q. So you don't know then if she had a different computer system whether she would be more comfortable with actually preparing the standard operating procedures? It wasn't the substance, it was more the mechanics of it?

MS. WEGRYNOWSKI:

A. It was using Word.

MS. NEWBURY:

Q. Okay, well that's understandable. I believe in early September, 2005, you received some

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preliminary information from Barry Dyer and he had indicated that their IHC lab, I believe, does about 80 immunos a day, among their three rotating staff.

MS. WEGRYNOWSKI:

A. Uh-hm.

MS. NEWBURY:

Q. I think that was the evidence that you gave yesterday. And would all of these immuno tests have standard operating procedures?

MS. WEGRYNOWSKI:

A. They should.

MS. NEWBURY:

Q. So it doesn't depend upon the type of tests or the purpose of the test as to whether or not you have standard operating procedures?

MS. WEGRYNOWSKI:

A. Correct.

MS. NEWBURY:

Q. So the fact that a test is not a class 2 test used for treatment would not mean that we won't bother with standard operating procedures?

MS. WEGRYNOWSKI:

A. That's correct.

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MS. NEWBURY:

Q. And do you have any knowledge if the technologists at Eastern Health, any of the ones that you encountered, I guess, and from your discussions with them, have familiarity in developing just the general task of developing standard operating procedures?

MS. WEGRYNOWSKI:

A. I couldn't comment to that.

MS. NEWBURY:

Q. You've discussed some comparison or contrasting between CAP, the College of American Pathologist's program for external quality assurance and NEQAS, I believe, and I just want to make sure I understand one of the distinctions that you had identified and what I took from what you said, NEQAS has its own assessors to do the tests; where as CAP, the results are compared from different--so you send out your test results to a bunch of people and you compare one with the other.

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. So CAP doesn't have its own assessors?

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MS. WEGRYNOWSKI:

A. No, the assessors for CAP do their inspections on site, but we don't send our slides for the EQA to them in that manner, that is correct.

MS. NEWBURY:

Q. And are there any other differences between the two programs in terms of the frequency of the program, the percentages or the numbers of tests done through each program on an annual basis?

MS. WEGRYNOWSKI:

A. I'm trying to recall. I couldn't comment on that, but what I could say is with CAP it's a very general, so you would get four cases, they can be a compilation of different disease types, different tissue types, with UK NEQAS, you can sign up for particular modules, so that you can sign up for a general pathology module, an ER module and so on, so they're different in that respect. Does that answer your question?

MS. NEWBURY:

Q. It certainly does, yes. So CAP then wouldn't necessarily be able to assist you if you've got a concern about ER/PR testing, in terms of

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your external quality assurance--or is it done randem?

MS. WEGRYNOWSKI:

A. I couldn't comment on that.

MS. NEWBURY:

Q. Okay. Are you familiar at all with the Accreditation Canada, the Canadian Council of Health Services Accreditation?

MS. WEGRYNOWSKI:

A. I have very little knowledge on that.

MS. NEWBURY:

Q. And you, I believe in your resume and your evidence indicated that you have been an inspector with CAP?

MS. WEGRYNOWSKI:

A. Yes, I have.

MS. NEWBURY:

Q. And an assessor with OLA?

MS. WEGRYNOWSKI:

A. I wrote my exams for them, but I never went out and assessed.

MS. NEWBURY:

Q. Okay. And how many inspections have you done under the CAP program?

MS. WEGRYNOWSKI:

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A. Two.
MS. NEWBURY:
Q. Pardon?
MS. WEGRYNOWSKI:
A. Two.
MS. NEWBURY:
Q. I just wanted to ask you a couple of questions, I guess on the comparison between internal quality control procedures and external quality assurance procedures, just to try and get a better understanding in my mind as to how they each work. Do internal quality control procedures enable a lab to detect a possible problem with testing, more or less contemporaneously with the testing?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And does this enable the lab to take corrective action right away?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And so would that typically be within, say if a biopsy is done or if there's a surgical

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excision, would it be normally within days that a problem might be identified and then corrected or -
MS. WEGRYNOWSKI:
A. It would depend on the circumstances.
MS. NEWBURY:
Q. Okay, and in terms of ER/PR testing, when would you expect to identify a problem through internal quality control procedures?
MS. WEGRYNOWSKI:
A. That's a very difficult question to answer.
MS. NEWBURY:
Q. There is no sort of set -
MS. WEGRYNOWSKI:
A. It would depend on the circumstances.
MS. NEWBURY:
Q. Okay, is it fair to say that many of the problems could be detected while the technologist is actually preparing the slides for the testing?
MS. WEGRYNOWSKI:
A. Not necessarily preparing the slides, preparing the slides if something was recognized that was abhorrent about the block, that would certainly be recorded. If the

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controls failed for that particular day, the testing would not go forward.
MS. NEWBURY:
Q. Okay, that's the testing on anything in the lab or -
MS. WEGRYNOWSKI:
A. Correct.
MS. NEWBURY:
Q. And if you have optimal quality control procedures in place, would that, in theory, enable the lab to detect problems on each and every slide or each and every test that's conducted?
MS. WEGRYNOWSKI:
A. It would assist, yes.
MS. NEWBURY:
Q. And I guess the advantage of that is that you could take corrective action to prevent that slide from continuing on for the next number of tests that are coming out that day or that week.
MS. WEGRYNOWSKI:
A. Correct.
MS. NEWBURY:
Q. And would it also enable the lab to take steps

