

COMMISSION OF INQUIRY  
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

June 24, 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

Chesley 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

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MS. TRISH WEGRYNOWSKI - SWORN

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Certificate

1 COMMISSIONER:  
2 Q. Please be seated. Ms. Chaytor.  
3 CHAYTOR, Q.C.:  
4 Q. Good morning, Commissioner. Our next witness  
5 is Patricia Wegrynowski, and I would ask,  
6 please, that she be sworn or affirmed.  
7 MS. TRISH WEGRYNOWSKI (SWORN) EXAMINATION BY SANDRA  
8 CHAYTOR, Q.C.  
9 REGISTRAR:  
10 Q. And would you please state and spell your  
11 complete name for the Commission?  
12 MS. WEGRYNOWSKI:  
13 A. My name is Trish Wegrynowski. It’s spelled T-  
14 r-i-s-h, and my surname is W-e-g-r-y-n-o-w-s-  
15 k-i.  
16 REGISTRAR:  
17 Q. Thank you.  
18 MS. WEGRYNOWSKI:  
19 A. You’re welcome.  
20 CHAYTOR, Q.C.:  
21 Q. Good morning, Ms. Wegrynowski.  
22 MS. WEGRYNOWSKI:  
23 A. Good morning.  
24 CHAYTOR, Q.C.:  
25 Q. I’m sorry, I called you Patricia, but your

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1 name is actually Trish?  
 2 MS. WEGRYNOWSKI:  
 3 A. It is Patricia, but I go by Trish.  
 4 CHAYTOR, Q.C.:  
 5 Q. By Trish, okay. Thank you. We have a number  
 6 of new exhibits this morning, Commissioner, I  
 7 would ask to have entered. And they are P-  
 8 1730 through to P-1766, inclusive.  
 9 COMMISSIONER:  
 10 Q. Entered.  
 11 EXHIBITS P-1730 THROUGH P-1766, INCLUSIVE, ENTERED INTO  
 12 EVIDENCE.  
 13 CHAYTOR, Q.C.:  
 14 Q. Thank you. If I could have, please, P-1730?  
 15 Ms. Wegrynowski, we'll begin with, if you  
 16 could take us through the highlights of your  
 17 educational and professional background.  
 18 MS. WEGRYNOWSKI:  
 19 A. Sure.  
 20 CHAYTOR, Q.C.:  
 21 Q. And 1730 is your curriculum vitae. And we see  
 22 here at--we could start at the education and  
 23 licensure. It indicates that in 1977 you  
 24 graduated from Toronto Institute of Medical  
 25 Technology with an RT?

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1 MS. WEGRYNOWSKI:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. Perhaps you could tell us what that is?  
 5 MS. WEGRYNOWSKI:  
 6 A. That's a two-year program that was run out of  
 7 the Institute of Medical Technology. In that  
 8 program the first year is 10 months of  
 9 learning based on the five areas of the  
 10 laboratory, that would be chemistry,  
 11 hematology, microbiology, blood bank and  
 12 pathology. The second year is 12 months in  
 13 hospital, so that's your clinical year. When  
 14 you complete that and your examinations in  
 15 those two years you then sit your national  
 16 examinations.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And I take it RT is registered  
 19 technologist?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes. The nomenclature changed to medical  
 22 laboratory technologist many years later.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. And then in 1983 you're at Humber  
 25 College and you have a business communications

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1 diploma?  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. 1986 Michener Institute, OHA Management,  
 6 Series 1 certificate?  
 7 MS. WEGRYNOWSKI:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. And in 1998 you have a BAS with merit from  
 11 York University?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. And in your licensure it shows--perhaps you  
 16 could tell us what a BAS is?  
 17 MS. WEGRYNOWSKI:  
 18 A. It's a Bachelor of Administrative Studies.  
 19 CHAYTOR, Q.C.:  
 20 Q. Thank you.  
 21 MS. WEGRYNOWSKI:  
 22 A. You're welcome.  
 23 CHAYTOR, Q.C.:  
 24 Q. And what's involved in a Bachelor of  
 25 Administrative Studies?

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1 MS. WEGRYNOWSKI:  
 2 A. I took that program specifically because I  
 3 believe that laboratories need to be run like  
 4 businesses; there's different aspects to it.  
 5 It's the training of organization, finance,  
 6 the whole gamut of what went well with  
 7 science.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And your licensure, from 1977 to 1993  
 10 was through the Canadian Society of Laboratory  
 11 Technologists?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. And then 1994 through the present the College  
 16 of Medical Laboratory Technologists of  
 17 Ontario?  
 18 MS. WEGRYNOWSKI:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. And so why is there the switch from '93 to  
 22 '94?  
 23 MS. WEGRYNOWSKI:  
 24 A. The CSLT stopped and became then the Canadian  
 25 Society for Medical Laboratory Science. The

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1 laboratory technologists then became  
 2 registered with the government and that's when  
 3 we received our own college, so I have been in  
 4 the college. We are required to be members of  
 5 the college to practice in Ontario.  
 6 CHAYTOR, Q.C.:  
 7 Q. And in Ontario you're subject to legislation?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes. I have to ensure that my education is  
 10 kept up and I have a number of continuing  
 11 education hours and we are tested--I should  
 12 rephrase that. We are given an opportunity  
 13 provide our information to the college, it's  
 14 almost on a roulette wheel, your number gets  
 15 chosen and it's your time up. So what you  
 16 need to do is they will go through your  
 17 education for the previous two years to ensure  
 18 that you're keeping your scope of practice up.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. And under your professional  
 21 affiliations and activities you have "Canadian  
 22 Society for Medical" -  
 23 MS. WEGRYNOWSKI:  
 24 A. "Laboratory Science."  
 25 CHAYTOR, Q.C.:

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1 Q. - "Laboratory Science."  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. So what would that be?  
 6 MS. WEGRYNOWSKI:  
 7 A. That's our national organization.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And CMLTO Pathology Practice Guidelines  
 10 Committee, what -  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes, I worked on that committee. We were  
 13 determining what guidelines we could use for  
 14 the histology laboratory in the Province of  
 15 Ontario. We were looking what expectations  
 16 would be for benchmarking.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And you are or have been an invigilator  
 19 for MLA examinations?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes, I am.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. And what does that mean?  
 24 MS. WEGRYNOWSKI:  
 25 A. There are presently the CSMLS are looking at

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1 including the MLAS in their umbrella as are  
 2 the CMLTO. There are a number of  
 3 organizations that are out there that are  
 4 providing education, the OSMT at this point is  
 5 the only one providing, to my knowledge,  
 6 providing an examination.  
 7 CHAYTOR, Q.C.:  
 8 Q. And so MLA, the Medical Laboratory?  
 9 MS. WEGRYNOWSKI:  
 10 A. Technician.  
 11 CHAYTOR, Q.C.:  
 12 Q. Technician, okay. And the National Society of  
 13 Histotechnology, you've been involved with  
 14 that?  
 15 MS. WEGRYNOWSKI:  
 16 A. For many years. They are an American  
 17 organization. Their whole mandate is in the  
 18 area of histotechnology, so they do histology  
 19 and they have a tremendous amount of  
 20 information in immunohistochemistry. And I  
 21 have the pleasure of sitting on the executive  
 22 for a number of years and have attended  
 23 several of their conventions and I'm also a  
 24 member of their immunohistochemistry research  
 25 group.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. And you're also part of  
 3 Immunohistochemistry Users Group, Toronto.  
 4 What is that?  
 5 MS. WEGRYNOWSKI:  
 6 A. There will be several meetings during the year  
 7 at different hospitals where members of the  
 8 immunohistochemistry community will get  
 9 together and we will have a key note speaker  
 10 and different suppliers will be there.  
 11 CHAYTOR, Q.C.:  
 12 Q. And is that just technologists or does that  
 13 also include pathologists?  
 14 MS. WEGRYNOWSKI:  
 15 A. Technologists. It's -  
 16 CHAYTOR, Q.C.:  
 17 Q. Technologists?  
 18 MS. WEGRYNOWSKI:  
 19 A. Yeah.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And the College of American  
 22 Pathologists Inspector, what does that  
 23 involve?  
 24 MS. WEGRYNOWSKI:  
 25 A. I have inspected several laboratories from the

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1 CAP, using the CAP guidelines.  
 2 CHAYTOR, Q.C.:  
 3 Q. Ontario Accreditation Assessor's Certificate?  
 4 MS. WEGRYNOWSKI:  
 5 A. I originally sat my exam for that particular  
 6 certificate, that's when QMPLS was coming out  
 7 and the Ontario Lab Accreditation.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And technical advisor, Canadian  
 10 Consensus for Her2/neu Testing Guidelines in  
 11 Breast Cancer?  
 12 MS. WEGRYNOWSKI:  
 13 A. Those guidelines were published last year.  
 14 Frances O'Malley and Wedad Hanna, I believe,  
 15 are co-authors of that and I was approached to  
 16 be the technical advisor.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And your employment, if we just start  
 19 at the next page.  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay.  
 22 CHAYTOR, Q.C.:  
 23 Q. You began in 1978 through to 1983 with Women's  
 24 College Hospital in Toronto?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes. That was my first job, and I worked in  
 2 histology. And it was around 1983 that  
 3 immunohistochemistry was coming into being and  
 4 I was asked if I would like to lead that area,  
 5 which I did. And I remained in that position  
 6 until 1990.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. So you moved to immunohistochemistry in  
 9 1983 and you've been involved with  
 10 immunohistochemistry ever since then?  
 11 MS. WEGRYNOWSKI:  
 12 A. Except between '90 and '99 when I went to  
 13 Credit Valley, that was my hiatus.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. Yes, and we see that here. So from  
 16 1990 to 1999 you're back to histology?  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. And 2000 to 2005 you indicate you're at  
 21 Mount Sinai Hospital and you're key LIS  
 22 operator, pathology. What does that mean?  
 23 MS. WEGRYNOWSKI:  
 24 A. In addition to taking on my general duties, I  
 25 was also involved with the laboratory

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1 information system, so I was implementing  
 2 that, as well.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. So that would include report forms?  
 5 MS. WEGRYNOWSKI:  
 6 A. Synoptic reporting, including the stain codes,  
 7 ensuring that the processing that workload  
 8 units were being captured, yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. So was this a new system brought in in Mount  
 11 Sinai in this time period?  
 12 MS. WEGRYNOWSKI:  
 13 A. The system, yes, the system was brought in  
 14 around 2000, that's correct.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay. And from 2000 to the present, of  
 17 course, you're senior MLT,  
 18 immunohistochemistry?  
 19 MS. WEGRYNOWSKI:  
 20 A. That is correct.  
 21 CHAYTOR, Q.C.:  
 22 Q. So you went back to, or you went to Mount  
 23 Sinai from 1999 to 2000 as a general MLT?  
 24 MS. WEGRYNOWSKI:  
 25 A. Correct.

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1 CHAYTOR, Q.C.:  
 2 Q. And within a year became a senior MLT?  
 3 MS. WEGRYNOWSKI:  
 4 A. That's correct.  
 5 CHAYTOR, Q.C.:  
 6 Q. And what's the difference?  
 7 MS. WEGRYNOWSKI:  
 8 A. In the present scope I'm responsible for five  
 9 different--responsible for five employees, I'm  
 10 responsible for the immunohistochemistry  
 11 laboratory and everything that comes out of  
 12 there.  
 13 CHAYTOR, Q.C.:  
 14 Q. And you've been an invited lecturer?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. On a number of occasions?  
 19 MS. WEGRYNOWSKI:  
 20 A. I've--yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. Perhaps you can take us through that?  
 23 MS. WEGRYNOWSKI:  
 24 A. Okay. I've had the opportunity to speak at  
 25 the Michener Institute for Applied Science to

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1 the second, first or second year students, I  
 2 can't recall. I gave a lecture with Dr. Aaron  
 3 Pollett at the NSH convention when it was here  
 4 in Toronto. I've done a number of in-service  
 5 continuing education programs for  
 6 immunohistochemistry at Mount Sinai, and when  
 7 we do have rotating students from different  
 8 sites, I also provide a lecture for them.  
 9 Because I was involved with the laboratory  
 10 information system at that time we were doing  
 11 an integration between up--excuse me, between  
 12 cytology and histology, one of the  
 13 cytotechnologists and I did a lecture at that  
 14 particular convention. And then recently I  
 15 did several lectures at Lakeridge Health  
 16 Corporation in Oshawa.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And then we have a number of  
 19 publications you've been involved in?  
 20 MS. WEGRYNOWSKI:  
 21 A. Um-hm.  
 22 CHAYTOR, Q.C.:  
 23 Q. And courses attended include 1997,  
 24 immunohistochemistry workshop?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes. May I go back to 1983?  
 2 CHAYTOR, Q.C.:  
 3 Q. Sure, absolutely.  
 4 MS. WEGRYNOWSKI:  
 5 A. Okay. In 1983 it was very fledging in  
 6 immunohistochemistry and there was no formal  
 7 course out there to really find, and this  
 8 particular course was offered that Michener  
 9 Institute and it certainly provided me with  
 10 the groundwork of what I've learned today. We  
 11 learned about the proteins and the epitopes  
 12 and words that were completely strange because  
 13 they were certainly nothing that you take in  
 14 your training.  
 15 CHAYTOR, Q.C.:  
 16 Q. It was nothing you had learned in your formal  
 17 education?  
 18 MS. WEGRYNOWSKI:  
 19 A. Absolutely not.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay.  
 22 MS. WEGRYNOWSKI:  
 23 A. From there it was finding workshops from  
 24 different suppliers. And at that time because  
 25 it was such a fledgling area, many of the

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1 suppliers were bringing in guest lecturers and  
 2 providing lectures, so I took one through  
 3 Biogenex and then I took one through Miles,  
 4 that one was held at Sick Children's. So  
 5 that's basically where a lot of the knowledge  
 6 came from. I attended the OHA convention,  
 7 that was again QMPLS, understanding the  
 8 accreditation proposal requirements. The one  
 9 in 2001 actually was a very interesting  
 10 workshop, it was a multi-functional lab  
 11 station. I'll go in this later in my lecture,  
 12 but I could just, if you'd like, just point on  
 13 it. They were different pretreatments that we  
 14 use in the laboratory, and at this particular  
 15 workshop they presented a microwave that would  
 16 assist us, so it was--it's having the ability  
 17 to go to different workshops for the  
 18 technologists that provides them with what is  
 19 out there in the marketplace. And then, of  
 20 course, Brian Hewlett's lecture on optimizing  
 21 IHC techniques.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay.  
 24 MS. WEGRYNOWSKI:  
 25 A. I've gone to a number of workshops with the

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1 NSH, but this one in particular I highlighted  
 2 because it was immunoenzymatic double staining  
 3 methods. So a lot of the staining that is done  
 4 in immunohistochemistry is just done as a  
 5 single staining method, you're just looking  
 6 for one particular epitope. When we get into  
 7 the double staining methods, we were looking  
 8 for more than one. I went to a workshop in  
 9 DAKO, excuse me, in Santa Barbara, they were  
 10 releasing a new autostainer. And then last  
 11 year I had the privilege of going to the  
 12 Biological Stain Commission meeting in  
 13 Baltimore, Maryland.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And if we could just go back then to  
 16 your employment. You started out at Women's  
 17 College Hospital in Toronto. And that's where  
 18 you were initiated in 1983 into IHC. Were you  
 19 actually involved in the setting up of the IHC  
 20 lab at that time?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, I was. We didn't have anything at the  
 23 time, it was a brand new area, and I had the  
 24 opportunity to work with Dr. Wedad Hanna and  
 25 Harriett Kaha, both of whom are at Sunnybrook

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1 and Wedad Hanna is also respected in the  
 2 breast community as it Frances O'Malley. At  
 3 that time they were beginning to look at  
 4 different epitopes in tissue. We did not have  
 5 the knowledge to be able to use formalin fixed  
 6 paraffin-imbedded tissue, so at that time we  
 7 were using frozen tissue, and one of the first  
 8 antibodies that we began working with was  
 9 estrogen and progesterone.  
 10 CHAYTOR, Q.C.:  
 11 Q. And that was back in 1983?  
 12 MS. WEGRYNOWSKI:  
 13 A. That is correct.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And what did you have to do at that  
 16 point in time to validate your process?  
 17 MS. WEGRYNOWSKI:  
 18 A. Validating the process was very similar as to  
 19 what we do today. It was--if I could just  
 20 step back? Because we could not find the  
 21 epitope in paraffin-imbedded tissue, we only  
 22 used frozen material. At that time, I believe  
 23 Frances spoke to you about this yesterday,  
 24 there was a DCC, the charcoal method, and they  
 25 were able to get a quantitative figure. So

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1 what we were looking at was determining  
 2 whether or not the estrogen and progesterone  
 3 that we were finding in frozen tissue was  
 4 mirroring what they were finding in that  
 5 particular method.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. And had you been involved in the prior  
 8 method?  
 9 MS. WEGRYNOWSKI:  
 10 A. No.  
 11 CHAYTOR, Q.C.:  
 12 Q. So were you comparing your results then in the  
 13 new IHC method to what they had been using  
 14 through the, I guess it was the bioassay  
 15 method?  
 16 MS. WEGRYNOWSKI:  
 17 A. That's correct. So the word "validation" I'm  
 18 not sure would apply in the same sense as it  
 19 would today.  
 20 CHAYTOR, Q.C.:  
 21 Q. Yes. Because you're not comparing apples to  
 22 apples, I guess?  
 23 MS. WEGRYNOWSKI:  
 24 A. That's correct.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. Perhaps you could tell the Commissioner  
 2 then how IHC has evolved over time from the  
 3 time that you first got involved in the early  
 4 days in 1983?  
 5 MS. WEGRYNOWSKI:  
 6 A. Okay. Immunohistochemistry has evolved  
 7 immensely because we now have the opportunity  
 8 to find these epitopes in formalin fixed  
 9 paraffin-imbedded tissue. It's quite amazing  
 10 that these epitopes, if treated correctly from  
 11 the very beginning, survive decades. And we  
 12 have actually gone back and done work on  
 13 family members that are 20 and 30 year old  
 14 blocks. So we were not able to do this way  
 15 back in the '80s. We were not able to do our  
 16 lymphoma markers on paraffin-imbedded tissues.  
 17 All this is available to us today.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. And in terms of the number of  
 20 antibodies that you would be using, how has  
 21 that evolved over time?  
 22 MS. WEGRYNOWSKI:  
 23 A. When I first began, the bulk of the antibodies  
 24 were fluorochrome so they were simply what we  
 25 do now for kidney biopsies. But there were

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1 very few primary antibodies on the market, at  
 2 least at the service end. I'm sure there was  
 3 many more on the research end. And now in the  
 4 laboratory I presently have, there's over 200  
 5 antibodies, at least.  
 6 CHAYTOR, Q.C.:  
 7 Q. Over 200?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. At Mount Sinai?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Now, Ms. Wegrynowski, we understand that  
 16 you've been to St. John's before?  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. Welcome back.  
 21 MS. WEGRYNOWSKI:  
 22 A. Thank you.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you were originally asked to come in  
 25 September, 2005?

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1 MS. WEGRYNOWSKI:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. To carry out a review. So perhaps you could  
 5 tell the Commissioner who approached you to do  
 6 that review and what it was that you were  
 7 asked to do?  
 8 MS. WEGRYNOWSKI:  
 9 A. Okay. Frances O'Malley originally came to  
 10 speak to me, and from what I understand that  
 11 Bev Carter had contacted her and that they  
 12 were having some concerns with their estrogen  
 13 and progesterone receptors and that they  
 14 wanted someone to look at their processes. So  
 15 she ran that through my technical director and  
 16 I had, I believe there's some e-mails that  
 17 actually lay out the land of how I got here.  
 18 CHAYTOR, Q.C.:  
 19 Q. So if we could look at 1743, please? And this  
 20 is an e-mail communications from Dr. Carter to  
 21 yourself on July 28th, 2005.  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. And it says, "RE: Immunohistochemistry, St.

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1 John's"  
 2 MS. WEGRYNOWSKI:  
 3 A. Um-hm.  
 4 CHAYTOR, Q.C.:  
 5 Q. You say, "Hi Bev, Thank you very much for this  
 6 opportunity and I look forward to reviewing  
 7 your lab protocol. My employer has agreed to  
 8 give me two or three days to visit your site."  
 9 And you're talking about different dates.  
 10 MS. WEGRYNOWSKI:  
 11 A. Um-hm.  
 12 CHAYTOR, Q.C.:  
 13 Q. "I have some questions that perhaps you could  
 14 help me with. Total number of antibodies,  
 15 number of IHC tests run per month, charge  
 16 technologist involvement, contact and name and  
 17 number. Could I please contact them prior to  
 18 my arrival? MLT dedicated and rotating staff  
 19 type of equipment, date installation and  
 20 implementation, would you like me to review  
 21 your SOP's?" And we understand those are  
 22 standards of procedure?  
 23 MS. WEGRYNOWSKI:  
 24 A. That's standard operating procedures.  
 25 CHAYTOR, Q.C.:

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1 Q. Standard operating procedures?  
 2 MS. WEGRYNOWSKI:  
 3 A. That's correct.  
 4 CHAYTOR, Q.C.:  
 5 Q. Thank you. "Re: validation process prior to  
 6 the trip or would you like this done on site?  
 7 Would it be of any value to your staff if I  
 8 was to do a basic lecture on IHC?" Then it's  
 9 talk about your charges and your travel. And  
 10 "At the end I expect I will produce a written  
 11 summary of findings and recommendations within  
 12 a month of the visit." And then some  
 13 logistics about coordinating timing. Ms.  
 14 Wegrynowski why was this information  
 15 important, the total number of antibodies, the  
 16 number of IHC tests run per month, why did you  
 17 need that type of information?  
 18 MS. WEGRYNOWSKI:  
 19 A. I wanted to get a sense of the size of  
 20 laboratory and the complexity of the testing  
 21 that they were doing, how did they compare to  
 22 what I do, and it would also provide me with a  
 23 little bit of a sense of how much time I would  
 24 need to provide them with their needs.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And you asked whether or not they  
 2 wanted you to review their standard operating  
 3 procedures?  
 4 MS. WEGRYNOWSKI:  
 5 A. Right.  
 6 CHAYTOR, Q.C.:  
 7 Q. And whether that would be prior to coming or  
 8 after you've arrived. And did you receive an  
 9 answer to that?  
 10 MS. WEGRYNOWSKI:  
 11 A. I never received any standard operating  
 12 procedures or validation process before I  
 13 arrived.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And did you understand, though, that  
 16 that would be part of what you were coming to  
 17 St. John's to do?  
 18 MS. WEGRYNOWSKI:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And the question of whether or not it  
 22 would be value to the staff to do a basic  
 23 lecture on IHC, did you receive a response to  
 24 that?  
 25 MS. WEGRYNOWSKI:

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1 A. I did that and I did that all through Barry  
 2 Dyer, not Bev Cook.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. Bev Carter, I guess? And then if we  
 5 can -  
 6 MS. WEGRYNOWSKI:  
 7 A. Yes, sorry.  
 8 CHAYTOR, Q.C.:  
 9 Q. That's okay. And if we could have, please,  
 10 1731? On July 29th, 2005 Dr. Cook writes to  
 11 you and says, "Hi Patricia, As discussed, the  
 12 best time period for your review would be  
 13 September 20th to 25th" and you could contact  
 14 Mr. Barry Dyer, divisional manager for  
 15 anatomical pathology, and his numbers are  
 16 given.  
 17 MS. WEGRYNOWSKI:  
 18 A. Um-hm.  
 19 CHAYTOR, Q.C.:  
 20 Q. His contact information. So I take it then  
 21 you did contact Mr. Dyer?  
 22 MS. WEGRYNOWSKI:  
 23 A. To my recollection that's who I contacted,  
 24 yes.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And did you have discussions with Mr.  
 2 Dyer to arrange coming here?  
 3 MS. WEGRYNOWSKI:  
 4 A. Yes, I do, and I believe there's an e-mail  
 5 accordingly.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. If we could look at 1746, please? And  
 8 this is an e-mail exchange between yourself  
 9 and Mr. Dyer. And I'll take you--I believe  
 10 it's again is at the bottom and we'll work our  
 11 way up.  
 12 MS. WEGRYNOWSKI:  
 13 A. All right.  
 14 CHAYTOR, Q.C.:  
 15 Q. And you're writing to Mr. Dyer on--is that the  
 16 first one? Yes. Here it is.  
 17 MS. WEGRYNOWSKI:  
 18 A. Okay.  
 19 CHAYTOR, Q.C.:  
 20 Q. Writing to Mr. Dyer on August 19th, 2005 at  
 21 4:10 p.m. And you indicate that it was "nice  
 22 to touch base with you to discuss my upcoming  
 23 trip to your institution." And you sent along  
 24 a copy of your e-mail to Dr. Carter.  
 25 MS. WEGRYNOWSKI:

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1 A. Um-hm.  
 2 CHAYTOR, Q.C.:  
 3 Q. You indicate, "Thank you for your candour. I  
 4 have a better understanding of the situation.  
 5 I will await your call on Monday after your  
 6 meeting." What did Mr. Dyer explain to you in  
 7 your initial discussions with him?  
 8 MS. WEGRYNOWSKI:  
 9 A. To the best of my memory we spoke about they  
 10 were having issues with their ER/PR, that they  
 11 had changed and that they had changed  
 12 equipment.  
 13 CHAYTOR, Q.C.:  
 14 Q. And what equipment did you understand had been  
 15 changed?  
 16 MS. WEGRYNOWSKI:  
 17 A. I understand that their autostainer had  
 18 changed from the DAKO autostainer to the  
 19 Ventana benchmark, I believe.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And what equipment were you using at  
 22 Mount Sinai?  
 23 MS. WEGRYNOWSKI:  
 24 A. We use the DAKO autostainer.  
 25 CHAYTOR, Q.C.:

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1 Q. And you continue to use that?  
 2 MS. WEGRYNOWSKI:  
 3 A. To today.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and then it's just a copy of your e-mail  
 6 here that you sent to Dr. Carter with the same  
 7 questions, and I take it Mr. Dyer answered  
 8 some of those questions for you in the  
 9 telephone conversation?  
 10 MS. WEGRYNOWSKI:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And Mr. Dyer then responds to you on September  
 14 5th, 2005, and he says that he's "met with the  
 15 program director and clinical chief on Friday.  
 16 They inquired as to when you will be arriving.  
 17 I explained to them we conversed on Friday and  
 18 I have asked you to wait until Monday to  
 19 decide," and then there's just some logistics  
 20 there. Do you recall this as some period,  
 21 because you had spoken to him, it appears,  
 22 sometime prior to August 19th and he's  
 23 indicating that he's spoken to you, it  
 24 appears, another time, conversed on Friday.  
 25 Do you know what discussions you had with Mr.



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1 Dyer in the interim, between August 19th -  
 2 MS. WEGRYNOWSKI:  
 3 A. No, no.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. Was there any further information  
 6 provided to you?  
 7 MS. WEGRYNOWSKI:  
 8 A. Not that I recall. This is something -  
 9 CHAYTOR, Q.C.:  
 10 Q. Sure.  
 11 MS. WEGRYNOWSKI:  
 12 A. No. Thank you.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and he's wondering about a conference  
 15 room for a meeting with the appointed  
 16 pathologists over immunos, and his techs will  
 17 be available for all three days that you are  
 18 here.  
 19 MS. WEGRYNOWSKI:  
 20 A. Um-hm.  
 21 CHAYTOR, Q.C.:  
 22 Q. And I take it those are people that you met  
 23 with. You met with the technologists and the  
 24 pathologist -  
 25 MS. WEGRYNOWSKI:

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1 A. I did.  
 2 CHAYTOR, Q.C.:  
 3 Q. - in charge of immunos?  
 4 MS. WEGRYNOWSKI:  
 5 A. I did.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and who was that person?  
 8 MS. WEGRYNOWSKI:  
 9 A. Dr. Ejeckam.  
 10 CHAYTOR, Q.C.:  
 11 Q. Dr. Ejeckam, okay, and then you're back to Mr.  
 12 Dyer the next day confirming that you've  
 13 booked to come from September 20th to the  
 14 22nd. "After our conversation, I think it is  
 15 best if I concentrate on the role of  
 16 validation in the IHC laboratory." What was  
 17 it about your conversation with him that made  
 18 you concentrate then on the role of  
 19 validation?  
 20 MS. WEGRYNOWSKI:  
 21 A. Because they were having concerns with the  
 22 estrogen and progesterone receptor and I felt  
 23 that if they were having concerns, then we  
 24 need to look at how it is that they were  
 25 validating it or ensuring that the product--

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1 the marker was exhibiting the way it should.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and you go on to offer to do a lecture  
 4 for the technologists?  
 5 MS. WEGRYNOWSKI:  
 6 A. Yes.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, and did you in fact do that?  
 9 MS. WEGRYNOWSKI:  
 10 A. Yes, I did one on basic immunohistochemistry  
 11 and another one quality control or quality  
 12 assurance in the laboratory.  
 13 CHAYTOR, Q.C.:  
 14 Q. And I understand that you're going to walk us  
 15 through that today as well?  
 16 MS. WEGRYNOWSKI:  
 17 A. If you'd like, yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay, and those will be the same presentations  
 20 that you gave to the technologists when you  
 21 were in St. John's in 2005?  
 22 MS. WEGRYNOWSKI:  
 23 A. That is correct.  
 24 CHAYTOR, Q.C.:  
 25 Q. Then why did you choose to do basic IHC and

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1 quality control in the IHC lab?  
 2 MS. WEGRYNOWSKI:  
 3 A. Because they were rotating technologists, I  
 4 felt that a basic lecture never hurts and it's  
 5 a good way to learn from others as well, with  
 6 their input, and quality control/quality  
 7 assurance because immunohistochemistry, you  
 8 must ensure that your pre-analytical,  
 9 analytical and post-analytical. So it was  
 10 more just a brush up. I wasn't sure where  
 11 they were in the process. It was more, this  
 12 is what we could look at, and if it fits your  
 13 needs, that's terrific. If it doesn't, we can  
 14 certainly skip by it.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and you went ahead with the lectures, so  
 17 I take it you determined that it did fit their  
 18 needs?  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. And you indicate, as for the meeting, "as for  
 23 meeting the pathologists, I would like to do  
 24 this at the beginning so as to understand the  
 25 policies and procedures of the IHC

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1 department." So that was Dr. Ejeckam, I take  
 2 it?  
 3 MS. WEGRYNOWSKI:  
 4 A. Correct.  
 5 CHAYTOR, Q.C.:  
 6 Q. And you met with him and you found -  
 7 MS. WEGRYNOWSKI:  
 8 A. I did.  
 9 CHAYTOR, Q.C.:  
 10 Q. - did you find that helpful?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes.  
 13 CHAYTOR, Q.C.:  
 14 Q. And were you able to obtain information about  
 15 the policies and procedures of the IHC  
 16 department?  
 17 MS. WEGRYNOWSKI:  
 18 A. No, not really.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and why not?  
 21 MS. WEGRYNOWSKI:  
 22 A. I didn't find any.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you indicate, you go on to say that "I do  
 25 want to spend time with your technologists,

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1 understanding the processes that they are  
 2 presently doing, so that I can assist you with  
 3 making recommendations," and you ask for the  
 4 name of the Ventana equipment and kit that  
 5 you're using, and a list of equipment that  
 6 they have in the IHC lab?  
 7 MS. WEGRYNOWSKI:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. Was that information provided to you?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes, it was.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and you ask a few questions again about  
 15 the number of tests and whether or not the  
 16 staff are dedicated or rotating?  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. And your "goal is to assist you in evaluating  
 21 your IHC procedures and to make  
 22 recommendations from my observations, based on  
 23 CAP," and again, you can just remind us,  
 24 please, what CAP -  
 25 MS. WEGRYNOWSKI:

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1 A. College of American Pathologists.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and OLA standards?  
 4 MS. WEGRYNOWSKI:  
 5 A. Ontario Lab Accreditation.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and I take it in Ontario, at Mount  
 8 Sinai, your lab is actually put through an  
 9 evaluation or accreditation process? Is that  
 10 right?  
 11 MS. WEGRYNOWSKI:  
 12 A. Every lab in Ontario is, that's correct, for  
 13 QMPLS, that's correct.  
 14 CHAYTOR, Q.C.:  
 15 Q. And CAP is a form of external proficiency  
 16 testing?  
 17 MS. WEGRYNOWSKI:  
 18 A. It is. It's an American organization that we  
 19 also belong to.  
 20 CHAYTOR, Q.C.:  
 21 Q. And you voluntarily participate in that, I  
 22 understand?  
 23 MS. WEGRYNOWSKI:  
 24 A. Correct.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and you're going to divide your day or  
 2 your time. "I will spend my first day  
 3 orientating myself and determining a course of  
 4 action for the rest of the visit. Day two  
 5 would be ideal for the lectures, if desired,  
 6 as at this point in time, I should know what  
 7 to highlight in the talks. Day three could be  
 8 used with a follow up day with your staff."  
 9 And then Mr. Dyer is back to you on the 8th of  
 10 September with some logistics about where you  
 11 could stay and he gives you the information  
 12 about the Ventana benchmark, the type of kits,  
 13 and he indicates that they do about 80 immunos  
 14 a day by three rotating staff.  
 15 MS. WEGRYNOWSKI:  
 16 A. Um-hm.  
 17 CHAYTOR, Q.C.:  
 18 Q. And how does that compare to at the time about  
 19 what you were doing at Mount Sinai?  
 20 MS. WEGRYNOWSKI:  
 21 A. We do several hundred a day.  
 22 CHAYTOR, Q.C.:  
 23 Q. Several hundred a day?  
 24 MS. WEGRYNOWSKI:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And how many staff do you have?

3 MS. WEGRYNOWSKI:

4 A. We have five that report to me.

5 CHAYTOR, Q.C.:

6 Q. Okay, and are they rotating or dedicated?

7 MS. WEGRYNOWSKI:

8 A. Dedicated.

9 CHAYTOR, Q.C.:

10 Q. "Only two are scheduled daily on immunos. One

11 staining and one cutting. The pathologists

12 want three dedicated staff on immunos. This

13 may be a good recommendation." When you read

14 this, Ms. Wegrynowski, did you have any

15 concern?

16 MS. WEGRYNOWSKI:

17 A. My concern was the rotating staff, but I

18 wasn't sure what that rotation was, so it was

19 just something I tucked at the back of my

20 mind.

21 CHAYTOR, Q.C.:

22 Q. Okay, and then Mr. Dyer concludes with

23 suggesting that you contact Mary Butler, who

24 is the senior tech and the most knowledgeable

25 with immunos, and I take it you met with Ms.

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1 Butler when you were in St. John's?

2 MS. WEGRYNOWSKI:

3 A. I did.

4 CHAYTOR, Q.C.:

5 Q. Okay. Other than the indication here that the

6 pathologists want to have three dedicated

7 staff, prior to coming to St. John's or during

8 your time here in your evaluation and review,

9 were there any other ideas suggested to you

10 that Eastern Health thought or Eastern Health

11 personnel thought might be a good idea or a

12 good way forward?

13 MS. WEGRYNOWSKI:

14 A. They too wanted--the pathologists, yes, they

15 wanted to have permanent staff in there as

16 well, and I got a sense, once I came here,

17 that the technologists welcomed that idea as

18 well.

19 CHAYTOR, Q.C.:

20 Q. And were there any other things that they had

21 in their mind that might be good ideas that

22 they bounced off you and thought -

23 MS. WEGRYNOWSKI:

24 A. They were talking at that time about pathology

25 assistants as well.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and if we could look, please, at 1747?

3 I take it there's nothing else that you recall

4 about your discussions leading up to coming to

5 St. John's?

6 MS. WEGRYNOWSKI:

7 A. No.

8 CHAYTOR, Q.C.:

9 Q. And this is a fax transmittal to you then on

10 September 14th, and you're scheduled to come,

11 I believe, on September 20th, and this is from

12 Dr. Cook, and he's sending to you terms of

13 reference, external quality review of the

14 immunohistochemistry service. It indicates

15 that your "purpose would be to review the

16 operation and make recommendations as to the

17 processes involved in a service of laboratory

18 medicine program." Did you understand were

19 you to undertake any peer review of the

20 technologists?

21 MS. WEGRYNOWSKI:

22 A. Of the process only.

23 CHAYTOR, Q.C.:

24 Q. The process only?

25 MS. WEGRYNOWSKI:

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1 A. Yes.

2 CHAYTOR, Q.C.:

3 Q. So a review of the process?

4 MS. WEGRYNOWSKI:

5 A. That is correct.

6 CHAYTOR, Q.C.:

7 Q. And "accountability, the external quality

8 review consultant will take direction from and

9 make recommendations to the leadership team of

10 the laboratory medicine program." First of

11 all, did you receive this fax prior to coming

12 to St. John's?

13 MS. WEGRYNOWSKI:

14 A. Yes, very shortly before.

15 CHAYTOR, Q.C.:

16 Q. Okay, and did you know you would be receiving

17 such a document?

18 MS. WEGRYNOWSKI:

19 A. I believe I did.

20 CHAYTOR, Q.C.:

21 Q. Okay.

22 MS. WEGRYNOWSKI:

23 A. I believe I did, because they had--as it was

24 set up as a peer review, it was to be

25 maintained as confidential.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and who had that discussion with you?

3 MS. WEGRYNOWSKI:

4 A. I believe it was Dr. Cook.

5 CHAYTOR, Q.C.:

6 Q. And even though it's set up as a peer review,

7 you were not to undertake a peer review of the

8 people?

9 MS. WEGRYNOWSKI:

10 A. No, it was the processes.

11 CHAYTOR, Q.C.:

12 Q. Okay, and who did you understand the

13 leadership team of the laboratory medicine

14 program to be?

15 MS. WEGRYNOWSKI:

16 A. I thought it was your chief pathologist, your

17 chief technologist, your managers.

18 CHAYTOR, Q.C.:

19 Q. And the time frame, they're looking to have

20 you review and report within three months.

21 MS. WEGRYNOWSKI:

22 A. Yes.

23 CHAYTOR, Q.C.:

24 Q. And the responsibilities were: to review the

25 current practices and procedures within the

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1 immunohistochemistry service of the laboratory

2 medicine program.

3 MS. WEGRYNOWSKI:

4 A. Um-hm.

5 CHAYTOR, Q.C.:

6 Q. To interview individuals who may have relevant

7 facts or current and background information of

8 the service, with particular emphasis in

9 ER/PR. So I take it you weren't limited to

10 ER/PR, but they're asking you to concentrate

11 on ER/PR?

12 MS. WEGRYNOWSKI:

13 A. To focus on that, yes.

14 CHAYTOR, Q.C.:

15 Q. Okay, and I take it that you did that, you

16 interviewed people?

17 MS. WEGRYNOWSKI:

18 A. Yes, I did.

19 CHAYTOR, Q.C.:

20 Q. Okay, and who is it that you spoke with

21 besides you've told us Dr. Ejeckam and Ms.

22 Butler, Mr. Dyer. Who else did you speak

23 with?

24 MS. WEGRYNOWSKI:

25 A. It would be Dr. Bev Carter, Dr. Don Cook and

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1 it would be Les and Ken and Mary.

2 CHAYTOR, Q.C.:

3 Q. Okay. So Les Simms, Ken Green, Mary Butler,

4 the technologists?

5 MS. WEGRYNOWSKI:

6 A. Yes.

7 CHAYTOR, Q.C.:

8 Q. Yes, okay.

9 MS. WEGRYNOWSKI:

10 A. And of course, Barry Dyer.

11 CHAYTOR, Q.C.:

12 Q. Okay, and then thirdly, to interview other

13 issues of concern using a systems approach,

14 which may have contributed to the situation

15 being reviewed. So number one is to

16 concentrate on the current practices. Number

17 three, you're to identify other issues of

18 concern using a systems approach which may

19 have contributed to the situation they're

20 experiencing, I take it with the ER/PR issue?

21 MS. WEGRYNOWSKI:

22 A. Correct.

23 CHAYTOR, Q.C.:

24 Q. Okay. What did you understand it to mean when

25 it says using a systems approach?

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1 MS. WEGRYNOWSKI:

2 A. Immunohistochemistry is based on the product

3 that you receive from the specimen when it is

4 first excised from the OR. So to assess the

5 quality of that particular block, one needed

6 to go back to see where it had originally

7 arrived or derived from. So that's what I

8 took that to mean.

9 CHAYTOR, Q.C.:

10 Q. So to follow the tissue right from the time

11 it's produced in the OR all the way through to

12 a slide being -

13 MS. WEGRYNOWSKI:

14 A. Presented to the pathologist.

15 CHAYTOR, Q.C.:

16 Q. - presented to the pathologist.

17 MS. WEGRYNOWSKI:

18 A. That's correct.

19 CHAYTOR, Q.C.:

20 Q. Okay, and in looking at what may have

21 contributed to the situation being reviewed, I

22 take it if you could shed any light on what

23 may have caused or contributed to the problem,

24 they were asking you to do that?

25 MS. WEGRYNOWSKI:

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1 A. Yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. And to provide recommendations as appropriate  
 4 to deal with any issues identified during your  
 5 review?  
 6 MS. WEGRYNOWSKI:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. And you, in fact, did that?  
 10 MS. WEGRYNOWSKI:  
 11 A. I did that.  
 12 CHAYTOR, Q.C.:  
 13 Q. In your report.  
 14 MS. WEGRYNOWSKI:  
 15 A. Um-hm.  
 16 CHAYTOR, Q.C.:  
 17 Q. And to summarize the findings of the quality  
 18 review in a confidential report.  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. And then you're given a case summary, which  
 23 indicates "in 1997, a DAKO semi-automated  
 24 manual system was installed for  
 25 immunohistochemistry service and replaced the

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1 bioassay method for testing for ER/PR  
 2 receptors, and this DAKO system was replaced  
 3 in 2004 by an automated Ventana system with on  
 4 board antigen retrieval." And then "a  
 5 patient, in 2005, initially tested in 2002  
 6 with the DAKO system reported as ER/PR  
 7 negative, had been retested with the Ventana  
 8 and now indicated strong positivity." And  
 9 then "four other patients initially tested as  
 10 negative were also retested and all tested  
 11 positive with the Ventana system. Retesting  
 12 was expanded to include all samples initially  
 13 tested as negative in 2002 on the DAKO system.  
 14 Of the 57 retested on the Ventana, 38 showed  
 15 positive results. This high conversion rate  
 16 then placed the sensitivity of the Ventana  
 17 system in question and as a result, all  
 18 negative samples since 1997 had been sent to  
 19 an external laboratory for testing" and we  
 20 understand that was your laboratory, Mount  
 21 Sinai.  
 22 MS. WEGRYNOWSKI:  
 23 A. It was at Mount Sinai, correct.  
 24 CHAYTOR, Q.C.:  
 25 Q. And were you provided any other information in

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1 terms of the background leading up to the  
 2 issue?  
 3 MS. WEGRYNOWSKI:  
 4 A. No.  
 5 CHAYTOR, Q.C.:  
 6 Q. This was it?  
 7 MS. WEGRYNOWSKI:  
 8 A. This was it.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, and the idea of a conversion, a patient  
 11 converting, going from negative to then being  
 12 strongly positive, when you read this or were  
 13 told this, was that of concern to you? Had  
 14 you heard of this happening before?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. You had heard of this happening before?  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay, and in what context had you heard of  
 23 such a situation?  
 24 MS. WEGRYNOWSKI:  
 25 A. I should rephrase that. Maybe not this

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1 situation, but the first thing that cued off  
 2 in my mind is I wanted to look at the  
 3 processes and the validations and the  
 4 procedure manuals to determine how this could  
 5 have come about.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay.  
 8 MS. WEGRYNOWSKI:  
 9 A. There had to be something that happened.  
 10 CHAYTOR, Q.C.:  
 11 Q. And the idea then that "there was a high  
 12 conversion rate placing the sensitivity of the  
 13 Ventana system in question," did you then look  
 14 at that while you were at their lab?  
 15 MS. WEGRYNOWSKI:  
 16 A. Not the sensitivity of the Ventana system, no.  
 17 CHAYTOR, Q.C.:  
 18 Q. Did you think that that was an issue?  
 19 MS. WEGRYNOWSKI:  
 20 A. At that point, I can't comment to that. I  
 21 don't recall that being one of the top  
 22 priorities or top thoughts in my mind.  
 23 CHAYTOR, Q.C.:  
 24 Q. And when you were here, in terms of observing  
 25 the system, were you able to rule out whether

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1 or not the Ventana system in fact was too  
 2 sensitive?  
 3 MS. WEGRYNOWSKI:  
 4 A. The Ventana system as being too sensitive, I  
 5 can't comment to that. I didn't really have a  
 6 chance to review a lot of slides here, so I  
 7 wouldn't be the best to comment.  
 8 CHAYTOR, Q.C.:  
 9 Q. And again, Mount Sinai uses the DAKO system?  
 10 MS. WEGRYNOWSKI:  
 11 A. We do.  
 12 CHAYTOR, Q.C.:  
 13 Q. And how does that differ from the Ventana?  
 14 MS. WEGRYNOWSKI:  
 15 A. To the best of my knowledge, the Ventana has  
 16 on board retrieval, so it's--if I recall  
 17 correctly, you put your slides in and the  
 18 entire process is done in an automated  
 19 fashion. Sometimes we call it the plug and  
 20 play system. You just put it in, off it goes,  
 21 everything is pre-dilute and if optimized  
 22 correctly and validated in the laboratory,  
 23 should give you reproducible results. The  
 24 DAKO system is using a autostainer, which is  
 25 taking nothing more than a pipette that's

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1 timed. It works on an XYZ axis, so it--you  
 2 program it and you say what you would like  
 3 dispensed for what period of time. The rest  
 4 of the procedures are all done outside the  
 5 autostainer.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and in terms of the DAKO system, we've  
 8 heard reference to a 40-step process. Do you  
 9 know what that refers to?  
 10 MS. WEGRYNOWSKI:  
 11 A. I believe what people are speaking to is the  
 12 process of actually taking a section from the  
 13 block and walking it through all the way until  
 14 it completes its staining. Where in the  
 15 Ventana system, there is much less hands on.  
 16 CHAYTOR, Q.C.:  
 17 Q. So if we were to count up from the time that  
 18 the tissue is excised, all the way through to  
 19 producing the slide, perhaps there could be 40  
 20 steps in the process?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. Sort of like a recipe in carrying out.  
 25 MS. WEGRYNOWSKI:

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1 A. It's cumulative.  
 2 CHAYTOR, Q.C.:  
 3 Q. Yes, to get to your end product.  
 4 MS. WEGRYNOWSKI:  
 5 A. Correct.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and then in terms of your report, it  
 8 says "the external quality review shall be in  
 9 writing and include the team's  
 10 recommendations. The recommendations shall be  
 11 shared with involved staff members. The peer  
 12 review, its conclusions and the final report  
 13 are protected under the Evidence Act and as  
 14 such, the final report will not be available  
 15 to any third party and as well, the final  
 16 report is protected from any subsequent legal  
 17 proceedings." And Ms. Wegrynowski, it seems  
 18 to differentiate between the external quality  
 19 review and the peer review. What did you  
 20 understand, which portion are you involved in  
 21 here?  
 22 MS. WEGRYNOWSKI:  
 23 A. I felt that I was under the peer review, that  
 24 the conclusions that I would derive in the  
 25 final report were to be protected under the

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1 Evidence Act.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and that was told to you by whom?  
 4 MS. WEGRYNOWSKI:  
 5 A. I can't recall whose name to use to that, but.  
 6 CHAYTOR, Q.C.:  
 7 Q. Did you expect that your report would be  
 8 shared with others in the lab?  
 9 MS. WEGRYNOWSKI:  
 10 A. I thought it would be curtailed to the  
 11 laboratory to the chief pathologist and the  
 12 laboratory manager, yes, I did.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and would such distribution in fact be  
 15 something you would expect and be a positive  
 16 move, to have your report shared with those  
 17 who are carrying out the process?  
 18 MS. WEGRYNOWSKI:  
 19 A. Correct.  
 20 CHAYTOR, Q.C.:  
 21 Q. So who did you understand would not be able to  
 22 see your report?  
 23 MS. WEGRYNOWSKI:  
 24 A. I never thought of it in an exclusionary way.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. So I take it September 20th comes, a  
 2 few short days later, and you arrive in St.  
 3 John's.  
 4 MS. WEGRYNOWSKI:  
 5 A. I did.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and tell us about that then. Take us  
 8 forward from there. Where did you go upon  
 9 arrival in St. John's?  
 10 MS. WEGRYNOWSKI:  
 11 A. I met with Barry Dyer on site at Eastern  
 12 Health.  
 13 CHAYTOR, Q.C.:  
 14 Q. And I understand there were two sites, the St.  
 15 Clare's Hospital and the Health Sciences. Did  
 16 you, in fact, visit both sites?  
 17 MS. WEGRYNOWSKI:  
 18 A. I did.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and you started at the Health Science  
 21 with Mr. Dyer?  
 22 MS. WEGRYNOWSKI:  
 23 A. I did.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and what did Mr. Dyer talk to you about

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1 then or what observations did you make?  
 2 MS. WEGRYNOWSKI:  
 3 A. Could we--is there--my notes, are they in  
 4 here?  
 5 CHAYTOR, Q.C.:  
 6 Q. I think we do have your notes at P-1745,  
 7 please. Are those your notes?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes, they are.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. So if you could just walk us through  
 12 that, please?  
 13 MS. WEGRYNOWSKI:  
 14 A. I had a conversation with Mr. Barry Dyer on  
 15 Tuesday, September the 20th '05 and it was in  
 16 his office, and he gave me an overview. I  
 17 asked him to tell me a little bit about the  
 18 organization and that's what he did for me.  
 19 He explained to me that the organization was  
 20 reorganized in 1996 and that fixation was site  
 21 dependent. In 2002 -  
 22 CHAYTOR, Q.C.:  
 23 Q. What did that mean, sorry, fixation was site  
 24 dependent?  
 25 MS. WEGRYNOWSKI:

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1 A. I take that to mean that each site was  
 2 following their own processes and procedures.  
 3 CHAYTOR, Q.C.:  
 4 Q. So there wasn't a standard procedure between -  
 5 MS. WEGRYNOWSKI:  
 6 A. No.  
 7 CHAYTOR, Q.C.:  
 8 Q. - St. Clare's and the Health Science?  
 9 MS. WEGRYNOWSKI:  
 10 A. That's correct.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay.  
 13 MS. WEGRYNOWSKI:  
 14 A. And that in 2002, the organizations, all the  
 15 immuno was done then at Eastern Health for the  
 16 St. John's area. He explained to me that 60  
 17 to 70 percent of the breast cases are actually  
 18 done at the St. Clare's site. He also told me  
 19 that -  
 20 CHAYTOR, Q.C.:  
 21 Q. So meaning the surgeries? I'm sorry, I didn't  
 22 mean to interrupt.  
 23 MS. WEGRYNOWSKI:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

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1 Q. So most of the surgeries, but the actual IHC,  
 2 the producing of the slides was taking place  
 3 at the Health Science?  
 4 MS. WEGRYNOWSKI:  
 5 A. That was my understanding.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, I'm sorry, go ahead.  
 8 MS. WEGRYNOWSKI:  
 9 A. And he spoke to me that 50 percent of the  
 10 blocks from St. Clare's are needing to be  
 11 reprocessed.  
 12 CHAYTOR, Q.C.:  
 13 Q. And what does that mean, in your world?  
 14 MS. WEGRYNOWSKI:  
 15 A. In my world, that means that the blocks were  
 16 not handled correctly from the beginning.  
 17 That there would be concerns whether or not  
 18 the protein was actually stable and we could  
 19 find it.  
 20 CHAYTOR, Q.C.:  
 21 Q. Perhaps you can explain to the Commissioner,  
 22 and for those of us who, like myself, who were  
 23 not in the know, tell us what reprocess is and  
 24 why that is of concern.  
 25 MS. WEGRYNOWSKI:

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1 A. Okay. I'll start at fixation. The theory for  
 2 fixation is to actually fix the protein and  
 3 that's exactly what we're looking for in  
 4 immunohistochemistry, and in doing so, it  
 5 stops two things. One is autolysis which is  
 6 the breakdown of a cell. When the cell breaks  
 7 down, first you lose your cytoplasm, then you  
 8 lose your cell surface membrane. It becomes  
 9 very fuzzy, and then you start to lose your  
 10 chromatin and your nucleus and that's where  
 11 you start seeing hollow nuclear pattern and  
 12 you won't be able to find a signal.  
 13 The other thing that fixation arrests is  
 14 putrefaction, which simply means that when the  
 15 body dies, all of the natural flora or any  
 16 other bacteria that you have starts eating  
 17 away at the body because it's hungry.  
 18 Fixation also is able to harden the tissues,  
 19 so that when we move through processing, we  
 20 are able to produce a block. So from your  
 21 original fixation in neutral buffered  
 22 formalin, you then move into gradient  
 23 alcohols, so you will start off with, like a  
 24 70 or 95 percent alcohol and this is also a  
 25 form of post fixation. Once it reaches a

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1 hundred percent alcohol, it then moves into  
 2 the cylene. From the cylenes it moves into  
 3 the wax and that is how one is able to make  
 4 those little blocks that I'm sure you have  
 5 seen where the slides are created. When you  
 6 start talking about reprocessing, it tells you  
 7 something has gone awry within the system. It  
 8 can either be that your alcohols were not  
 9 clean, so that you were not able to remove the  
 10 water. If you do not move the water, the  
 11 water is not miscible in the cylene and so  
 12 you're going to end up with this mush and you  
 13 will not be able to get a section.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, and so Mr. Dyer indicated to you about  
 16 fifty percent of the blocks at St. Clare's  
 17 were having this problem and were having to be  
 18 reprocessed?  
 19 MS. WEGRYNOWSKI:  
 20 A. That's what he stated.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay, and if you could continue on then,  
 23 please?  
 24 MS. WEGRYNOWSKI:  
 25 A. This has taught me to print neater next time.

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1 Health Sciences and St. Clare's, he spoke to  
 2 me a little bit about where things were  
 3 coming, biopsies would come in in formalin and  
 4 larges would come from St. Clare's and there  
 5 was a grossing and processing going on at St.  
 6 Clare's. There was no weekend processing at  
 7 the Health Sciences, but they were planning to  
 8 bring this on.  
 9 CHAYTOR, Q.C.:  
 10 Q. So what did you understand then was happening  
 11 with tissues over the weekend?  
 12 MS. WEGRYNOWSKI:  
 13 A. That they were hopefully sitting in formalin,  
 14 is my understanding.  
 15 CHAYTOR, Q.C.:  
 16 Q. Yes, okay, sorry, go ahead.  
 17 MS. WEGRYNOWSKI:  
 18 A. Okay, and the embedding, cutting and staining  
 19 was done at the Health Sciences and then the  
 20 slides were being sent back to the original  
 21 site for the pathologists to review. For  
 22 fixation, he said to me that the policy at  
 23 Health Sciences was to fix for 24 hours and  
 24 St. Clare's site, he told me the fixation was  
 25 up to the pathologist. But I did not get that

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1 confirmed by the pathologist and I have  
 2 written here it was because there was a lack  
 3 of policies and procedures and I'm not sure  
 4 where that communication came from, but that's  
 5 what I was told. He just spoke to me a little  
 6 bit about the workload, that they were four  
 7 days behind, that they were doing about 150  
 8 biopsies a day and three hundred large blocks  
 9 and he stated to me that the protocols they  
 10 used were very informal. He wanted to change  
 11 the transport of tissue to come over to Health  
 12 Sciences to be fresh and that he would also  
 13 like to have a PA and they were beginning to--  
 14 they didn't have one, but they wanted to get  
 15 one and that they were beginning to write  
 16 their standard operating procedures.  
 17 CHAYTOR, Q.C.:  
 18 Q. And I take it then at this point in time when  
 19 he's telling you the protocols are very  
 20 informal and you've noted here a lack of  
 21 policies and procedures, up to this point in  
 22 time you were still expecting to see  
 23 documentation with standard operating  
 24 procedures?  
 25 MS. WEGRYNOWSKI:



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1 A. Absolutely, because this was just my first  
 2 introduction to him and I just met him in his  
 3 office, so I wasn't quite sure what I was  
 4 going to find.  
 5 CHAYTOR, Q.C.:  
 6 Q. And were you surprised by that?  
 7 MS. WEGRYNOWSKI:  
 8 A. It was--I couldn't use that term, I was just  
 9 there for information gathering.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, continue on please?  
 12 MS. WEGRYNOWSKI:  
 13 A. As I said, he spoke that they didn't have any  
 14 PA's and that they were beginning to write  
 15 their SOP's and we just kind of went through,  
 16 you know, what sort of specimens that they  
 17 were looking at, the skin, the bowel, the  
 18 breast, the thyroid and that St. Clare had the  
 19 same mix as what Eastern Health did, and we're  
 20 talking about specimens, but their focus was  
 21 on breast, head and neck. And he told me that  
 22 they did have someone over there, I'm--at this  
 23 point, I couldn't tell you if it was a  
 24 technologist or not, that they were doing the  
 25 gross assists and they were doing about 20 per

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1 day. They took care of the frozens and two  
 2 autopsies a month because all the biopsies  
 3 came over to the Health Sciences. He just  
 4 gave me a little bit about what their  
 5 expectations were, that their urgent specimens  
 6 or their stats had to be cut by 7 a.m.; the  
 7 biopsies were to be cut by 9 and then the  
 8 routine would follow. The cutting was done at  
 9 St. Clare, they had four technologists there.  
 10 Okay, I'll have to come back to that one, I'm  
 11 not sure what that means. So then this would  
 12 be back over at the other site, they had 9  
 13 technologists who assisted with the grossing.  
 14 They did the cutting, the staining, the  
 15 labelling, they were handling about a thousand  
 16 slides a day. Their slide labels were not  
 17 interfaced with the computer, but they did  
 18 have a Meditech system. They also had two  
 19 technicians that were included in the mix of  
 20 the nine technologists, but these technicians  
 21 had 30 years experience and according to  
 22 Barry, that they were doing everything a  
 23 technologist does.  
 24 CHAYTOR, Q.C.:  
 25 Q. So what does that mean, that they weren't

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1 dedicated to one particular specialty, I take  
 2 it?  
 3 MS. WEGRYNOWSKI:  
 4 A. That meant to me that their scopes of practice  
 5 were being used the same as a technologist, as  
 6 opposed to being used as a technician. They  
 7 had a data entry operator who entered all the  
 8 specimens and sent out some receiving  
 9 specimens. And their cut off was some 75  
 10 patient cases a day, but the biopsies were 35  
 11 and the routine get dropped if the biopsies  
 12 get picked up. It's just what you would do if  
 13 you have to get your work through. Prior to  
 14 2003, he advised me that the formalin was made  
 15 up in house and then sent out to everyone and  
 16 since then, they had purchased the--they were  
 17 purchasing their ten percent neutral buffered  
 18 formalin.  
 19 CHAYTOR, Q.C.:  
 20 Q. And did he tell you why they had made the  
 21 change in January, 2003?  
 22 MS. WEGRYNOWSKI:  
 23 A. I don't recall what the reason was.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay.

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1 MS. WEGRYNOWSKI:  
 2 A. I just remember making myself a note saying  
 3 that we needed to look at the pH's for that,  
 4 the pathologist fill out requisitions--oh,  
 5 this is when it goes to the  
 6 immunohistochemistry group and so the surgical  
 7 pathology number and the requisition would be  
 8 filled out and cut by the immuno and so I as  
 9 thinking, okay, let's start looking at our  
 10 microtomes, our numbers, our documentation  
 11 because in immunohistochemistry you're not the  
 12 first person to touch the block, you want to  
 13 ensure that you're not cutting through the  
 14 block, you're not cutting through the tumor,  
 15 so in my world it's called enfacing the block  
 16 where the section, the block is taken up to  
 17 the microtome knife so that the technologist  
 18 would not lose any of the crucial tissue. So  
 19 I wanted to see what they had in their  
 20 protocols about that and how they were doing  
 21 it. I just mentioned histocolometer there,  
 22 that's a particular item that we use at Mount  
 23 Sinai Hospital, but it depends on your  
 24 microtome whether or not it can assist you.  
 25 We talked about the number of pathologists a

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1 day, one does biopsy, the technologist does  
 2 the gross and one pathologist routinely does  
 3 gross and reads. Just talking about the  
 4 routine and how it comes through and that the  
 5 medical director is in charge of  
 6 immunohistochemistry. And then this later on  
 7 goes on to, this is a little bit later in the  
 8 process.  
 9 CHAYTOR, Q.C.:  
 10 Q. So this is not your initial meeting on the  
 11 next page with -  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes, no, that's a little bit later on.  
 14 CHAYTOR, Q.C.:  
 15 Q. This comes later.  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes, it does.  
 18 CHAYTOR, Q.C.:  
 19 Q. All right, and perhaps then we can continue on  
 20 though, this is all information that you  
 21 gathered during your visit?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes, it is.  
 24 CHAYTOR, Q.C.:  
 25 Q. What's written here on page 5?

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1 MS. WEGRYNOWSKI:  
 2 A. Okay, I asked him whether or not there were  
 3 any competency programs in place for the  
 4 technologists and there wasn't any.  
 5 CHAYTOR, Q.C.:  
 6 Q. And what's a competency program?  
 7 MS. WEGRYNOWSKI:  
 8 A. You want to ensure that the individuals  
 9 performing the procedures are well within  
 10 their scope of practice, that they have the  
 11 knowledge, the skills and the tools to perform  
 12 them.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay.  
 15 MS. WEGRYNOWSKI:  
 16 A. I asked him whether or not there was any  
 17 external quality assurance programs and they  
 18 did not have one.  
 19 CHAYTOR, Q.C.:  
 20 Q. Is it standard to be involved in a competency  
 21 program?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and when you set up, for example, the

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1 lab at Women's College Hospital back in 1983,  
 2 were the competency programs put in place  
 3 then?  
 4 MS. WEGRYNOWSKI:  
 5 A. They were rather informal, I must say that as  
 6 I was preparing for this, I found my procedure  
 7 manual that I wrote around that time, so even  
 8 in there these things were addressed and what  
 9 the expectations of the technologists were,  
 10 were in that -  
 11 CHAYTOR, Q.C.:  
 12 Q. Back in 1983?  
 13 MS. WEGRYNOWSKI:  
 14 A. Yeah, I think it was a little bit later than  
 15 that, but yes, within that timeframe.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, and EQA, don't have one, what's EQA?  
 18 MS. WEGRYNOWSKI:  
 19 A. External Quality Assurance programs, he wanted  
 20 to ensure that what you're testing is--how it  
 21 compares to those in the external, so what  
 22 you're getting is correct.  
 23 CHAYTOR, Q.C.:  
 24 Q. And again, is that standard to have an  
 25 external quality assurance or be involved in -

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1 MS. WEGRYNOWSKI:  
 2 A. You know, to speak to that, I couldn't say  
 3 back in the '80's--it was more interlaboratory  
 4 comparison at that point, if you, you know,  
 5 pathologists would look at some slides and  
 6 they would both -  
 7 CHAYTOR, Q.C.:  
 8 Q. And by 2005, is it standard?  
 9 MS. WEGRYNOWSKI:  
 10 A. Oh absolutely.  
 11 CHAYTOR, Q.C.:  
 12 Q. And I take it it became standard sometime  
 13 before that? Would you be able to say around  
 14 when, being involved in external quality  
 15 assurance program would have become standard  
 16 in the industry?  
 17 MS. WEGRYNOWSKI:  
 18 A. From my personal--when I became involved with  
 19 Mount Sinai Hospital in 1999, they were  
 20 already presently enrolled in the CAP.  
 21 CHAYTOR, Q.C.:  
 22 Q. And if you could continue on please? And I'll  
 23 get you to explain a little more about  
 24 external quality assurance when you do your  
 25 presentation.

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1 MS. WEGRYNOWSKI:  
 2 A. All right. So I did ask about new antibodies,  
 3 how they were brought into the laboratory  
 4 setting and it was explained to me that the  
 5 pathologist would provide the controls and  
 6 they would check the slides and it was up to  
 7 them whether or not the product would go  
 8 forward. They would only use positive  
 9 controls when they were doing their  
 10 validation, not negative in a composite block.  
 11 I asked whether or not there was any technical  
 12 input, were the technologists abreast of why  
 13 this antibody was coming into the laboratory?  
 14 Were they given articles to read and they were  
 15 not. I was looking for whether there was  
 16 documentation, a formal documentation about  
 17 the validation process. I did not find that.  
 18 I asked about what validation--do you want me  
 19 to explain a little bit about what validation  
 20 is?  
 21 CHAYTOR, Q.C.:  
 22 Q. Sure. That was not occurring, validation.  
 23 MS. WEGRYNOWSKI:  
 24 A. Was not occurring, is not what I found. If  
 25 you were to purchase a product and you run

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1 through the product, you are going to order a  
 2 new one and it may not be of the same lot, it  
 3 may come from a different lot, so you want to  
 4 assure that that lot is working in the exact  
 5 same manner as the previous lot because things  
 6 can change between lot to lot, there's  
 7 definitely lot to lot variation. So I asked  
 8 about that in regards to the antibodies, the  
 9 detection system that they were using and any  
 10 ancillary products that they were using. They  
 11 were not running negative controls.  
 12 CHAYTOR, Q.C.:  
 13 Q. And what's the importance of negative  
 14 controls?  
 15 MS. WEGRYNOWSKI:  
 16 A. The sensitivity of your testing, you want to  
 17 ensure that you are not getting any non-  
 18 specific staining.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay.  
 21 MS. WEGRYNOWSKI:  
 22 A. This is much later, this is probably when I  
 23 was getting together to write the report,  
 24 these are all the questions that I was asking  
 25 when I was there for those three days. I

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1 asked about the water. Water has a huge  
 2 impact in IHC, the calibre of the water, we  
 3 use deionized water and I can tell you for a  
 4 fact that at Mount Sinai when we have our  
 5 chambers changed, we do not use the water for  
 6 at least 24 hours because of the amount of  
 7 oxygen that gets into the system, so we  
 8 actually stock pile our water and then we go  
 9 forward with that. We need to ensure that our  
 10 buffers are maintained.  
 11 CHAYTOR, Q.C.:  
 12 Q. And what were they doing in St. John's?  
 13 MS. WEGRYNOWSKI:  
 14 A. I wasn't able to find any information out on  
 15 that. They didn't know what type of water  
 16 they were using, there is different types of  
 17 water depending on the amount of, I believe  
 18 it's bacteria in the water, so the purer the  
 19 water, the more you have to just be cognizant  
 20 of this, but I never got a sense of what type  
 21 they were using.  
 22 CHAYTOR, Q.C.:  
 23 Q. And does this say "water on tap"?  
 24 MS. WEGRYNOWSKI:  
 25 A. Yeah, it's not tap water.

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1 CHAYTOR, Q.C.:  
 2 Q. I was hoping -  
 3 MS. WEGRYNOWSKI:  
 4 A. Sorry, my deionized water is tapped into the  
 5 laboratory, so we have a central still and it  
 6 comes through all the labs and we have little  
 7 indicator lights on them and whatnot. No, I  
 8 wasn't using tap water, sea water.  
 9 CHAYTOR, Q.C.:  
 10 Q. And then that's the next bullet then, micro -  
 11 MS. WEGRYNOWSKI:  
 12 A. Oh, and I was asking because what does your  
 13 micro and chemistry department use because  
 14 you're going to use that for your  
 15 autoanalyzers, so I would assume -  
 16 CHAYTOR, Q.C.:  
 17 Q. Yes, okay. I think it says "calibration  
 18 records, type unknown".  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes, and that would be in regards to the  
 21 water, what type of water it was. I asked  
 22 whether or not their pipettes were being  
 23 calibrated and no, they were not.  
 24 CHAYTOR, Q.C.:  
 25 Q. And perhaps you could just tell us what does

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1 that mean? What is a pipette and why would  
 2 you need to calibrate it?  
 3 MS. WEGRYNOWSKI:  
 4 A. Okay. The pipette in immunohistochemistry,  
 5 when you are using concentrated antibodies is  
 6 the most important tool that you would use on  
 7 a daily forum. You will have predetermined  
 8 what all your dilutions are and from those  
 9 pipettes, you are going to make that dilution.  
 10 If your pipettes are not calibrated and  
 11 maintained, then you never have the assurance  
 12 that the dilution is made correctly. In  
 13 addition to that, you must always assure that  
 14 your pipette tips are sterilized because you  
 15 do not want to include any contaminants into  
 16 the antibody.  
 17 CHAYTOR, Q.C.:  
 18 Q. And if you could continue on, please?  
 19 MS. WEGRYNOWSKI:  
 20 A. I asked to see, well at this point I guess one  
 21 of the thought processes would have been  
 22 service records. You need to ensure that all  
 23 of your equipment is working, your PMS,  
 24 preventative maintenance, on annually, daily,  
 25 weekly, monthly, quarterly, whatever they

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1 should be for whatever instrument, they need  
 2 to be done and there needs to be documentation  
 3 for that. And I've written something in the  
 4 corner, but I can't read that. Oh, Sakura  
 5 from Ventana apparently from Montreal,  
 6 perhaps, had looked at their Ventana but that,  
 7 I think that's just going by memory, that's  
 8 perhaps why I scrawled that. They were doing  
 9 manual staining for the HER2/neu and using the  
 10 DAKO kit and for their immunofluorescence,  
 11 they were doing that manually and they were  
 12 doing kidney biopsies. Their medical  
 13 laboratory technologists are--they write the  
 14 same national exams as all other technologists  
 15 in the country; however there is no provincial  
 16 college, but they do have a medical laboratory  
 17 group and I was told that they are supportive  
 18 of continuing education.  
 19 CHAYTOR, Q.C.:  
 20 Q. I'm sorry, who was supportive of continuing  
 21 education?  
 22 MS. WEGRYNOWSKI:  
 23 A. This would be from Barry.  
 24 CHAYTOR, Q.C.:  
 25 Q. The medical technical group was supportive of

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1 continuing education?  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes, so that there was--I know that he had  
 4 stated that he was going to--he had gone to  
 5 the National Society of Histotechnology and I  
 6 believe that was in one of the e-mails that we  
 7 had corresponded with. So we were talking  
 8 just about on rotating technologists and the  
 9 grossing, that they were doing grossing and  
 10 immuno and just the different techniques that  
 11 were being done and who was doing what, but  
 12 nothing in--they were sending their FISH to  
 13 Sunnybrook and did you want to know what FISH  
 14 was?  
 15 CHAYTOR, Q.C.:  
 16 Q. Sure, it might mean something different in  
 17 Newfoundland.  
 18 MS. WEGRYNOWSKI:  
 19 A. It's fluorochrome in situ hybridization. It's  
 20 your goal standard when you start doing the  
 21 HER2/neu testing. HER2/neu testing leads to  
 22 breast cancer patients receiving Herceptin.  
 23 So a patient which would be equivocal would  
 24 be, their case would be reflux to FISH.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MS. WEGRYNOWSKI:  
 3 A. Re-embedding, I needed to look at their  
 4 temperatures, I wasn't quite sure where they  
 5 were at and they did have a fridge in the  
 6 immunohistochemistry on an alarm, which is  
 7 very important because there's thousands of  
 8 dollars worth of antibodies in that particular  
 9 fridge.  
 10 THE COMMISSIONER:  
 11 Q. I'm sorry, they had it on a?  
 12 MS. WEGRYNOWSKI:  
 13 A. They did have it on an alarm.  
 14 THE COMMISSIONER:  
 15 Q. Oh, an alarm.  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes, because some of these antibodies can cost  
 18 several thousand dollars for one ml., so  
 19 that's quite critical. They weren't using  
 20 NIST traceable thermometers.  
 21 CHAYTOR, Q.C.:  
 22 Q. And what's that?  
 23 MS. WEGRYNOWSKI:  
 24 A. NIST just is a acronym for the National  
 25 Institute of Standardized Testing, so all the

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1 equipment that I use at Mount Sinai Hospital  
 2 is traceable, all the timers, thermometers,  
 3 that kind of stuff. They had stated that they  
 4 had changed equipment from a DAKO to the  
 5 Ventana, so I wanted to know what the protocol  
 6 for purchasing the new equipment was.  
 7 CHAYTOR, Q.C.:  
 8 Q. And what were you told about that?  
 9 MS. WEGRYNOWSKI:  
 10 A. You know, I don't have a sense of a response  
 11 for you right now.  
 12 CHAYTOR, Q.C.:  
 13 Q. So do you recall whether you were given a  
 14 response or was anybody able to tell you what  
 15 happened through that change over?  
 16 MS. WEGRYNOWSKI:  
 17 A. I really can't recall that.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MS. WEGRYNOWSKI:  
 21 A. They had three technologists, they were  
 22 training a MLT, this was with a go-ahead plans  
 23 that they were wanting to have three  
 24 technologists that were to be permanent, train  
 25 MLT, I was surprised they were doing their--

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1 immunofluorescence was being done in the light  
 2 and there was no controls being run. The  
 3 specimen storage and that we can speak to, if  
 4 we may, when I have my notes up from my  
 5 report.  
 6 CHAYTOR, Q.C.:  
 7 Q. Sure.  
 8 MS. WEGRYNOWSKI:  
 9 A. They had fume hood that was stuck in the  
 10 corner of the immunohistochemistry laboratory  
 11 and they had different chemicals on top and  
 12 they should be put away, that's just for  
 13 safety. Oh, it was, their last comment here,  
 14 "does our institution support your Ventana  
 15 computer?" If I recall correctly the  
 16 technologists were telling me or explaining to  
 17 me, rather, when they were doing some of their  
 18 maintenance, it wouldn't be the daily, I  
 19 believe it would be either quarterly or semi-  
 20 annually that that was done, actually with  
 21 inside of the computer and that they didn't  
 22 have the ability to get that, so I had  
 23 suggested that perhaps they look at their  
 24 computer people to assist them with that.  
 25 CHAYTOR, Q.C.:

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1 Q. And does this say "Have IF SOP.  
 2 MS. WEGRYNOWSKI:  
 3 A. I must have left them a standard operating  
 4 procedure for IF, could very well be.  
 5 CHAYTOR, Q.C.:  
 6 Q. Did they have their own?  
 7 MS. WEGRYNOWSKI:  
 8 A. For me to leave that note, I'm suggesting I  
 9 did not see a formal one.  
 10 CHAYTOR, Q.C.:  
 11 Q. And on the top of the next page says "ER/PR  
 12 300 to 400 cases". Is that what you  
 13 understood they were doing per year?  
 14 MS. WEGRYNOWSKI:  
 15 A. Could be, yes.  
 16 CHAYTOR, Q.C.:  
 17 Q. And what does this say?  
 18 MS. WEGRYNOWSKI:  
 19 A. The notes on the express, I made notation in  
 20 my actual report about the express, it's a  
 21 different processing and different fixations.  
 22 CHAYTOR, Q.C.:  
 23 Q. And I'll ask you to take us through that and  
 24 explain it when we get to your report.  
 25 MS. WEGRYNOWSKI:

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1 A. I'd be happy to do that.  
 2 CHAYTOR, Q.C.:  
 3 Q. Kohler illumination?  
 4 MS. WEGRYNOWSKI:  
 5 A. They were not doing that.  
 6 CHAYTOR, Q.C.:  
 7 Q. Calibration (unintelligible - 113) no, and  
 8 what's this say?  
 9 MS. WEGRYNOWSKI:  
 10 A. Again, as I spoke to Madam Commissioner about  
 11 the sterilizing of the tips so that you ensure  
 12 that you're not contaminating any of your  
 13 antibodies, the answer to that was no. They  
 14 were using a product from Ventana called  
 15 Easyprep for the deparaffinization and I asked  
 16 whether or not they were pHing it to ensure  
 17 that it was doing what--it was living up to  
 18 what the commercial standards of what the  
 19 company had said and they weren't doing that.  
 20 The reaction--I can't read that, oh again,  
 21 that would be again with their buffers, their  
 22 DABS, they're presently not neutralizing them.  
 23 I asked about gloves and goggles, negative  
 24 patients were not done.  
 25 CHAYTOR, Q.C.:

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1 Q. And I take it again that's a safety concern?  
 2 MS. WEGRYNOWSKI:  
 3 A. That's a safety concern because some  
 4 diaminobenzidine is carcinogenic, negative  
 5 patient controls were not being done and dates  
 6 on the slides were missing.  
 7 CHAYTOR, Q.C.:  
 8 Q. Dates on the slides -  
 9 MS. WEGRYNOWSKI:  
 10 A. I'm going to take that--oh, there's Ken's e-  
 11 mail address he left for me. So this would be  
 12 Wednesday, September 21st, we're just talking  
 13 about the quality of tissue.  
 14 CHAYTOR, Q.C.:  
 15 Q. And do you recall who you had that discussion  
 16 with the next day?  
 17 MS. WEGRYNOWSKI:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. And then on the next page, I believe is notes  
 21 of, a brief note of your discussion with Dr.  
 22 Ejeckam, so I take it Dr. Ejeckam, you said  
 23 was able to assist you in understanding the  
 24 current state of affairs. Did he also give  
 25 you any indication as to what may have been

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1 the state of affairs over the last couple of  
 2 years? Anything that had happened in the  
 3 past?  
 4 MS. WEGRYNOWSKI:  
 5 A. No, not to me, but I recall meeting with Dr.  
 6 Ejeckam and we sat and we spoke about  
 7 immunohistochemistry. He felt that they  
 8 should not be rotating in there, he would have  
 9 liked the technologist to start reading the  
 10 controls. He had begun to teach the  
 11 technologists about the theory, I got the  
 12 sense that he was rather frustrated because  
 13 they were rotating, it was very difficult to  
 14 get all three or how many people that you were  
 15 using in that area at the same time. He was  
 16 also rather frustrated because he felt that  
 17 he, and I wrote this, this was the only  
 18 comment that I wrote from that entire meeting,  
 19 that they had to get clearance from Barry. So  
 20 he did not feel as being the director of that  
 21 particular subsection that he was able to go  
 22 and speak with the technologists directly, but  
 23 rather he was to speak to the manager and the  
 24 manager was then to speak to the technologist.  
 25 CHAYTOR, Q.C.:

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1 Q. What were you able to conclude from your  
 2 discussion with Dr. Ejeckam as to his own  
 3 understanding and level of knowledge of IHC?  
 4 MS. WEGRYNOWSKI:  
 5 A. I felt that Dr. Ejeckam had a very good  
 6 thorough knowledge of immunohistochemistry.  
 7 He certainly understood the procedures and we  
 8 talked about some of the textbooks that are  
 9 out there and we both agreed that they were  
 10 very strong textbooks, that certainly would  
 11 assist one in the troubleshooting area of  
 12 immunohistochemistry. It's the  
 13 troubleshooting of immunohistochemistry that  
 14 is truly where your knowledge needs to lay.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and I believe there is actually  
 17 reference to the Dabbs text here.  
 18 MS. WEGRYNOWSKI:  
 19 A. Yes, we both kind of agreed on that one and I  
 20 like Delias, so there you go.  
 21 CHAYTOR, Q.C.:  
 22 Q. So this was in trying to recommend a textbook  
 23 for the laboratory?  
 24 MS. WEGRYNOWSKI:  
 25 A. They had nothing, yes.