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to be able to do the test properly?
MS. WEGRYNOWSKI:
A. Yes, if you recognize there is a problem, you need to stop it and determine what the problem was and then restart.
MS. NEWBURY:
Q. Okay, so if you discover a problem on a particular patient slide, then you can--would you expect that you can definitely correct the problem so that you can give a full report to the pathologist for that particular patient--or that the pathologist can give a full report to that particular patient?
MS. WEGRYNOWSKI:
A. This is a hypothetical?
MS. NEWBURY:
Q. Yes.
MS. WEGRYNOWSKI:
A. If there was a problem with it and for example, it would depend on whether or not it was an in-house case or a consult case, because then we need to go back and say how was this handled from the very beginning and actually look at that particular case.
MS. NEWBURY:

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Q. Okay. So in terms of in-house consults, does that give you more flexibility in terms of being able to sort out what the source of the problem is, with a view to giving--ultimately the pathologist being able to give a report?
MS. WEGRYNOWSKI:
A. It it's an in-house case, there's much more tracking that can be done.
MS. NEWBURY:
Q. Okay, so that's an advantage over in-house consults verses something coming from outside the organization?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And when a problem is detected and you go back and try to trace what happened and to take steps, I guess, to get--I assume that the view that you have is to try to do the test properly so that you can give valid results, ultimately--you and I mean the organization can give valid results ultimately to the patient who is being tested. When you encounter a problem with a single patient slide, for example or anything with the block

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or anything along the way that calls into question the validity--the possibility of you giving valid results ultimately to the patient, I understand from your evidence yesterday that you do have some document procedures to follow?
MS. WEGRYNOWSKI:
A. Yes, we have, what we refer to as a client satisfaction form and it provides the technologist with the opportunity to provide that information to the pathologists, so that when the slides are given to the pathologists at the end of business day, they have that information that they can take to use when they are writing their reports.
MS. NEWBURY:
Q. And if you have discovered a problem that might affect multiple patients and multiple samples, do you follow that same procedure of completing a client satisfaction form?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. And would they be individual forms, say if you had 50 tests that are in question, would you

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have 50 separate client satisfaction forms going to -
MS. WEGRYNOWSKI:
A. I've not ever experienced that, so I couldn't comment to that.
MS. NEWBURY:
Q. Have you ever experienced a case where you had more than one problem at a time, you know, sort of in a group?
MS. WEGRYNOWSKI:
A. If it was going to one pathologist, they should have--well, you know, it's possible they could all be put on one form and it's possible they could have--if it was the same problem, I could see somebody putting more than one number, if it's going to the same pathologist, I could also see separate forms being done, so I think that mix could be there.
MS. NEWBURY:
Q. And would you expect that the record would ultimately be available to the patient in question? Would that form part of that patient's health record?
MS. WEGRYNOWSKI:

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A. You know, I couldn't comment on that, I wouldn't know that.
MS. NEWBURY:
Q. And in terms of comparing the internal quality procedures with the external quality assurance, is it fair to say that depending on the frequency of your external quality assurance, that if you have a problem in a lab, it may not be detected contemporaneously with the testing?
MS. WEGRYNOWSKI:
A. My goodness, internal quality control is there to ensure that on a daily basis you are providing reproducible results. The external quality assurance, you're comparing yourself with others.
MS. NEWBURY:
Q. Uh-hm.
MS. WEGRYNOWSKI:
A. If the issue is occurring, your internal quality control should be picking this up.
MS. NEWBURY:
Q. Right, so is the external quality assurance more of a safety net? Your first recourse, I assume, would be to look to quality control

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procedures and to try to identify immediately any problems that you have with slides and with test results for IHC testing.

MS. WEGRYNOWSKI:

A. Yes.

MS. NEWBURY:

Q. And you wouldn't look first to external quality assurance?

MS. WEGRYNOWSKI:

A. No, I would not.

MS. NEWBURY:

Q. And is that why this morning you commented that you wouldn't start at the bottom with the external quality assurance? I think that was a comment that you made earlier this morning, with the NEQAS program.

MS. WEGRYNOWSKI:

A. I'm sorry, you -

MS. NEWBURY:

Q. I'm just trying to understand what your evidence was this morning. You had mentioned at some point in time when you were looking at what had been done by Eastern Health between your first visit and your second visit, that one of the things that they did was to sign up

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for the NEQAS program and you were happy with that.

MS. WEGRYNOWSKI:

A. Okay.

MS. NEWBURY:

Q. But you thought that that might not be starting in the first logical place, that perhaps they did this, whereas they should have focused on doing something else first.

MS. WEGRYNOWSKI:

A. I understand the question now. Thank you for explaining it to me.

MS. NEWBURY:

Q. Yes, okay.

MS. WEGRYNOWSKI:

A. I concur with what you're saying, it's one thing to say that yes, they went ahead and they did the external quality assurance, which is really terrific and they were comparing themselves amongst their peers, but you need to take care of the nuts and bolts that you're doing on a daily basis.