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1 CHAYTOR, Q.C.:  
 2 Q. They had nothing. And this was a text that  
 3 you and Dr. Ejeckam agreed would be useful?  
 4 MS. WEGRYNOWSKI:  
 5 A. That would be correct.  
 6 CHAYTOR, Q.C.:  
 7 Q. Did Dr. Ejeckam or anybody else, while you  
 8 were in St. John's, indicate to you that he  
 9 had detected some issues in 2003 and in fact  
 10 had shut down the laboratory for a period of  
 11 weeks at that point in time?  
 12 MS. WEGRYNOWSKI:  
 13 A. No.  
 14 CHAYTOR, Q.C.:  
 15 Q. That wasn't told to you?  
 16 MS. WEGRYNOWSKI:  
 17 A. No.  
 18 MR. SIMMONS:  
 19 Q. Not the whole lab.  
 20 CHAYTOR, Q.C.:  
 21 Q. Not the whole lab, I'm sorry, not the whole  
 22 lab, they had stopped doing certain stains,  
 23 including the ER/PR. I think there were eight  
 24 stains altogether.  
 25 MS. WEGRYNOWSKI:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. That wasn't made known to you.  
 4 MS. WEGRYNOWSKI:  
 5 A. No.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and in terms of 2005 and the concerns  
 8 that he raised, there was the issue obviously  
 9 of the communications or the reporting channel  
 10 to Mr. Dyer.  
 11 MS. WEGRYNOWSKI:  
 12 A. Correct.  
 13 CHAYTOR, Q.C.:  
 14 Q. The fact that the staff were rotating. Did he  
 15 identify any other concerns? Did he identify  
 16 anything in terms of consistency or standards  
 17 that were being maintained, anything along  
 18 those lines?  
 19 MS. WEGRYNOWSKI:  
 20 A. I can't recall. It was more that there was  
 21 this frustration and trying to be able to  
 22 teach the technologists about  
 23 immunohistochemistry.  
 24 CHAYTOR, Q.C.:  
 25 Q. About the theory.

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1 MS. WEGRYNOWSKI:  
 2 A. Yeah, and to be fair because at this point I  
 3 didn't know what the cycle was of people  
 4 rotating, I got the sense after meeting with  
 5 the technologists, if I may interject at this  
 6 point, they too felt this sense because if you  
 7 received a phone call from someone that this  
 8 didn't work, you have to recall they are not  
 9 reading any of their controls and you did not  
 10 do that work that day, you really don't have a  
 11 sense of where you can start as well, so there  
 12 was a lot of frustration, I would say on both  
 13 sides.  
 14 CHAYTOR, Q.C.:  
 15 Q. So were the technologists reading the  
 16 controls?  
 17 MS. WEGRYNOWSKI:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. And did Dr. Ejeckam indicate to you whether or  
 21 not these were issues that, you said he's  
 22 frustrated, you sense a frustration.  
 23 MS. WEGRYNOWSKI:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

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1 Q. So was it that these were issues that he had  
 2 identified and brought forward but was having  
 3 difficulty getting his concerns addressed?  
 4 Was that the nature of the frustration?  
 5 MS. WEGRYNOWSKI:  
 6 A. That was my sense, he had asked me what we  
 7 were doing at Mount Sinai Hospital and I told  
 8 him what we were doing there. So that's  
 9 basically what our conversation was about.  
 10 CHAYTOR, Q.C.:  
 11 Q. And the reference to the textbook and you  
 12 indicated they didn't have any textbooks, was  
 13 the internet available to the technologists?  
 14 MS. WEGRYNOWSKI:  
 15 A. They had nothing.  
 16 CHAYTOR, Q.C.:  
 17 Q. What was your sense of the role that the  
 18 technologists were being asked to play at  
 19 Eastern Health as compared to your role as a  
 20 technologist at Mount Sinai?  
 21 MS. WEGRYNOWSKI:  
 22 A. As a technologist at Mount Sinai Hospital, I  
 23 am expected to produce a product at the end of  
 24 the day that is reproducible, as is my staff.  
 25 We do not sign out anything out of the

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1 laboratory if it does not pass our control, so  
 2 if our positive control does not pass, none of  
 3 the slides go out that day until that problem  
 4 is rectified. At Eastern Health the  
 5 technologists were simply doing what stain was  
 6 being ordered and they would put it through  
 7 and then it would end up in the pathologist's  
 8 desk and then they would be working backwards.  
 9 CHAYTOR, Q.C.:  
 10 Q. And I believe Ms. Wegrynowski in your  
 11 interview you made a statement that it was  
 12 your sense that they were to come and do, not  
 13 to think, is that a fair statement?  
 14 MS. WEGRYNOWSKI:  
 15 A. I think that's a rather fair statement. It's  
 16 not meant to be critical, but if you don't  
 17 have the tools, you can't think to  
 18 troubleshoot. If I may, there's a difference  
 19 between working in a regular histology  
 20 laboratory and doing special stains, as  
 21 compared to immunohistochemistry when you're  
 22 actually doing, it's an enzymatic process, so  
 23 it's very different and you need to know this.  
 24 CHAYTOR, Q.C.:  
 25 Q. And so you need to have a high level of

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1 knowledge to be able to do your job?  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes, and simply because of all the issues that  
 4 can occur.  
 5 THE COMMISSIONER:  
 6 Q. Can you elaborate a little on that and that is  
 7 the requirement that the technologist  
 8 understand more than what it is you physically  
 9 have to do in the context of this kind of  
 10 testing.  
 11 MS. WEGRYNOWSKI:  
 12 A. Okay, I guess this would then go back to the  
 13 academic setting because when you're in  
 14 school, you're not learning about  
 15 immunohistochemistry, so a lot of what goes on  
 16 in immunohistochemistry one learns on the job.  
 17 If everything thing is working perfectly, then  
 18 you are going to have a positive result. So  
 19 if I may just use something so simple as a  
 20 hepatitis surface antibody, so you have an  
 21 infected liver and we have a hepatitis surface  
 22 antigen and we find the antibody and it's  
 23 stained. If we were to do that same test the  
 24 next day and it was to be negative, that would  
 25 tell us that something has gone askew. In so

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1 doing, it would be then our role to determine  
 2 what that was prior to sending that work out,  
 3 so you would go back and look at the  
 4 processes. So it's a very analytical  
 5 departmental learning. Does that answer your  
 6 -  
 7 THE COMMISSIONER:  
 8 Q. I think it does in part, so what you're saying  
 9 is that you really need people who are not  
 10 just going through the motions, they are  
 11 acutely aware of what they have to do and do  
 12 they also need the knowledge of what can go  
 13 wrong if they do not do things in a particular  
 14 way?  
 15 MS. WEGRYNOWSKI:  
 16 A. They need to understand the why they are doing  
 17 things.  
 18 THE COMMISSIONER:  
 19 Q. Okay, but it makes sense to me, but it seems  
 20 to me that if you do not understand the  
 21 importance of doing things correctly, then you  
 22 just don't have that mindset which says it  
 23 matters.  
 24 MS. WEGRYNOWSKI:  
 25 A. I agree.

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1 THE COMMISSIONER:  
 2 Q. When small measurements are slightly off or  
 3 whatever.  
 4 MS. WEGRYNOWSKI:  
 5 A. I agree and that also brings into the  
 6 different types of testing that occurs in  
 7 immunohistochemistry. The majority of the  
 8 testing that we do are class 1, but there are  
 9 some class 2 testing which affects definitely  
 10 the patient's therapies and this would be one  
 11 of them.  
 12 THE COMMISSIONER:  
 13 Q. And class 1 verses class 2 means?  
 14 MS. WEGRYNOWSKI:  
 15 A. It's just a level of testing, so class 2  
 16 testing would have a direct impact on the  
 17 patient, so in that category we have things  
 18 like HER2/neu and our ER/PR's.  
 19 THE COMMISSIONER:  
 20 Q. Okay.  
 21 CHAYTOR, Q.C.:  
 22 Q. And I take it that during your visit when you  
 23 went to St. Clare's, you met with Dr. Cook, I  
 24 take it, at St. Clare's?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes, I did and Bev Carter.  
 2 CHAYTOR, Q.C.:  
 3 Q. And Bev Carter.  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. Just based on what you've told us so far and  
 8 through review of your notes, at any point in  
 9 time did your expectations as to what you were  
 10 coming to St. John's to do, did those  
 11 expectations change and if so, why?  
 12 MS. WEGRYNOWSKI:  
 13 A. I thought I was coming to St. John's, and as I  
 14 detailed in the original e-mail, to look at  
 15 their standard operating procedures and I  
 16 wanted--they had an issue, so I thought, all  
 17 right, if I can look at your standard  
 18 operating procedures before I arrive, it will  
 19 save me a lot of time, so if perhaps there's  
 20 something in them that we can focus on and I  
 21 wanted to see them not just for the  
 22 immunohistochemistry laboratory, but right  
 23 from when they are excised from the patient.  
 24 So when I didn't receive them, I wasn't quite  
 25 sure--I thought, okay, well maybe they're--



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1 there's not going to be a lot to read, I  
 2 really didn't have a sense of what was going  
 3 to unfold.  
 4 CHAYTOR, Q.C.:  
 5 Q. So then at some point in time your  
 6 expectations, I take it, did change as to what  
 7 you were here to do?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. And what you could do?  
 12 MS. WEGRYNOWSKI:  
 13 A. That would be correct.  
 14 CHAYTOR, Q.C.:  
 15 Q. Were you aware that the lab, the IHC lab had  
 16 been running the ER/PR testing since 1997?  
 17 MS. WEGRYNOWSKI:  
 18 A. I believe that was set out for me in the  
 19 initial e-mail, yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and the state of affairs that you  
 22 observed then in St. John's in 2005, given  
 23 that the lab had been running since 1997 with  
 24 respect to those two stains, were you--did you  
 25 have any concerns as to the state of affairs

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1 that you found?  
 2 MS. WEGRYNOWSKI:  
 3 A. I was surprised.  
 4 CHAYTOR, Q.C.:  
 5 Q. And what is it--why were you surprised?  
 6 MS. WEGRYNOWSKI:  
 7 A. That there were not standard operating  
 8 procedures, that documentation was completely  
 9 remiss.  
 10 CHAYTOR, Q.C.:  
 11 Q. At St. Clare's did you also visit the lab  
 12 there and the operating room?  
 13 MS. WEGRYNOWSKI:  
 14 A. I went to the lab. The reason I wanted to  
 15 look at the lab and the main reason that I  
 16 went there, in my mind, was because of the  
 17 reprocessing rate that had been highlighted by  
 18 Barry Dyer. I wanted to look at their  
 19 processors, I wanted to see their  
 20 documentation. I wanted to see their standard  
 21 operating procedures for how they were  
 22 handling the breast tissue. There has to be a  
 23 reason for that number to be so high.  
 24 CHAYTOR, Q.C.:  
 25 Q. And what did you observe then at St. Clare's?

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1 MS. WEGRYNOWSKI:  
 2 A. I didn't find any documentation.  
 3 CHAYTOR, Q.C.:  
 4 Q. And in terms of your visit to the operating  
 5 room?  
 6 MS. WEGRYNOWSKI:  
 7 A. I looked in the operating room, I wanted to  
 8 ensure that there are refrigerators in the  
 9 operating room. There are times when porters  
 10 can't obviously pick up every second, every  
 11 specimen as soon as it is excised, so you need  
 12 to put your specimens into the refrigerator to  
 13 maintain them at 4 degrees, because you want  
 14 to stop autolysis and putrefaction, you need  
 15 to arrest that and they had no refrigerators,  
 16 things were left on bench.  
 17 CHAYTOR, Q.C.:  
 18 Q. Perhaps we could look then at P-1736 please?  
 19 And these aren't your notes, these are -  
 20 MS. WEGRYNOWSKI:  
 21 A. No, I've never seen this.  
 22 CHAYTOR, Q.C.:  
 23 Q. No, these are notes of Dr. Cook, it just  
 24 indicates in his notes here, he's doing a bit  
 25 of a chronology, we understand, and he

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1 indicates here that "On September 21st, 2005,  
 2 Dr. Cook, Dr. Carter interviewed Trish" and we  
 3 understand that's just his notation of your  
 4 meeting.  
 5 MS. WEGRYNOWSKI:  
 6 A. Uh-hm.  
 7 CHAYTOR, Q.C.:  
 8 Q. The actual "at St. Clare's" and you met there  
 9 with Dr. Cook and Dr. Carter, your review of  
 10 the lab itself, the lab process itself, did  
 11 you actually observe what was happening in the  
 12 lab, how the tissue was being processed?  
 13 MS. WEGRYNOWSKI:  
 14 A. No, I did not. The technologists--I don't  
 15 recall anybody doing any of those, there were  
 16 technologists there and that's how I asked to  
 17 see the standard operating procedures. I  
 18 wanted to see their temperature checks and  
 19 they were telling me that they were just  
 20 looking at the temperatures by the digital  
 21 read out and I explained to them that the  
 22 digital read out on a piece of equipment is  
 23 not acceptable because there can be  
 24 differences between that particular read out  
 25 and the actual read out, especially for the

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1 paraffin wax. The reason I mention that is  
 2 that some of the antibodies are heatedly  
 3 laible so you can lose them at high  
 4 temperatures.  
 5 CHAYTOR, Q.C.:  
 6 Q. And is ER/PR though in that category?  
 7 MS. WEGRYNOWSKI:  
 8 A. I can't comment. Off the top of my head, I  
 9 wouldn't comment.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, if we could look at P-1738 please?  
 12 MS. WEGRYNOWSKI:  
 13 A. Okay.  
 14 CHAYTOR, Q.C.:  
 15 Q. And this again is not your notes, these are  
 16 notes that Dr. Cook took, "Spoke to Trish, Dr.  
 17 Bev Carter September 21st, 2005 at 11 a.m.",  
 18 he's indicating and these are some notes that  
 19 he took, apparently, from your meeting.  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay.  
 22 CHAYTOR, Q.C.:  
 23 Q. And it looks like he's saying "Start with CAP  
 24 proficiency testing, techs are overwhelmed."  
 25 Are these things that you would have indicated

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1 to Dr. Cook and Dr. Carter?  
 2 MS. WEGRYNOWSKI:  
 3 A. I did have a conversation with them while we  
 4 were at St. Clare's. I had not met with the  
 5 technologists, I don't believe at that point.  
 6 I believe I met with Barry Dyer and then went  
 7 straight to St. Clare's.  
 8 CHAYTOR, Q.C.:  
 9 Q. And so was this something that was related to  
 10 you by Barry Dyer or perhaps this is, do you  
 11 recall Dr. Cook and Dr. Carter telling you  
 12 this?  
 13 MS. WEGRYNOWSKI:  
 14 A. You know, I have not seen this before, I  
 15 couldn't comment.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, well tell us what you recall about your  
 18 meeting with Dr. Carter and Dr. Cook.  
 19 MS. WEGRYNOWSKI:  
 20 A. Okay, I recall Dr. Cook just knowing that  
 21 there was something wrong, he didn't know what  
 22 it was, but he definitely just wanted it fixed  
 23 and Bev Carter had trained in Ontario and I  
 24 didn't know it at that point and she had told  
 25 me this, and she had explained to me that she

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1 knew something was wrong, she just knew that  
 2 this would never have happened and she told me  
 3 the name of the technologist that she had  
 4 worked with. She said this just would not  
 5 have happened and his name was Brian Hewlett  
 6 and he's also a colleague of mine and we were  
 7 talking about, like what is happening when  
 8 something goes wrong, what is it that you do  
 9 if you get these slides and you recognize that  
 10 they're not working, the controls are not  
 11 working. And this is when I found that they  
 12 were then calling over to the  
 13 immunohistochemistry laboratory at Eastern  
 14 Health and telling them, you know, this didn't  
 15 work and then the technologist at the other  
 16 end of the phone--it gets back to this issue  
 17 if you're rotating and you didn't do it, so  
 18 there was this sense of frustration. There  
 19 was no continuity of service.  
 20 CHAYTOR, Q.C.:  
 21 Q. So did you understand that Dr. Carter and Dr.  
 22 Cook both had recognized there was a problem,  
 23 that their controls weren't working and were  
 24 trying to communicate with the technologists  
 25 to figure out what--why that would be? What

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1 was going wrong in the process?  
 2 MS. WEGRYNOWSKI:  
 3 A. That was my sense.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and how long did you understand that  
 6 they were aware there was problems with the  
 7 staining?  
 8 MS. WEGRYNOWSKI:  
 9 A. I didn't get a timeline from them.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, was that something that had just come up  
 12 in 2005 or -  
 13 MS. WEGRYNOWSKI:  
 14 A. Ms. Chaytor, I really don't know that.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, do you recall anything else then from  
 17 your meeting with them?  
 18 MS. WEGRYNOWSKI:  
 19 A. Not much more. A lot of it would have just  
 20 been, you know, the validation processes,  
 21 policy manuals, I mean -  
 22 CHAYTOR, Q.C.:  
 23 Q. These are things that he's noted here.  
 24 MS. WEGRYNOWSKI:  
 25 A. Yeah, that would have been very basic things

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1 that I would have been looking for, so I mean,  
 2 they could have asked me what it was that I  
 3 was looking for. They did put their controls,  
 4 they have--they do put their positive controls  
 5 on slides and so, I mean, that is terrific.  
 6 We don't have that opportunity at Mount Sinai  
 7 Hospital, we batch ours. We just don't have  
 8 that same amount of control tissue. So  
 9 they're really at a terrific advantage out  
 10 here. We spoke--I did speak to them about  
 11 fixation and that stemmed again from the  
 12 reprocessing. You definitely need  
 13 standardized fixation, you need the same  
 14 processing at both sites. This is just  
 15 basically all the things that I would have  
 16 gone through.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and it indicates here that "need to be  
 19 trained how to read controls", I take it  
 20 that's the technologists?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you indicate "keep the control tissue on  
 25 the slides" -

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1 MS. WEGRYNOWSKI:  
 2 A. Uh-hm  
 3 CHAYTOR, Q.C.:  
 4 Q. You saw that as a good thing.  
 5 MS. WEGRYNOWSKI:  
 6 A. Uh-hm, absolutely.  
 7 CHAYTOR, Q.C.:  
 8 Q. And the fixation issue again, and I can't  
 9 confess to be able to read all of his writing,  
 10 but this appears, what you're saying to be a  
 11 list of things that you would have discussed  
 12 with them.  
 13 MS. WEGRYNOWSKI:  
 14 A. You know, it's almost as if this was--yes,  
 15 yes.  
 16 CHAYTOR, Q.C.:  
 17 Q. And the issue of validation, need to validate  
 18 the lots, which you've already mentioned.  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. Need to document pH.  
 23 MS. WEGRYNOWSKI:  
 24 A. This would have been the big picture of what I  
 25 would have looked for.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay, and I think it's written over here "DAKO  
 3 system worked fine", would that be something  
 4 you discussed with them?  
 5 MS. WEGRYNOWSKI:  
 6 A. Yes, I do because Bev, I believe, had had  
 7 experience with the DAKO and I gather there  
 8 were those that thought it was the DAKO itself  
 9 that had led to this, so there was some  
 10 discussion with that, as well.  
 11 CHAYTOR, Q.C.:  
 12 Q. I take it though the DAKO system they had been  
 13 using was no longer at Eastern Health -  
 14 MS. WEGRYNOWSKI:  
 15 A. I never saw it.  
 16 CHAYTOR, Q.C.:  
 17 Q. You never saw it.  
 18 MS. WEGRYNOWSKI:  
 19 A. I never saw it, no.  
 20 CHAYTOR, Q.C.:  
 21 Q. And did you understand that it was no longer  
 22 there?  
 23 MS. WEGRYNOWSKI:  
 24 A. Yeah.  
 25 CHAYTOR, Q.C.:

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1 Q. And this says, does it say "no calibration of  
 2 the DAKO system" or -  
 3 MS. WEGRYNOWSKI:  
 4 A. It says that, but I mean there was nothing for  
 5 me to review. It wasn't as if I could go back  
 6 and say could you please show me how you  
 7 calibrated that DAKO to begin with, what you  
 8 used and how you changed to this. I did not  
 9 find that.  
 10 CHAYTOR, Q.C.:  
 11 Q. And you would have expected to have that  
 12 information where?  
 13 MS. WEGRYNOWSKI:  
 14 A. In your service manuals.  
 15 CHAYTOR, Q.C.:  
 16 Q. And this also says "no assurance things can be  
 17 done the same day, no standardization of DAKO  
 18 system, no validation of system, don't know  
 19 where to look to troubleshoot" and again,  
 20 that's referring to the technologists, I take  
 21 it?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. "Need Ken or Mary to be in charge of

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1 immunoservice?"

2 MS. WEGRYNOWSKI:

3 A. You need somebody to be responsible and there.

4 CHAYTOR, Q.C.:

5 Q. Okay. And over on this column then,

6 continuing on down it says, "need protocol"

7 and I believe we spoke about that one, "for

8 fixation".

9 MS. WEGRYNOWSKI:

10 A. Uh-hm.

11 CHAYTOR, Q.C.:

12 Q. "Things are being done but no documents, need

13 to be trained to troubleshoot. Need to get

14 involved with the CAP program. Techs don't

15 have the skills, need training at"--looks like

16 "computer" and "need PA's"--that's the

17 pathology assistants.

18 MS. WEGRYNOWSKI:

19 A. Yes.

20 CHAYTOR, Q.C.:

21 Q. "Need spec sheets"?

22 MS. WEGRYNOWSKI:

23 A. Yes.

24 CHAYTOR, Q.C.:

25 Q. And what are the spec sheets?

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1 MS. WEGRYNOWSKI:

2 A. The spec sheets are the sheets that come in--

3 they're documentation that come in with the

4 antibodies, they tell you about the clone, the

5 lot, the expiry date, the approaching

6 concentration, what the subclass is of the

7 antibody, so it's all the vital information

8 that you need to use to be able to work with

9 the product.

10 CHAYTOR, Q.C.:

11 Q. And "Need external QA program" and we'll talk

12 about that some more in your presentation.

13 MS. WEGRYNOWSKI:

14 A. Yes.

15 CHAYTOR, Q.C.:

16 Q. "Need to send to well organized, well run lab"

17 and I take it you're referring to getting the

18 techs further training?

19 MS. WEGRYNOWSKI:

20 A. Yes, I think that was something that Dr. Cook

21 suggested, not myself.

22 CHAYTOR, Q.C.:

23 Q. Okay, other than Dr. Ejeckam, Dr. Carter and

24 Dr. Cook, did you meet with any of the other

25 pathologists?

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1 MS. WEGRYNOWSKI:

2 A. Not that I recall.

3 CHAYTOR, Q.C.:

4 Q. And the technologists then, you believe your

5 meeting with the technologists came after your

6 meeting with the doctors?

7 MS. WEGRYNOWSKI:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. And what do recall about your meeting with

11 Mary Butler, Les Simms and Ken Green?

12 MS. WEGRYNOWSKI:

13 A. If I could just back this up just a bit.

14 CHAYTOR, Q.C.:

15 Q. Sure, absolutely.

16 MS. WEGRYNOWSKI:

17 A. So on the first day I met with Barry, Bev, Don

18 and Dr. Ejeckam, so that was what--so when I

19 completed that day, I needed to go on a

20 forward basis and because I had not found any

21 documentation or supporting evidence for what

22 I was looking for, I took it upon myself to

23 use the rest of the visit as simply a learning

24 took because there was not any documentation

25 to review.

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1 CHAYTOR, Q.C.:

2 Q. So to teach the technologists?

3 MS. WEGRYNOWSKI:

4 A. Yes.

5 CHAYTOR, Q.C.:

6 Q. Okay, and your discussions then with them, did

7 they voice any concerns to you?

8 MS. WEGRYNOWSKI:

9 A. No. Any concerns other than they too were

10 very frustrated, they felt that they were

11 being pulled in many different directions, you

12 know, they were trying to do their very best,

13 they certainly were doing so, but they

14 couldn't because they were being pulled in far

15 too many directions.

16 CHAYTOR, Q.C.:

17 Q. And did they feel they had the tools to be

18 able to do their job properly?

19 MS. WEGRYNOWSKI:

20 A. I would think they would have preferred had

21 they had more.

22 CHAYTOR, Q.C.:

23 Q. And did they express to you that they felt

24 things were inconsistent or that there was a

25 lack of continuity in the lab?

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1 MS. WEGRYNOWSKI:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. When was it that you met with the  
 5 technologists?  
 6 MS. WEGRYNOWSKI:  
 7 A. I met with them on my second day.  
 8 CHAYTOR, Q.C.:  
 9 Q. So that was on the second day?  
 10 MS. WEGRYNOWSKI:  
 11 A. Correct.  
 12 CHAYTOR, Q.C.:  
 13 Q. And then you decided to use this as a teaching  
 14 time for them?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. Did you feel that they had the information  
 19 that they required for them to understand the  
 20 theory of IHC sufficient for them to be able  
 21 to actually put it into practice?  
 22 MS. WEGRYNOWSKI:  
 23 A. You know, I never evaluated that, I couldn't  
 24 comment.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. Did you meet at any point with Mr.  
 2 Gulliver?  
 3 MS. WEGRYNOWSKI:  
 4 A. Very briefly.  
 5 CHAYTOR, Q.C.:  
 6 Q. And at what stage of your visit would that  
 7 have happened?  
 8 MS. WEGRYNOWSKI:  
 9 A. It was more, hello, how are you, glad to see  
 10 you here, but nothing -  
 11 CHAYTOR, Q.C.:  
 12 Q. Nothing substantial?  
 13 MS. WEGRYNOWSKI:  
 14 A. No.  
 15 CHAYTOR, Q.C.:  
 16 Q. And no discussion around the issue or issues  
 17 of concern?  
 18 MS. WEGRYNOWSKI:  
 19 A. Not that I recall.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. Well then perhaps what we can do is  
 22 move into looking at your PowerPoint that you  
 23 would have taken the technologists through.  
 24 Did anyone else attend the presentations?  
 25 MS. WEGRYNOWSKI:

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1 A. No, I would have liked it, I would have hoped  
 2 that we could have set it up in a conference  
 3 room of some sort, at least for the quality  
 4 assurance portion, but that did not occur.  
 5 THE COMMISSIONER:  
 6 Q. Ms. Chaytor, I just wanted to remind you it's  
 7 about 11:00 and ask you your preference in  
 8 terms of the morning break, would you prefer  
 9 to take it before this or -  
 10 CHAYTOR, Q.C.:  
 11 Q. Sure, we're going to go through two or three  
 12 PowerPoint presentations then, so perhaps this  
 13 is a good time.  
 14 THE COMMISSIONER:  
 15 Q. All right. Why don't we take the morning  
 16 break now then.  
 17 (RECESS)  
 18 THE COMMISSIONER:  
 19 Q. Please be seated. Ms. Chaytor.  
 20 CHAYTOR, Q.C.:  
 21 Q. Thank you, Commissioner. I believe when we  
 22 broke, Ms. Wegrynowski, we were about to go  
 23 into the presentations that you gave to the  
 24 technologists during your visit in September  
 25 of 2005.

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1 MS. WEGRYNOWSKI:  
 2 A. Okay.  
 3 CHAYTOR, Q.C.:  
 4 Q. When you met with the technologists on the  
 5 second day that you were here, where did you  
 6 meet with them?  
 7 MS. WEGRYNOWSKI:  
 8 A. I met with them in Barry Dyer's office and I  
 9 gave the three of them the lecture on his  
 10 computer, so they sat behind me.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, so it was done in Mr. Dyer's office with  
 13 them standing behind you looking at the  
 14 computer screen?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and the first presentation that we have  
 19 is P-1765 and I understand this is basically a  
 20 summary of what you do in Toronto or basically  
 21 what your lab has in Toronto. So if you just  
 22 want to take us through from there, you can go  
 23 ahead.  
 24 MS. WEGRYNOWSKI:  
 25 A. I just started the PowerPoint off just a

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1 little bit about Toronto. I always find that  
 2 when I ever go places, people always like to  
 3 know where you're from, so--anyway, that's  
 4 just a picture of our waterfront, not nearly  
 5 as beautiful as yours, of course, but it is  
 6 ours. Okay, this is just--this is the  
 7 legislature for the Province of Ontario and  
 8 this is Mount Sinai Hospital. Mount Sinai  
 9 Hospital is located on University Avenue in  
 10 Toronto, affectionately known as "hospital  
 11 world" so we have Hospital of Sick Children  
 12 across the street from us and we're flanked on  
 13 either side then of the UHN and then we have  
 14 the Queen Elizabeth Rehab Centre to the other  
 15 side of us. This was just a little bit about  
 16 the amount of work that we do at, what was in  
 17 the year of 2004, and Mount Sinai Hospital  
 18 just to provide--it's a comparative. People  
 19 like to know how you compare with them in size  
 20 and structure and whatnot. So at that point  
 21 we were doing 21,000 surgical specimens, 7000  
 22 outside consultations, 203 autopsies of which  
 23 177 were perinatal. Mount Sinai has one of  
 24 the largest NICUs in the Province of Ontario,  
 25 so that explains that number.

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1 CHAYTOR, Q.C.:  
 2 Q. So the 7000 outside consultations were coming  
 3 from hospitals?  
 4 MS. WEGRYNOWSKI:  
 5 A. Everywhere.  
 6 CHAYTOR, Q.C.:  
 7 Q. Everywhere?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yeah. Presently for my work in  
 10 immunohistochemistry over half my work is  
 11 global consults. This was just to give a  
 12 little breakdown of the number of people that  
 13 are on site, that we has 14 pathologists, 3  
 14 pathology assistants, 35 MLTs, 4 technicians  
 15 and we have secretarial and transcriptional  
 16 pool of 16.  
 17 The pathology sections that we have at  
 18 Mount Sinai Hospital is basic histology, we  
 19 also have sarcoma because that's one of the  
 20 leading programs at Mount Sinai. We have  
 21 electron microscopy department,  
 22 immunopathology, we have special histology  
 23 which does morphology and plastics, which then  
 24 evolved into doing immunohistochemistry and  
 25 many other things. We have autopsy services

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1 and then the research services also went into  
 2 special histology since that time. Woops.  
 3 In 2004 we were doing 40,000 tests  
 4 annually. At that point our consultation  
 5 group was 35 percent. We were doing about 200  
 6 slides a day, 150 antibodies and the kind of  
 7 immunohistochemistry, we were working on  
 8 paraffin sections, cytopspins, which would come  
 9 out of the Department of Cytology and frozen  
 10 material. This is mainly for IF. And again,  
 11 we do over 200 IF cases a year, and we had  
 12 four MLTs at that time.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. And since then, since 2005 your number  
 15 of antibodies are now over 200?  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. And you now have five MLTs?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes. And our global consultations are over 50  
 22 percent, yes. Okay. So this is the--at that  
 23 particular time this was the equipment that we  
 24 had in the immunohistochemistry laboratory at  
 25 Mount Sinai Hospital. We had two DAKO

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1 autostainers, we had a micromED T/T Mega, a  
 2 microscope, the Accumet pH meter, the mettler  
 3 balance, two incubators, slide drier,  
 4 pipettes, fridges, freezer, microtomes, water  
 5 bath, cover, slippers. The main portion of  
 6 the screen is just to let you know that  
 7 there's documentation for all these products  
 8 and their maintenance schedules and whatnot.  
 9 Again, we had at that time four detection  
 10 systems, we were doing single and double  
 11 labelling for cocktails, we used different  
 12 chromogens and--chromogens are just the  
 13 colour, so whether you get the brown or the  
 14 red, that's all that is.  
 15 CHAYTOR, Q.C.:  
 16 Q. And what's a detection system?  
 17 MS. WEGRYNOWSKI:  
 18 A. A detection system is how you--what you use to  
 19 be able to find the antibody. So if you have  
 20 an antibody, it's the detection system that  
 21 you use, then you apply a chromogen to be able  
 22 to identify it.  
 23 CHAYTOR, Q.C.:  
 24 Q. And the chromogen is the colour?  
 25 MS. WEGRYNOWSKI:

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1 A. The colour. It's the -  
 2 CHAYTOR, Q.C.:  
 3 Q. So in the ER/PR it's the brown colour that  
 4 shows up when it's positive?  
 5 MS. WEGRYNOWSKI:  
 6 A. Right. That's correct. It's an enzymatic  
 7 reaction. So it's not a dye, it's not a  
 8 stain, okay.  
 9 CHAYTOR, Q.C.:  
 10 Q. And what's, I'm sorry, FITC?  
 11 MS. WEGRYNOWSKI:  
 12 A. FITC, it's the green fluorochrome that you  
 13 would use when you're using your kidney  
 14 biopsies. It's very common. The EQA that we  
 15 were presently using at that point was the CAP  
 16 and OLA and there was some external quality  
 17 assurance going on with involvement with the  
 18 immuno users group. Whoops. That's the end  
 19 of that one. That was just my little  
 20 introduction.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. And if we could have then, please,  
 23 1764? So that was basically, I take it, to  
 24 give the technologists some idea of the  
 25 equipment that you have in your lab?

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1 MS. WEGRYNOWSKI:  
 2 A. Yeah.  
 3 CHAYTOR, Q.C.:  
 4 Q. The size of your lab and how it would compare  
 5 to what they have?  
 6 MS. WEGRYNOWSKI:  
 7 A. That's right, who I am, what we have and what  
 8 we do, that's correct. Okay, so you want to  
 9 do this one next. Okay, immunohistochemistry,  
 10 this was a PowerPoint, it's basic IHC, talking  
 11 about what we do in immunohistochemistry, a  
 12 little bit about the theory.  
 13 Immunohistochemistry is an accurate  
 14 localization of tissue or cellular  
 15 constituents within antibodies.  
 16 So there are three major functional roles  
 17 of our antibodies. We identify the tissue of  
 18 origin in a metastatic tumor; we can provide  
 19 data for therapy; and we can measure tumor  
 20 antigen levels.  
 21 When we talk about tumor of origin,  
 22 again, this is just very basic, it's not meant  
 23 in any way, shape or form to be, you know,  
 24 this is the only way. When we're looking for  
 25 carcinoids, they would use, a pathologist

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1 would select a panKeratin; for sarcoma  
 2 specimens they would be looking at Vimentin  
 3 and Desmin; neuroendocrine tumors stain with  
 4 Synaptophysin and lymphomas would stain with  
 5 CD45, which is just your BNT cells. Okay.  
 6 When we talk about therapies, and this is  
 7 where it comes in for hormone receptors, and  
 8 this again, Madam Commissioner was talking  
 9 about with the Class 2 because it has a direct  
 10 impact on patient. We are talking about  
 11 estrogen and progesterone because the results  
 12 of that will result in the patient either  
 13 receiving or not receiving Tamoxifen therapy.  
 14 The same can be said of Her2/neu and the  
 15 patient receiving or not receiving Herceptin.  
 16 And with gastrointestinal stromal tumors it's  
 17 the positivity of a CD117, which would provide  
 18 the clinician with the knowledge to provide  
 19 the patient with Glivex.  
 20 Tumor antigen levels are almost  
 21 ancillary. No one would take a biopsy out  
 22 just to look at a tumor antigen levels because  
 23 these can all be found during a serum, so you  
 24 would just use blood work. But occasionally  
 25 we use this, if the tumor has been taken out,

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1 this would be just part of the product. So  
 2 CA125 will mark your ovarian cancer; CA will  
 3 mark, excuse me, your colon and gastric  
 4 cancer; and the prostate, specific antibodies  
 5 for your prostate cancer. But we have, we use  
 6 other things now for our prostate cancers.  
 7 Okay.  
 8 So what is an antigen? An antigen is a  
 9 substance that can induce an detectable immune  
 10 response and in that antigen we are looking  
 11 for the epitope, and that's your structural  
 12 part of the antigen. So it's that epitope  
 13 that is sitting on the cell surface that  
 14 you're actually looking for.  
 15 And antibodies are immunoglobulins that  
 16 are produced as a result of the introduction  
 17 of an antigen. So, for example, you would go  
 18 to your doctor, you would get an immunization  
 19 and your body would get the antibody, your  
 20 body produces the antigen.  
 21 This is a brief, just a schematic of the  
 22 IGG molecules, got your two heavy and two  
 23 light chains. You've got your interdisulfide  
 24 bonds, and that's just something in my world  
 25 that we have to look at.

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1 This is the Fc portion that carries the  
 2 specific antigen determinant which is raised  
 3 towards that particular IGG. So if you're  
 4 looking at the structure of the IGG molecule  
 5 you know at which end the antigen will bind  
 6 and which end the antibody will bind.  
 7 And I have a schematic and I use that a  
 8 lot for teaching, because I think it provides  
 9 people--if it's all going on in a test tube  
 10 and it's clear, it's very difficult to  
 11 visualize. So what you have is your primary  
 12 antibody. Your primary binds to the antigen  
 13 in the tissue, your epitope, and then it  
 14 becomes, it acts as an antigen for the second  
 15 antibody and then the second antibody binds to  
 16 the antigenic sites of the Fc portion of the  
 17 primary antibody molecule. The best way I  
 18 could describe it, it makes a sandwich. And  
 19 there it is. So if we use the cell surface as  
 20 being the green portion and your little white  
 21 portions, that would be your little epitopes  
 22 and you can see that your primary antibody is  
 23 bound. You can see that the shape is correct,  
 24 that it absolutely fits right in. So, it  
 25 wouldn't non-specifically bind had that been

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1 like perhaps a cube or a triangle, it could be  
 2 washed away. So, you would not have that  
 3 binding and that's why you have that  
 4 specificity. If you were to imagine those  
 5 great big floaty balloons out there with the  
 6 little IG molecule floating down was to bind  
 7 to the primary, they would just absolutely  
 8 slip right in, almost like docking when you  
 9 think of a jet or something.  
 10 In my world we use three kinds of  
 11 antibodies. I think in this lecture we just  
 12 talked about two, but they're monoclonal and  
 13 polyclonal. For ER and PR I think we can  
 14 concentrate on the monoclonal because that's  
 15 what they are, they have particular clones.  
 16 Polyclonals don't have clones. So polyclonals  
 17 are just immunochemically dissimilar, they  
 18 react to various epitopes. So you inject the  
 19 antigen, the titre gets measured of the rabbit  
 20 and once it's high enough, it's bled and then  
 21 the serum has to be purified.  
 22 Monoclonal antibodies, that's exactly  
 23 what you may be talking about. They have  
 24 identical clones of plasma and they're  
 25 directed towards one epitope. So in the

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1 estrogen you're talking about the clone 6F11  
 2 and the progesterone that we were using at  
 3 Mount Sinai, we used the 1294. And so this is  
 4 just a little tiny bit of how it's created.  
 5 The--it's injected into the antigen. They  
 6 sacrifice the mouse and their B-lymphs are  
 7 fused with the myeloma cell and their hybrid  
 8 myeloma cell. And what ends up actually  
 9 happening is that they're harvested at the  
 10 manufacture level, so then that's what they  
 11 sell to the public or to the laboratories. So  
 12 that's at that point that they can--that's  
 13 where your protein concentration, how much of  
 14 that antibody is actually in that particular  
 15 natant (phonetic).  
 16 Okay, so we talked a little bit about  
 17 antibody characteristics, the affinity and the  
 18 avidity.  
 19 CHAYTOR, Q.C.:  
 20 Q. And maybe you could tell us what those are?  
 21 MS. WEGRYNOWSKI:  
 22 A. I did, it's definitions of all. The affinity  
 23 is the binding sites, they fit well with the  
 24 antigen sites on a specific antigen because  
 25 you don't want any other antibody to bind. So

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1 it's almost like this affinity is like an  
 2 attraction, it is so strong that it is the  
 3 only way that those two sites will bind. And  
 4 I think that the first schematic showed that  
 5 very well.  
 6 The avidity is the binding strength and  
 7 stickiness. And it depends on the number of  
 8 fitting sites between the antigen and the  
 9 antibody. And that occurs so what when you  
 10 wash your sections off, that the antibody does  
 11 not come dislodged from the epitope.  
 12 The staining methods that we reviewed  
 13 that day were the direct method, two step  
 14 indirect method, a PAP method and an Avidin  
 15 Biotin Method. There are other methods out in  
 16 the market, but that's what we discussed that  
 17 particular day.  
 18 So we're going to look right now at the  
 19 requirements for immunohistochemistry. You  
 20 must have the preservation of the antigen in  
 21 the tissue and this goes right back to the  
 22 cornerstone of formalin fixation and how the  
 23 specimens are procured. We talk about  
 24 specific an sensitive staining. And then we  
 25 speak about the efficient labelling and



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1 detection.

2 Preservation is achieved by fixation.

3 You want the antigen made insoluble but

4 available for detection. So by using formalin

5 you get the cross linking of the formaldehyde

6 fixation and it is there to preserve the

7 protein. The longer piece of tissue is left

8 in formalin, the greater degree of cross

9 linkages.

10 So in the direct method, the most basic

11 example I could give you would be if you had a

12 kidney biopsy taken, the kidney biopsy would

13 be brought to the laboratory. We use a

14 transport media called Michelles, but the

15 reason you do this is that the work will be

16 done on the tissue in a frozen state. All you

17 need to do is then the technologist would cut

18 the sections and apply the correctly diluted

19 primary antibody which is already conjugated

20 to the fluorochrome and if the deposit is

21 there, then it stains, and if it's not there,

22 it's not. So that's a very, very simplistic,

23 not the most sensitive but very simplistic.

24 The two step indirect technique is very

25 rarely used in immunohistochemistry. It's used

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1 more in hematology. But it's the same premise

2 where you have in green the primary antibody

3 attached to the epitope, which is the blue,

4 and in the yellow you have your conjugated

5 enzyme being labelled so that you'd be able to

6 visualize it.

7 The PAP method is one of the first

8 methods that were used in

9 immunohistochemistry. It's peroxidase,

10 antiperoxidase where the secondary antibody

11 was against the specific animal. So if the

12 primary was a monoclonal, then we would have a

13 secondary against that mouse and then our

14 tertiary, the last one that goes on is the

15 peroxidase, antiperoxidase. And if you notice

16 at the top of the scheme, there are two

17 fushcia coloured dots. So this is binding

18 sites of the chromogen. So for every one

19 epitope that you can detect there are two

20 chromogen binding sites. The reason why I

21 bring this to your attention is that with

22 sensitivity and with different methods your

23 amount of chromogen that you have is greater

24 so that actually you can use less antibody.

25 So in using concentrates this is more, when

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1 you're using pre-dilutes it isn't as much a

2 big deal because manufacturers have taken care

3 of this for you.

4 This is the Avidin and Biotine method we

5 presently use just in immunohistochemistry and

6 this is actually what is used on our estrogen

7 and progesterone. So if I can walk you

8 through that. If we have the epitope at the

9 bottom, say that's a SF11 and we're applying--

10 okay, so we have an epitope at the base, which

11 is our nucleus, and then we apply our 6F11

12 which is a teal green, to that we're going to

13 put our secondary antibody which is a

14 Biotinylated horse anti-mouse, so it's going

15 to be against that primary antibody. The

16 Strip Avidin, there's such a strong affinity

17 between Strip Avidin and Biotin that they

18 cannot be taken apart, and that's why this

19 method, just basic science, works as well as

20 it does. You can see the number of chromogen

21 binding sites are greatly increased than we

22 have seen in any of the previous slides, which

23 has provided us with a very sensitive method.

24 So then we talked about the controls that

25 are necessary in the immunohistochemistry

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1 laboratory. So as far as reagent controls, we

2 were talking about the primary antibodies,

3 controls to do with the reagent and the

4 detection system, and again to do with the

5 chromogens. With tissue you need to ensure

6 that there's positive controls and negative

7 controls and internal controls but only when

8 they are present. Internal controls are not

9 present in every single tissue, only in some.

10 For example, if you were looking for--how

11 about if we go back to the hepatitis surface.

12 You would have no internal control there

13 because that would mean the patient had the

14 virus. But on a piece of skin, and were to do

15 a panKeratin, that would cover all the

16 different parts of skin, you would expect it

17 to stain. Does that provide some clarity?

18 Okay.

19 So then I went on to speak a little bit

20 about what these reagent controls and all the

21 different controls mean. For reagent

22 controls, when we're looking at positive and

23 negative, we are doing this to validate the

24 staining technique. We can do an assessment

25 of the handling and fixation of the tissue.

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1 We can standardize our methods and results  
 2 among laboratories and we also use it for  
 3 education and for performance and  
 4 interpretation. We want to ensure that every  
 5 single reagent that we use in any procedure is  
 6 working optimally.  
 7 The one thing that you must know about  
 8 your tissue controls is that they must always  
 9 be processed identically to the specimen. And  
 10 I recognize that this becomes an issue because  
 11 for fixation there are no national standards,  
 12 there's no one that says every single piece of  
 13 tissue is going to be fixed at the exact same  
 14 rate. But what you need to do is ensure that  
 15 in your particular facility that they are  
 16 processed identically to the specimen and that  
 17 is why your standard operating procedures must  
 18 be in place describing this. So with our  
 19 positive control we ensure that, again, it's  
 20 processed identically and that it contains  
 21 your target protein because if it didn't, it  
 22 wouldn't be positive. And the negative,  
 23 again, the same thing is true, so that it does  
 24 not contain that tumor marker or that tissue  
 25 marker. And internal controls are built-in

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1 controls. And again, they're not always  
 2 present in every tissue, they can't possibly  
 3 be. But when they are, they're a really great  
 4 backup.  
 5 CHAYTOR, Q.C.:  
 6 Q. And in doing ER/PR testing, would they  
 7 normally be an internal control would be  
 8 present in doing ER/PR testing?  
 9 MS. WEGRYNOWSKI:  
 10 A. I can speak to this, although this is outside  
 11 of my scope of practice because I would not be  
 12 selecting the section that would be used for  
 13 the testing. You know, you certainly are at  
 14 liberty to ask a pathologist this if you don't  
 15 -  
 16 CHAYTOR, Q.C.:  
 17 Q. Yes. And I take it the--you can go ahead,  
 18 though.  
 19 MS. WEGRYNOWSKI:  
 20 A. Oh.  
 21 CHAYTOR, Q.C.:  
 22 Q. Your knowledge of it, as well.  
 23 MS. WEGRYNOWSKI:  
 24 A. Okay. The knowledge is that if you use normal  
 25 tissue, the ducts will stain, so you would try

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1 and pick a piece that is not just totally  
 2 tumor.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. So usually what you see and what block  
 5 would be presented to you would include both  
 6 normal epithelium and tumor?  
 7 MS. WEGRYNOWSKI:  
 8 A. I wouldn't be looking at that, but that would  
 9 be the pathologist's call, that is in their  
 10 scope of practice.  
 11 CHAYTOR, Q.C.:  
 12 Q. Yes. But when you see it and what gets put  
 13 onto then eventually the slide, it would  
 14 normally include the normal tissues as well as  
 15 the tumor in doing ER/PR testing?  
 16 MS. WEGRYNOWSKI:  
 17 A. I wouldn't be reviewing the HNES to determine  
 18 that.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay.  
 21 MS. WEGRYNOWSKI:  
 22 A. Okay.  
 23 CHAYTOR, Q.C.:  
 24 Q. Fair enough.  
 25 MS. WEGRYNOWSKI:

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1 A. Yeah, okay. Oh, my goodness, I think I've  
 2 done something, it's not going forward.  
 3 CHAYTOR, Q.C.:  
 4 Q. If we can get rid of that? Okay. Here we go,  
 5 we're good.  
 6 MS. WEGRYNOWSKI:  
 7 A. Okay, thank you. I think I pushed one too  
 8 many buttons. So then we discussed  
 9 pretreatments. So there are several  
 10 pretreatments that we use in  
 11 immunohistochemistry presently. The first  
 12 being and the gentlest would be proteolytic  
 13 digestion. The next would be heat-induced  
 14 epitope retrieval. For proteolytic digestion,  
 15 the two proteins that we use are Pepsin and  
 16 proteinase K, proteinase K being the gentlest  
 17 of the two. So by scientific theory we  
 18 recognize that formalin fixes by forming cross  
 19 linking methylene bridges. And this goes  
 20 back, even back to the '80s when I first  
 21 described in immunohistochemistry how we were  
 22 only able to work on formalin, excuse me, on  
 23 fresh tissue, that we were not able to work on  
 24 formalin. It wasn't until the advent of heat  
 25 retrieval on digestive natures that we were

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1 able to expose the epitopes, so this is a  
 2 little bit down the line. So what it does is  
 3 the digestion compensates for the impermeable  
 4 nature of the fixative, which is formalin and  
 5 it's very gentle and the enzyme enters the  
 6 tissue allowing the epitope to be exposed.  
 7 So this is just a photomicrograph of  
 8 panKeratin without Pepsin, so it's a piece of  
 9 skin and it's supposed to show all the  
 10 epithelium, so your squamous epithelium. And  
 11 so once you do your digestion, I'm sure you  
 12 can see that it's quite noticeably different.  
 13 So by doing so, by doing that one  
 14 pretreatment, you have now been able to expose  
 15 the epitope and you are able to visualize it.  
 16 Heat retrieval, heat retrieval, it was  
 17 described by SHE (phonetic), it's almost, I  
 18 don't really understand myself how it all  
 19 works and I--there are many pieces in  
 20 literature, but really no one understands the  
 21 direct mechanism because we speak about  
 22 maintaining temperatures and not having your  
 23 waxes, but yet, here we are taking things up  
 24 to 115 degrees celsius, 120 degrees celsius  
 25 under pressure. It's quite a phenomenal

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1 science. Heating provides the energy to  
 2 rupture the hydroxyl bonds and releases the  
 3 tissue bound calcium ions which breaks a  
 4 fixative bond, permanently exposing epitope.  
 5 Efficiency of heat induced epitope retrieval  
 6 is a function of time, temperature, pH and the  
 7 chemical composition of the buffer. And those  
 8 are definitely the cornerstones of heat  
 9 induced epitope retrieval.  
 10 This is just an example of particular  
 11 antibody PGP, and what we're looking for here  
 12 are nerve cells, that's all you need to know.  
 13 So this would be a very basic validation  
 14 process. You can say, okay, so how do we get  
 15 to expose this epitope, what is it going to  
 16 take to be view it? I can tell you that in  
 17 this particular example, I've kept everything  
 18 the same in relationship to the dilution and  
 19 the detection system. The only thing that was  
 20 changed was the pretreatment.  
 21 So this one we used Pepsin under 37  
 22 degrees, ten minutes, and there's obviously no  
 23 staining because all you see are blue dots.  
 24 So then when we took it into heat retrieval  
 25 and we use something called a Citrate buffer

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1 at pH 6 for three minutes at 115 degrees  
 2 celsius, you start seeing that some of the  
 3 nerve cells are starting to come up. But  
 4 maybe it didn't photograph very well, but rest  
 5 assured that when we took that pH up to 9 for  
 6 the same time at temperature, the end product  
 7 was intensified and the high signal low noise  
 8 would then be done and then this is where you  
 9 would go on with the process. So at this  
 10 point you would say--because there was a  
 11 question raised to me, I know that you raised  
 12 it to me in Toronto, maybe I could -  
 13 CHAYTOR, Q.C.:  
 14 Q. Sure.  
 15 MS. WEGRYNOWSKI:  
 16 A. If I could take the liberty now? Someone  
 17 asked me, and I don't recall which of you,  
 18 does a pathologist see all the slides when you  
 19 validate? And I'll tell the answer is no. If  
 20 I had showed the pathologist the first slide  
 21 and there was absolutely no staining, he would  
 22 probably, or she would look at me and say, why  
 23 are you bothering showing me this. So it is  
 24 the judgment of the technologist at that point  
 25 to say, okay, there's no signal here, where do

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1 we go from here. So at this point if we had  
 2 moved through this process and recognized that  
 3 this was already giving us the best signal to  
 4 noise, then from there we would start working  
 5 on our dilutions.  
 6 COMMISSIONER:  
 7 Q. Signal to noise?  
 8 MS. WEGRYNOWSKI:  
 9 A. Signal to noise. Signal being the brown or  
 10 the chromogen, what we're seeing, and the  
 11 noise being the background is very clear.  
 12 COMMISSIONER:  
 13 Q. Okay.  
 14 MS. WEGRYNOWSKI:  
 15 A. Because you want to ensure that the signal  
 16 that you're seeing, it's much, it's much  
 17 easier to interpret than if you have this  
 18 noise in the background, which would also  
 19 indicate that the validation process wasn't  
 20 correct.  
 21 COMMISSIONER:  
 22 Q. Okay.  
 23 MS. WEGRYNOWSKI:  
 24 A. Okay. Is that okay?  
 25 CHAYTOR, Q.C.:

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1 Q. Yes, thank you.  
 2 MS. WEGRYNOWSKI:  
 3 A. Okay. So section quality. Section quality,  
 4 there is no part of immunohistochemistry  
 5 laboratory that is not important. There is no  
 6 role in there that is not important. The  
 7 section quality taken by the microtome is  
 8 imperative. The reason for this in this  
 9 example, and if I was to explain it to you, it  
 10 was like the ridge going down the centre is a  
 11 fold, so the tissue is absolutely, it's  
 12 overlapping on itself. So you can see that  
 13 this is, you know, this is using the DAKO, I  
 14 don't have the Ventana so I don't know what it  
 15 would look like on the particular equipment  
 16 that you have here, but on the DAKO  
 17 autostainer, it applies by drop, so it drops  
 18 in two or three different sections. So the  
 19 antibody will spread but if it hits this wall,  
 20 it will not be able to spread any further  
 21 because we are only using 100 microlitre  
 22 drops, which are very small volumes. And as  
 23 you can see, that if you provide a section  
 24 like that, there is no staining if you look at  
 25 the right side of the screen, so this would be

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1 an invalid test.  
 2 The score works in the exact same manner,  
 3 except obviously in reverse. The score then  
 4 acts as a well. And as you can see, the  
 5 antibody will--the detection systems and  
 6 chromogens will only be able to spread a  
 7 certain amount and then they can't go any  
 8 further and I think there's a higher power of  
 9 that, so this is a cycling--it's a self--it's  
 10 a CD marker, cluster differentiating marker,  
 11 so that you can see that even in the sections  
 12 that are underneath in the well, the  
 13 antibodies start getting up underneath it  
 14 because it lives, so these are invalid tests.  
 15 CHAYTOR, Q.C.:  
 16 Q. So and what was it that made these tests  
 17 invalid?  
 18 MS. WEGRYNOWSKI:  
 19 A. Because the staining is not complete.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And why would that be, does it have  
 22 anything to do with how the tissue was sliced,  
 23 the size of the tissue?  
 24 MS. WEGRYNOWSKI:  
 25 A. No. This has all got to do--geez, I've done

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1 it again, sorry. This has all got to do with  
 2 the microtome.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay.  
 5 MS. WEGRYNOWSKI:  
 6 A. Okay. So at sections, taking the sections in  
 7 the laboratory so the pathologist is provided,  
 8 the technologist says this is the test I want  
 9 done, so they are now preparing the slides.  
 10 And these are some TMAs, I think Frances  
 11 provided me with for this lecture. And you  
 12 can start seeing even they start to lift. And  
 13 that's an issue that you can find with TMAs,  
 14 tissue microrays. How they're created very  
 15 simply is that a pathologist would look at a  
 16 slide, they would mark the area of tumor and  
 17 it's like a very fancy hole punch, and they  
 18 just pop up that piece and then they get put  
 19 into blocks, and that's basically what tissue  
 20 microrays are.  
 21 CHAYTOR, Q.C.:  
 22 Q. So in your laboratory if you were--would you  
 23 look at those slides and determine yourself  
 24 that this had not worked effectively and it  
 25 would never go to the pathologist?

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1 MS. WEGRYNOWSKI:  
 2 A. Shouldn't go out. And I can speak to this is  
 3 that, well, I shouldn't say never, things do  
 4 happen, if it was an antibody that you were  
 5 expecting to stain the entire slide, let's  
 6 say, and it was a lymphoma and you were doing  
 7 a marker that should show every B and T cell  
 8 on that and you noticed yourself that there  
 9 was only half a staining, you would stop and  
 10 take a look yourself, of course.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. And you would have a microscope in your  
 13 lab and -  
 14 MS. WEGRYNOWSKI:  
 15 A. We have a microscope in our laboratory, yes.  
 16 CHAYTOR, Q.C.:  
 17 Q. And when you arrived in St. John's in 2005,  
 18 did the technologists have a microscope in  
 19 their lab?  
 20 MS. WEGRYNOWSKI:  
 21 A. I don't believe they did, no. I should say I  
 22 don't recall, I don't--they certainly didn't  
 23 have a multi-header, that's for sure. Okay,  
 24 so then we're talking a little bit about  
 25 background staining. There are two reasons

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1 that you can get background staining. The  
 2 first is the endogenous peroxidase activity  
 3 and the second one is endogenous Avidin Biotin  
 4 activity but this is completely dependent upon  
 5 the detection system that one employs. Okay.  
 6 So this is endogenous peroxidase. This is  
 7 just a section of spleen. Okay, bottom line  
 8 here is the dark dots, that's the  
 9 proliferating cell marker. The little brown  
 10 dots, that's red blood cells, which should not  
 11 be staining, and it's simply because they  
 12 haven't, we haven't--it's endogenous  
 13 peroxidase that we have to remove prior to  
 14 testing. And you do this, and again, once I  
 15 show you the next photograph, then you'll see  
 16 that it's gone. Again, that's that noise to  
 17 signal. So it's just part of the procedure,  
 18 just part of the regular, every  
 19 immunohistochemistry test.

20 Endogenous Avidin binding activity is a  
 21 little bit different. This goes back to that  
 22 photo that I showed you, the photo of--  
 23 schematic, I should say, of the Avidin and  
 24 Biotin procedure. Because Biotin is a vitamin  
 25 coenzyme, it binds specifically with Avidin or

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1 Streptavidin. That's just science. So non-  
 2 specific staining resembles a very diffuse  
 3 cytoplasmic pattern and you can very easily  
 4 eliminate this with Avidin and Biotin  
 5 blocking. We, if we use the Avidin Biotin  
 6 technology, we always block for it, we do not  
 7 select by specimen, it's automatically gets  
 8 done. And I have a photograph I should be  
 9 able to show you. This is a section of gut  
 10 and you can see in the mucosa--okay. See at  
 11 the top of the screen how it's beige, kind of,  
 12 like they have little round holes and they  
 13 kind of like beige, okay, that's non-specific  
 14 staining, that's absolutely it. But when we  
 15 block for it, you end up with this clear,  
 16 again, it's that low noise. Just part of the  
 17 technology. There are certain tissues that  
 18 exhibit endogenous biotin at very great  
 19 amounts and I don't know if it's in this  
 20 lecture, but if you didn't block for it, you  
 21 would never know what you were marking because  
 22 it's laden with it.

23 Then we moved into the chromogens and  
 24 there are two types of chromogens that we use  
 25 in immunohistochemistry, the first being for

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1 immunofluorescence and the second being for  
 2 immunoenzymatic. Immunofluorescence are the  
 3 most common fluorochrome that is used is FITC  
 4 and that is presently used at St. John's, as  
 5 it is for Mount Sinai for the kidney biopsies.  
 6 TEXAS RED is another color and DAPI is just  
 7 the name of--it's a nuclear marker. So this  
 8 is just an example of what you would expect to  
 9 see with a positive kidney biopsy. So that's  
 10 a glumeruli, all lit up with the fluorochrome.  
 11 So, you can see that great apple green.

12 So, when the fluorochrome is left in  
 13 light, the actual amplification diminishes, as  
 14 does the staining intensity, so that you'll  
 15 get a much less bright signal. So when the  
 16 pathologist reads it, you never--you don't  
 17 work in light with these. You don't cover  
 18 slip in light with these and even when the  
 19 work is being read by the pathologist, it's  
 20 not--the slides are left in the fridge and  
 21 they're not repeatedly looked at, because once  
 22 the light hits it, it excites it and the  
 23 emissions reduce. This is just an example of  
 24 a project I did with just--anyway, it just  
 25 shows the three different chromogens, that

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1 it's doable.

2 CHAYTOR, Q.C.:

3 Q. And was the lighting an issue here in St.  
 4 John's?

5 MS. WEGRYNOWSKI:

6 A. In St. John's, they were not--I did it again.  
 7 In St. John's, they were not doing their  
 8 fluorescence in the dark and they weren't  
 9 using controls and they weren't storing their  
 10 tissues. So yes, it was an issue.

11 Immunoenzymatic staining, this is more to  
 12 do with the regular everyday paraffin stuff.  
 13 It allows the visualization of a cell  
 14 component, and if I could just reiterate  
 15 again, it's so different than doing a special  
 16 stain because with the special stain, you're  
 17 going to put on your hematoxylin and all your  
 18 nuclei are going to stain, and then you're  
 19 going to put in your eosin and everything else  
 20 is going to stain. Immunohistochemistry does  
 21 not work like that. It's that enzyme  
 22 substrate reaction that allows you to  
 23 visualize that colored end product. It's a  
 24 very different theory. So the end  
 25 precipitates and at best site and the antigen

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1 is localized and the reaction is insoluble  
 2 upon oxidization. So in other words, once  
 3 it's there, it's not going anywhere.  
 4 We don't use Nova Red any more, but we  
 5 can go through that. DAB, which is, I think  
 6 most people use, gives you that brown end  
 7 product. I'm sure you've all seen pictures  
 8 with the brown, and it is extremely insoluble  
 9 in alcohol and other organic solvents and so  
 10 that once it's bound to the site, it is not  
 11 coming out. The red products, well, they can.  
 12 They can be insoluble in alcohol and other  
 13 organic solvents, so if you're not careful,  
 14 you can use them, but that was not an issue  
 15 here at St. John's.  
 16 This is just an example of what the  
 17 different colors look like. We use HMB45 as a  
 18 melanoma marker. We use Nova Red with all our  
 19 melanoma markers, only because of the amount  
 20 of melon--melanin is a natural pigment and  
 21 it's brown. So if you stain stuff with brown,  
 22 it can be more difficult to see. So if you  
 23 put red in, it's just very easy for the  
 24 pathologist to see it. It's just quicker and  
 25 easier. It does not change the sensitivity,

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1 nor the specificity. Again, might want to--  
 2 there you go.  
 3 Okay, so then, we worked on the kinds of  
 4 specimens that we work with at Mount Sinai  
 5 Hospital. We worked at with formalin fix,  
 6 paraffin embedded tissues and then we walked a  
 7 little bit through the pre-treatments that we  
 8 used to expose the epitopes. Frozen  
 9 specimens, acetone fixed, and again, this  
 10 would be just like St. John's with working on  
 11 your kidney biopsies. We occasionally do  
 12 blood smears, not very often, but we do, and  
 13 we also work on some cytopspins, which are  
 14 alcohol fixed.  
 15 Factors that affect the quality of  
 16 immunostaining. Okay, all these factors are  
 17 used not only for validation, but these are  
 18 the same critical components that you would  
 19 look at when you were doing your  
 20 troubleshooting. So you would look at your  
 21 antibody titre. During the validation process  
 22 that antibody titre would be used--would you  
 23 like me to go both ways with it?  
 24 CHAYTOR, Q.C.:  
 25 Q. Yes, and you can explain to us what exactly

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1 that means.  
 2 MS. WEGRYNOWSKI:  
 3 A. Okay. So antibody titre is the amount of  
 4 antibody compared to diluent that you need to  
 5 use to give you this end product. So, for  
 6 example, you may try different titres to get  
 7 that final end product, whether it be 1 in 50,  
 8 1 in 100, it doesn't really matter. At the  
 9 other end of it, this is one of the components  
 10 that you need to look at if you have negative  
 11 staining or if your staining is not correct.  
 12 The question then arises did you make that  
 13 dilution correctly. To make that dilution,  
 14 you need to ensure that your pipettes were  
 15 calibrated. You needed to ensure that your  
 16 diluting buffer was pHed and that your lot had  
 17 lot to lot comparison.  
 18 So everything that we go forward with, we  
 19 go back with. It's a circular--maybe I'm not  
 20 coming up with the right words, but -  
 21 THE COMMISSIONER:  
 22 Q. Wait now, let's make sure I understand this.  
 23 You are saying that in the process--if we go  
 24 back to getting in a new batch.  
 25 MS. WEGRYNOWSKI:

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1 A. Okay.  
 2 THE COMMISSIONER:  
 3 Q. When you get your new batch in, you do a  
 4 series of what I shall loosely call tests,  
 5 which you then compare with your old batch to  
 6 make sure that you have that continuity? Is  
 7 that correct?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes, that would be if it was an antibody  
 10 already in service, that is correct.  
 11 THE COMMISSIONER:  
 12 Q. Okay. Assuming that, for the moment, then you  
 13 get your new batch, which I, a knitter, like  
 14 to think of as dye lots, but that's just my  
 15 way -  
 16 MS. WEGRYNOWSKI:  
 17 A. Okay, no, that's good.  
 18 THE COMMISSIONER:  
 19 Q. You get your new batch and if somewhere along  
 20 the way, using your new batch, the product  
 21 that you are getting, you begin to doubt, you  
 22 will go back through those -  
 23 MS. WEGRYNOWSKI:  
 24 A. I would.  
 25 THE COMMISSIONER:

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1 Q. - same kinds of things you did to make sure  
 2 that, in fact, you did it the proper way in  
 3 the sense of the percentages used were what  
 4 you had determined should have been used?  
 5 MS. WEGRYNOWSKI:  
 6 A. Correct. So that's why when we go back and we  
 7 look at those spec sheets from the antibody  
 8 when they first come in, that's where we're  
 9 looking at the protein concentration. Is that  
 10 protein concentration the same for this lot as  
 11 it was for the last lot?  
 12 THE COMMISSIONER:  
 13 Q. Okay.  
 14 MS. WEGRYNOWSKI:  
 15 A. That is correct.  
 16 THE COMMISSIONER:  
 17 Q. All right. So it's a matter of determining  
 18 what you do with this new batch and then  
 19 having determined that, if something goes  
 20 wrong, you check every single one of those  
 21 little steps -  
 22 MS. WEGRYNOWSKI:  
 23 A. Absolutely.  
 24 THE COMMISSIONER:  
 25 Q. - along the way to determine what caused it to

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1 go wrong?  
 2 MS. WEGRYNOWSKI:  
 3 A. That's correct.  
 4 THE COMMISSIONER:  
 5 Q. Was the mix correct? Was the -  
 6 MS. WEGRYNOWSKI:  
 7 A. That's correct. It gets a little bit more -  
 8 THE COMMISSIONER:  
 9 Q. - sterilization done, etcetera, etcetera.  
 10 MS. WEGRYNOWSKI:  
 11 A. That's right. It gets a little bit more  
 12 multi-layered and I can walk you through that  
 13 as well, if you want, but that's the basic  
 14 premise.  
 15 THE COMMISSIONER:  
 16 Q. Okay.  
 17 MS. WEGRYNOWSKI:  
 18 A. Okay. So then antibody titre and then you  
 19 have your antibody dilution which you've seen,  
 20 and I'm not sure why I wrote that twice, but I  
 21 did. So we start talking about the incubation  
 22 time, inconsistencies, but once your stainers  
 23 are set up, regardless of what you're using,  
 24 that is all going to be logged in in the set  
 25 up. So that is not as critical an issue.

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1 Incubation temperature most certainly can  
 2 be. Most people in the service environment,  
 3 you are going to be doing it at room  
 4 temperature. It becomes an issue in the  
 5 summer time with humidity and whatnot and we  
 6 end up getting specific background staining,  
 7 but that we can't do much about.  
 8 Pre-treatments. Ah, yes, pre-treatments.  
 9 When you are doing pre-treatments, regardless  
 10 if you're making them in house or you're  
 11 buying them commercially, you must ensure that  
 12 there is no lot to lot variability. So before  
 13 any product goes into service, you must ensure  
 14 that you do a side by side comparative with  
 15 the previous to ensure it's giving you the  
 16 same results. If you are making it up, it's  
 17 the same thing. You want to make sure, if  
 18 you're making that buffer, that your scales  
 19 have all had the preventative maintenance on  
 20 it, so that they are actually weighing the  
 21 correct way, that your water is correct, so  
 22 that the whole process is correct, and of  
 23 course, your pH is correct at the end. Again,  
 24 we did that with pre-treatments and then  
 25 buffers, again it's the same thing. So your

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1 buffers that you're using, just in the  
 2 laboratory, that they're all pHed.  
 3 If I may, there are times when something  
 4 can go wrong with a test, but everything else  
 5 worked, and so you have to go back through the  
 6 process as well there and look at how that was  
 7 handled. Was the detection system the same?  
 8 And you start going through the row. Okay,  
 9 the detection was the same. Then it can't be  
 10 that. And you just start working through it  
 11 at a bigger picture to start coming down to  
 12 what you think the issue could be, because as  
 13 you can appreciate, there are a number of  
 14 steps and as you don't visualize anything  
 15 along the way, it can be rather labour  
 16 intensive and sometimes frustrating.  
 17 THE COMMISSIONER:  
 18 Q. Tell me, is there a recording process along  
 19 the way that goes with this as well, in terms  
 20 of when you are starting to work with a new  
 21 batch, for example -  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes.  
 24 THE COMMISSIONER:  
 25 Q. - and going through the process of ensuring

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1 that the results are consistent with your old  
 2 batch, is there a recording process for  
 3 recording each of the steps you took or is  
 4 that sort of something that everybody does so  
 5 automatically that you don't record these  
 6 things?  
 7 MS. WEGRYNOWSKI:  
 8 A. I do record them. So what ends up happening,  
 9 if I may, depending on what the uses is going  
 10 to be, if I am going to purchase a product  
 11 that I'm going to be using every single day  
 12 and I have a pretty good idea of what the  
 13 volumes are going to be, then I will contact  
 14 the supplier and we will sequester lots, so  
 15 that I have that lot for an extended period of  
 16 time.  
 17 THE COMMISSIONER:  
 18 Q. Okay.  
 19 MS. WEGRYNOWSKI:  
 20 A. Those lot numbers are then recorded in a book.  
 21 We have the date that we receive them. We  
 22 have all that information there. We do the  
 23 same thing, not only for our buffers, but we  
 24 do the same thing for antibodies. For  
 25 example, we do--we are one of the two

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1 laboratories in the province of Ontario that  
 2 do HER2/neu testing. So I will sequester lots  
 3 that will last us almost--well, I hope to last  
 4 us a year, so that we don't have issues with  
 5 reproducibility.  
 6 THE COMMISSIONER:  
 7 Q. Okay.  
 8 MS. WEGRYNOWSKI:  
 9 A. But that is all--we have all that documented,  
 10 yes.  
 11 THE COMMISSIONER:  
 12 Q. Okay, thank you.  
 13 CHAYTOR, Q.C.:  
 14 Q. If you could continue on then, please.  
 15 MS. WEGRYNOWSKI:  
 16 A. Okay.  
 17 CHAYTOR, Q.C.:  
 18 Q. Is there anything else on this slide that you  
 19 -  
 20 MS. WEGRYNOWSKI:  
 21 A. I don't think so. I think that's it.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay.  
 24 MS. WEGRYNOWSKI:  
 25 A. Oh, yes, okay. So antigen loss upon storage,

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1 I'm sure everyone in the room is familiar that  
 2 we have blocks and from the blocks, we create  
 3 slides, and one of the wonderful things about  
 4 immunohistochemistry is that you learn  
 5 something all the time, and this actually came  
 6 from a researcher, and they had given us some  
 7 slides and we had run the work for the day,  
 8 and this was a control slide and I'm telling  
 9 you, it was a failure, and I couldn't figure  
 10 it out. I thought I know we did everything  
 11 right. There were tests that we had run that  
 12 day in that batch and they had worked. So  
 13 what had happened to the control? So one of  
 14 the things I looked at was when the date of  
 15 that control was cut, and the antigenicity of  
 16 this particular epitope does not survive  
 17 storage, long-term storage. So when we re-cut  
 18 it, there you go, there's your staining. So  
 19 we are of a habit of always writing on our  
 20 slides, our control slides, the date we cut  
 21 them, and even in our control slides, they all  
 22 have their own, some like to be frozen, some  
 23 are kept at room temp--well, they're never  
 24 kept at room temperature, but they're always  
 25 covered and kept at four degrees. So even

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1 with that, it's--and you don't find that  
 2 information on spec sheets.  
 3 THE COMMISSIONER:  
 4 Q. Okay.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay, thank you.  
 7 MS. WEGRYNOWSKI:  
 8 A. And that's it.  
 9 CHAYTOR, Q.C.:  
 10 Q. Ms. Wegrynowski, how was your--how was this  
 11 presentation received by the technologists?  
 12 MS. WEGRYNOWSKI:  
 13 A. Very well.  
 14 CHAYTOR, Q.C.:  
 15 Q. And I take it they found it informative?  
 16 MS. WEGRYNOWSKI:  
 17 A. I believe so.  
 18 CHAYTOR, Q.C.:  
 19 Q. And they asked questions of you?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yeah, we walked through it. I mean, there was  
 22 things obviously they knew and you know, they  
 23 were just--it was a very collegial  
 24 environment. It was--I was certainly there  
 25 only to teach. If they had wanted me to skip



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1 through slides, I would certainly have done  
 2 that for them, but this was up to them what  
 3 they chose to do with it.  
 4 CHAYTOR, Q.C.:  
 5 Q. And they seemed to learn from what you were  
 6 doing and what you were telling them?  
 7 MS. WEGRYNOWSKI:  
 8 A. They seemed to be very accepting of the--I  
 9 think the schematics helped them the most, if  
 10 I recall. Again, as I say, because everything  
 11 is colorless, it's very difficult sometimes to  
 12 grasp in your mind the schematic and they're  
 13 very helpful, I think.  
 14 CHAYTOR, Q.C.:  
 15 Q. And Ms. Wegrynowski, where did you, yourself,  
 16 learn all this information, such that you're  
 17 now able to teach it to others?  
 18 MS. WEGRYNOWSKI:  
 19 A. As again, it started with the base course in  
 20 1983, all the different courses along the way,  
 21 a tremendous amount of reading and most of it  
 22 is just troubleshooting in the laboratory.  
 23 It's being in there every single day and  
 24 seeing what can go wrong and recognizing that  
 25 it's okay to say it didn't work and go

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1 backwards. But if I can add to that?  
 2 CHAYTOR, Q.C.:  
 3 Q. Sure.  
 4 MS. WEGRYNOWSKI:  
 5 A. I also have the support of the pathologists  
 6 that when I say it's not working, that's where  
 7 it stops.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and if we could look then, please, the  
 10 third presentation you did, I believe was  
 11 called quality processes. That's 1761,  
 12 please, and perhaps you could walk us through  
 13 this presentation as well.  
 14 MS. WEGRYNOWSKI:  
 15 A. Okay. Okay, so the quality processes, all  
 16 right, so we're talking about--we're following  
 17 a specimen from the physician order to the  
 18 reported results. So we're going to be  
 19 talking about the pre-analytical, the  
 20 analytical and the post-analytical parts of  
 21 immunohistochemistry. They all vary a little  
 22 bit, depending on where your start-off point  
 23 is, but I'll explain that, flow charts, how  
 24 important they are, and of course,  
 25 documentation.