MS. NEWBURY:

Q. And the nuts and bolts that you're doing on a daily basis, that can potentially pick up--if

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they're done optimally, they can pick up problems on each and every slide for each and every patient -

MS. WEGRYNOWSKI:

A. They should.

MS. NEWBURY:

Q. - whereas the external quality assurance, if that's all you rely upon or if that's what you rely upon primarily, it doesn't have that same benefit.

MS. WEGRYNOWSKI:

A. No, it does not.

MS. NEWBURY:

Q. And it doesn't have the benefit of identifying, you know, if you're doing it every two or three years or twice a year, then you might have to wait until that six-month period to identify that there is even a problem in your lab?

MS. WEGRYNOWSKI:

A. Correct.

MS. NEWBURY:

Q. And what happens if a problem is detected through an external quality assurance program, such as NEQAS or the CAP? How do you respond

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in the lab to that?

MS. WEGRYNOWSKI:

A. I haven't had experience to tell you how that would occur.

MS. NEWBURY:

Q. Okay, would you have any standard operating procedures in place to say if and when the time comes that we have a problem identified, this is what we are to do?

MS. WEGRYNOWSKI:

A. There could very well be in the actual laboratory one.

MS. NEWBURY:

Q. Okay, you don't know that offhand?

MS. WEGRYNOWSKI:

A. Yes, I don't have that one offhand.

MS. NEWBURY:

Q. I believe you've indicated that you do a fair amount of global consultancy work as part of your own practice and that relates to ER/PR testing, I guess, as well as other IHC testing. When you do this consultancy work, what are the types of results that you can provide to the person seeking your advice?

MS. WEGRYNOWSKI:

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A. You need to speak to Brendan Mullen about this because this is part of our service work.
MS. NEWBURY:
Q. Okay, so that's not something that you can speak to.
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. I'd like to refer to exhibit P-0110 please? This is not a document that you're familiar with, I wouldn't expect. This is an excerpt of a transcript of a news conference, dated May 18th, 2007 and George Tilley, who was a former CEO of Eastern Health, was speaking at that particular conference and made a couple of comments that I just want to ask you about to see if you are familiar at all with these ideas. I'd like to refer to page 3 of that exhibit, please? So about midway down the page there is a large quote attributed to George Tilley, and I'll just read it out for you, "We saw a change in results for 317 patients and as you point out, there is an element of uncertainty in this particular test and it's quite well known, both nationally and

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internationally, when we first became aware of this and decided to suspend treatment, our physicians and technologists spent a great deal of time looking inside the organization, looking at the procedure for that test. We also sought the input of technologists, a technologist and a physician more independent of the organization, to come and give us an objective assessment as to what we do and how we do it. I recall that the comment of the physician were that he considered us to be in the middle of the pack, in terms of laboratory services with regards to ER/PR." And he goes on to say that he's not satisfied with being in the middle of the pack and they want to be amongst the top laboratories for this procedure in the country. And now during Mr. Tilley's evidence, he had indicated that he had not spoken directly to the physician and was a little unsure as to whether he spoke with the physician or the technologist, which I understand from his evidence could be either you or Dr. Banerjee. First of all, did you ever make this comment?
MS. WEGRYNOWSKI:

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A. No.,
MS. NEWBURY:
Q. And would you have agreed with that comment if it had been suggested to you?
MS. WEGRYNOWSKI:
A. I can't comment on that.
MS. NEWBURY:
Q. Is it fair to say that if Eastern Health lab, that the IHC lab, as it relates to ER/PR testing, was in the middle of the pack in terms of the laboratory services, that you would not have been surprised about the absence of standard operating procedures? I'm just wondering if that remark about being in the middle of the pack is at all surprising to you, from your perspective, just in terms of what you saw in your own review of the lab?
MS. WEGRYNOWSKI:
A. Could you rephrase this for me, please?
MS. NEWBURY:
Q. I'm just wondering if you, you said that you can't comment on whether or not Eastern Health could be considered to be in the middle of the pack, in terms of laboratory services, but you've indicated yesterday and again today,

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that you were surprised by the absence of standard operating procedures, and I take it that, you know, if the middle of the pack--if this lab were in the middle of the pack, then you wouldn't be as surprised about the lack of standard operating procedures because it might mean that many other labs don't have standard operating procedures.
MS. WEGRYNOWSKI:
A. No, no, laboratories--I would be surprised if middle of the pack meant that, no.
MS. NEWBURY:
Q. So from your perspective then, you don't agree that Eastern Health is in the middle of the pack, in terms of what the technologists are doing, the procedures that they have in place at the lab?
MS. WEGRYNOWSKI:
A. In respect to standard operating procedures being absent?
MS. NEWBURY:
Q. Yes.
MS. WEGRYNOWSKI:
A. Then that is not middle of the pack.
MS. NEWBURY:

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Q. Okay, is there anything else that would not be considered middle of the pack from your perspective?
MS. WEGRYNOWSKI:
A. I think my report outlines what I had to say.
MS. NEWBURY:
Q. Did anyone at Eastern Health ever ask you where does the lab fit in, how does this particular lab compare with other labs in Canada?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. Are you aware of any labs in Canada that don't have any standard operating procedures for tests such as ER/PR testing?
MS. WEGRYNOWSKI:
A. I do not have that information.
MS. NEWBURY:
Q. Did you ever have any interaction with the physician who conducted the external review, that's Dr. Banerjee?
MS. WEGRYNOWSKI:
A. I've never met him.
MS. NEWBURY:

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Q. You've never met him, okay. You never spoke to him on the phone?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. Okay, did you ever share, you know, through e-mail or have any information exchanged with him, perhaps indirectly?
MS. WEGRYNOWSKI:
A. Not to my knowledge.
MS. NEWBURY:
Q. Do you think it would have been of benefit for you to have shared your findings with each other?
MS. WEGRYNOWSKI:
A. No.
MS. NEWBURY:
Q. Yours is a stand alone -
MS. WEGRYNOWSKI:
A. I think it was more interesting for me to have the opportunity to read his reports at the end and recognize how I feel that both our reports collaborate each others.
MS. NEWBURY:
Q. Right, okay. You've mentioned from time to

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time about the communication, the importance of having communication between technologists and pathologists, so I was just wondering if that, you know, if that would have been of any benefit at all for you to do that. But you did find that sharing--or reading his findings were useful to you?
MS. WEGRYNOWSKI:
A. Yes.
MS. NEWBURY:
Q. Or informative, perhaps would be a better word?
MS. WEGRYNOWSKI:
A. Correct.
MS. NEWBURY:
Q. Do you think it would have been helpful to Eastern Health for you to have returned to do a final review of the lab once it had completed recommendations that you had set out in your two reports?
MS. WEGRYNOWSKI:
A. That would have been up to Eastern Health to determine.
MS. NEWBURY:
Q. But do you think, from your perspective, that

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it would have been helpful?
MS. WEGRYNOWSKI:
A. From what I understand that QMPLS has come since then and I think that they -
MS. NEWBURY:
Q. Okay, so they would basically be able to do the types of things that you would have done, had you done your return visit?
MS. WEGRYNOWSKI:
A. Absolutely.
MS. NEWBURY:
Q. Thank you, Ms. Wegrynowski, those are all my questions.
MS. WEGRYNOWSKI:
A. Thank you.
THE COMMISSIONER:
Q. Mr. Crosbie?
MR. PRITCHARD:
Q. Commissioner?
THE COMMISSIONER:
Q. Yes.
MR. PRITCHARD:
Q. Sorry, I don't mean to interrupt, but I wonder if at some point before the Commission counsel re-direct if I would be permitted to ask one

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or two follow up questions.

THE COMMISSIONER:

Q. Follow up to the questioning that you had asked, as opposed to -

MR. PRITCHARD:

Q. Yes, it's not in response to -

THE COMMISSIONER:

Q. Oh, I'm sorry, okay. All right then. Mr. Crosbie?

CROSBIE, Q.C.:

Q. Thank you.

MS. TRISH WEGRYNOWSKI, EXAMINATION BY CHES CROSBIE, Q.C.

CROSBIE, Q.C.:

Q. Good morning, I introduced myself yesterday, Ches Crosbie and I think you know who I represent.

MS. WEGRYNOWSKI:

A. I do.

CROSBIE, Q.C.:

Q. Perhaps there's a bit of housekeeping business to do first, Commissioner. There's a few documents, so I'd ask to enter as exhibits -

THE COMMISSIONER:

Q. I understood it was 1850, 51, 52 and 53, is that correct?

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CROSBIE, Q.C.:

Q. That is correct.

THE COMMISSIONER:

Q. Entered.

EXHIBITS ENTERED AND MARKED P-1850, P-1851, P-1852 AND P-1853

CROSBIE, Q.C.:

Q. Do I need to describe them or are they -

THE COMMISSIONER:

Q. No, I've been provided--the Registrar has provided me with a list of what you intended to enter, so that's fine, thank you.

CROSBIE, Q.C.:

Q. Good, so that's taken care of, thank you. So these are entered then, Madam Commissioner, thank you very much. Let me ask you, you may have stated this before, but what did you understand about the quality or end result of the product that was being turned out in relation to staining before you came and did your first investigation or your first report here. Did you understand there was a problem and if so, what as the problem?

MS. WEGRYNOWSKI:

A. The information that I was given was what I wrote in my report that there had been a conversion of a patient and that they had gone back to look at the ER/PR, that was all I was given.

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CROSBIE, Q.C.:

Q. So you didn't have information about the dimension of the problem being on the one conversion?

MS. WEGRYNOWSKI:

A. I had simply what was written in my reports.

CROSBIE, Q.C.:

Q. Thank you. You may have been asked this question in other terms, but I'll try a different term, if you knew nothing about the quality of the stains being produced by the lab here -

MS. WEGRYNOWSKI:

A. Yes.

CROSBIE, Q.C.:

Q. What would you expect that to be, from what you observed when you came and did your examination of the facility?

MS. WEGRYNOWSKI:

A. I can't comment to that because I never looked at any of the slides while I was here either.

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CROSBIE, Q.C.:

Q. Okay, so you can't draw a link, you're not in a position to draw any link between the state of organization or disorganization of the lab and the quality of the end product it was producing? That's just not something you evaluated?