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1 All right, the processes that we're going  
 2 to discuss in this lecture are the pre-  
 3 analytical, the analytical, the post-  
 4 analytical, equipment and reagents, quality  
 5 assurance. So just to break it down a little  
 6 bit, so we talk about specimen collection.  
 7 How is the specimen collected? You need to  
 8 always be cognizant of specimen transport,  
 9 both internally and externally. Receipt of  
 10 the specimen in the lab, that they must be  
 11 labelled correctly, that all viable patient  
 12 information is there, and then it gets  
 13 successional into the laboratory information  
 14 system. There should be the responsibility  
 15 that if any of these things are not correct,  
 16 there should be a mechanism in place to send  
 17 the specimen back to the originator.  
 18 For example, if there's--just for  
 19 example, if something came without a patient  
 20 name and birth date, you would automatically  
 21 send that back from whence it came, because  
 22 upon receipt, you could never validate or  
 23 verify that that's whose specimen it was. So  
 24 in a hospital setting, all your specimens are  
 25 going to come--I don't know what they're

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1 called, bradma plates, you know, those little  
 2 sticker things that they go on the specimen.  
 3 So you want to ensure that the name on the  
 4 requisition would match that of the specimen  
 5 container.  
 6 These are really helpful if you start  
 7 doing audits, because if you find that a  
 8 particular area has not been able to do that,  
 9 maybe they need an in-service to understand  
 10 what the mechanisms are. It gets hard with  
 11 nursing sometimes, because they're working  
 12 24/7, to be able to track people down. So it's  
 13 something you'd like to stop at the front  
 14 door.  
 15 CHAYTOR, Q.C.:  
 16 Q. And if we could, just the specimen transport,  
 17 I take it that would include the actual  
 18 getting the specimen from the OR, in the case  
 19 of breast surgery, getting the specimen from  
 20 the OR down to the lab?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. And there would be protocols then in place for  
 25 that to take place?

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1 MS. WEGRYNOWSKI:  
 2 A. There has to be protocols for everything in  
 3 place to take place.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay.  
 6 MS. WEGRYNOWSKI:  
 7 A. So that you know what to expect.  
 8 CHAYTOR, Q.C.:  
 9 Q. And internal being within your hospital and  
 10 external being samples that you receive or  
 11 specimens you receive from outside Mount  
 12 Sinai?  
 13 MS. WEGRYNOWSKI:  
 14 A. Anywhere outside, yes.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and in terms of if we just think  
 17 internal for a moment, what is appropriate  
 18 transport to have the sample come down from  
 19 the OR down to the lab?  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay. So you're talking about porters being  
 22 able to pick up specimens out of the  
 23 refrigerator up in the OR, so in the OR, we  
 24 would have a sticker in our OR book that would  
 25 match the sticker on the requisition and on

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1 the specimen, so that when the porter would  
 2 pick it up, they would look at the two pieces  
 3 and sign off in time that they've actually  
 4 removed them from the refrigerator and then  
 5 brought them down. Is that what you're  
 6 looking for?  
 7 CHAYTOR, Q.C.:  
 8 Q. Yes, that's--yes, and in terms of, I take it,  
 9 that the protocol would say how often the  
 10 porter would -  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes, the times and things.  
 13 CHAYTOR, Q.C.:  
 14 Q. The times and -  
 15 MS. WEGRYNOWSKI:  
 16 A. I'm not familiar with that part of it.  
 17 CHAYTOR, Q.C.:  
 18 Q. - and you would document then--is there  
 19 documentation then which would indicate when  
 20 it arrived in the lab as well?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, they do.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay.  
 25 MS. WEGRYNOWSKI:

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1 A. So then requisitions, what is the expectation  
 2 of your requisitions, what information needs  
 3 to be on that requisition for you to accept it  
 4 from the patient. Okay.  
 5 All right, so I deal, in my world, with  
 6 the analytical stage. Pre-analytical, for me,  
 7 is everything that kind of shows up at my  
 8 front door. So for me, I'm looking at my  
 9 methodology. I want to maintain it that it's  
 10 current, that it's based on published practice  
 11 guidelines or in-house procedures validated by  
 12 the laboratory and that they're approved by my  
 13 laboratory director or designate, and I  
 14 actually have a medical director that I report  
 15 to who will sign off on this. All my  
 16 procedures are documented. All the procedures  
 17 are available at the workstation for the end  
 18 user, and all the documents are reviewed  
 19 annually.  
 20 CHAYTOR, Q.C.:  
 21 Q. And who is the medical director that you would  
 22 report to in Mount Sinai?  
 23 MS. WEGRYNOWSKI:  
 24 A. My medical director is Dr. Bob Riddell.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and is this, I take it, when you say "I"  
 2 this is for all technologists who work within  
 3 your group?  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. And they would stay current on published  
 8 practice guidelines as well as your in-house  
 9 procedures?  
 10 MS. WEGRYNOWSKI:  
 11 A. Absolutely, yes. It's--I don't know whether  
 12 you want to go into this now, but when you  
 13 talk about procedures, Bob Riddell will sign  
 14 off on my procedure manual, but when we're  
 15 talking about different antibodies and  
 16 whatnot, his specialty is gut, so he doesn't  
 17 necessarily--no, let me rephrase that. When  
 18 it comes to the breast work, so we're talking  
 19 about a HER2/neu and our ER and PR, when I do  
 20 my validation slides, they go to the  
 21 pathologist of interest with those particular  
 22 antibodies, because those are the pathologists  
 23 that read those slides. The ER/PR are not  
 24 read by every pathologist, neither are  
 25 HER2/neu. The lines get very blurred. A lot

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1 of bosses at times.  
 2 So as I say, all our procedures are  
 3 documented. Everything must be available at  
 4 the workstation for the end user. It is not  
 5 unusual for pathologists to come in and take a  
 6 look at our procedure manuals, our antibodies  
 7 data sheets. Everything is--it's transparent  
 8 and they're all there for everyone to use, and  
 9 we do use them.  
 10 Okay, annual review. For us, it's a  
 11 little--our documentation is all done online.  
 12 We have a--I don't know what--the company is  
 13 called Paradigm, so all our procedure manuals  
 14 are up online so that everybody can see.  
 15 CHAYTOR, Q.C.:  
 16 Q. Can we just go back, please, for a moment?  
 17 MS. WEGRYNOWSKI:  
 18 A. Sure.  
 19 CHAYTOR, Q.C.:  
 20 Q. The annual review, is that annual review of  
 21 your methods? Annual review of your  
 22 technologists? What is that referencing?  
 23 MS. WEGRYNOWSKI:  
 24 A. It can be both.  
 25 CHAYTOR, Q.C.:

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1 Q. So what gets reviewed annually?  
 2 MS. WEGRYNOWSKI:  
 3 A. Our procedure manual would get reviewed.  
 4 There'd be updates on it. You would--I mean,  
 5 manuals are living, breathing documents. They  
 6 are never stagnant. So if you were to bring  
 7 in a new antibody, it would get introduced to  
 8 that manual long before the annual review  
 9 would come up. If you are changing detection  
 10 systems, that would be included in your  
 11 procedure. So, they're not stagnant. It's  
 12 not like once a year, okay, you read this and  
 13 you do it. They're always being worked on.  
 14 CHAYTOR, Q.C.:  
 15 Q. So, it's reviewed more frequently as required,  
 16 but at least annually the entire -  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes, documents -  
 19 CHAYTOR, Q.C.:  
 20 Q. - manual is reviewed.  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, it's signed off then.  
 23 CHAYTOR, Q.C.:  
 24 Q. Thank you, that's fine, go ahead.  
 25 MS. WEGRYNOWSKI:

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1 A. Okay. So, postanalytical, so most of this--  
 2 well, the reporting is not done by the  
 3 technologist. That is done by the pathologist  
 4 and there's certain parts that they need to  
 5 do. The turnaround times and stats, that  
 6 falls more into the technologist side. We  
 7 want to ensure that things are done in a very  
 8 timely manner and record retention, I don't  
 9 throw anything out.  
 10 CHAYTOR, Q.C.:  
 11 Q. So, turnaround times and what's STAT?  
 12 MS. WEGRYNOWSKI:  
 13 A. Stats, we get something if somebody comes in  
 14 and says that we need this now. How quickly -  
 15 CHAYTOR, Q.C.:  
 16 Q. So, urgent -  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes, how quickly we can move it through the  
 19 process and then record retentions. All our  
 20 records are maintained, so that we can  
 21 certainly go back to them.  
 22 CHAYTOR, Q.C.:  
 23 Q. And are they maintained electronically or hard  
 24 copy?  
 25 MS. WEGRYNOWSKI:

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1 A. Prior to Paradigm for our documents, for our  
 2 procedure manuals it was hard copy, but I  
 3 have, like, the hard copies on old antibodies  
 4 that go back a decade or whatever. They're  
 5 all maintained.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. Anything else?  
 8 MS. WEGRYNOWSKI:  
 9 A. I don't think so. Okay, equipment and  
 10 reagents. Okay, so, for example, if I could  
 11 speak to what we just done at Mount Sinai. We  
 12 have two autostainers and we've purchased  
 13 more. So, we're looking at some new  
 14 equipment. You can't just go and plug in the  
 15 equipment and say, we're ready to go. You  
 16 must ensure that the equipment is working and  
 17 it is reproducible and consistent and the  
 18 results are comparable to what you're  
 19 presently using. So, I think the next slide  
 20 may explain that. Okay.  
 21 So, when we're looking at new equipment,  
 22 we will do a market evaluation and that's what  
 23 we did when we purchased these new stainers.  
 24 There are certain criteria that will fit to  
 25 your institution, whether you want an open

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1 system, closed system or whatever it is that  
 2 your institution is looking for. You want to  
 3 look at who's got what out there. But more  
 4 importantly you must ensure that the  
 5 manufacturers performance claims must be  
 6 validated prior to use. People can tell you a  
 7 whole lot of stuff, it doesn't necessarily  
 8 work like that or may not work for you in your  
 9 settings. So, you have to ensure that.

10 THE COMMISSIONER:  
 11 Q. Tell me more about validating, that kind of  
 12 thing.

13 MS. WEGRYNOWSKI:  
 14 A. Would you like me to walk you through that?

15 THE COMMISSIONER:  
 16 Q. Yes, I'm curious actually.

17 MS. WEGRYNOWSKI:  
 18 A. Okay.

19 THE COMMISSIONER:  
 20 Q. I'm not sure in the end it means anything, but  
 21 -

22 MS. WEGRYNOWSKI:  
 23 A. Okay, all right. So, we just bought on a  
 24 couple of months ago, have all the slides and  
 25 the documentation for this. So, one of the

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1 first things we did was we took, this is for  
 2 ease of expense as well, we took a marker that  
 3 was relatively inexpensive on a tissue that I  
 4 could get lots of. So, I used CD31, it's an  
 5 endothelium marker. So, what we did is that  
 6 we set up two runs. Our machines hold 48  
 7 slides, so we had 48 slides set up for our  
 8 regular machine and 48 slides set up for the  
 9 next machine. Everything was handled the same  
 10 way. The tissues were cut the same time,  
 11 everything was the same. They were taken down  
 12 and pretreated until they got to the stainers,  
 13 the dilution. So, what we did, when we knew  
 14 how much of the reagents we required, we made  
 15 up double of everything so that we could  
 16 ensure that the dilutions were exactly the  
 17 same. So, we just loaded up the machines and  
 18 let them run. So, what you want to see at the  
 19 end was that the staining that was exhibited  
 20 from the machine that you're presently using  
 21 is showing up in the second machine. When it  
 22 passed that and it did, then I knew that I was  
 23 going to be using this particular piece of  
 24 equipment for my estrogen and progesterone and  
 25 my HER2/neu testing.

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1 So then what I needed to do is I went  
 2 through that process again, but using those  
 3 specific antibodies because we wanted to make  
 4 that I'm getting the stain--well, the real  
 5 reason was that I was using antibodies that  
 6 stained the three different cell sites. So, I  
 7 was staining the cell surface, the cell  
 8 cytoplasm and the nucleus. So then once that  
 9 was done and we were satisfied that that was  
 10 done, we brought that product--then we started  
 11 using that machine to process.

12 THE COMMISSIONER:  
 13 Q. Okay, thank you.

14 MS. WEGRYNOWSKI:  
 15 A. And then we have all our records, of course,  
 16 that we keep.

17 CHAYTOR, Q.C.:  
 18 Q. Okay. If you could continue on then please.

19 MS. WEGRYNOWSKI:  
 20 A. Okay. So, existing equipment, you must always  
 21 maintain your service records. It doesn't  
 22 matter what you product is, your autostainers,  
 23 your microscopes. There should always be a  
 24 routine PM done. Service problems and  
 25 documentation. If for whatever reason--I

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1 could give you an example that we've had on  
 2 our autostainer. It'll tell us that there's  
 3 not enough antibody or whatever in there and  
 4 it's partially picking up. But you will  
 5 visually see that there's enough product in  
 6 there. You have to have the wherewithal to  
 7 stop the process and call in the manufacturer  
 8 and say, we've got a problem; this is what the  
 9 problem is; describe the problem to them and  
 10 expect that a technical person will show up to  
 11 make sure that that machinery is working  
 12 properly. You have the documentation that  
 13 you've made the call which corrective action  
 14 is followed by the documentation given to you  
 15 by the technical person from the company.

16 CHAYTOR, Q.C.:  
 17 Q. Ms. Wegrynowski, when you were in St. John's  
 18 was there any discussion or did you make any  
 19 inquiries of the people that you met with as  
 20 to what they did in bringing in the new  
 21 Ventana machines?

22 MS. WEGRYNOWSKI:  
 23 A. I don't -

24 CHAYTOR, Q.C.:  
 25 Q. Did you ask whether or not there had been any

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1 comparisons done?  
 2 MS. WEGRYNOWSKI:  
 3 A. No, and I didn't find any document, like there  
 4 was not binders there for me review. So, -  
 5 CHAYTOR, Q.C.:  
 6 Q. So, there was no documentation -  
 7 MS. WEGRYNOWSKI:  
 8 A. No.  
 9 CHAYTOR, Q.C.:  
 10 Q. - which would have give you the answers.  
 11 MS. WEGRYNOWSKI:  
 12 A. No, and to be fair, I was only there for three  
 13 days. So, if you can understand, the first  
 14 day, I was meeting people. The second day I  
 15 was doing my lectures and trying to look  
 16 through the laboratory and try to glean as  
 17 much information as I could. And on the third  
 18 day, it was a shortened day, I needed to get  
 19 to the airport and I was also meeting with the  
 20 VP. So, you know, I did the best I could with  
 21 what I had.  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, absolutely. Now, in terms then of the  
 24 existing equipment and service records,  
 25 maintenance records, were you able to observe

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1 any documentation regarding that?  
 2 MS. WEGRYNOWSKI:  
 3 A. No. They told me that they were cleaning the  
 4 machines and so I suggested then maybe they'd  
 5 like to start printing that up on a daily  
 6 basis.  
 7 CHAYTOR, Q.C.:  
 8 Q. So, was it that you just didn't have time to  
 9 review it or it didn't exist?  
 10 MS. WEGRYNOWSKI:  
 11 A. I'd say both.  
 12 CHAYTOR, Q.C.:  
 13 Q. Do you know whether or not they had any  
 14 records, service records and maintenance  
 15 records?  
 16 MS. WEGRYNOWSKI:  
 17 A. I didn't see them.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. And did you ask to see it?  
 20 MS. WEGRYNOWSKI:  
 21 A. I don't recall.  
 22 CHAYTOR, Q.C.:  
 23 Q. You can continue on please.  
 24 MS. WEGRYNOWSKI:  
 25 A. Okay. So, the service records though, I mean,

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1 we're talking for absolutely every single  
 2 piece of equipment. I mean, we know there  
 3 wasn't any for the pipettes. So, I mean, we  
 4 could -  
 5 CHAYTOR, Q.C.:  
 6 Q. I'm sorry, you know that -  
 7 MS. WEGRYNOWSKI:  
 8 A. I know there wasn't any for the pipettes  
 9 because I asked if they had ever been  
 10 calibrated. So, if we want to answer the  
 11 service one for the pipettes, we could say  
 12 definitely no to that one.  
 13 When we're talking about maintenance  
 14 records, we talking about replacement of  
 15 scheduled parts, pH standardization and that  
 16 was definitely not being done.  
 17 CHAYTOR, Q.C.:  
 18 Q. So, the pH standardization was not being done?  
 19 MS. WEGRYNOWSKI:  
 20 A. No.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. So, there wouldn't be, I take it, any  
 23 record of it if it's not being done.  
 24 MS. WEGRYNOWSKI:  
 25 A. That is correct.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. And the pipettes again, you said had  
 3 never been calibrated?  
 4 MS. WEGRYNOWSKI:  
 5 A. Not to my knowledge.  
 6 CHAYTOR, Q.C.:  
 7 Q. And you asked that specifically?  
 8 MS. WEGRYNOWSKI:  
 9 A. I certainly did.  
 10 CHAYTOR, Q.C.:  
 11 Q. And so we won't expect to see any  
 12 documentation if it's not being done.  
 13 MS. WEGRYNOWSKI:  
 14 A. No.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay.  
 17 MS. WEGRYNOWSKI:  
 18 A. And again, your scales as well.  
 19 CHAYTOR, Q.C.:  
 20 Q. And what's the importance of the pH  
 21 standardization? What's the importance of  
 22 that?  
 23 MS. WEGRYNOWSKI:  
 24 A. Okay. They were using--Eastern Health uses  
 25 the Ventana system, it's a closed system. So,

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1 they purchase all their products from Ventana.  
 2 And even on the literature that comes with the  
 3 product, they will tell you themselves to pH  
 4 it. Regardless if that information is there  
 5 or not, you should know that you have to  
 6 assure that the pH is as written by the  
 7 manufacturer. So that you can ensure that  
 8 you're getting a final end product. And one  
 9 of the issues that I bring this up for was  
 10 because of the demographics of this Island, I  
 11 don't imagine you have the same store houses  
 12 that I would have in Toronto. So, certain  
 13 pieces or certain reagents are not going to do  
 14 well if left to the elements, so you have to  
 15 ensure that there's no freezing and you have  
 16 different climate than I do, so you want to  
 17 ensure that that is all in place and that that  
 18 pH is as expecting.  
 19 CHAYTOR, Q.C.:  
 20 Q. And what can be the effect if that's not done  
 21 to -  
 22 MS. WEGRYNOWSKI:  
 23 A. Your staining would be completely off. You  
 24 could have incorrect staining.  
 25 CHAYTOR, Q.C.:

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1 Q. And could you have no staining?  
 2 MS. WEGRYNOWSKI:  
 3 A. I couldn't speak directly to that, but your  
 4 staining procedure would be off because you're  
 5 not following your standard operating  
 6 procedure. Because you're not following your  
 7 standard operating procedure, then the  
 8 consistency between the work that you were  
 9 doing yesterday would not be the same as that  
 10 of today.  
 11 CHAYTOR, Q.C.:  
 12 Q. And it take it that could run the full gambit?  
 13 MS. WEGRYNOWSKI:  
 14 A. Absolutely. And that was as well again is  
 15 with your formalin because you find, formalin  
 16 is bought in great big carboys and it can  
 17 start dissipating up to formic acid.  
 18 CHAYTOR, Q.C.:  
 19 Q. Sorry, if you'd like to continue on?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes, okay. Temperature dependant, you must  
 22 daily check the temperature on day of use of  
 23 any product that you're using. It is not  
 24 acceptable to use the digital read outs on  
 25 equipment, they have been known--well they can

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1 fail and -  
 2 CHAYTOR, Q.C.:  
 3 Q. Is that what was happening here in St. John's?  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes, yes. And that one needs to use internal  
 6 thermometers that must be NIST certified and I  
 7 spoke to that, that is a standardized  
 8 thermometer. Even those standardized  
 9 thermometers have due dates on them, so  
 10 they're only good for so long as well.  
 11 Monitoring devices with alarms, we have, at  
 12 Mount Sinai, I can only speak to Mount Sinai,  
 13 all my fridges and freezers are on a resystem  
 14 so that if there's any change in the  
 15 temperature that we can get in there and  
 16 either we have to relocate them or make sure  
 17 that the manufacturer is aware so that we can  
 18 get those serviced, but as I stated, yours was  
 19 on an alarm here.  
 20 CHAYTOR, Q.C.:  
 21 Q. Yes, the fridge that you observed here was on  
 22 an alarm -  
 23 MS. WEGRYNOWSKI:  
 24 A. Absolutely, because you must maintain those  
 25 temperatures, they must be stringent.

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1 CHAYTOR, Q.C.:  
 2 Q. Sorry, go ahead.  
 3 MS. WEGRYNOWSKI:  
 4 A. Okay, you want to use up-to-date instructions.  
 5 Again, they must be on the workbench and they  
 6 must be approved, so standard operating  
 7 procedures, instructions, whatever term you  
 8 would like to use.  
 9 CHAYTOR, Q.C.:  
 10 Q. So that's the same thing, instructions are  
 11 your standard operating procedures?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yeah, I mean, even if you have equipment, I  
 14 mean, your equipment comes with instructions,  
 15 you must be using it the correct way as well,  
 16 correct, so you would have all your manuals  
 17 for that as well.  
 18 CHAYTOR, Q.C.:  
 19 Q. Thank you, continue on.  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay, so I think I've spoken a little bit  
 22 about this, so when we're talking about  
 23 equipment and reagents, you want to ensure  
 24 that your storage requirements are maintained.  
 25 Manufacturers will tell you on their data

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1 sheets what the storage requirements are, so  
 2 it's not unusual for them to say 48 degrees  
 3 celsius and then the list would just go into  
 4 your refrigerator or they'll say freeze  
 5 aliquots or whatever, and then we have like  
 6 the freezers for that. They'll tell you  
 7 whether they have to be at room temperature.  
 8 It's all on your data sheets what you need to  
 9 do with it and it's your job to ensure that  
 10 that occurs. Inspection and I think we've  
 11 highlighted this a little bit. We have the  
 12 ability to accept and reject different kits  
 13 that come in if they don't perform as expected  
 14 and it does occur. You can bring something in  
 15 and for whatever reason, that lot does not  
 16 work, we've had it happen with our slides,  
 17 we've had slides come in and we used a  
 18 particular kind of slide so that the section  
 19 doesn't come off the slide and they have not  
 20 done what they're supposed to do and so it is  
 21 my job to stop the process and say, we call  
 22 the manufacturer, we look for all the lot, we  
 23 pull the lot, it doesn't go forward and they  
 24 need to come and explain to us what has  
 25 occurred and we do do this and it is

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1 documented.  
 2 CHAYTOR, Q.C.:  
 3 Q. And that's part of your job of  
 4 troubleshooting, as you say?  
 5 MS. WEGRYNOWSKI:  
 6 A. That's part of my job, yes, it is. We must  
 7 always verify performance prior to use.  
 8 Again, whether it's a pH or a result  
 9 comparison, you have to ensure that  
 10 reproducibility is there on a day-to-day  
 11 basis.  
 12 CHAYTOR, Q.C.:  
 13 Q. And in this situation what was happening in  
 14 St. John's if they were running, they ran out  
 15 of a reagent and a new batch was brought in,  
 16 what was their procedure?  
 17 MS. WEGRYNOWSKI:  
 18 A. My understanding was they took another  
 19 (phonetic) fridge and used it.  
 20 CHAYTOR, Q.C.:  
 21 Q. And the prior slide where you were talking  
 22 about the importance of the daily check on the  
 23 temperatures, what's the possible effect if  
 24 your temperature is off?  
 25 MS. WEGRYNOWSKI:

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1 A. Heat lability of the protein so that the  
 2 protein would break down so that you would not  
 3 be able to find it, so, it would be gone.  
 4 CHAYTOR, Q.C.:  
 5 Q. And it wouldn't stain.  
 6 MS. WEGRYNOWSKI:  
 7 A. It wouldn't stain. But again, as I showed you  
 8 in that previous lecture, just that slide  
 9 storage at room temperature could do the same  
 10 thing as well.  
 11 CHAYTOR, Q.C.:  
 12 Q. Could do the same -  
 13 MS. WEGRYNOWSKI:  
 14 A. Absolutely.  
 15 CHAYTOR, Q.C.:  
 16 Q. Sorry, I don't know if there's anything else  
 17 on this slide that you wanted to point out to  
 18 us.  
 19 MS. WEGRYNOWSKI:  
 20 A. I don't think so. Okay, so then we start  
 21 talking about our reagents and so this is  
 22 where a lot of the binders come from, all the  
 23 documentation that goes through bringing the  
 24 product into the marketplace or into the  
 25 laboratory using it. Inventory control is a

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1 very huge component of immunohistochemistry.  
 2 Every single thing that comes into the lab is  
 3 logged in, so all the lots are maintained.  
 4 Even with our antibody data sheets, so for a  
 5 particular antibody, even with that, I will  
 6 have a historical data sheet that sits on top  
 7 if it, so I can tell you how quickly I went  
 8 through it, what the expiry dates were, if  
 9 there was a change in how that produce was  
 10 used. It's just a--I use it like historical  
 11 data just in case there's changes in the--in  
 12 how it's used or how it's performing, so we  
 13 keep all of that. We have, as I say, we have  
 14 our lot numbers, our expiry dates, our date in  
 15 service and all the conditions that go with  
 16 it. We have a workplace--we don't--I don't  
 17 keep that information in the  
 18 immunohistochemistry laboratory, we keep that  
 19 information in the pathology laboratory which  
 20 is right across the hall from me, and in there  
 21 all our manufacturer's safety data sheets are  
 22 kept. We use very few chemicals in the  
 23 immunohistochemistry laboratory, so -  
 24 CHAYTOR, Q.C.:  
 25 Q. And that's for Workplace Health Management

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1 Informational Systems.  
 2 MS. WEGRYNOWSKI:  
 3 A. Yeah.  
 4 CHAYTOR, Q.C.:  
 5 Q. The record keeping, the idea of keeping track  
 6 of the lot number expiry dates, keeping track  
 7 of reagents that in fact had expired, was that  
 8 happening here in St. John's?  
 9 MS. WEGRYNOWSKI:  
 10 A. On my first visit? No.  
 11 CHAYTOR, Q.C.:  
 12 Q. And how were the antibodies stored?  
 13 MS. WEGRYNOWSKI:  
 14 A. Well the data sheets were kept in a box in the  
 15 cupboard and the antibodies were simply put in  
 16 the fridge.  
 17 CHAYTOR, Q.C.:  
 18 Q. And what would you have expected to see?  
 19 MS. WEGRYNOWSKI:  
 20 A. At the very least I would have expected the  
 21 antibody data sheets to be at the very least  
 22 in alphabetical order. I would have expected  
 23 them, to each of them have their own  
 24 instructions for use. What was the lot?  
 25 What was the expiry date? What was the

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1 dilution? What was the pre-treatment?  
 2 Everything, I would have expected to see  
 3 there, so that it would have been a very easy  
 4 reference for all the technologists to use. I  
 5 thought that was critical, especially because  
 6 they were rotating, and one of the issues then  
 7 is when you have people that are not in a  
 8 place every single day, communication, in my  
 9 opinion, then becomes even more important, as  
 10 does transparency.  
 11 CHAYTOR, Q.C.:  
 12 Q. And the antibodies being stored in the fridge,  
 13 as you say, what would you have expected to  
 14 see there?  
 15 MS. WEGRYNOWSKI:  
 16 A. Nice orderly fashion, alphabetical.  
 17 CHAYTOR, Q.C.:  
 18 Q. So I take it there were quite a number of  
 19 these antibodies in the fridge?  
 20 MS. WEGRYNOWSKI:  
 21 A. They were all stored correctly, yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, they were stored in the fridge where they  
 24 should be?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes, they were.  
 2 CHAYTOR, Q.C.:  
 3 Q. But it was just that in terms of being able to  
 4 access them -  
 5 MS. WEGRYNOWSKI:  
 6 A. Ease of use.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, so that was the issue, and were there  
 9 any issues though in terms of, I guess, what's  
 10 the consequence or possible consequence if an  
 11 antibody is expired?  
 12 MS. WEGRYNOWSKI:  
 13 A. You have to guard against expiration dates in  
 14 ensuring that the efficacy of the antibody is  
 15 still in use. Now they were using the Ventana  
 16 system. The Ventana system, to the best of my  
 17 knowledge, will not allow you to use a product  
 18 post expiry. So it's a done deal with them,  
 19 the bar coding. The issue, however, becomes  
 20 if you are loading your own cylinders--I'm not  
 21 familiar with the term that they use--with a  
 22 concentrated antibody that you yourself  
 23 dilute, because you can--I'm not sure, I don't  
 24 know enough about that equipment. I don't  
 25 want to say something out of turn, but if I

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1 could, in layman's terms, say override the  
 2 system and apply that antibody onto it, if  
 3 that antibody was expired and the efficacy had  
 4 not been ensured, then you would not know  
 5 that.  
 6 CHAYTOR, Q.C.:  
 7 Q. Now we understand that from 1997 to April  
 8 2004, they were using the DAKO system.  
 9 MS. WEGRYNOWSKI:  
 10 A. Okay.  
 11 CHAYTOR, Q.C.:  
 12 Q. And does the DAKO system also not allow you to  
 13 use an expired antibody?  
 14 MS. WEGRYNOWSKI:  
 15 A. The DAKO system is a completely open system so  
 16 that it's the technologist who creates  
 17 absolutely everything on the system. So you  
 18 would employ your own detection system, your  
 19 own primary antibodies, whatever dilutions  
 20 that you saw fit. Yes, you could go ahead and  
 21 use an expired antibody.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay, and the system wouldn't alarm you to  
 24 that?  
 25 MS. WEGRYNOWSKI:



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1 A. It's not--no.  
 2 CHAYTOR, Q.C.:  
 3 Q. Or alert you to that?  
 4 MS. WEGRYNOWSKI:  
 5 A. No, that's not it's -  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. Sorry, if you could continue on then  
 8 with this slide. Water, I think you're up to  
 9 the bullet about water.  
 10 MS. WEGRYNOWSKI:  
 11 A. Okay, and I believe I have spoken about water  
 12 earlier this morning, that you--it doesn't--I  
 13 can't give you the numbers off the top of my  
 14 head, but there are certain different kinds of  
 15 water or the criteria that is used to select  
 16 the appropriate water is very, very important.  
 17 Okay, so then we spoke a little bit about  
 18 quality assurance, and I've broken it down  
 19 into three areas. We have internal quality  
 20 control, interlaboratory comparatives, and  
 21 external quality assessment. Okay. So under  
 22 internal quality control, I have five bullets.  
 23 You must ensure that there's a policy and  
 24 protocol established.  
 25 CHAYTOR, Q.C.:

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1 Q. And I take it based on what we've already  
 2 discussed today, that wasn't--that hadn't  
 3 happened?  
 4 MS. WEGRYNOWSKI:  
 5 A. No, it had not.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay.  
 8 MS. WEGRYNOWSKI:  
 9 A. You must assess with an each user defined run.  
 10 CHAYTOR, Q.C.:  
 11 Q. What does that mean?  
 12 MS. WEGRYNOWSKI:  
 13 A. Well, it's going to mean something different  
 14 for Eastern Health than what it does for me at  
 15 Mount Sinai, and I've spoken of this as well.  
 16 Because we run a control with a batch, we want  
 17 to ensure that everything run in that batch,  
 18 so let's say we have five of antibody A and  
 19 four of antibody B, we would only have one  
 20 control for antibody A and antibody B,  
 21 although every single patient would have their  
 22 own negative control. So we want to ensure  
 23 that within that run, everything is working as  
 24 compliant. In the Ventana system, it would be  
 25 the same way, and you would be checking that

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1 within that run, your controls were always  
 2 working, whether they be positive or negative.  
 3 CHAYTOR, Q.C.:  
 4 Q. So if you run two different runs, you're going  
 5 to ensure that your results are reproducible?  
 6 MS. WEGRYNOWSKI:  
 7 A. Absolutely.  
 8 CHAYTOR, Q.C.:  
 9 Q. By doing it the same way each and every time?  
 10 MS. WEGRYNOWSKI:  
 11 A. Each and every time, absolutely. The  
 12 stringencies that are required to do  
 13 reproducible immunohistochemistry are  
 14 paramount. Okay. Controls must be treated in  
 15 the same manner as the patient sample. There  
 16 was--in the notes that Barry had--no, when  
 17 Barry had spoken to me the first day, I  
 18 believe I made an exert in my note about the  
 19 tissue express, the Sakura express.  
 20 CHAYTOR, Q.C.:  
 21 Q. Yes.  
 22 MS. WEGRYNOWSKI:  
 23 A. That particular piece of equipment does not--  
 24 the fundamentals of that equipment are not the  
 25 same as what the historical processing are.

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1 It's based on alcohol fixatives.  
 2 CHAYTOR, Q.C.:  
 3 Q. So what you're saying is that the control  
 4 tissues that they would have had in their  
 5 system would have been processed a different  
 6 way?  
 7 MS. WEGRYNOWSKI:  
 8 A. Yes. If you are going to use a completely  
 9 different system, then you must ensure that  
 10 the controls that you are using are the same  
 11 as what your tests are. You must compare  
 12 apples to apples and oranges to oranges,  
 13 right.  
 14 CHAYTOR, Q.C.:  
 15 Q. And so the Sakura Express, how is that  
 16 different?  
 17 MS. WEGRYNOWSKI:  
 18 A. It's based on alcohol based fixatives, as  
 19 opposed to formalin.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and so -  
 22 MS. WEGRYNOWSKI:  
 23 A. I don't know whether they were using it or  
 24 not. It was something that was stated to me,  
 25 so I put it in my report and it was just to

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1 guard against that. It's not that they were  
 2 doing it.  
 3 CHAYTOR, Q.C.:  
 4 Q. So if they were to in the future use this  
 5 Sakura Express, they would have to build up a  
 6 control bank or a bank of controls based on  
 7 the alcohol-based system.  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. The Sakura Express, as opposed to what they  
 12 had used, the formalin based controls which  
 13 they would have in their bank?  
 14 MS. WEGRYNOWSKI:  
 15 A. Yes, so that you can ensure that the testing  
 16 that you're doing is accurate for the way the  
 17 tissue was handled.  
 18 CHAYTOR, Q.C.:  
 19 Q. So then your patient tissue, if it's tested on  
 20 the Sakura Express, is treated in the same  
 21 manner as what the control slide is?  
 22 MS. WEGRYNOWSKI:  
 23 A. That is correct.  
 24 CHAYTOR, Q.C.:  
 25 Q. Yes, okay.

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1 MS. WEGRYNOWSKI:  
 2 A. And again, this is exactly what this speaks  
 3 to. New reagent lots are checked prior to use  
 4 against prior reagent lots for reference  
 5 material, and it's the same thing, just  
 6 reiterated yet again that to get that  
 7 consistency, you must ensure that every single  
 8 piece of the puzzle is done in the exact same  
 9 way and that each piece is behaving or  
 10 reproducible.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, thank you.  
 13 MS. WEGRYNOWSKI:  
 14 A. Okay.  
 15 CHAYTOR, Q.C.:  
 16 Q. And then interlaboratory comparisons.  
 17 MS. WEGRYNOWSKI:  
 18 A. I think I went too far again. I'm sorry,  
 19 Sandy.  
 20 CHAYTOR, Q.C.:  
 21 Q. That's all right.  
 22 MS. WEGRYNOWSKI:  
 23 A. Okay. It's optimal that an evaluation of  
 24 performance and/or laboratory competence in  
 25 the testing of defined samples by two or more

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1 laboratories. Interlaboratory comparison can  
 2 also be done within your own site with case  
 3 and control review and histological and  
 4 cytological correlation, and this is much more  
 5 focused at what the pathologist would do than  
 6 what a technologist would do. But it's a way  
 7 for the pathologist to ensure that the  
 8 technical accuracy of their work is right.  
 9 CHAYTOR, Q.C.:  
 10 Q. And can you give us an example of how does  
 11 Mount Sinai do interlaboratory comparison?  
 12 MS. WEGRYNOWSKI:  
 13 A. Okay. Well, we belong to QA testing with OLA,  
 14 so our work is--we send our work to them and  
 15 then our work is compared to those of our  
 16 peers.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, so external quality assessment then can  
 19 be something different than -  
 20 MS. WEGRYNOWSKI:  
 21 A. Than internal. If you have--okay, so if you  
 22 have more than one laboratory in your area or  
 23 whatever, you could certainly, if you don't  
 24 want to go into a big external, the two  
 25 laboratories can even just ensure that both

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1 sides are producing--okay. If you are  
 2 producing blocks at St. Clare's and you are  
 3 producing blocks at Eastern Health.  
 4 CHAYTOR, Q.C.:  
 5 Q. At the Health Sciences.  
 6 MS. WEGRYNOWSKI:  
 7 A. Yes, yes, I'm sorry, at Health Sciences, and  
 8 I'm just talking something very basic as HNE  
 9 section. You want to ensure that the quality  
 10 of the staining is the same regardless of  
 11 where the blocks are taken from. So you can  
 12 take it out of the--take it out of IHC and  
 13 just take it down to the very rudimentary  
 14 values. It doesn't matter where the work is  
 15 done. This is the same organization. You  
 16 want to ensure that both sites are providing  
 17 you with the same quality work.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MS. WEGRYNOWSKI:  
 21 A. Does that make sense?  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, and was that the -  
 24 THE COMMISSIONER:  
 25 Q. Really no different than treating the other

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1 site as a separate institution?  
 2 MS. WEGRYNOWSKI:  
 3 A. Absolutely, and that's example of two or more  
 4 laboratories because you're both doing the  
 5 same work and you want to ensure the  
 6 consistency and reproducibility both sites.  
 7 CHAYTOR, Q.C.:  
 8 Q. And with standard operating procedures, you  
 9 would ensure that that was taking place? If  
 10 they were implemented and being followed.  
 11 MS. WEGRYNOWSKI:  
 12 A. Absolutely. Do you see how they all start--  
 13 it's very interwoven. Okay, so then again,  
 14 you have your case control review and this is,  
 15 you know, the pathologists. I have no idea. I  
 16 didn't ask for any documentation on this, but  
 17 an example of this would be you have your  
 18 frozen sections, how do they compare with what  
 19 your paraffin sections look like? You know,  
 20 if you're calling it malignant at frozen, what  
 21 are we seeing post, and what are we seeing--  
 22 what's our correlation between our histology  
 23 and our fine needle aspirates of cytology?  
 24 Those are just examples.  
 25 CHAYTOR, Q.C.:

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1 Q. And in terms of your internal quality control  
 2 within Mount Sinai, I take it you keep records  
 3 of that?  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes, and our records are kept for years.  
 6 CHAYTOR, Q.C.:  
 7 Q. And who--I realize within the laboratory that  
 8 you are the senior person there, but who  
 9 ensures that you're doing your job, from a  
 10 quality assurance point of view?  
 11 MS. WEGRYNOWSKI:  
 12 A. That's where we belong to external quality  
 13 assurance programs.  
 14 CHAYTOR, Q.C.:  
 15 Q. That's the external. Is there anyone else  
 16 within Mount Sinai, in terms of the quality  
 17 department, is there anyone else who ensures  
 18 that "well, Ms. Wegrynowski has her SOPs. The  
 19 SOPs are in place."  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. That they are doing the maintenance checks.  
 24 How does that happen at Mount Sinai?  
 25 MS. WEGRYNOWSKI:

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1 A. Well, we have a quality manager by the name of  
 2 Gaman Modi. We belong to CAP. We belong to  
 3 OLA. They send us their checklists. So we  
 4 must ensure that what we do is that we have  
 5 everything that they're stating on the  
 6 checklist. So we do this again in this  
 7 document control and we will put it in there  
 8 and then hyperlink it to our manual, so we can  
 9 answer our questions that way. But prior to  
 10 having that, it would be the same way. We  
 11 would still get your checklist, no different  
 12 than anything I came to Eastern Health with,  
 13 and just start looking through it. It's a  
 14 really great just basic building block, what  
 15 is here, and what you need to do your work.  
 16 CHAYTOR, Q.C.:  
 17 Q. Yes, okay, and so I see how when you send your  
 18 product out and it comes back and you do your  
 19 comparison to make sure that it's satisfactory  
 20 and I'm just thinking, what checks and  
 21 balances are in the system though to make sure  
 22 that when it came back and it wasn't okay,  
 23 that then the follow up takes place?  
 24 MS. WEGRYNOWSKI:  
 25 A. Can you reiterate the last comment?

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1 CHAYTOR, Q.C.:  
 2 Q. Yes, I'm just thinking, within Mount Sinai  
 3 itself, what roles does the quality department  
 4 play to ensure that, yes, the external quality  
 5 assurance is taking place. We have the  
 6 programs we're registered with and that that  
 7 is taking place, that the product coming back  
 8 is fine and I understand that you personally  
 9 take responsibility for that, but who makes  
 10 sure that it's done?  
 11 MS. WEGRYNOWSKI:  
 12 A. Okay.  
 13 CHAYTOR, Q.C.:  
 14 Q. What if there wasn't a Trish? Who makes sure  
 15 that it happens?  
 16 MS. WEGRYNOWSKI:  
 17 A. Okay. What ends up happening is the  
 18 documentation goes to Gaman Modi. He signs  
 19 off on it and then sends it to me.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. So it goes to the quality -  
 22 MS. WEGRYNOWSKI:  
 23 A. So there's somebody above me.  
 24 CHAYTOR, Q.C.:  
 25 Q. - someone above you.

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1 MS. WEGRYNOWSKI:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. It goes to your quality department. They have  
 5 to sign off?  
 6 MS. WEGRYNOWSKI:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. All right, thank you.  
 10 MS. WEGRYNOWSKI:  
 11 A. You're welcome.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay. I'm sorry, continue on then. I think  
 14 we're on to the next slide then.  
 15 MS. WEGRYNOWSKI:  
 16 A. Okay. So this is when we discuss the external  
 17 quality assessment. So we're talking about  
 18 the proficiency testing and we spoke about the  
 19 interlaboratory testing. So again, if there's  
 20 no formal EQA program, they need some  
 21 mechanism to compare results with other sites  
 22 and I mean, I just went through the very loose  
 23 one of just doing the HNES, if you have two  
 24 sites and the same thing. It's still the same  
 25 thing. It's between laboratories. A peer

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1 review assessment, you can certainly sent it  
 2 to your peers and it doesn't have to be the  
 3 most rigid of it. You know, this is what we  
 4 see. This is what you see, and you want to  
 5 ensure that. But what you want to do is that  
 6 you want to ensure that the quality of the  
 7 lab's results, to determine accuracy and  
 8 reliability of the procedure. That's the  
 9 whole goal of this.  
 10 CHAYTOR, Q.C.:  
 11 Q. And at the time you were here in September  
 12 2005, your first visit, Eastern Health was not  
 13 enrolled in any external quality program?  
 14 MS. WEGRYNOWSKI:  
 15 A. No, not at that point in time, no.  
 16 CHAYTOR, Q.C.:  
 17 Q. And do you know whether or not there was  
 18 anything happened then through interlaboratory  
 19 to compare the results?  
 20 MS. WEGRYNOWSKI:  
 21 A. Not that I can recall.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. Is there anything else on this  
 24 particular issue?  
 25 MS. WEGRYNOWSKI:

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1 A. I don't think so.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay.  
 4 MS. WEGRYNOWSKI:  
 5 A. Okay, so then I walked them through the  
 6 validation process. Okay, so this is the  
 7 definition of validation. Validation refers  
 8 to establishing documented evidence that a  
 9 process or system, when operated within  
 10 established parameters, can perform  
 11 effectively and reproducibly to produce pre-  
 12 determined specifications and quality  
 13 attributes. So if you keep your parameters  
 14 the same every single time and you perform  
 15 effectively, you are going to get that pre-  
 16 determined end result, and that's what you're  
 17 looking for.  
 18 CHAYTOR, Q.C.:  
 19 Q. And why is that important?  
 20 MS. WEGRYNOWSKI:  
 21 A. Consistency and reproducibility.  
 22 CHAYTOR, Q.C.:  
 23 Q. And in terms of the issue that you mentioned  
 24 earlier, I believe you said about  
 25 manufacturers can change the protein

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1 concentration?  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. What do you do then? If you've noted that and  
 6 the protein concentration has been changed,  
 7 what do you do to guard against that?  
 8 MS. WEGRYNOWSKI:  
 9 A. Okay. So if I was to receive a new lot of  
 10 antibody and the protein concentration was,  
 11 just for simplicity, half as much as what I  
 12 originally had, I would never start the  
 13 dilution as where I was before. I would cut  
 14 that in half as well, probably go down below a  
 15 half and then a little bit above. So it's  
 16 like a sliding scale. You need to have that  
 17 information so that you can produce that best  
 18 end product.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and you still dilute your own  
 21 antibodies?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes, we do.  
 24 CHAYTOR, Q.C.:  
 25 Q. And I believe that procedure changed in St.

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1 John's. That's not--that they use the  
 2 manufacturers antibodies.  
 3 MS. WEGRYNOWSKI:  
 4 A. When I was here, they were still using some  
 5 concentrated antibodies from DAKO. I don't  
 6 know what they're using now, but they  
 7 certainly had switched a fair amount over to  
 8 the Ventana, which were all pre-dilutes.  
 9 CHAYTOR, Q.C.:  
 10 Q. And do you know what they were using for  
 11 ER/PR?  
 12 MS. WEGRYNOWSKI:  
 13 A. You know, I don't want to hazard a guess.  
 14 CHAYTOR, Q.C.:  
 15 Q. That's fine.  
 16 MS. WEGRYNOWSKI:  
 17 A. I thought they were the DAKOs, but I don't  
 18 want to hazard a guess.  
 19 CHAYTOR, Q.C.:  
 20 Q. And even if it is though a pre-diluted  
 21 antibody, do you still have to do these checks  
 22 and balances?  
 23 MS. WEGRYNOWSKI:  
 24 A. Absolutely.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MS. WEGRYNOWSKI:  
 3 A. Absolutely. If an antibody is only supposed  
 4 to stain the nucleus and you're getting test  
 5 results back that more than nucleus, so you're  
 6 getting the cytoplasm and the nucleus is  
 7 coming up, then I suggest perhaps you may want  
 8 to go back and look at that protocol, because  
 9 if the antibody only resides in the nucleus,  
 10 then how come you're getting this cytoplasmic  
 11 staining? So the validation process needs to  
 12 be looked at, whether or not it's incubations  
 13 that are correct, pre-treatments that are too  
 14 strong. There's something--that result is  
 15 telling you something and you need to guard  
 16 against it.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. Thank you.  
 19 MS. WEGRYNOWSKI:  
 20 A. You're welcome.  
 21 CHAYTOR, Q.C.:  
 22 Q. And if you can continue on then.  
 23 MS. WEGRYNOWSKI:  
 24 A. Okay. So what are we going to validate?  
 25 Well, antibodies, detection systems,

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1 chromogens, pre-treatments, buffers ancillary  
 2 products and I'm sure, as you can tell, the  
 3 lectures how they all start melding together  
 4 and it's to drive home the same point of the  
 5 importance of the same things and how they all  
 6 inter-react and interrelate together. So I've  
 7 gone through this, I think.  
 8 CHAYTOR, Q.C.:  
 9 Q. Maybe just the buffers. We haven't spent much  
 10 time on that. Maybe you could explain what  
 11 that is and how you validate your buffers?  
 12 MS. WEGRYNOWSKI:  
 13 A. Okay. Well, there's a number of buffers that  
 14 we use at Mount Sinai. I can tell you that we  
 15 use two particular buffers for pre-treatments.  
 16 We use a citrate buffer pH6 and we use a Tris  
 17 pH9, that you need to know that part. But  
 18 what we need to guard against is that when we  
 19 make up these buffers that they're made up in  
 20 the exact same manner every single time. So  
 21 what we'll do is we'll take them and then  
 22 we'll pH them and send them through to  
 23 process. The same thing comes true with our  
 24 washing buffers as well. Everything has to be  
 25 pHed.

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1 At Eastern Health, they're receiving in  
 2 buffers and they too need to be pHed. Whether  
 3 it's for washing, diluting, it doesn't matter.  
 4 They have to live up to what the  
 5 manufacturers.  
 6 CHAYTOR, Q.C.:  
 7 Q. And was that happening?  
 8 MS. WEGRYNOWSKI:  
 9 A. Not to my knowledge. There was no pH meter,  
 10 so no.  
 11 CHAYTOR, Q.C.:  
 12 Q. Sorry?  
 13 MS. WEGRYNOWSKI:  
 14 A. I did not find the pH meter in the  
 15 immunohistochemistry laboratory, so I'm going  
 16 to say no, and I found no documentation.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and what are you referring to by  
 19 ancillary products?  
 20 MS. WEGRYNOWSKI:  
 21 A. Oh, all your extras, your haematoxylin, your  
 22 cover slips, your glass slides, anything else  
 23 that you would use in the course of staining  
 24 that does not fit into these particular  
 25 categories.

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1 CHAYTOR, Q.C.:

2 Q. So it all has to be validated?

3 MS. WEGRYNOWSKI:

4 A. Yes.

5 CHAYTOR, Q.C.:

6 Q. Okay. Next slide then, please.

7 MS. WEGRYNOWSKI:

8 A. Okay. So this was a little bit--and when we

9 were talking about, Ms. Chaytor, when you

10 asked me about the antibodies and you were

11 asking me about the spec sheets and you asked

12 what had I expected.

13 CHAYTOR, Q.C.:

14 Q. Yes.

15 MS. WEGRYNOWSKI:

16 A. This is probably the list that I would have

17 expected, and it mirrors very much what we do

18 at Mount Sinai. You want to know the clone,

19 because there are so many different clones out

20 on the market for different antibodies and the

21 clone that is selected is always selected by

22 the pathologist. The storage conditions and

23 temperature, and I know we've spoken to that.

24 The supplier manufacturer information, we've

25 spoken to that, the lot number, the expiry

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1 date. The iso-type and concentration, we've

2 spoken to that. The antibody dilution, what I

3 would put on my sheet was I would put in all

4 my testing criteria and then what we came up

5 with at the end. Incubation temperature, pre-

6 treatments, detection system. The control

7 tissue that is used and then the signatures,

8 and signatures just mean who did the work, who

9 signed off on it, and where do we go from

10 here.

11 CHAYTOR, Q.C.:

12 Q. And you would expect all that to be

13 documented?

14 MS. WEGRYNOWSKI:

15 A. Well, I would expect at least some of this

16 information. I mean, this is just something

17 that I came up with at Mount Sinai. This is

18 certainly not an all-inclusive list. I mean,

19 you can even add things to it where you would

20 expect the staining to be seen. There is no

21 standardized form that needs to be filled.

22 CHAYTOR, Q.C.:

23 Q. But at least this?

24 MS. WEGRYNOWSKI:

25 A. Yes, some of this, at least.

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1 CHAYTOR, Q.C.:

2 Q. I'm sorry, then go ahead.

3 MS. WEGRYNOWSKI:

4 A. All right, can I got to the next screen?

5 CHAYTOR, Q.C.:

6 Q. Absolutely.

7 MS. WEGRYNOWSKI:

8 A. So this is just an example. It's taken from

9 my standard operating procedure that I brought

10 to Eastern Health. I didn't know--I mean, I

11 didn't know what they did have or did not in

12 place, but I always find that no matter where

13 you go, you can always learn something. So I

14 thought it would be an opportunity I could see

15 what you had and we could come up with a

16 better end product. So this is just from my

17 SOPs, which I left here at Eastern Health, and

18 so it's just everything that was on those

19 previous pages, just put up -

20 CHAYTOR, Q.C.:

21 Q. So you gave them your SOPs?

22 MS. WEGRYNOWSKI:

23 A. I gave them this particular template from my

24 SOPs, I did.

25 CHAYTOR, Q.C.:

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1 Q. Okay, and the purpose being so they could

2 develop their own?

3 MS. WEGRYNOWSKI:

4 A. Absolutely. I mean, if you had one, then

5 maybe there would be something here of value

6 that you would wish to add to yours, or in

7 this case, they didn't have one, so perhaps

8 you would like to use this as a starting point

9 to create your own.

10 Again, this is part of my antibody

11 record, when I spoke to you about some--just

12 historical data. So in my book, I have--

13 they're all sitting on top of each other, so I

14 know the dates when products received, who

15 manufactures it. Just--you probably may not

16 know, but in my world, manufacturers stop

17 carrying things because they don't sell. So

18 then you have to go looking around, if that

19 antibody is still required, you need to go

20 find different manufacturers and then what

21 ends up happening is you have to start the

22 validation process again. But it's that

23 information that would be kept in here in the

24 antibody record that you can see where it is,

25 when that antibody would change from one

1 manufacturer to the other.  
 2 The flip side of that is that the actual  
 3 documentation from that previous manufacturer  
 4 then goes into another binder which is called  
 5 the old expired antibody. It's not a very  
 6 fancy name, but it all stays there, and then  
 7 there's always a reason given why we've done  
 8 that. So it's a really great concise history.  
 9 We have our expiry dates, iso-types,  
 10 concentrations, dating service, dilution, pre-  
 11 treatment systems and MLTs and that's our  
 12 signature, of course, that goes on the far  
 13 right-hand corner.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, thank you.  
 16 MS. WEGRYNOWSKI:  
 17 A. You're welcome. And again, this was another  
 18 template from my SOP that I left here at  
 19 Eastern Health.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay.  
 22 MS. WEGRYNOWSKI:  
 23 A. So now we're moving into detection systems.  
 24 You must always inspect your products when  
 25 they come in. You want to make sure that if

1 Again, when you prepare things in-house,  
 2 it's a little bit different because you don't  
 3 have all the lot numbers and whatnot. I'll  
 4 give you an example. We prepare our own  
 5 Mayer's hematoxylin in-house. We've tried  
 6 different commercial ones, but we like ours  
 7 the best, so we make it. And so when we make  
 8 it up, we have to ensure that it is working  
 9 correctly, the same thing with our pepsin. So  
 10 we will always test a lot before we go live  
 11 with it and we'll sign off on that as well.  
 12 CHAYTOR, Q.C.:  
 13 Q. So why does Mount Sinai choose to do that, as  
 14 opposed to purchasing the pre-diluted? I hear  
 15 what you're saying, you like your own better,  
 16 but is there any other reason? Is there--do  
 17 you have more control over the process by  
 18 making your own?  
 19 MS. WEGRYNOWSKI:  
 20 A. I'm sorry, in what--to what are you speaking  
 21 to?  
 22 CHAYTOR, Q.C.:  
 23 Q. No, I'm sorry, I'm just thinking--I'm thinking  
 24 back to the conversation we had about the  
 25 antibodies.

1 they're supposed to come in on ice, they come  
 2 in on ice. I mean, HER2/neu, those detection  
 3 systems are thousands and thousands of dollars  
 4 and they have to be received on dry ice. If  
 5 they are not, we are not going to accept them  
 6 and we have no problems calling manufacturers  
 7 and telling them so. Again, there's  
 8 documentation, lot number, expiry dates. I  
 9 think I've said it enough. Then again, the  
 10 acceptance, once you test the validation, the  
 11 ability of someone in that laboratory to be  
 12 able to say "this isn't working, this old  
 13 batch, new batch comparison," and just stop it  
 14 before it goes into the actual service. It's  
 15 much easier to stop it than once it gets in.  
 16 It's insidious.  
 17 Okay, chromogens, again, it's the same  
 18 thing for everything. Whether or not you  
 19 purchase it or you make it up, you have to  
 20 follow these same guidelines. I don't think  
 21 there's any need for me to reiterate that.  
 22 Pre-treatments, it's the exact same thing  
 23 again, regardless of whether you're making it  
 24 or you're purchasing it. These are standards  
 25 that one must do.

1 MS. WEGRYNOWSKI:  
 2 A. Oh, antibodies.  
 3 CHAYTOR, Q.C.:  
 4 Q. And why is it that you choose to do your own?  
 5 MS. WEGRYNOWSKI:  
 6 A. Well, we have an open--we use an open system  
 7 at Mount Sinai. I would assume some of it's  
 8 historical. Some of it is cost analysis.  
 9 We're very--you can get a tremendous dilution  
 10 out of some different products. We have found  
 11 that different antibodies work with different  
 12 detection systems and different pre-  
 13 treatments, but that is what we have found at  
 14 our house. When you are using a closed  
 15 system, the manufacturer is selling you  
 16 products that are all supposed to work  
 17 together. It's a very different--it's just a  
 18 different way of doing work.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. So in terms of an advantage at the end  
 21 of the day, in terms of producing a higher end  
 22 product, do you feel you have any more control  
 23 over that by doing it your way?  
 24 MS. WEGRYNOWSKI:  
 25 A. I don't know if the word is control as of the

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1 amount or perhaps the amount of antibodies  
 2 that we would carry could be greater, because  
 3 if you're into a closed system, you are locked  
 4 into only what that manufacturer can produce  
 5 for you. So if I could, we don't purchase our  
 6 antibodies just from one source. We go to a  
 7 multitude of sources. So if we were to tie it  
 8 into one particular company, then we would not  
 9 be able to offer that product and we would  
 10 like to be able to do that.  
 11 CHAYTOR, Q.C.:  
 12 Q. So it gives you more flexibility?  
 13 MS. WEGRYNOWSKI:  
 14 A. Absolutely.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, thank you.  
 17 MS. WEGRYNOWSKI:  
 18 A. You're welcome.  
 19 CHAYTOR, Q.C.:  
 20 Q. And are we finished with this slide then?  
 21 MS. WEGRYNOWSKI:  
 22 A. I think so.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, and we can go to the next one.  
 25 MS. WEGRYNOWSKI:

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1 A. Buffers, again, it's--you're going to hear the  
 2 same thing. I feel like a record.  
 3 CHAYTOR, Q.C.:  
 4 Q. And we just discussed that.  
 5 MS. WEGRYNOWSKI:  
 6 A. Yeah, so I think we can go on from there.  
 7 CHAYTOR, Q.C.:  
 8 Q. Sorry.  
 9 MS. WEGRYNOWSKI:  
 10 A. Again, it's the same thing, whether they're  
 11 purchased or prepared in-house. Again, it's  
 12 the same thing again, all your ancillary  
 13 products, they all have to be maintained the  
 14 same way.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and if you'd like to go to the next  
 17 slide then. Okay, and we're about to then go  
 18 into the ER and PR evaluation, so perhaps this  
 19 would be a good point then for us to take the  
 20 lunch break, please.  
 21 THE COMMISSIONER:  
 22 Q. We'll adjourn to ten after two.  
 23 CHAYTOR, Q.C.:  
 24 Q. Thank you.  
 25 (LUNCH BREAK)

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1 THE COMMISSIONER:  
 2 Q. Please be seated. Ms. Chaytor.  
 3 CHAYTOR, Q.C.:  
 4 Q. Good afternoon, Commissioner. Good afternoon,  
 5 Ms. Wegrynowski. We're about to turn to the  
 6 ER and PR evaluation part of your presentation.  
 7 Before we do that, is there any peculiar about  
 8 ER/PR antibodies as opposed to other IHC  
 9 stains?  
 10 MS. WEGRYNOWSKI:  
 11 A. I wouldn't use the peculiar other than these  
 12 are one of the fewer antibodies that live in  
 13 the nucleus, the proteins are available in the  
 14 nucleus.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay. And what's the import of that?  
 17 MS. WEGRYNOWSKI:  
 18 A. The importance of it?  
 19 CHAYTOR, Q.C.:  
 20 Q. Yes, what's the importance of -  
 21 MS. WEGRYNOWSKI:  
 22 A. Fixation, localization, so that when you're  
 23 interpreting the slides and you're going  
 24 through the validation process you know  
 25 exactly where you're to find the epitope.

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1 That is only in the nucleus and nowhere else.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. And if we can then, if you wouldn't  
 4 mind, please, take us through the next slides.  
 5 MS. WEGRYNOWSKI:  
 6 A. Okay. I did a portion of these slides with  
 7 Dr. Frances O'Malley when I was getting ready  
 8 to come here because we knew that it was about  
 9 ER/PR. So, we thought we'd give a little bit  
 10 of an overview. So, when we talked about the  
 11 clinical validation, we wanted to ensure that  
 12 the test identified sub-sets of patients with  
 13 significantly different risks of recurrence to  
 14 survival. So, we had to ensure that the test  
 15 is sensitive, specific, reproducible and  
 16 interpreted in a uniform manner from lab to  
 17 lab.  
 18 CHAYTOR, Q.C.:  
 19 Q. Thank you.  
 20 MS. WEGRYNOWSKI:  
 21 A. On the technical portion, we must ensure that  
 22 the test is sensitive, specific, reproducible  
 23 and interpreted again in a uniform manner from  
 24 lab to lab. So, with ER validation we have a  
 25 technical validation. So, we have several



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1 antibodies against the estrogen. We have  
 2 several antibodies to ensure its specificity.  
 3 So, we tried out several and then this is how  
 4 they've come up with what they wanted to use.  
 5 It's reproducible. We've tried different IHC  
 6 methods and that's what we did during  
 7 validation. So that we made sure that the one  
 8 that we were using was what we needed to do.  
 9 And this is part of the pathologist portion  
 10 where arbitrary cutoffs and methods of scoring  
 11 have been determined. So, in IHC the signals  
 12 can be difficult to quantify and the reasons  
 13 are the results can be affected by tissue  
 14 handling; fixation; processing; the  
 15 specificity and sensitivity of the primary  
 16 antibody; the detection systems; antigen  
 17 retrieval and of course, your methods of  
 18 scoring. A little bit of the history, so you  
 19 had the DCC charcoal method and then you had  
 20 the IHC all or none method. So, if--present  
 21 or not. And then they're presently using the  
 22 Allred scoring method. And some places are  
 23 also beginning with image analysis.  
 24 For ER and PR you must ensure there's  
 25 quality control and quality assurance as you

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1 are with every antibody.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. Maybe you could just tell us what the  
 4 difference between those two, quality control  
 5 and quality assurance.  
 6 MS. WEGRYNOWSKI:  
 7 A. Okay. With quality control, you want to make  
 8 sure that you've batched batch  
 9 reproducibility, that your controls are all  
 10 working with quality assurance, that it's  
 11 working within the bigger picture.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, thank you. You can go ahead.  
 14 MS. WEGRYNOWSKI:  
 15 A. Okay. So, this is--and I'm sure Frances used  
 16 this same slide yesterday. So, you've got a  
 17 tumor that is negative, but then we're looking  
 18 at the internal controls of the ductal  
 19 epithelium which are positives, so that you  
 20 would know this was a true negative stain.  
 21 Okay.  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, I think that is the same -  
 24 MS. WEGRYNOWSKI:  
 25 A. This is the same slide -

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1 CHAYTOR, Q.C.:  
 2 Q. - that she showed us yesterday, yes.  
 3 MS. WEGRYNOWSKI:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay.  
 7 MS. WEGRYNOWSKI:  
 8 A. So, we just went over a little bit of what we  
 9 were using. So, we fix in 10 percent neutral  
 10 buffered formalin for eight to ten hours  
 11 followed slicing to allow adequate fixation.  
 12 They use the--Frances has followed the  
 13 Baylor's methodology. The antibody clone that  
 14 use for estrogen is 6F11 and for the PGR we're  
 15 using the 1294. And they use the Allred  
 16 scoring system.  
 17 CHAYTOR, Q.C.:  
 18 Q. And in terms of the impact of fixation, and in  
 19 particular the impact of under fixation, can  
 20 you speak to that?  
 21 MS. WEGRYNOWSKI:  
 22 A. With under fixation you can have an  
 23 opportunity to lose the staining and end up  
 24 with hollow nuclei in your nucleus because it  
 25 had never been fixed. So that--actually the

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1 cell begins to degrade.  
 2 CHAYTOR, Q.C.:  
 3 Q. So your protein is deteriorated.  
 4 MS. WEGRYNOWSKI:  
 5 A. That's right. You wouldn't see your chromatin  
 6 pattern in your nucleus.  
 7 CHAYTOR, Q.C.:  
 8 Q. And that's of particular importance, I take  
 9 it, then to ER/PR in particular?  
 10 MS. WEGRYNOWSKI:  
 11 A. Yes, because that's where the protein should  
 12 be exhibited.  
 13 CHAYTOR, Q.C.:  
 14 Q. What could cause under fixation?  
 15 MS. WEGRYNOWSKI:  
 16 A. Not leaving the sections--well, either not--  
 17 under fixation? Not keeping it in a fixative  
 18 long enough, not slicing it properly, so that  
 19 even if you took a thick section and the  
 20 fixative would not be able to penetrate the  
 21 section in an adequate amount of time.  
 22 CHAYTOR, Q.C.:  
 23 Q. And we've heard about -  
 24 MS. WEGRYNOWSKI:  
 25 A. Bread loafing.

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1 CHAYTOR, Q.C.:

2 Q. - bread loafing, yes. Could you just explain

3 that to us?

4 MS. WEGRYNOWSKI:

5 A. So that if you had a piece of tissue you would

6 want to cut it, serely (phonetic) section like

7 a bread loaf. Oftentimes paper towels will be

8 inserted to increase the absorbency so that

9 the formalin will be able to absorb into and

10 starting fixing the tissue.

11 CHAYTOR, Q.C.:

12 Q. Okay. Sorry, if you could continue on then.

13 MS. WEGRYNOWSKI:

14 A. Okay. So, this was a the scoring that they're

15 presently using at Mount Sinai. So, and I

16 know you did this yesterday, so zero percent

17 would be negative, low positive is one to nine

18 and then the positive is ten to hundred. The

19 technologist doesn't do the scoring. That's

20 all done by the pathologist, but this was more

21 to show this to the technologists so that they

22 understood how the tests were going to be used

23 and what interpretation was going to be given

24 to it. Next?

25 CHAYTOR, Q.C.:

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1 Q. Yes, thank you.

2 MS. WEGRYNOWSKI:

3 A. Once again this is from Frances', so again,

4 estrogen receptor protein, you'd want it

5 greater than 90 percent of your cells,

6 antibody use was 6F11 and the progesterone

7 receptor protein was approximately 60 percent.

8 So, the positive and negative laboratory

9 controls stained appropriately and so they

10 came up with their threshold. So, I can't

11 speak exactly to the numbers here. As I say,

12 I've taken this from Frances just to provide

13 the technologist with some information.

14 CHAYTOR, Q.C.:

15 Q. Okay.

16 MS. WEGRYNOWSKI:

17 A. So this is just a piece of tissue. It's a

18 core biopsy. No, excuse me, it's a TMA and

19 it's positive for ER and it's just an example

20 so that you can see it. It's on the nuclear

21 detail. Again, it's the same thing. So, you

22 can see, it's just your nuclei. You don't

23 have any of the cytoplasm around it. It's

24 just--they look like dots. So, it's just the

25 nuclear--and then a TMA and this is just some

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1 HER2/neu work that we were showing. And then

2 you can just see that cell membrane. That's a

3 completely different marker, but just how it

4 exhibits a pattern. And that's my joke, my

5 levity.

6 CHAYTOR, Q.C.:

7 Q. It's good. So, thank you and thank you for

8 taking us through that.

9 MS. WEGRYNOWSKI:

10 A. You're welcome.

11 CHAYTOR, Q.C.:

12 Q. The issue of fixation and the importance of

13 fixation, when, in your career, did you become

14 aware of that as being important, particularly

15 with respect to nuclear staining.

16 MS. WEGRYNOWSKI:

17 A. Fixation is a cornerstone of pathology. So,

18 this would have been taken--I would have

19 learned about this when I was in first year

20 school, med lab tech.

21 CHAYTOR, Q.C.:

22 Q. And as a technologist, you're dealing with the

23 analytical stages you told us, are you able to

24 tell when there are problems with fixation?

25 MS. WEGRYNOWSKI:

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1 A. It would be represented in the quality of a

2 block that we would receive. We can tell that

3 there problems with processing, a block will

4 become concave or if there's a lot fat in it

5 and it's never fixed, you can actually feel,

6 on the block, the oily surface. Other issue

7 occur when the microtomist is trying to obtain

8 a section and they're not able to get a full

9 section. And they end up getting holes

10 actually in the section.

11 CHAYTOR, Q.C.:

12 Q. Okay. So, you took the technologists through

13 those three presentations while you were here

14 in St. John's in September 2005.

15 MS. WEGRYNOWSKI:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. What happened next in your visit?

19 MS. WEGRYNOWSKI:

20 A. That took up most of the day. So, we just did

21 a little bit of a walk around through the

22 laboratory and that was about it for the day.

23 I can't remember anything else highlighted.

24 CHAYTOR, Q.C.:

25 Q. Okay. And then on your third day, how did you

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1 spend your time?  
 2 MS. WEGRYNOWSKI:  
 3 A. On my third day it was--I needed to determine  
 4 how I was going to write my report. And so  
 5 that was what most of the day was spent on,  
 6 just checking through the laboratory, but  
 7 nothing there was highlighted, I don't recall.  
 8 CHAYTOR, Q.C.:  
 9 Q. And did you have what we call an exit  
 10 interview?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes, I did.  
 13 CHAYTOR, Q.C.:  
 14 Q. Who met with you?  
 15 MS. WEGRYNOWSKI:  
 16 A. Dr. Bob Williams.  
 17 CHAYTOR, Q.C.:  
 18 Q. Anybody else?  
 19 MS. WEGRYNOWSKI:  
 20 A. There were other people at the table. I don't  
 21 recall their names.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. And if we could look please at P-1737  
 24 and these again, I believe, Ms. Wegrynowski,  
 25 these are notes from Dr. Cook.

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1 MS. WEGRYNOWSKI:  
 2 A. Okay.  
 3 CHAYTOR, Q.C.:  
 4 Q. And September 22, 2005 "meeting with Trish,  
 5 Dr. Williams, Kara Laing, Terry Gulliver and  
 6 Heather Predham", would that seem about right?  
 7 Dr. Ejeckam's name is mentioned there as a  
 8 point man, did he attend your exit interview?  
 9 MS. WEGRYNOWSKI:  
 10 A. No, I don't think so.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. And do you recall if Dr. Laing, Mr.  
 13 Gulliver and Ms. Predham attended?  
 14 MS. WEGRYNOWSKI:  
 15 A. I couldn't put a face to the names, so, I  
 16 couldn't comment.  
 17 CHAYTOR, Q.C.:  
 18 Q. So there were a number of people -  
 19 MS. WEGRYNOWSKI:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. And what then did you discuss with Dr.  
 23 Williams and the others before you left St.  
 24 John's?  
 25 MS. WEGRYNOWSKI:

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1 A. I had determined before I had left St. John's  
 2 basically what I was going to outline to them  
 3 as far as the recommendations. So, I looked  
 4 at the large picture and just started at the  
 5 very beginning and thought I would speak to  
 6 each point and from there I derived my report.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. And did you take--what observations did  
 9 you find or conclusions did you find to be  
 10 most important to speak to them about and  
 11 alert them to?  
 12 MS. WEGRYNOWSKI:  
 13 A. That there was absolutely no standard  
 14 operating procedures and that documentation  
 15 was not being done.  
 16 CHAYTOR, Q.C.:  
 17 Q. So, I take it basically this interview you  
 18 outlined any concerns that you were able  
 19 identify.  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. What was their reaction? What was Dr.  
 24 Williams' reaction?  
 25 MS. WEGRYNOWSKI:

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1 A. I think they were rather surprised. I mean,  
 2 they were--I don't think they had an  
 3 understanding of the depth of the concerns or  
 4 the issues that I brought to them. They were  
 5 certainly very interested in them.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, but somewhat surprised as to the extent  
 8 of the issues?  
 9 MS. WEGRYNOWSKI:  
 10 A. I think so.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. And I take it based on your CV that we  
 13 looked at earlier, you have done similar  
 14 reviews for other laboratories?  
 15 MS. WEGRYNOWSKI:  
 16 A. Correct.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. And how did what you observed here  
 19 compare to what you have observed in other  
 20 laboratories that you've assessed?  
 21 MS. WEGRYNOWSKI:  
 22 A. It was very different, but the other  
 23 laboratories that I had gone to had already  
 24 been through a CAT process. So, they were a  
 25 little bit more aware of what one might be

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1 coming to look for. Where, in this  
 2 laboratory, it was walking in and I was on the  
 3 understanding I was here to do a peer review,  
 4 to look at their processes and procedures and  
 5 that's what I had asked for in my initial e-  
 6 mail. So, for me I was surprised that I  
 7 didn't find what I thought I was coming to see  
 8 and that prior to coming here, no one had  
 9 explained to me that those weren't in place.  
 10 So, it was very different.

11 CHAYTOR, Q.C.:

12 Q. So, I take it, in saying that, that the basic  
 13 or the basic cornerstones of what you were  
 14 expecting to see weren't there.

15 MS. WEGRYNOWSKI:

16 A. Correct.

17 CHAYTOR, Q.C.:

18 Q. Okay. And if we could just look then, please  
 19 at those notes to see if there's anything  
 20 there. Now, perhaps this will all come out in  
 21 your report. There's certainly the  
 22 recommendation for external CAP, need this,  
 23 you indicate. So, that's for the external  
 24 q u a l i t y a s s u r a n c e a n d " h a v e  
 25 frustrated/overwhelmed individuals" and we've

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1 spoken about that.

2 MS. WEGRYNOWSKI:

3 A. Yes.

4 CHAYTOR, Q.C.:

5 Q. Both sides, I take it, the technology side and  
 6 on the pathology side?

7 MS. WEGRYNOWSKI:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. Not sure what that one says. "Don't  
 11 understand the theory, work as a group" and  
 12 that would have been something you would have  
 13 pointed out in your meeting?

14 MS. WEGRYNOWSKI:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. "Need to have good lines of communications"  
 18 and you've discussed that with us. "Need one  
 19 technical director" I think that says. "Need  
 20 better fixation", so that was something that  
 21 you were able to determine while you were here  
 22 in St. John's? "Standardization, fixation  
 23 need pathology assistance" and we've talked  
 24 about that. "Outside labs, need outside labs  
 25 to advise if there's fixation". And the

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1 outside labs being the labs outside of Eastern  
 2 Health that were sending their samples in, was  
 3 that an issue that you raised?

4 MS. WEGRYNOWSKI:

5 A. One of the thoughts that I had was that if you  
 6 were going to be doing the work for a number  
 7 of other institutions in the area, that it  
 8 would be wise to have you look at their  
 9 protocols to ensure that they were doing the  
 10 same thing as you.

11 CHAYTOR, Q.C.:

12 Q. Okay. And it says, "Health Care Corporation,  
 13 St. John's, needs to advise other hospitals of  
 14 fixation. So, they would need to advise of  
 15 the fixation issue". Is that what you were  
 16 indicating?

17 MS. WEGRYNOWSKI:

18 A. Yes.

19 CHAYTOR, Q.C.:

20 Q. And "consider disclaimer on reports for  
 21 referral labs", is that something that you  
 22 brought up in the meeting?