MS. WEGRYNOWSKI:

A. That's correct.

CROSBIE, Q.C.:

Q. Can we have exhibit P-0101, Madam Registrar? This is the Dr. Carter letter that was looked at yesterday.

MS. WEGRYNOWSKI:

A. Right.

CROSBIE, Q.C.:

Q. Can you take us to page two, please? The foot of page two--must be three then. Thank you. The end paragraph there ends up saying "I would be happy after a presentation by Mr. Dyer proving"--and emphasis is given to that word--"that all of the above have occurred and a tour of the immunohistochemistry laboratory to review the changes made to advise my clinical colleagues at our laboratory and the

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results it generates are reliable, accurate and not dangerous to those Newfoundlanders and Labradorians having breast cancer." The premise there is Dr. Carter, I guess, is asking for a demonstration or proof that things have been fixed and that the end result, the product of the lab in relation to ER/PR testing in particular is not dangerous, is that a fair summary?

MS. WEGRYNOWSKI:

A. Correct.

CROSBIE, Q.C.:

Q. If I told you that the false negative rate in the period from 1997 through 2005 was in the neighbourhood of 44 percent, are you in any position to--do your qualifications enable you to evaluate the safety or dangerousness of that kind of result?

MS. WEGRYNOWSKI:

A. I think you best ask Brendan Mullen.

CROSBIE, Q.C.:

Q. Then that's what I'll do, thank you. I don't know if you're in a position to help us out and there may be someone who is in a better position to do that, but we've heard tell of

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an organization called the CCHA, I guess the Canadian Council on Health Services Accreditation, it used to be called, is that right?

MS. WEGRYNOWSKI:

A. I'm not familiar with that acronym.

CROSBIE, Q.C.:

Q. And I think we heard from Dr. Pritzker, it's now got a new name, Accreditation Canada?

MS. WEGRYNOWSKI:

A. Okay.

CROSBIE, Q.C.:

Q. These are the people who go around and, you know, I want to check your paperwork, randomly pull files, make sure everything is in order and they accredit hospitals and other health care facilities. Do you know anything about their activities?

MS. WEGRYNOWSKI:

A. No.

CROSBIE, Q.C.:

Q. Well you're the wrong person to ask.

MS. WEGRYNOWSKI:

A. Okay.

CROSBIE, Q.C.:

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Q. Now I would like to turn to the documents that I've entered, asked to be entered, starting with P-1850 and this is a memorandum from a Dr. Khalifa, it's addressed, as you can see there, to All Newfoundland Pathologists, February, 1998. It's about the reporting of estrogen and progesterone receptor immunohistochemical results, and I don't mean to rush you through it, you're welcome -

MS. WEGRYNOWSKI:

A. No, no, that's fine.

CROSBIE, Q.C.:

Q. - if you wish to take time and get an overview, but when you're able, I'd like to bring you to page three. Maybe the thing to do is just get an overview of what the document seems to be about. You can skim it right to the end, if you want.

MS. WEGRYNOWSKI:

A. Got it.

CROSBIE, Q.C.:

Q. And then with that context, I just have a couple of specific questions.

MS. WEGRYNOWSKI:

A. Yes.

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CROSBIE, Q.C.:

Q. Are you satisfied you got the overall? On page three, the statement under paragraph one is made, "the first component is a statement of whether the stain is positive or negative. Positivity is defined by nuclear staining detected by any number of malignant cells." And then he goes on and he mentions the figure of 30 percent, in paragraph three.

MS. WEGRYNOWSKI:

A. Um-hm.

CROSBIE, Q.C.:

Q. And there's a citation of a journal there, The American Journal of Surgical Pathology, an article in 1990, and then the number 30 percent, and I guess a piece of information or a quotation from that journal article in 1990 is used at example two at the foot of the page.

MS. WEGRYNOWSKI:

A. Yes.

CROSBIE, Q.C.:

Q. Can you tell us, in your understanding, what's going on there?

MS. WEGRYNOWSKI:

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A. You need to speak to Brendan Mullen about this. That would be in his scope of practice.
CROSBIE, Q.C.:
Q. Can you go to the top of page four?
MS. WEGRYNOWSKI:
A. Oh yes, okay.
CROSBIE, Q.C.:
Q. And he has a table there.
MS. WEGRYNOWSKI:
A. Um-hm.
CROSBIE, Q.C.:
Q. And then on the top of page six, there seems to be, in relation to estrogen and progesterone, a summary box for a set of testings done for ER/PR under the IHC method. Am I correct in my statement so far?
MS. WEGRYNOWSKI:
A. Yes.
CROSBIE, Q.C.:
Q. And in the comments section, it seems there were 19 cases run in relation to estrogen and 17 in relation to PR. That's paragraph--comments paragraph one and paragraph two, and that correlates with the totals in the boxes?
MS. WEGRYNOWSKI:

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A. Yes.
CROSBIE, Q.C.:
Q. So this would seem to be a--and if you go back to page four, he's saying a report of our experience over a nine-month period, January '97 to September '97, and that seems to be a record of their experience running a series of 19 and then 17 cases.
MS. WEGRYNOWSKI:
A. Okay.
CROSBIE, Q.C.:
Q. Again, can you assist us in explaining what's going on?
MS. WEGRYNOWSKI:
A. You need to speak to Brendan Mullen about this.
CROSBIE, Q.C.:
Q. Okay. Are you able to say whether this appears to be a validation exercise?
MS. WEGRYNOWSKI:
A. To me, it appears as a concordance exercise.
CROSBIE, Q.C.:
Q. Just explain that.
MS. WEGRYNOWSKI:
A. They want to determine the number of cases, where they're coming up, are they coming up with a biochemical assay in the same manner what they're coming up with the immunohistochemistry assay.
CROSBIE, Q.C.:
Q. I couldn't help but notice you mentioned yesterday, when you got a new batch of antibody, you run 100 cases to validate that
MS. WEGRYNOWSKI:
A. The example that I used was for HER2/neu.
CROSBIE, Q.C.:
Q. I see.
MS. WEGRYNOWSKI:
A. And that's what we did. We took cases that were positive, cases that were negative and cases that were equivocal, and they had already been tabulated by the FISH method.
CROSBIE, Q.C.:
Q. What do you do for a new batch of antibody that you would use for ER/PR readings? How many cases would you use to validate?
MS. WEGRYNOWSKI:
A. Presently now?
CROSBIE, Q.C.:
Q. Yes.

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MS. WEGRYNOWSKI:
A. We use our gold standard which would be our TMA block, which we would have a positive, a low positive and our negative, and that's what we would validate our new batch with.
CROSBIE, Q.C.:
Q. Is there a number of cases that you would look at to do the validation?
MS. WEGRYNOWSKI:
A. No, that was done historically.
CROSBIE, Q.C.:
Q. Pardon me?
MS. WEGRYNOWSKI:
A. That was done historically.
CROSBIE, Q.C.:
Q. And you don't know what was done historically?
MS. WEGRYNOWSKI:
A. It would have been methodology such as this.
CROSBIE, Q.C.:
Q. But you don't know numbers?
MS. WEGRYNOWSKI:
A. No, I do not.
CROSBIE, Q.C.:
Q. Okay. If I understood it correctly, again, my ears pricked up, I think you said yesterday

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that you noticed--maybe I don't have the terminology quite exactly correct. You have these microtomes which do the very fine slices for the placement of the tissue sample on the slides, and some of them are cold microtomes. Is that what you told us?

MS. WEGRYNOWSKI:

A. Oh, that was a cryostat, yes. They use that for frozen work.

CROSBIE, Q.C.:

Q. Frozen work. Did you say that specimens were left in these machines or around these machines overnight, in which case they would thaw out?

MS. WEGRYNOWSKI:

A. Yes.

CROSBIE, Q.C.:

Q. And what would be the result of that for the specimens?

MS. WEGRYNOWSKI:

A. They would be rendered useless.

CROSBIE, Q.C.:

Q. Would you agree that human tissue should be treated with respect?

MS. WEGRYNOWSKI:

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A. Yes.

CROSBIE, Q.C.:

Q. Is that treating human tissue with respect?

MS. WEGRYNOWSKI:

A. No.

CROSBIE, Q.C.:

Q. Thank you. I have nothing further.

THE COMMISSIONER:

Q. Mr. Pike?

MR. PIKE:

Q. No questions, thank you.

THE COMMISSIONER:

Q. Now Mr. Pritchard, you were indicating you wanted to ask another question.

MR. PRITCHARD:

Q. Yes.

THE COMMISSIONER:

Q. Okay. Let's see where this question is going.

MS. PATRICIA WEGRYNOWSKI, EXAMINATION BY MR. ROLF PRITCHARD

MR. PRITCHARD:

Q. Thank you, Commissioner. I was going to ask two questions, but as you say, we'll see where they're going. Ms. Wegrynowski, earlier this morning, I asked you about whether or not you

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had any knowledge if the Premier had read your report in connection with the phone call that you received from Mr. Dyer that the Premier was going to read your report, and you indicated you had no knowledge of that, and what I should have asked you then as well was if you had any knowledge if, in fact, the Premier had even received the report.

MS. WEGRYNOWSKI:

A. I do not.

MR. PRITCHARD:

Q. Okay. Ms. Wegrynowski, we heard evidence from Mr. Abbott, who was the former deputy minister of Health and Community Services, that in May of 2007, spring of 2007, if you will, after these events became public knowledge, he inquired with Mr. Tilley, who was then the CEO of Eastern Health, about obtaining the reports.

MS. WEGRYNOWSKI:

A. Okay.

MR. PRITCHARD:

Q. Including yours, and I wondered if you had any knowledge if perhaps the phone call from Mr. Dyer was in response to Mr. Tilley intending

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to turn over those reports at that time. Do you have any knowledge about that?

MS. WEGRYNOWSKI:

A. I do not have any knowledge of that.

MR. PRITCHARD:

Q. Okay, and we heard from Mr. Tilley that in the fullness of time, he did not actually get an opportunity to send those reports. He had put them in an envelope and left them on his desk, and then when he resigned, they rested on his desk or thereabouts and subsequently, Ms. Jones, who became the acting CEO, found the envelope and it was her judgment that that should not be disclosed, and so she did not send those on. We've also heard evidence from various ministers that they claim not to have received the report. We also heard from a representative of the Premier's office that they hadn't received the report, and I just wanted to be clear. You're not offering any evidence to contradict those assertions, are you?

MS. WEGRYNOWSKI:

A. I am not.

MR. PRITCHARD:

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Q. All right. Thank you, very much, Commissioner.
COMMISSIONER:
Q. All right. No, it's just I'm not sure how this witness could possibly know unless somebody had told her, but -
MR. PRITCHARD:
Q. No, and I--just to clarify, Commissioner, I just wanted to be certain. She had testified that she was told by phone that her report was going to be read -
COMMISSIONER:
Q. Yes.
MR. PRITCHARD:
Q. - by the premier. I just wanted to make sure that she has no knowledge about whether or not it was read or, indeed, given to the premier or anyone else in government.
COMMISSIONER:
Q. All right.
MR. PRITCHARD:
Q. Thank you, Commissioner.
COMMISSIONER:
Q. Thank you. Do you have anything? I'm sorry, Mr. Clements?

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MR. CLEMENTS:
Q. No questions.
COMMISSIONER:
Q. My apologies again. That's twice I forgot -
MR. CLEMENTS:
Q. (Inaudible) no questions, thanks.
COMMISSIONER:
Q. Ms. Chaytor?
MS. TRISH WEGRYNOWSKI, RE-EXAMINATION BY SANDRA CHAYTOR, Q.C.
CHAYTOR, Q.C.:
Q. Just a couple of quick points in clarification. I think you were asked by Mr. Simmons about the issue of when you became licensed in Ontario. If we could just look at 1730, page 3 just to clarify that point for the record? And I believe here it indicates--top of page 3, is that right? I'm sorry, it's the next page. Here we go, sorry, page 2. 1994 to the present, College of Medical Laboratory Technologists of Ontario. So I take it you've been licensed since, is that 1994?
MS. WEGRYNOWSKI:
A. Yes, I got my licensure and passed my national exams and the CSLT was the national body from when I graduated until 1993 and then the College of Medical Laboratory Technologists of Ontario was founded in 1994.

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CHAYTOR, Q.C.:
Q. Okay. And another question that arose from Mr. Simmons questions, he indicated perhaps that Mount Sinai is foremost in labs across the country and referred to the term "gold standard". And you, I think, in answering said the stringency should be in all laboratories?
MS. WEGRYNOWSKI:
A. Yes.
CHAYTOR, Q.C.:
Q. And I'm just wondering through the recommendations that you set out in your two reports here for Eastern Health were you aiming at creating a gold standard for Eastern Health or a centre of excellence, was that your goal?
MS. WEGRYNOWSKI:
A. My goal was to try to provide Eastern Health with the cornerstones for the -
CHAYTOR, Q.C.:

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Q. I'm sorry?
MS. WEGRYNOWSKI:
A. To provide the cornerstones for the pathology laboratory.
CHAYTOR, Q.C.:
Q. So the basics?
MS. WEGRYNOWSKI:
A. The very basics.
CHAYTOR, Q.C.:
Q. And you indicated you came thinking you were going to do a peer review in 2005. Why did you not do a peer review?
MS. WEGRYNOWSKI:
A. There were no standard operating procedures to review.
CHAYTOR, Q.C.:
Q. Mr. Simmons asked a question about how long you've been enrolled in QMPLS and you indicated that's been mandated for the past two years. I take it prior to that, however, that Mount Sinai was doing external quality assurance, and you were enrolled prior to that in CAP and UK NEQAS?
MS. WEGRYNOWSKI:
A. No, before that was CAP. I don't have the

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exact time for QMPLS, that's my mistake.
CHAYTOR, Q.C.:
Q. Okay.
MS. WEGRYNOWSKI:
A. And we also do, I think it's called the CIHQ, the Canadian Immunohistochemistry Quality where we do ER/PRs with them.
CHAYTOR, Q.C.:
Q. And how long has that been the case, how long have you been enrolled in CAP and I take it that predates the mandated QMPLS?
MS. WEGRYNOWSKI:
A. That's correct. CAP was already at Mount Sinai Hospital when I arrived.
CHAYTOR, Q.C.:
Q. When you went there.
MS. WEGRYNOWSKI:
A. So prior to '99.
CHAYTOR, Q.C.:
Q. So sometime prior to 1999?
MS. WEGRYNOWSKI:
A. Correct.
CHAYTOR, Q.C.:
Q. Okay. Thank you. The issue of Mr. Simmons brought up in the e-mail where you referred to

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rotating, you posed a question before you came here in the e-mail exchange as to whether or not the technologists were rotating or dedicated?
MS. WEGRYNOWSKI:
A. Um-hm.
CHAYTOR, Q.C.:
Q. I just wanted to clarify your answer in that. In posing the question as to whether or not the technologists in IHC were rotating or dedicated, were you suggesting that rotating for IHC technologists might, in fact, be acceptable?
MS. WEGRYNOWSKI:
A. No, that wasn't my intention at all. I didn't know how the organization was set up. I didn't have a sense of whether or not the immunohistochemistry department was a separate entity, whether it was just part of the histology so you put somebody on that bench that one week and they were treating it more as a special stain as opposed to an actual dynamic laboratory.
CHAYTOR, Q.C.:
Q. And I think in Mr.--my final question. In Mr.