23 MS. WEGRYNOWSKI:

24 A. I might have done that. I know we certainly  
 25 do that.

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1 CHAYTOR, Q.C.:

2 Q. Okay. And controls "need to run positive and  
 3 negative controls".

4 MS. WEGRYNOWSKI:

5 A. Yes.

6 CHAYTOR, Q.C.:

7 Q. And we've spoke about that. And negative  
 8 controls for specificity, is that right.

9 MS. WEGRYNOWSKI:

10 A. Correct, ensure they're negative.

11 CHAYTOR, Q.C.:

12 Q. And validation then and we spoke, I think,  
 13 about most of those points on validation.

14 MS. WEGRYNOWSKI:

15 A. Correct.

16 CHAYTOR, Q.C.:

17 Q. And I'm sure we can cover it off in what's  
 18 written, in any event, in your report. So, we  
 19 can see here that Dr. Cook wrote two fairly  
 20 detailed pages of notes from your exit  
 21 interview. How long was that meeting?

22 MS. WEGRYNOWSKI:

23 A. I don't recall.

24 CHAYTOR, Q.C.:

25 Q. But I take it, it was fairly thorough in terms

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1 of what you had discovered and you relayed to  
 2 them most of what ultimately ends in your  
 3 report.  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. And if we could look then at P-0596. And  
 8 again, this is not a document, this is not  
 9 your document.  
 10 MS. WEGRYNOWSKI:  
 11 A. Okay.  
 12 CHAYTOR, Q.C.:  
 13 Q. And you've probably not seen it before, but  
 14 it's another couple pages of hand written  
 15 notes. And we understand this is Dr.  
 16 Williams' notes and you'll see it's two and  
 17 bit pages.  
 18 MS. WEGRYNOWSKI:  
 19 A. Okay.  
 20 CHAYTOR, Q.C.:  
 21 Q. And this again is September 22nd, 2005 and it  
 22 appears to be Dr. Cook, Dr. Laing, Ms.  
 23 Predham, Mr. Gulliver, Dr. Williams and the  
 24 Mount Sinai technical person. So this appears  
 25 to be his notes then of your exit interview as

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1 well and we'll see the state of affairs,  
 2 frustrated and overwhelmed comments, again  
 3 referring to the staff. "Causes,  
 4 communication issues, do not understand the  
 5 theory." So similar items being mentioned  
 6 here, the fixation being mentioned, the  
 7 controls being mentioned and validation and it  
 8 goes on from there. So this is, we understand  
 9 Dr. Williams' notes of your exit interview and  
 10 again, I just show that to you and I take it  
 11 that's in keeping with the types of issues  
 12 that you covered off with the senior  
 13 management of Eastern Health before you left  
 14 St. John's?  
 15 MS. WEGRYNOWSKI:  
 16 A. Correct.  
 17 CHAYTOR, Q.C.:  
 18 Q. If we could have, please, P-0047? Actually  
 19 before we go there, if we could look at P-  
 20 1755? And perhaps you can just explain what  
 21 this document is?  
 22 MS. WEGRYNOWSKI:  
 23 A. Okay, this was the CAP guidelines for the year  
 24 2004, I believe, isn't it up there?  
 25 CHAYTOR, Q.C.:

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1 Q. Yes, it's there in the corner.  
 2 MS. WEGRYNOWSKI:  
 3 A. So it would have been in keeping in what we  
 4 would have been looking at for accreditation  
 5 in that year to do with anatomic pathology.  
 6 CHAYTOR, Q.C.:  
 7 Q. So is this what you used as a reference in  
 8 carrying out your assessment?  
 9 MS. WEGRYNOWSKI:  
 10 A. I did use this as, yes, as some of the  
 11 reference points, yes, I did.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay. And if we could have then, please, P-  
 14 0047?  
 15 MS. WEGRYNOWSKI:  
 16 A. Okay.  
 17 CHAYTOR, Q.C.:  
 18 Q. Ms. Wegrynowski, this is your first report  
 19 which is dated November 9th, 2005 and it  
 20 appears that we're looking at copy seven of  
 21 eight, May 23rd, '07. And it's a fairly  
 22 detailed report. I believe it goes on for  
 23 some twenty pages--twenty-one pages. Does  
 24 this report contain everything that you  
 25 observed or could have written about?

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1 MS. WEGRYNOWSKI:  
 2 A. I could have written more, there's no doubt  
 3 about it, but at some point I had to take  
 4 stalk and look at the large picture and went  
 5 after the very large components. It could  
 6 have been much more detailed, but I wasn't  
 7 sure that's what they wanted.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and what were you trying to then achieve  
 10 or convey in writing this report?  
 11 MS. WEGRYNOWSKI:  
 12 A. I wanted to provide them with a blueprint of  
 13 what their deficiencies were and provide them  
 14 with a set of recommendations that I thought  
 15 would assist them in correcting the issue that  
 16 they had at hand.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and we have your table of contents and  
 19 then we have "Introduction, Executive Summary"  
 20 and here you write, "The inconsistencies  
 21 associated with formalin fixation, tissue  
 22 processing and pretreatment methodology,  
 23 compounded by a rotating staff directly  
 24 affected the repeatability of the  
 25 immunohistochemistry results." What are you--

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1 what is it exactly that you are saying there,  
 2 Ms. Wegrynowski?  
 3 MS. WEGRYNOWSKI:  
 4 A. Well the formalin fixation, there was no  
 5 standard operating procedures as we've already  
 6 discussed, so the amount of--well just  
 7 inconsistency between case to case. The  
 8 tissue processing, we knew that the  
 9 processors, there was no documentation to  
 10 ensure that they were being changed and  
 11 corrected. We also knew that the reprocessing  
 12 rate was very, very high. The pretreatment  
 13 methodology of choice, I believe at that time  
 14 what they were using was a steam pretreatment  
 15 on the bench. I never found that they had any  
 16 thermometers in there again, as we speak to  
 17 NIST traceable, there were no NIST traceable  
 18 timers around, so I would venture to say that  
 19 I'm not sure that even the pretreatment was  
 20 done in a very consistent manner, so you would  
 21 also have lot-to-lot variation or day-to-day  
 22 variation with that as well.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you go on to say, "Also the lack of  
 25 standard operating procedures across the

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1 pathology lab contributed to the problem. The  
 2 high degree of proficiency required to  
 3 perform, evaluate, and interpret  
 4 immunohistochemistry testing must be assessed,  
 5 as both the technical and professional staff  
 6 are accountable for the final outcome." And  
 7 what are you trying to emphasize in that  
 8 statement?  
 9 MS. WEGRYNOWSKI:  
 10 A. Well they had no standard operating procedures  
 11 either for the technical side or for the  
 12 professional side or pathologist's side. So  
 13 to ensure that there's proficiency, you need  
 14 to have that. You want to ensure that the  
 15 evaluation and the interpretation of the  
 16 immunohistochemistry tests are done  
 17 collectively. I never found any correlation  
 18 between even the pathologists if they had ever  
 19 taken a set of slides and looked at them and  
 20 come up with their own results, so I--that's  
 21 what that was meant to mean.  
 22 CHAYTOR, Q.C.:  
 23 Q. And under "Background", you indicate that from  
 24 1997 until 2004 the semi-automated  
 25 DAKOCytomation, is that correct?

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1 MS. WEGRYNOWSKI:  
 2 A. Yes, those two companies were linked at that  
 3 time.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, auto-stainer was used for IHC staining.  
 6 A heat induced epitope retrieval pretreatment  
 7 using steam was performed manually outside of  
 8 the auto-stainer and concentrated primary  
 9 antibodies were diluted at the discretion of  
 10 the laboratory." Can you just explain that to  
 11 us laypeople? What is a heat induced epitope  
 12 retrieval pretreatment?  
 13 MS. WEGRYNOWSKI:  
 14 A. So the sections are taken and the slides, you  
 15 have to remove the wax, the tissue sections on  
 16 the slide and to do that, you go through  
 17 solvents, you go from cylene through alcohols,  
 18 gradient alcohols to get down to water. Once  
 19 they're into water, then you can remove the  
 20 indogenous peroxidase, as I showed you in my  
 21 PowerPoint this morning with hydrogen peroxide  
 22 and water. Some antibodies to be able to see  
 23 them, you need to use a pretreatment and for  
 24 the particular one that they were using, they  
 25 were using steam, and that is performed prior

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1 to the slides being put on the auto-stainer.  
 2 It was what they chose to use at Eastern  
 3 Health to break the aldehyde bonds to expose  
 4 the epitope.  
 5 CHAYTOR, Q.C.:  
 6 Q. They use steam.  
 7 MS. WEGRYNOWSKI:  
 8 A. They use steam, yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. And then you go on to talk about in 2004 how  
 11 that was replaced with the automated Ventana  
 12 benchmark.  
 13 MS. WEGRYNOWSKI:  
 14 A. Uh-hm.  
 15 CHAYTOR, Q.C.:  
 16 Q. "Prior to January 2003, the formalin fixative  
 17 was prepared in-house at the Health Science  
 18 Centre and distributed; however, no  
 19 documentation concerning the pH of this  
 20 fixative was found. It has since been  
 21 replaced with commercially prepared ten  
 22 percent neutral buffered fixative." And again  
 23 the importance of having documentation or what  
 24 would you expect to have in the way of  
 25 documentation around the pH of the fixative?

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1 MS. WEGRYNOWSKI:  
 2 A. That they would ensure that it was the same,  
 3 regardless of whether it was being made in-  
 4 house or just commercially prepared.  
 5 CHAYTOR, Q.C.:  
 6 Q. So that you can compare it then and reproduce  
 7 the same results?  
 8 MS. WEGRYNOWSKI:  
 9 A. Absolutely, absolutely.  
 10 CHAYTOR, Q.C.:  
 11 Q. And then you outline the objectives of your  
 12 review which were to "review the current  
 13 practices and procedures within the IHC  
 14 service, identify issues of concern which may  
 15 have contributed to the present situation and  
 16 provide recommendations pertaining to issues  
 17 identified." And you indicate in your scope  
 18 that you visited both sites, that you focused  
 19 on the immunohistochemistry service and the  
 20 procurement and processing from both sites,  
 21 because tissue fixation and processing provide  
 22 the basis for accountable immunohistochemical  
 23 staining."  
 24 MS. WEGRYNOWSKI:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:  
 2 Q. And your methodology we've talked about, you  
 3 met with the technologists, the pathology  
 4 manager, laboratory director, chief  
 5 pathologist and pathologist.  
 6 MS. WEGRYNOWSKI:  
 7 A. Uh-hm.  
 8 CHAYTOR, Q.C.:  
 9 Q. And at the histology lab, again you speak  
 10 about the lack of consistency with fixation  
 11 and the issue of reprocessing, both had had a  
 12 direct effect on the staining outcome with  
 13 IHC. And perhaps you could just spend, I know  
 14 we've talked about that, but perhaps you could  
 15 just once again explain why you think that had  
 16 an effect on the staining outcome?  
 17 MS. WEGRYNOWSKI:  
 18 A. Because if you never fix the protein at the  
 19 beginning and stopped it and kept it in as  
 20 true a form as it was as when it left the  
 21 body, the results that you would get would not  
 22 be indicative of that particular time.  
 23 THE COMMISSIONER:  
 24 Q. Is there a guideline, as I understand it it's  
 25 in formalin hopefully from the time it's taken

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1 out of the body, it's placed in formalin and  
 2 then it goes through the process of getting  
 3 from the OR to the lab.  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes.  
 6 THE COMMISSIONER:  
 7 Q. And then at some point there's the cutting  
 8 done.  
 9 MS. WEGRYNOWSKI:  
 10 A. Yes.  
 11 THE COMMISSIONER:  
 12 Q. And then it goes back into formalin.  
 13 MS. WEGRYNOWSKI:  
 14 A. Yes.  
 15 THE COMMISSIONER:  
 16 Q. The smaller pieces.  
 17 MS. WEGRYNOWSKI:  
 18 A. Uh-hm.  
 19 THE COMMISSIONER:  
 20 Q. For the optimum period of time.  
 21 MS. WEGRYNOWSKI:  
 22 A. Uh-hm.  
 23 THE COMMISSIONER:  
 24 Q. Does the question of when it's sliced make a  
 25 difference?

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1 MS. WEGRYNOWSKI:  
 2 A. Well -  
 3 THE COMMISSIONER:  
 4 Q. Do you know what I mean, in the sense of as I  
 5 understood what Dr. O'Malley was saying  
 6 yesterday that one of the concerns about  
 7 slicing is to make sure that the formalin  
 8 actually gets to the material which is going  
 9 to be eventually placed -  
 10 MS. WEGRYNOWSKI:  
 11 A. Correct.  
 12 THE COMMISSIONER:  
 13 Q. - in your little paraffin blocks.  
 14 MS. WEGRYNOWSKI:  
 15 A. Uh-hm.  
 16 THE COMMISSIONER:  
 17 Q. And that's one of the important reasons for  
 18 slicing and I guess my question is really,  
 19 follows on from that and maybe I should have  
 20 asked her, but is there an optimum time to  
 21 slice? As I understand it, there is a period  
 22 of time in which the tissue should be in  
 23 formalin, you can't take it out too early and  
 24 you can't take it out too late, is that -  
 25 MS. WEGRYNOWSKI:

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1 A. Correct.  
 2 THE COMMISSIONER:  
 3 Q. There's an optimum period and I suppose I'm  
 4 asking whether within that timeframe does it  
 5 matter when you slice?  
 6 MS. WEGRYNOWSKI:  
 7 A. Slicing it at the beginning would be the best.  
 8 THE COMMISSIONER:  
 9 Q. Okay, the earlier you slice -  
 10 MS. WEGRYNOWSKI:  
 11 A. The earlier the better, yes.  
 12 THE COMMISSIONER:  
 13 Q. Okay.  
 14 CHAYTOR, Q.C.:  
 15 Q. And this issue of reprocessing, how harmful  
 16 can that be to the tissue?  
 17 MS. WEGRYNOWSKI:  
 18 A. It can be very harmful because you're going  
 19 back up through temperature to melt that wax  
 20 again and then going back through the  
 21 different solvents to get it back to formalin,  
 22 but if your formalin was never fixed properly  
 23 at the beginning, your section, your tumor  
 24 section will never be the same. You cannot  
 25 have what you had originally had.

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1 CHAYTOR, Q.C.:  
 2 Q. And could that then result in no stain?  
 3 MS. WEGRYNOWSKI:  
 4 A. I couldn't say that as an absolute.  
 5 CHAYTOR, Q.C.:  
 6 Q. And if we continue on then, if there's  
 7 anything else in this paragraph that you would  
 8 want to point out, if--perhaps, however, you  
 9 speak here again about, "however refrigeration  
 10 storage is not available for larger unfixed  
 11 specimens after hours."  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. And again, you've indicated the importance of  
 16 refrigeration and storage.  
 17 MS. WEGRYNOWSKI:  
 18 A. Absolutely, you need to stop the process of  
 19 autolyses and putrefaction and that can be  
 20 done by at least on off hours getting your  
 21 specimens into refrigerators, they were just  
 22 leaving it at room temperature.  
 23 CHAYTOR, Q.C.:  
 24 Q. And your recommendations, your first  
 25 recommendation, of course, is "standard

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1 operating procedures relating specifically to  
 2 the grossing/fixation procedures must exist  
 3 for each tissue type to ensure the  
 4 reproducibility and reliability of results."  
 5 MS. WEGRYNOWSKI:  
 6 A. Correct.  
 7 CHAYTOR, Q.C.:  
 8 Q. And you're recommending secondly that "Three  
 9 pathologist assistant positions be created to  
 10 facilitate this and the PA's will be  
 11 responsible for quick sections. Thirdly, a  
 12 refrigerator to be available in the quick  
 13 section rooms." And then your next section of  
 14 your report is 2.2 and it's called  
 15 "Processing" and you note that "Currently each  
 16 site maintains a tissue processor. All  
 17 specimens grossed each day are placed in the  
 18 tissue processor at that particular site, with  
 19 the exception of biopsy specimens. Procedure  
 20 manuals outlining the standard operating  
 21 procedures for the tissue processors were not  
 22 found. Neither signed documentation for the  
 23 daily maintenance of the processors, nor  
 24 temperature monitoring of the paraffin wax was  
 25 found." And your recommendations are "To

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1 ensure that tissue processing is reproducible,  
 2 it should be amalgamated to one site." And  
 3 you're recommending that the St. Clare's  
 4 tissue processor be relocated to the Health  
 5 Sciences. "Signed daily cleaning and  
 6 maintenance schedules for the tissue  
 7 processors must be maintained and retained.  
 8 Temperature of the paraffin wax must be  
 9 recorded daily, this is especially important  
 10 as some antibodies are heat laible. Standard  
 11 operating procedures to be written for the  
 12 tissue processing including identifying  
 13 different processing and cleaning and  
 14 maintenance of schedules, directions to load  
 15 and unload the processors." And you indicate  
 16 it's not a mutually exclusive list. "Blocks  
 17 to remain at the Health Science and couriering  
 18 of stain slides to remain at status quo." Is  
 19 there anything amongst all of that that we  
 20 haven't covered that you would like to comment  
 21 on?  
 22 MS. WEGRYNOWSKI:  
 23 A. No, I think it's been covered.  
 24 CHAYTOR, Q.C.:  
 25 Q. The issue of the paraffin wax, I know we



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1 talked about temperatures in other context,  
 2 but what difference would it make for the  
 3 temperature of the paraffin wax, for that to  
 4 be recorded daily?  
 5 MS. WEGRYNOWSKI:  
 6 A. Because you want to make sure that it fits  
 7 within the optimum melting points. You don't  
 8 want it to get too high where you're going to  
 9 lose a heat laible of proteins and if it's not  
 10 warm enough, it's not going to melt, so  
 11 there's a particular reference range.  
 12 CHAYTOR, Q.C.:  
 13 Q. And is ER and/or PR an antibody that would be  
 14 sensitive to that?  
 15 MS. WEGRYNOWSKI:  
 16 A. I think the heat laibility could affect  
 17 anything.  
 18 CHAYTOR, Q.C.:  
 19 Q. If we go on then to the next page, it deals  
 20 with the immunohistochemistry laboratory and  
 21 you talk about the staffing issue, 3.1, "three  
 22 registered technologists rotate through the  
 23 IHC area with an additional registered  
 24 technologist performing the microtomy", is  
 25 that correct?

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1 MS. WEGRYNOWSKI:  
 2 A. Microtomy.  
 3 CHAYTOR, Q.C.:  
 4 Q. Thank you. All right. "And approximately 80  
 5 IHC tests are performed daily with majority  
 6 done on the automated Ventana." You note that  
 7 there's no medical section head for the IHC  
 8 laboratory and you also note "Both the  
 9 technologists and the pathologists I spoke  
 10 with are frustrated with the present situation  
 11 as there are no clear lines of communication,  
 12 in addition, the technologists are overwhelmed  
 13 as they do not completely understand the  
 14 theory of IHC and this testing required high  
 15 technical proficiency to troubleshoot the  
 16 methodology." And your recommendations  
 17 flowing from that are that "Three  
 18 technologists be dedicated to perform IHC  
 19 staining, optimization and validation. One of  
 20 the three registered technologists to be given  
 21 the additional responsibility and title to  
 22 oversee the IHC lab and a medical section head  
 23 be designated and responsible for the IHC  
 24 lab." And is there anything else in any of  
 25 that, Ms. Wegrynowski that you could expand

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1 upon or feel that we have not already covered?  
 2 MS. WEGRYNOWSKI:  
 3 A. If I could just, please, when I spoke to the  
 4 technologists, they were being put on  
 5 rotations and they were doing one week in  
 6 three different things, so they were in for  
 7 one week in immunohistochemistry and then gone  
 8 for another two weeks and then they would be  
 9 dropped back into immunohistochemistry.  
 10 Because it's a very dynamic laboratory and  
 11 things had changed and the communication would  
 12 not have always been delivered to them, I  
 13 think that was part of the frustration, as  
 14 well, so that even if Dr. Ejeckam had taken  
 15 the time and the energy to train them, he was  
 16 always dealing with a workforce that was  
 17 always changing, and I feel that that really  
 18 needs to be reiterated.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay.  
 21 MS. WEGRYNOWSKI:  
 22 A. And that a lot of the communications weren't  
 23 just going through them, they were going  
 24 through others and back to them.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And you indicated earlier this morning  
 2 in your evidence, though, that I think you  
 3 sort of made a joke and said, "I have many  
 4 bosses" and a lot of people communicating with  
 5 you. How is that different from what you  
 6 observed in St. John's?  
 7 MS. WEGRYNOWSKI:  
 8 A. It's very fluid where I come from. It's not  
 9 unusual for me to see, I don't know, 10, 12  
 10 different pathologists in any given day just  
 11 dropping by, ordering, asking questions,  
 12 whatever. As I said, I do have a technical  
 13 head and I do have a medical head, but because  
 14 of the nature of the work that we do there, we  
 15 work for every pathologist, so if they come to  
 16 us, it is not one pathologist that goes to  
 17 another pathologist, they take it upon  
 18 themselves if they're not pleased with  
 19 something, they come to us directly and ask  
 20 the questions directly. If they're looking  
 21 for a new antibody, they will come to us  
 22 directly and tell us what they're looking for.  
 23 And we work, it's a very large team.  
 24 CHAYTOR, Q.C.:  
 25 Q. And I take it you have your standard operating

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1 procedures in place so regardless, things are  
 2 going to be done the same way in your lab  
 3 regardless of how many channels of information  
 4 may be coming at you or instructions may be  
 5 coming at you?  
 6 MS. WEGRYNOWSKI:  
 7 A. That's correct. So then we have a  
 8 communication board so that if something does  
 9 change, if it's something a large change, that  
 10 we're bringing a new antibody in or any large  
 11 changes that would fit outside that, we do  
 12 have a board where all that would fit on, as  
 13 well. But because we work together every day  
 14 there is always that communication that  
 15 there's much less chance of it falling  
 16 through.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. So I take it in your day to day at  
 19 Mount Sinai you have a lot of interaction with  
 20 the pathologists?  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, we do.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. And what kind of atmosphere do you work  
 25 in there in terms of, well, what's the culture

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1 in terms of is this a team atmosphere or how  
 2 does that work?  
 3 MS. WEGRYNOWSKI:  
 4 A. It's very collegial, it's very collegial.  
 5 When we run into issues with troubleshooting  
 6 ourselves, and everybody has them, we'd be  
 7 remiss to say we don't, it's a wonderful  
 8 opportunity for the team to sit together and  
 9 say, okay, this is what has happened, what do  
 10 we think it can be and go through the  
 11 processes and try and rule out what can and  
 12 cannot be done. Because in the end what we're  
 13 doing is you're learning, so from the  
 14 troubleshooting that's where you gain your  
 15 most experience. And because there is so many  
 16 people at work, not one person is handling the  
 17 slides, because we all do it the same way, we  
 18 must ensure that we get that final outcome.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. And you say you have both a technical  
 21 head and a medical head in your laboratory?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yeah, I have a charge technologist that sits  
 24 over me, she's in pathology, and then I have a  
 25 medical, technical--a medical IHC director, as

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1 well.  
 2 CHAYTOR, Q.C.:  
 3 Q. And who do you--what, on what issues would you  
 4 report to one as opposed to the other?  
 5 MS. WEGRYNOWSKI:  
 6 A. Well, that gets blurry. It depends on what  
 7 the process is. If it's about completely  
 8 technical, where it's to do with the staining,  
 9 usually it's my medical head. My technical--  
 10 my charge technologist knows very little about  
 11 immunohistochemistry so it's more if I need to  
 12 get large equipment purchased or whatever  
 13 through capital.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And your recommendation here, No. 12 on  
 16 page 8 of the exhibit, "Lines of authority,  
 17 communication and organization to be  
 18 determined prior to establishing these  
 19 positions." You write, "The technologist  
 20 responsible for the IHC laboratory will report  
 21 to both the pathology manager and the medical  
 22 section head, depending upon the issue at  
 23 hand." So I take it that would be similar to  
 24 what you have in Mount Sinai?  
 25 MS. WEGRYNOWSKI:

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1 A. That's correct.  
 2 CHAYTOR, Q.C.:  
 3 Q. And did you understand that to be different  
 4 than what they had at the time in St. John's?  
 5 MS. WEGRYNOWSKI:  
 6 A. It would be unfair for me to answer that  
 7 because the technologists were rotating, so  
 8 I'm not sure that they even had this  
 9 capability of doing this. I think everything  
 10 was just going through Barry Dyer and then it  
 11 was getting reflexed to wherever, or whoever  
 12 was in the area.  
 13 CHAYTOR, Q.C.:  
 14 Q. "The pathologists need to establish a  
 15 mechanism as to how their IHC concerns, issues  
 16 will be addressed. Documentation of all  
 17 concerns, issues, must be maintained with the  
 18 corrective action." And there's also a note  
 19 of succession planning. So if there's nothing  
 20 else on that, we can move on.  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, please.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. IHC documentation, and we've spent some  
 25 time, I think, on the documentation, in

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1 general you say it was deficient. And then  
 2 there's a list of key areas that you've  
 3 identified. Is there anything there that you  
 4 would like to highlight or speak to that we  
 5 haven't already spoken of?  
 6 MS. WEGRYNOWSKI:  
 7 A. No. This is just a very sizable, it's very,  
 8 very surprise--I reiterate, I came to St.  
 9 John's and asked to look at the procedures  
 10 before I came and I was very surprised that  
 11 they weren't, they weren't there to see.  
 12 CHAYTOR, Q.C.:  
 13 Q. And so "No test procedure manual, including  
 14 the standard operating procedures. Lacking  
 15 organized current manufacturer specification  
 16 data sheets." If we could just look for a  
 17 second at 1605, please, page 15? And this is  
 18 just a--page 15, yes, thank you. Is this what  
 19 you're referring to as a specification sheet,  
 20 this is an example we have here -  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes, so you'll see your code there, your lot  
 23 number. It's telling you your total protein  
 24 concentration, it's telling you subclass, your  
 25 G1, it'll tell you what you can use it for,

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1 it'll give you your storage conditions, how  
 2 it's prepared. They often even give you,  
 3 there's a little bit about the specificity,  
 4 they'll even give you recommended suggestions  
 5 on how you can go ahead and use it.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. And if we could go back then, please,  
 8 to 47, page 9? And so this is the kind of  
 9 specification data sheet that you were  
 10 suggesting should be -  
 11 MS. WEGRYNOWSKI:  
 12 A. Absolutely, so that you know and whoever comes  
 13 into your laboratory, the pathologist knows  
 14 what is the antibody that you are currently  
 15 producing from this laboratory and let's look  
 16 at the spec sheets about it.  
 17 CHAYTOR, Q.C.:  
 18 Q. And again, I take it it comes down to making  
 19 sure, then, that you're doing things  
 20 consistently so that you can have reproducible  
 21 results?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. And then "The minimal record daily keeping of

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1 the equipment maintenance" I think we've  
 2 talked about that. "No pipette and  
 3 thermometer calibration of accuracy." And  
 4 we'll talk some more about that in a moment.  
 5 "No reagent antibody or detection system  
 6 evaluation and no validation documentation."  
 7 MS. WEGRYNOWSKI:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. "No equipment documentation and no calibration  
 11 records. Retirement of procedures or  
 12 antibodies not documented. Retention of  
 13 records not done. Lacking complete error log  
 14 and corrective action." What's an error log  
 15 and correction action?  
 16 MS. WEGRYNOWSKI:  
 17 A. Again, this comes back if the pathologist is  
 18 finding something that's incorrect, that you  
 19 would go ahead, we call it our error log, if  
 20 it's a whatever, and then we'll go in and  
 21 correct it.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. So if there's something that's not  
 24 optimal, you would record that and then figure  
 25 out how to do it differently next time?

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1 MS. WEGRYNOWSKI:  
 2 A. Or determine what went wrong in the process to  
 3 correct it, that's right.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. And then "No distilled water monitoring  
 6 and documentation." and we spoke of that  
 7 earlier?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Recommendations then again is the procedural  
 12 manual outlining the standard operating  
 13 procedures. And you're talking about having  
 14 that available at the bench?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes. I provided them with the--how the manual  
 17 should be written and gave them the reference  
 18 for that.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. So you gave them material by which they  
 21 would be able to draft that?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yeah. And those guidelines were published in  
 24 1999.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MS. WEGRYNOWSKI:  
 3 A. Yeah.  
 4 CHAYTOR, Q.C.:  
 5 Q. 1999?  
 6 MS. WEGRYNOWSKI:  
 7 A. Um-hm.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And that's the Clinical Laboratory  
 10 Standard Institute's Guidelines?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. "It would be prudent," you say, "to  
 15 send the technologist responsible for  
 16 compiling and maintaining procedural manual to  
 17 a computer course." And you finish by saying,  
 18 "The benchmark--Ventana benchmark operator's  
 19 manual is available at the workbench. It is  
 20 an acceptable component of the overall IHC  
 21 departmental procedure, but does not replace a  
 22 procedure manual."  
 23 MS. WEGRYNOWSKI:  
 24 A. No.  
 25 CHAYTOR, Q.C.:

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1 Q. And why is that?  
 2 MS. WEGRYNOWSKI:  
 3 A. Because these are just operator's manual, it's  
 4 just how to operate the machine, it's not how  
 5 you're actually making your procedures and  
 6 processes work.  
 7 CHAYTOR, Q.C.:  
 8 Q. And if we go on then, your recommendation No.  
 9 15 is "Antibody data specification sheets to  
 10 be available for all antibodies currently in  
 11 use." So I take it that's similar to the sheet  
 12 that I just showed you?  
 13 MS. WEGRYNOWSKI:  
 14 A. That's correct.  
 15 CHAYTOR, Q.C.:  
 16 Q. "Routine equipment maintenance must be  
 17 performed and documented." And then you've  
 18 broken this down between internal checks and  
 19 external checks. Perhaps you could just speak  
 20 to us a bit about this recommendation?  
 21 MS. WEGRYNOWSKI:  
 22 A. Okay. So the internal check we're talking  
 23 about the Ventana staining module, which had  
 24 its own maintenance programs. They told me  
 25 that they were performing a daily maintenance

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1 but they didn't always document it, so they  
 2 had to change that. And then the other  
 3 portion was that it was a quarterly  
 4 maintenance but they were unable to access the  
 5 process. So I had suggested that they go to  
 6 their information technology department and  
 7 see if they could assist them with that.  
 8 Internally that you must always set up your  
 9 microscope up for Kohler illumination. And  
 10 that should be done daily and should also be  
 11 signed off because you want to ensure that you  
 12 have a correct contrast and resolution. And  
 13 again, the laboratory personnel are  
 14 responsible for the reliability and proper  
 15 function of the instruments that they work on,  
 16 hence, service and repair, records or copies  
 17 must be available to the technical staff  
 18 operating the equipment. As well, an  
 19 alternate protocol must exist in case of  
 20 failure of the automated equipment.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. And the external check?  
 23 MS. WEGRYNOWSKI:  
 24 A. These are when people can come in from the  
 25 outside, these are things that you don't

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1 necessary take care of. So you want to make  
 2 sure that you have your annual preventative  
 3 maintenance records on your microtome, your  
 4 weigh balance, your microscope, any other  
 5 people of equipment that are not mentioned  
 6 here that are annually inspected.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. And I'm going to leave No. 27 for a  
 9 moment because we're going--I understand  
 10 you're going to do a demonstration for us  
 11 around that.  
 12 MS. WEGRYNOWSKI:  
 13 A. I can.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. About the Guarantee Pipette and  
 16 temperature accuracy and calibration, so we'll  
 17 come back to that.  
 18 MS. WEGRYNOWSKI:  
 19 A. All right.  
 20 CHAYTOR, Q.C.:  
 21 Q. No. 18, "Documented evaluation must be  
 22 performed to ensure the sensitivity and  
 23 specificity of the test results. Each  
 24 component used in IHC staining must be  
 25 optimized and validated individually to ensure

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1 the outcome and assist in troubleshooting.  
 2 Presently this is not being done."  
 3 MS. WEGRYNOWSKI:  
 4 A. No.  
 5 CHAYTOR, Q.C.:  
 6 Q. And then you talk about the primary antibodies  
 7 being pre-diluted and concentrated. "Any  
 8 change in lot number of concentration, the  
 9 specificity of the antibody must be verified  
 10 prior to use. The staining results should be  
 11 compared to the previous lot using the  
 12 appropriate controls." And I believe you  
 13 spoke to us today about that. And "The  
 14 validation documentation must be approved and  
 15 signed off by the medical section head prior  
 16 to use in routine service." So I take it that  
 17 was not taking place?  
 18 MS. WEGRYNOWSKI:  
 19 A. No.  
 20 CHAYTOR, Q.C.:  
 21 Q. "Stain, slides used for validation to be kept  
 22 for reference."  
 23 MS. WEGRYNOWSKI:  
 24 A. Correct.  
 25 CHAYTOR, Q.C.:

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1 Q. And again, "The equipment selection criterion  
 2 calibration is to be documented." And you say  
 3 that, "No documentation for the selection  
 4 criteria used for the Ventana" was, I take it,  
 5 available?  
 6 MS. WEGRYNOWSKI:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. "For any new equipment or instruments  
 10 purchased protocol and records must be  
 11 maintained of the calibration performance and  
 12 functional checks and verification performed  
 13 and evidence of training and competency of  
 14 technical staff on equipment must be  
 15 available." So I take it that was not  
 16 available in this case?  
 17 MS. WEGRYNOWSKI:  
 18 A. No, it wasn't.  
 19 CHAYTOR, Q.C.:  
 20 Q. "Retired procedures and antibodies information  
 21 must be retained for two years and readily  
 22 available." And "It is recommended that they  
 23 be retained for longer for reference." Why  
 24 two years?  
 25 MS. WEGRYNOWSKI:

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1 A. Industry standards.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. "All issues, concerns and corrective  
 4 actions again must be documented and this  
 5 should be done by the technical and  
 6 professional staff." And "Distilled water is  
 7 available on tap in the laboratory.  
 8 Documentation of the suitable quality of this  
 9 water for the testing being performed was not  
 10 found, nor was it known." So I take it nobody  
 11 was able to give you that information?  
 12 MS. WEGRYNOWSKI:  
 13 A. No, they were not.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. The next section then, Ms. Wegrynowski,  
 16 deals with immunofluorescence staining. And  
 17 you spoke about this briefly in your slide  
 18 show, some of the problems you encountered  
 19 there. I take it this didn't--this doesn't  
 20 have anything to do with ER/PR, as such?  
 21 MS. WEGRYNOWSKI:  
 22 A. No.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay.  
 25 MS. WEGRYNOWSKI:

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1 A. However, it is very valuable, as well.  
 2 CHAYTOR, Q.C.:  
 3 Q. Yes. And is there anything then, I believe  
 4 you already spoke about the fact that it was  
 5 being performed in a lit environment and no  
 6 controls were used. And is there anything  
 7 else about that that you -  
 8 MS. WEGRYNOWSKI:  
 9 A. They were not retaining their samples at all,  
 10 so what they were doing is they were just  
 11 taking their sections and then just letting  
 12 the--they were leaving the sections inside the  
 13 cryostat, the cryostat is just a frozen  
 14 microtome, so but what it does every night it  
 15 is comes back up to temperature and then goes  
 16 back down again for decontamination. And they  
 17 were just leaving their specimens in there so  
 18 they were completely destroyed. These are--  
 19 they would be kidney biopsies, oral biopsies,  
 20 buckle, whatever. So the frozen patient  
 21 samples should have been taken out, they  
 22 should have been labelled and stored correctly  
 23 to avoid desiccation in a frost-free freezer.  
 24 And to maintain the antigenicity longer, I  
 25 suggested that they were stored at minus 80.