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Crosbie's questioning he referred you to the document, the memo by Dr. Khalifa and you replied that you saw that more as a concordance exercise versus a validation exercise. Could you just clarify what is the difference between those two exercises?
MS. WEGRYNOWSKI:
A. In the way I'm using the terms, when I speak of validation, I am talking about bringing in a new lot or a new antibody and making sure that it is working or performing to the standards of our expectation. When I am speaking of concordance, I am looking at one method and comparing it the other. So we're looking at method for this particular example where you had a quantitative figure and you were getting your DCC numbers and you had that biochemical assay. So now you're moving towards something that is a little bit more subjective because when you start interpreting slides or the pathologist begins interpreting slides, it is quantitative but it is, it's semi-quantitative and that's what I meant by concordance.
CHAYTOR, Q.C.:

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Q. Okay. Thank you, Commissioner. Thank you, Ms. Wegrynowski.
MS. WEGRYNOWSKI:
A. Thank you.
COMMISSIONER:
Q. Thank you. And I want to add my appreciation to that which has already been expressed to you for coming all this way and enlightening us for a day and a half. And frankly, I found it a very interesting day and a half, so thank you, very much.
MS. WEGRYNOWSKI:
A. Thank you.
COMMISSIONER:
Q. Do we have plans for the afternoon?
CHAYTOR, Q.C.:
Q. We are trying--we had anticipated that Ms. Wegrynowski would go for the full two days, but we are trying to line up one, a witness who was here last week who didn't get an opportunity to be cross-examined, so we're waiting to hear back from that person. I don't believe there's any response at this point.
COMMISSIONER:

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Q. All right, so for those in the room who want to--how about this, I promise you a long lunch, and why don't you check with the office within the hour and we should be able to be definitive about whether we will continue the afternoon. I wouldn't want to start a witness that would run over because, as I understand it, Dr. Mullen will be here in the morning for -

CHAYTOR, Q.C.:

Q. That's correct.

COMMISSIONER:

Q. - an anticipated two days.

CHAYTOR, Q.C.:

Q. If we can get this particular witness we're-- it should certainly conclude this afternoon.

COMMISSIONER:

Q. Yes. This is one of the two that we have left over?

CHAYTOR, Q.C.:

Q. One of the two that we didn't have a chance for the -

COMMISSIONER:

Q. Yes, Mr. Crosbie?

CROSBIE, Q.C.;

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Q. May I ask the identity, is this Mr. Singleton?

CHAYTOR, Q.C.:

Q. Yes, it is.

CROSBIE, Q.C.:

Q. Because I don't think he will be more than an hour.

CHAYTOR, Q.C.:

Q. Yes.

CROSBIE, Q.C.:

Q. Will he?

COMMISSIONER:

Q. He won't--I don't--I'm afraid I'm very bad at predicting this from up here, Mr. Crosbie.

CROSBIE, Q.C.:

Q. Speaking for my own self, which I don't think--I think there are only one or two of us left.

MR. SIMMONS:

Q. Commissioner, just on the break I was asked to see if we could contact Mr. Singleton.

COMMISSIONER:

Q. Yes.

MR. SIMMONS:

Q. - and obviously while I'm in here, I can only use e-mail, I've tried by telephone earlier. I have no idea whatsoever whether I can even

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reach him, in order to -

COMMISSIONER:

Q. Yes, well that's why I'm suggesting we have kind of time limit. So if you're unable to-- are we dealing with two people or just one in terms of trying to contact?

CHAYTOR, Q.C.:

Q. Just one.

COMMISSIONER:

Q. Just one.

CHAYTOR, Q.C.:

Q. The other person that we were hoping would -

COMMISSIONER:

Q. Is not available?

CHAYTOR, Q.C.:

Q. - be Dr. Bradbury, who is not--has confirmed is not available this afternoon.

COMMISSIONER:

Q. But she's not available, all right. Mr. Simmons, can I ask you again to just see if you can contact Mr. Singleton and confirm or, indeed, confirm that he's not available within the hour to let us know. If you're not able to contact him within the hour, then we'll have to assume he's not available and indicate

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that to counsel when they check in. And that is not an invitation to everybody to call up Mr. Singleton and tell him not to answer his phone in the next hour. So I'll ask you to check with our office within the next hour and we can confirm that we'll either proceed at 2:00 or otherwise. Thank you, very much.

Upon conclusion.

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 25th day of June, 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 25th day of June, A.D., 2008

Judy Moss

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