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1 They did not use any controls when using this  
 2 particular test. "Interpretation at every  
 3 staining procedure must be substantiated with  
 4 the use of controls, both positive and  
 5 negative. Controls must be handled exactly in  
 6 the same manner as test samples. It is also  
 7 ideal that control sections used to have a  
 8 composition similar to the patients samples  
 9 being tested. Positive controls assure that  
 10 the specimen staining was correctly performed  
 11 when negative controls assess non-specific  
 12 staining. The use of frozen sections  
 13 previously confirmed positive and negative  
 14 cases offers the easiest and most practical  
 15 way to obtain controls for immunofluorescence  
 16 studies." And then again, as I had said  
 17 before, that it should have been protected  
 18 from light.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. And the Her2/neu testing, what were you  
 21 able to observe about how that was taking  
 22 place?  
 23 MS. WEGRYNOWSKI:  
 24 A. They were using it manually on the desk, they  
 25 were doing a manual pretreatment for these

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1 markers in the same way that was used for  
 2 ER/PR testing in the past. So for myself I  
 3 had an issue of reproducibility and  
 4 consistency was of concern. So my  
 5 recommendation is that "This methodology must  
 6 be performed in the strictest of conditions.  
 7 If you can automate the procedure, it was  
 8 greatly suggested. Variation in pretreatment  
 9 between testing batches must be guarded to  
 10 ensure that all test results be reproducible.  
 11 Strick adherence to temperature and time must  
 12 be maintained."  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. And again, this test, like the ER/PR  
 15 test is one which would be used for treatment  
 16 purposes?  
 17 MS. WEGRYNOWSKI:  
 18 A. Yes, it's a class 2.  
 19 CHAYTOR, Q.C.:  
 20 Q. Class 2. And then 3.5 is about controls. And  
 21 you note that "Currently positive tissue  
 22 controls are placed on every patient tested  
 23 slide." And that was good thing?  
 24 MS. WEGRYNOWSKI:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:  
 2 Q. And you're somewhat envious of our tissue  
 3 control bank?  
 4 MS. WEGRYNOWSKI:  
 5 A. Yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. "No negative controls, however, are being  
 8 used." And what would a negative control  
 9 show?  
 10 MS. WEGRYNOWSKI:  
 11 A. I think I explain it to you further below. It  
 12 might be--no, I didn't. You want to ensure  
 13 that the test is not--is giving you reliable  
 14 results, that there's no cross reaction, so  
 15 you would use, like, for example, if we were  
 16 using monoclonal antibodies and we use a  
 17 universal mouse control which is a compilation  
 18 all sorts of G markers that we buy  
 19 commercially. We do that to ensure that the  
 20 only marking that we are getting from using  
 21 all the pretreatments and all the detection  
 22 systems is actually the antibody.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. And you note again, "No daily  
 25 assessment and documentation of the controls

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1 is performed in the IHC laboratory. Without  
 2 assessing the controls, no troubleshooting of  
 3 the procedure is occurring. Presently the onus  
 4 is on the individual pathologist to assess the  
 5 control tissue with the patient sample. No  
 6 documentation from the pathologist was found."  
 7 What documentation would you have expected to  
 8 see from the pathologists?  
 9 MS. WEGRYNOWSKI:  
 10 A. Well, I would expect it somewhere to see that  
 11 what they were doing that day that the  
 12 controls were a pass.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. So was there any indication or any  
 15 documentation to show that controls were being  
 16 looked at and signed off?  
 17 MS. WEGRYNOWSKI:  
 18 A. I never found that information.  
 19 CHAYTOR, Q.C.:  
 20 Q. And again then your recommendations flowing  
 21 from that are to run the negative reagent  
 22 controls on every block of patient tissue?  
 23 MS. WEGRYNOWSKI:  
 24 A. Um-hm.  
 25 CHAYTOR, Q.C.:

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1 Q. "Negative tissue control slides to be run for  
 2 each antibody." And "IHC registered  
 3 technologist to be trained to interpret and  
 4 make an assessment of the quality and  
 5 specificity of staining for every positive and  
 6 negative control daily tested. Signed  
 7 documentation of this assessment must be  
 8 maintained. Also, a review of tissue  
 9 recognition would be an asset." So what  
 10 you're suggesting here about the technologists  
 11 being able to interpret and read, those are  
 12 the external controls, I take it?  
 13 MS. WEGRYNOWSKI:  
 14 A. At least to understand that the test was a  
 15 pass or a failure. They were very far from  
 16 that point, but that would be certainly  
 17 something that you could put ahead as a goal  
 18 in the future.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. So they were far from being to the  
 21 point to be able to do that?  
 22 MS. WEGRYNOWSKI:  
 23 A. There were far more basic things that I felt  
 24 that needed to be taken care of, but I  
 25 included this in the report as a

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1 recommendation, yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. For down the road?  
 4 MS. WEGRYNOWSKI:  
 5 A. Absolutely.  
 6 CHAYTOR, Q.C.:  
 7 Q. To be able to get them to the point where  
 8 they'd be able to interpret whether or not the  
 9 control had worked?  
 10 MS. WEGRYNOWSKI:  
 11 A. Correct.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay. And that's something that your  
 14 technologists at Mount Sinai have been doing  
 15 for quite some time?  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes. And I tried to elaborate that with the  
 18 sentence, "Without assessing the controls, no  
 19 troubleshooting of the procedure is occurring."  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. So if I could understand it, the  
 22 external controls were not being read by the  
 23 technologists, then they weren't trained to do  
 24 that so they weren't being read, and then  
 25 where the external controls went in terms of

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1 pathologists signing off on them, you couldn't  
 2 find any documentation to substantiate that  
 3 had happened?  
 4 MS. WEGRYNOWSKI:  
 5 A. That's right.  
 6 CHAYTOR, Q.C.:  
 7 Q. And what do you mean by "A review of tissue  
 8 recognition would be an asset."?  
 9 MS. WEGRYNOWSKI:  
 10 A. Just before they start reading the controls,  
 11 just to go over the architecture of the  
 12 different components of the different organs  
 13 so they know what they should be looking at.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And then page 16, if there's nothing  
 16 else there. Is there anything else there, Ms.  
 17 Wegrynowski?  
 18 MS. WEGRYNOWSKI:  
 19 A. No.  
 20 CHAYTOR, Q.C.:  
 21 Q. "Surgical Reports" then. And you've  
 22 indicated, "Presently each site had their own  
 23 unique report headings on the surgical  
 24 pathology reports. Also, a standard reporting  
 25 format was not identified." Why would a

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1 standard reporting format be of any benefit?  
 2 MS. WEGRYNOWSKI:  
 3 A. Standard reporting is of benefit so that all  
 4 people have the same information, so that the  
 5 pathologists input the information in the same  
 6 manner and all clinicians can interpret it in  
 7 the same manner.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. So everyone would use the same  
 10 terminology and it would appear in the same  
 11 place on the -  
 12 MS. WEGRYNOWSKI:  
 13 A. On the reports.  
 14 CHAYTOR, Q.C.:  
 15 Q. - reports?  
 16 MS. WEGRYNOWSKI:  
 17 A. Absolutely.  
 18 CHAYTOR, Q.C.:  
 19 Q. And the Commissioner--there's been some  
 20 indication and they'll certainly be more said  
 21 about in terms of trying to identify the  
 22 patients in this case, and in terms of the  
 23 fact that there wasn't a lot of standard  
 24 reporting. So I take it if that were to  
 25 happen and that there was a standardized

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1 report format, that shouldn't be as big an  
 2 issue should issues arise down the road?  
 3 MS. WEGRYNOWSKI:  
 4 A. Correct.  
 5 CHAYTOR, Q.C.:  
 6 Q. So if you were to go back and do something  
 7 like was done here and being able to identify  
 8 which patients need to be retested, for  
 9 example, if you're standardized in your  
 10 reporting, that should certainly make it  
 11 easier?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And you have three recommendations  
 16 flowing out of that. And you talk about  
 17 standard report headings and also "Standard  
 18 reporting for all predictive prognostic  
 19 information." And "Investigate synoptic  
 20 reporting capability with Meditech Medical  
 21 Information Technology Inc." What do you mean  
 22 by that, reporting, standard reporting for  
 23 predictive and prognostic information, can you  
 24 give us an example?  
 25 MS. WEGRYNOWSKI:

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1 A. So that you would want to see on the report  
 2 what the ER or PR was, you'd like to know what  
 3 the scoring method is below that, it's that  
 4 sort of thing, so that the clinician would  
 5 know, by looking at it, whether it was  
 6 positive, negative, what the rates were and  
 7 how you came up with those rates, what your  
 8 scoring basis were.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay. So instead of just using words  
 11 "positive" or "negative" using actual  
 12 percentages, for example, for the ER/PR test  
 13 and having everyone report in the same manner?  
 14 MS. WEGRYNOWSKI:  
 15 A. And definitely what, and what scoring method  
 16 you used, absolutely.  
 17 CHAYTOR, Q.C.:  
 18 Q. Was there any issue as to words used like the  
 19 word "diagnosis" versus the word  
 20 "interpretation" anything like that?  
 21 MS. WEGRYNOWSKI:  
 22 A. I don't recall.  
 23 CHAYTOR, Q.C.:  
 24 Q. "All IHC tests providing predictive prognostic  
 25 information must include information on the

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1 patient record on specimen processing,  
 2 antibody clone and the scoring method used."  
 3 MS. WEGRYNOWSKI:  
 4 A. Yeah.  
 5 CHAYTOR, Q.C.:  
 6 Q. So this information would actually show up on  
 7 the patient's chart?  
 8 MS. WEGRYNOWSKI:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. So, for example, for an ER/PR test what  
 12 would we expect to see on the patient's chart?  
 13 MS. WEGRYNOWSKI:  
 14 A. Oh, you could see, I would say, 6F11, ER 6F11,  
 15 which would be the clone. They would say, I  
 16 think what ours say, they'll have a percentage  
 17 point and then underneath it you'll see the  
 18 Allred's scoring pattern.  
 19 CHAYTOR, Q.C.:  
 20 Q. Is there anything else there?  
 21 MS. WEGRYNOWSKI:  
 22 A. Synoptic reporting makes it really easy  
 23 because it's almost like a Can Tac (phonetic),  
 24 so they can just go in and plunk in what they  
 25 need.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. Anything else along that then?  
 3 MS. WEGRYNOWSKI:  
 4 A. No.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay. And then "Quality Assurance" "Current  
 7 neither external quality assurance nor  
 8 interlaboratory comparisons, excluding the  
 9 retrospective analysis which was taking place  
 10 is performed. No documentation was seen  
 11 concerning internal quality assurance for both  
 12 the technical and professional components."  
 13 So I take it what you're saying here is that  
 14 there wasn't any external nor internal  
 15 laboratory QA taking place and there was no  
 16 documentation concerning what, if any,  
 17 internal quality assurance was taking place?  
 18 MS. WEGRYNOWSKI:  
 19 A. That is correct.  
 20 CHAYTOR, Q.C.:  
 21 Q. And you say "You need to ensure the quality of  
 22 your laboratory's results to determine the  
 23 accuracy and reliability of the procedure.  
 24 There must also be a mechanism to evaluate the  
 25 interobserver variability amongst all the



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1 pathologists' interpretation of IHC staining."  
 2 And can you give us an example of that, such  
 3 as what, what would such a mechanism be?  
 4 MS. WEGRYNOWSKI:  
 5 A. You could have a group of pathologists that  
 6 are reading a particular type of marker all  
 7 sit down and give them the slides and they  
 8 would sit down and everybody would grade them  
 9 and then collectively look together to ensure  
 10 that they're in line with each other.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. And is that the kind of thing that you  
 13 understand happens at Mount Sinai?  
 14 MS. WEGRYNOWSKI:  
 15 A. Yes, you can speak to Frances and Brendan  
 16 about that.  
 17 CHAYTOR, Q.C.:  
 18 Q. Thank you. And again then your  
 19 recommendations, these were some of the  
 20 recommendations for inter/intra laboratory  
 21 comparison and for external -  
 22 MS. WEGRYNOWSKI:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. - proficiency testing and QA. You also say,

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1 "It would be advantageous for the  
 2 technologists to attend any medical rounds  
 3 relevant to the work they are involved with to  
 4 understand the larger scope of practice."  
 5 Does that happen at Mount Sinai?  
 6 MS. WEGRYNOWSKI:  
 7 A. It used to. We've gotten far too busy for  
 8 that, but when we did have the opportunity,  
 9 it's very valuable. I think we work behind the  
 10 scenes and we very rarely get to see the  
 11 patients or actually have the movement within  
 12 clinicians and I think people sometimes lose  
 13 sight exactly what it is that they're doing  
 14 and the extent of what they're doing and how  
 15 it can truly impact. So I think sometimes  
 16 people, if they have an opportunity to go to  
 17 rounds, they have a chance to step back and  
 18 actually listen to some of the case histories  
 19 and put people behind it and see how their  
 20 impact goes. I mean, it's not something that  
 21 we can obviously all go to medical rounds, but  
 22 if the opportunity arises, I think it's  
 23 something that is of great value for all  
 24 members of the health care team.  
 25 CHAYTOR, Q.C.:

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1 Q. And when you have new technologists coming on,  
 2 is that something that happens at Mount Sinai?  
 3 MS. WEGRYNOWSKI:  
 4 A. We've tried very hard. We've not always been  
 5 successful, but we have tried. But if they  
 6 go, they are always welcome.  
 7 CHAYTOR, Q.C.:  
 8 Q. And then under miscellaneous, you mentioned  
 9 the competency testing and presently, no  
 10 documentation exists relating to the training  
 11 of staff to perform their assigned duties.  
 12 Competency assessment for all staff is not  
 13 performed in the pathology division, and the  
 14 pathology manager has begun to investigate  
 15 this.  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. And your recommendations are that staff must  
 20 be provided with training and given a  
 21 documented performance appraisal prior to  
 22 working without supervision. Staff to be  
 23 assessed for competence to perform tasks  
 24 following training, identify requirements of a  
 25 task, perform gap analysis and develop action

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1 plans.  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. So were you suggesting that that needed to  
 6 happen before--with the current staff or is  
 7 this new staff coming on?  
 8 MS. WEGRYNOWSKI:  
 9 A. Anyone, because there was nothing there. You  
 10 wanted to ensure that people knew what they  
 11 were doing. It's for their own safety as well  
 12 as the patient's safety. These are patient  
 13 safety issues.  
 14 CHAYTOR, Q.C.:  
 15 Q. And what's gap analysis?  
 16 MS. WEGRYNOWSKI:  
 17 A. What you can do and what we need you to do and  
 18 how do we get you there. We're going to  
 19 develop an action plan to get you there.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and then we see reference again to the  
 22 textbook and recommending internet and  
 23 textbooks.  
 24 MS. WEGRYNOWSKI:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And continuing education conferences, and you

3 indicate funding to be available for AIHC

4 technologists to attend the NSH convention.

5 What's the NSH convention?

6 MS. WEGRYNOWSKI:

7 A. The National Society of Histotechnology. It's

8 an American organization and in my opinion,

9 one of the very best in North America. It's

10 where there's the largest group of

11 histotechnologists and so there's a tremendous

12 lecturing from all sorts of different people

13 to do with not only histology, but with

14 immunohistochemistry as well.

15 CHAYTOR, Q.C.:

16 Q. Okay, and then equipment placement, you

17 indicated you recommended to relocate the

18 automated special staining equipment, and why

19 was that?

20 MS. WEGRYNOWSKI:

21 A. It was just--it was by something else and you

22 don't want it to be disturbed. It's just very

23 simple.

24 CHAYTOR, Q.C.:

25 Q. And there's a safety issue about acid storage?

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1 MS. WEGRYNOWSKI:

2 A. Yeah. The histocolometer wouldn't work for

3 them simply because of the type of microtome

4 that it was, but it certainly was meant to

5 highlight that if the microtome does not

6 align and orient the block for recutting the

7 sections in immunohistochemistry, there is

8 always that possibility that if it's a small

9 foci of tumor that it can be cut through.

10 CHAYTOR, Q.C.:

11 Q. Okay, and then the next page is a list of

12 resources, and then your conclusion, and

13 again, your conclusion, you talk about the

14 rotating pathology assistants providing the

15 grossing of large specimen would standardize

16 the procedures between the two sites.

17 Standardizing fixation time of every specimen

18 will have a direct correlation on the quality

19 of IHC staining, and the consolidation of

20 tissue processing at the Health Sciences site

21 should be implemented. The consolidation

22 would ensure that all specimens are processed

23 in the same manner, and the tissue processors

24 are maintained in the same way. Standardizing

25 the processing will positively impact the IHC

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1 staining. You talk about the procedure

2 manuals being written again, and the three

3 non-rotating registered technologists should

4 be employed or to be employed in IHC with one

5 appointed a level of responsibility, and the

6 three technologists will be responsible for

7 all aspects of IHC from validating all

8 elements to every staining procedures, to

9 assessing controls and a director of IHC

10 should be appointed, and it is essential the

11 laboratory become involved in a peer

12 assessment program, and I take it that's the

13 external proficiency.

14 MS. WEGRYNOWSKI:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. And standardization of all processes will

18 result in increased reliability and

19 reproducibility of the IHC results, and you

20 indicate that they are more than capable of

21 attaining this degree of competency.

22 MS. WEGRYNOWSKI:

23 A. Yes.

24 CHAYTOR, Q.C.:

25 Q. And is there anything else then in your

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1 report--I'm going to take you back to the

2 pipettes, but is there anything else that we

3 haven't covered that you feel is important to

4 mention?

5 MS. WEGRYNOWSKI:

6 A. No, I'm pleased with it.

7 CHAYTOR, Q.C.:

8 Q. Okay. Commissioner, Ms. Wegrynowski was going

9 to do a very brief demonstration for us, but

10 if we could have a quick break so she could

11 set up for that?

12 THE COMMISSIONER:

13 Q. Actually, it's near the time of the afternoon

14 break. Why don't we do that?

15 CHAYTOR, Q.C.:

16 Q. Okay, sure.

17 (RECESS)

18 THE COMMISSIONER:

19 Q. Please be seated. Ms. Chaytor.

20 CHAYTOR, Q.C.:

21 Q. Thank you, Commissioner. Commissioner, we

22 have a new exhibit please. It's P-1668, if we

23 could have that entered. I'm sorry, 1768,

24 thank you, Mr. Coffey.

25 THE COMMISSIONER:

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1 Q. They just slip up there so easily, don't they?  
 2 1768?  
 3 CHAYTOR, Q.C.:  
 4 Q. That's correct.  
 5 THE COMMISSIONER:  
 6 Q. All right, entered.  
 7 EXHIBIT ENTERED AND MARKED EXHIBIT P-1768  
 8 CHAYTOR, Q.C.:  
 9 Q. Thank you. Okay, Ms. Wegrynowski, if we could  
 10 go back, please, Registrar, to P-0047, page  
 11 11? And number 17, your 17th recommendation  
 12 was "guarantee pipette and temperature  
 13 accuracy and calibration. The accuracy of the  
 14 volume of the pipette delivers must be guarded  
 15 to ensure the reproducibility of the antibody  
 16 dilutions. A standard thermometric device or  
 17 reference thermometer is to be available to  
 18 check thermometers used on all temperature  
 19 controlled instruments. Digital temperature  
 20 readings do not suffice and thermometer  
 21 readings are to be recorded." Perhaps then  
 22 you could take it from there and tell us why  
 23 this is of importance?  
 24 MS. WEGRYNOWSKI:  
 25 A. I'm sorry, which part of--the thermometers?

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1 CHAYTOR, Q.C.:  
 2 Q. Yes, about the accuracy of the volume of the  
 3 pipette delivers must be guarded to ensure the  
 4 reproducibility.  
 5 MS. WEGRYNOWSKI:  
 6 A. Okay. This is just a little example. I  
 7 think--it's difficult to ascertain how small  
 8 some of these volumes are, so it was suggested  
 9 that perhaps that I bring a sample with me to  
 10 show you. So this--I'm using it from a DAKO  
 11 autostainer system because that's what we have  
 12 at Mount Sinai and this is what was in place  
 13 at Eastern Health prior to the Ventana  
 14 Benchmark. I don't know if you can see, but  
 15 this was the vial that they would have used,  
 16 and in this vial, I have placed one ml of  
 17 water. This actually would be enough to stain  
 18 four slides on the autostainer, so you start  
 19 understanding really how small our volumes  
 20 are.  
 21 So to that, I'm going to make you 1 and  
 22 100 dilution. I'm afraid I forgot the correct  
 23 tips for my other pipette, but this gives you  
 24 a little bit of an idea. So this is ten  
 25 microlitres and that's exactly what it looks

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1 like. So if you were to dispense that in  
 2 here, it's such a small volume, I think you  
 3 start understanding that if the calibration of  
 4 your pipettes are not maintained that the  
 5 volumes would begin to wane, that you would  
 6 never have the accurate dilution that you  
 7 required.  
 8 You can also see that on the exhibit  
 9 they're showing you or told you exactly what  
 10 it was sent when it was from Rainin, what the  
 11 volume settings were and what the expectations  
 12 are. Our pipettes are guarded for that. If  
 13 our pipettes are ever dropped, they certainly  
 14 are--we call in maintenance right away on  
 15 them. These are like our scalpel blades.  
 16 This is everything that we do every day. If  
 17 this falls and even though it may be saying  
 18 ten and it's never been calibrated, you have  
 19 never had that assurance. So I thought it was  
 20 well worth bringing this today, Madam  
 21 Commissioner.  
 22 THE COMMISSIONER:  
 23 Q. So that there is a special person who comes to  
 24 do this?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes, they have a company that comes in to do  
 2 this for us and they calibrate the pipettes  
 3 and it's supposed to be done a minimum of  
 4 twice a year, but we get them done, I would  
 5 say easily three to four times a year, simply  
 6 because of the volume that we do.  
 7 THE COMMISSIONER:  
 8 Q. So it would be three to four times a year, and  
 9 if you are concerned that one isn't working or  
 10 has been treated in a way that might interfere  
 11 with the calibration, you would get the person  
 12 to do it again?  
 13 MS. WEGRYNOWSKI:  
 14 A. Absolutely, and it's because those volumes are  
 15 so small.  
 16 CHAYTOR, Q.C.:  
 17 Q. And the amount that you're showing there is a  
 18 larger amount than what you would be dealing  
 19 with with some pipettes?  
 20 MS. WEGRYNOWSKI:  
 21 A. Absolutely. There are some pipettes, there  
 22 are some dilutions, we're only talking about  
 23 two microlitres, which is a fifth of the  
 24 volume that I just showed you.  
 25 CHAYTOR, Q.C.:

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1 Q. And I'm just wondering, Commissioner, if you  
 2 were able to see that or if we could -  
 3 THE COMMISSIONER:  
 4 Q. Actually, I could see it. I don't know if  
 5 anybody else in the room could, but I could.  
 6 CHAYTOR, Q.C.:  
 7 Q. Did you want to do it again and perhaps you  
 8 could just show people in the room the amount  
 9 that you're talking about?  
 10 MS. WEGRYNOWSKI:  
 11 A. Okay, I can do that for you. So that's what  
 12 ten microlitres would look like. So you can  
 13 see that it's a green diluent, but then when  
 14 you actually dilute it out, you would see  
 15 absolutely nothing in it. It's really a small  
 16 amount, so this is 1 to 100 dilution which is  
 17 certainly not anything unusual in  
 18 immunohistochemistry, so we're really talking  
 19 little tiny amounts. Anybody want to see  
 20 this? So it really gets small. So when you  
 21 start taking it down into smaller volumes, you  
 22 understand that the accuracy must be in place.  
 23 When you dilute it out, there's nothing. You  
 24 don't see anything.  
 25 CHAYTOR, Q.C.:

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1 Q. Thank you, Ms. Wegrynowski.  
 2 MS. WEGRYNOWSKI:  
 3 A. You're welcome.  
 4 CHAYTOR, Q.C.:  
 5 Q. Could you just tell us where, in doing the  
 6 ER/PR test, when--at what stage are you using  
 7 your pipette?  
 8 MS. WEGRYNOWSKI:  
 9 A. The pipettes are used primarily to make up the  
 10 primary antibody. So the dilution that is  
 11 required has been considered at validation.  
 12 It's not unusual to have dilutions go from 1  
 13 in 20 up to 1 in 2-3,000. So we use them to  
 14 make up our primaries. So some of our  
 15 secondary and tertiary antibodies, we use them  
 16 as well, but over 90 percent of it is all done  
 17 for the primary antibodies.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay, and I believe that pipette that you  
 20 showed us is probably five times more than the  
 21 one you actually showed us in Toronto that  
 22 day.  
 23 MS. WEGRYNOWSKI:  
 24 A. Yeah, this is it, because this is ten  
 25 microlitres and what I showed you was two

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1 microlitres. Yes, it is.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and if we could look then at 1768? This  
 4 is the latest exhibit, and could you just  
 5 explain, please, for us, what this document  
 6 is?  
 7 MS. WEGRYNOWSKI:  
 8 A. This is just what comes when you purchase your  
 9 pipettes. So that--I'm not fluent on this, I  
 10 have to admit, but it tells you what your  
 11 useful volume range is. It should only be  
 12 used between 100 microlitres and a thousand  
 13 microlitres, which would explain why we have a  
 14 wide variety of pipette measurements, so that  
 15 the accuracy, that we're guarding against it,  
 16 that we're using it in the actual spectrum  
 17 that it should be used in. It tells you  
 18 exactly what kind of pipette tip that you  
 19 should be using and we only buy sterilized  
 20 pipette tips so that we don't bring any  
 21 contaminant into our primary antibody. It'll  
 22 then tell you what your balance is and your  
 23 sensitivity, your correction factor. It tells  
 24 you a little bit about the weighings, what  
 25 they're getting, and so once that's done, it's

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1 also ISO standardized. The warranty can get  
 2 sent off, and then, as I say, we have our  
 3 pipettes calibrated at a minimum of twice a  
 4 year.  
 5 If there's any errors with these, then  
 6 the company will either fix it or if it's  
 7 beyond fix, they'll tell us to replace, and  
 8 then the company that I use, they come on site  
 9 and then on my pipette, it'll have the serial  
 10 number and the date that they did it. This  
 11 particular pipette was done February 6th of  
 12 this year, and I need to have it re-calibrated  
 13 by August 6th.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, and I take it there's no guarantee  
 16 otherwise that ten millilitres or whatever it  
 17 is, is in fact ten millilitres?  
 18 MS. WEGRYNOWSKI:  
 19 A. That's right. That's right, so they have to  
 20 be--and that's one of the things when you work  
 21 in the area every day, you start getting a  
 22 sense just visually of what they should look  
 23 like. So that's another indicator as well.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, thank you.

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1 MS. WEGRYNOWSKI:  
 2 A. You're welcome.  
 3 CHAYTOR, Q.C.:  
 4 Q. Commissioner, if we could take another quick  
 5 break, so we can set up again quickly?  
 6 THE COMMISSIONER:  
 7 Q. Yes, of course.  
 8 CHAYTOR, Q.C.:  
 9 Q. Thank you.  
 10 (RECESS)  
 11 THE COMMISSIONER:  
 12 Q. Please be seated. Ms. Chaytor.  
 13 CHAYTOR, Q.C.:  
 14 Q. Thank you, Commissioner, and thank you, Ms.  
 15 Wegrynowski, for the demonstration. So  
 16 November 9th, 2005, your report was--you sent  
 17 it on and submitted it to Eastern Health.  
 18 MS. WEGRYNOWSKI:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. Did you receive any feedback after submitting  
 22 your report?  
 23 MS. WEGRYNOWSKI:  
 24 A. Just a letter from Dr. Williams thanking me to  
 25 come.

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1 CHAYTOR, Q.C.:  
 2 Q. And if we could look at, please, P-1331? And  
 3 this is a letter here, private and  
 4 confidential to yourself from Dr. Williams  
 5 dated November 23rd, 2005. "I want to thank  
 6 you very much for coming to our province and  
 7 doing a review of the immunohistochemistry lab  
 8 operated by Eastern Health. I want to thank  
 9 you for the detailed and comprehensive report  
 10 that you have provided to us. You can be  
 11 assured that your recommendations will be used  
 12 as a template as we move forward to improve  
 13 the immunohistochemistry services that we  
 14 offer. We intend to achieve the degree of  
 15 competency that you have laid out in the  
 16 recommendations. Again, thank you very much  
 17 for your assistance. I'm sure Mr. Gulliver or  
 18 Dr. Cook may wish to contact you further to  
 19 get ongoing advice as we move forward in  
 20 implementing the recommendations in your  
 21 report."  
 22 Were you ever contacted by Mr. Gulliver  
 23 or Dr. Cook in that regard?  
 24 MS. WEGRYNOWSKI:  
 25 A. No.

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1 CHAYTOR, Q.C.:  
 2 Q. If we could look at P-1330 please? And this  
 3 is a letter, the same date, and private and  
 4 confidential to Dr. Cook and to Mr. Terry  
 5 Gulliver. "Dear Don and Terry, I have had an  
 6 opportunity to review in detail the reports of  
 7 Dr. Diponkar Banerjee and Ms. Trish  
 8 Wegrynowski with respect to the  
 9 immunohistochemistry services offered by  
 10 Eastern Health. I wonder if you could prepare  
 11 a spreadsheet to capture all the  
 12 recommendations embodied in both those  
 13 reports, i.e. this should include all  
 14 recommendations, even ones such as  
 15 refrigeration storage referenced on page four  
 16 of Trish Wegrynowski's report, in preparing  
 17 the spreadsheet and the current status with  
 18 respect to implementation of these  
 19 recommendations. You should assume that  
 20 funding will be provided, based on the  
 21 document you prepared for me on October 13th,  
 22 2005. Once you have the spreadsheet developed  
 23 and the current status of our implementation,  
 24 I would like to meet with you as soon as  
 25 possible to review where we go from here,

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1 especially in dealing with the institution of  
 2 the immunohistochemistry services."  
 3 So that's correspondence then from Dr.  
 4 Williams to both Dr. Cook and Mr. Gulliver  
 5 indicating that a spreadsheet would be  
 6 prepared with recommendations, including all  
 7 of your recommendations.  
 8 MS. WEGRYNOWSKI:  
 9 A. Okay.  
 10 CHAYTOR, Q.C.:  
 11 Q. We know that, of course, as the fall went on  
 12 at Mount Sinai and actually this letter I note  
 13 has a--the date is wrong, but we understand  
 14 this should be November 23rd, 2005, we  
 15 understand to be the date on that letter. As  
 16 the fall went on, of course, the retests were  
 17 taking place at Mount Sinai. Were you  
 18 involved in that process at all?  
 19 MS. WEGRYNOWSKI:  
 20 A. No, I was not.  
 21 CHAYTOR, Q.C.:  
 22 Q. And if we could look at P-1739, please,  
 23 Registrar? And these again are handwritten  
 24 notes of Dr. Cook and I just bring this to  
 25 your attention because on October 13th, 2005,

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1 he has a note "Spoke to Trish Wegrynowski  
 2 regarding immuno"--looks like immuno machine.  
 3 "She said machine should be up and running  
 4 soon. No delays in consultations, expects  
 5 some delays in retro cases." Do you recall  
 6 having that discussion or what that's about?  
 7 MS. WEGRYNOWSKI:  
 8 A. No, it doesn't ring a bell.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, were you involved in the ongoing  
 11 consultations for ER/PR for Newfoundland?  
 12 MS. WEGRYNOWSKI:  
 13 A. I do the forward going work, yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, so the work that was ongoing, the  
 16 current cases as such -  
 17 MS. WEGRYNOWSKI:  
 18 A. Uh-hm.  
 19 CHAYTOR, Q.C.:  
 20 Q. You were involved in doing those.  
 21 MS. WEGRYNOWSKI:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. And were you also involved in any, from the  
 25 retests that were sent up as consultations?

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1 MS. WEGRYNOWSKI:  
 2 A. No.  
 3 CHAYTOR, Q.C.:  
 4 Q. And so you don't recall having this discussion  
 5 with Dr. Cook?  
 6 MS. WEGRYNOWSKI:  
 7 A. No, I don't actually.  
 8 CHAYTOR, Q.C.:  
 9 Q. And the idea of, then again this is October,  
 10 2005, machine should be up and running soon.  
 11 Were you having difficulties with your  
 12 equipment at Mount Sinai?  
 13 MS. WEGRYNOWSKI:  
 14 A. I mean, anything is possible, I would have to  
 15 go back and check my service records at home  
 16 to determine whether or not that is so the  
 17 case.  
 18 CHAYTOR, Q.C.:  
 19 Q. But this doesn't ring any bells to you at all?  
 20 MS. WEGRYNOWSKI:  
 21 A. No, I mean, I think when they first took on  
 22 some of the retro work, this is something from  
 23 memory, I think they were using the auto-  
 24 stainers that were in the service laboratory,  
 25 so there could have been--there was one that

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1 did have some concerns that we took down, so  
 2 unless--that's the only thing I can think of,  
 3 but again, I would have to check the service  
 4 records.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay, and if we could look at please, P-0101?  
 7 And this is not a document that I expect you  
 8 to be familiar with here. It's a letter to  
 9 Dr. Williams, but it's dated December 11th,  
 10 2005 and it's written by Dr. Carter, who  
 11 you've met, of course and she copies it to Dr.  
 12 Cook, Mr. Gulliver and Dr. Ejeckam. And in  
 13 this letter she writes, "I was most recently  
 14 asked by Dr. Don Cook to comment on the  
 15 suggestion of Mr. Barry Dyer that stated that  
 16 he felt the Ventana testing for estrogen  
 17 receptor, progesterone receptor and HER2/neu  
 18 could be started at any time. I find this  
 19 comment quite startling in the face of the two  
 20 fairly damning reports sent by Dr. Banerjee  
 21 and Trish Wegrynowski on their review of our  
 22 immunohistochemistry laboratory, with special  
 23 emphasis on the predictive factors for breast  
 24 cancer patients." And she goes on to point  
 25 out several things in her letter and my point

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1 in showing you those things would be to ask  
 2 whether or not you agree with what has been  
 3 highlighted by Dr. Carter. She says "Breast  
 4 pathology, indeed all of anatomic pathologies  
 5 are often very difficult and is subject to a  
 6 myriad of influences that can lead to poor  
 7 outcomes for our patients. As stated by Dr.  
 8 Banerjee and Ms. Wegrynowski and vehemently  
 9 supported by me, there are multiple major  
 10 issues that must be addressed prior to any  
 11 breast testing being reported from our  
 12 immunohistochemistry laboratory. The most  
 13 important of these is organization of the  
 14 immunohistochemistry laboratory. Our  
 15 technologists need to be dedicated to the  
 16 immunohistochemistry laboratory. My most  
 17 recent ER/PR/HER2/neu validation meeting with  
 18 them booked in advance, required taking one  
 19 technologist from the frozen section room and  
 20 one from the grossing room and one of them  
 21 should be deemed the charged technologist or  
 22 other equal terms. These technologists need  
 23 then to be educated at an acceptable training  
 24 institution, not at individual local  
 25 pathologist's desks, in the theory of

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1 immunohistochemistry. They need to learn  
 2 about the pitfalls of immunohistochemistry,  
 3 troubleshooting and quality control." And I  
 4 take it, Ms. Wegrynowski if I could just stop  
 5 there and ask you about that, is that what you  
 6 were referring to as well in your report?  
 7 MS. WEGRYNOWSKI:  
 8 A. Yes, they needed to learn a lot more about the  
 9 theory.  
 10 CHAYTOR, Q.C.:  
 11 Q. "This education must be documented and  
 12 competency testing carried out. Textbooks and  
 13 internet references need to be made available  
 14 in the laboratory; further, there must be  
 15 documentation of training and competency of  
 16 the staff on all equipment used in the  
 17 laboratory. Continuing medical education of  
 18 an improved and pertinent manner must be  
 19 carried out and monies provided for it. These  
 20 technologists need to document the  
 21 optimization and validation of every antibody,  
 22 including ER/PR and HER2/neu currently in use.  
 23 All validations must be documented and readily  
 24 available, format available to any staff in  
 25 the absence of the technologist, signed off by

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1 the pathologist who acts as section head or a  
 2 designate and the slides kept permanently and  
 3 readily available. They need to derive  
 4 standard operating procedures for the staining  
 5 protocols for every antibody in the laboratory  
 6 and not a copy of the Ventana manual. These  
 7 SOP's need to be in agreement with well-known  
 8 regulatory guidelines such as CSLI. All  
 9 antibody specification sheets must be  
 10 available at the workbench, again in readily  
 11 available format. The technologist must set  
 12 up an appropriate internal and external  
 13 quality assurance program and alliance with a  
 14 large volume teaching hospital should be for  
 15 use as an occasional quality advisor. An  
 16 appropriate organizational chart must be  
 17 designed whereby the immunohistochemistry  
 18 technologists are professionally responsible  
 19 to the section head and designate and not to  
 20 the laboratory manager and laboratory  
 21 director. Of course, the technologist must  
 22 also be professionally responsible to them and  
 23 should not look to pathologists to solely make  
 24 decisions about the technical aspects of the  
 25 immunohistochemistry, rather the technologists

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1 must act as equal partners presenting their  
 2 decision to the section head for approval.  
 3 And there must be a well-documented user  
 4 friendly system, whereby individual  
 5 pathologist's complaints and concerns are  
 6 registered and a mechanism set up by which  
 7 these problems are investigated. Appropriate  
 8 positive and negative controls must be  
 9 selected for ER/PR and HER2/neu. The  
 10 immunochemistry technologists need to be  
 11 trained in the basics of interpretation of  
 12 ER/PR and HER2/neu, so that appropriately  
 13 stained slides only leave the laboratory. The  
 14 microscope needs to be placed in the  
 15 laboratory for the use of the technologists.  
 16 Routine equipment maintenance schedules must  
 17 be set up and carried out. Some of the  
 18 equipment in the immunohistochemistry lab must  
 19 be moved to ensure optimal operation. I feel  
 20 that all the above recommendations must be  
 21 fully in place before we can begin to release  
 22 ER/PR/HER2/neu status reports from our lab. I  
 23 am unaware that any of these have taken place.  
 24 The pathologists must standardize their  
 25 approach to the accessioning and gross

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1 handling of all breast specimens. All tissue  
 2 processing must be amalgamated and  
 3 standardized. Pathologists should be  
 4 educated"--and I think the rest of that is  
 5 more about the pathologists. "Standardized  
 6 reporting of immunohistochemistry results  
 7 should be used that list the clone percentage  
 8 positivity in the procedure to minimize  
 9 oncologist's chance of misrepresentation.  
 10 Inter- and intra- pathologist variability in  
 11 reporting must be assessed." So that's  
 12 basically what Dr. Carter wrote and again,  
 13 this is two and a half months after you were  
 14 in St. John's on December 7th, 2005. So I  
 15 just ask your comment on that in terms of how  
 16 consistent it is with what you had pointed  
 17 out?  
 18 MS. WEGRYNOWSKI:  
 19 A. I think this letter is very consistent with  
 20 what I wrote in my report.  
 21 CHAYTOR, Q.C.:  
 22 Q. If we could look, please, at P-1748? And  
 23 these are handwritten notes of Dr. Cook again,  
 24 February 8th, 2006. And it's a meeting from  
 25 10:30 to 11:30 a.m. And before I take you to

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1 that, are you aware of anybody from Eastern  
 2 Health going to Mount Sinai for further  
 3 training?  
 4 MS. WEGRYNOWSKI:  
 5 A. Bev Carter had been out to visit Frances at a  
 6 point in time, coming to the laboratory and I  
 7 had shown her around. She had wanted to see  
 8 the documentation that we had and she went  
 9 back and Mary Butler was sent up to Mount  
 10 Sinai Hospital.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, so Dr. Carter looked around your IHC  
 13 lab.  
 14 MS. WEGRYNOWSKI:  
 15 A. Yes.  
 16 CHAYTOR, Q.C.:  
 17 Q. And then out of that visit to Mount Sinai came  
 18 a request for Mary Butler, one of the  
 19 technologists to come up?  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes, Bev commented on how many different kinds  
 22 of manuals we have and just how many, just how  
 23 many binders we have in the place, just  
 24 recording everything that's going on.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and did you have any other discussion  
 2 with Dr. Carter at that time?  
 3 MS. WEGRYNOWSKI:  
 4 A. I don't recall, no.  
 5 CHAYTOR, Q.C.:  
 6 Q. And so Ms. Butler then attended?  
 7 MS. WEGRYNOWSKI:  
 8 A. Uh-hm.  
 9 CHAYTOR, Q.C.:  
 10 Q. And how long did she visit with you?  
 11 MS. WEGRYNOWSKI:  
 12 A. She was, I believe on site somewhere in the  
 13 two-week vicinity, but she was not with me for  
 14 that entire time.  
 15 CHAYTOR, Q.C.:  
 16 Q. So she was up there, though, in Mount Sinai  
 17 for about two weeks?  
 18 MS. WEGRYNOWSKI:  
 19 A. I think so.  
 20 CHAYTOR, Q.C.:  
 21 Q. And about how long did she spend in the IHC  
 22 lab with you?  
 23 MS. WEGRYNOWSKI:  
 24 A. I remember a couple of days.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And what kind of things did she do  
 2 while she was there? Or what did you do with  
 3 her?  
 4 MS. WEGRYNOWSKI:  
 5 A. From my understanding Mary was coming up to do  
 6 just an observation of the  
 7 immunohistochemistry laboratory, so we do have  
 8 clients that do come on board to do that, they  
 9 weren't coming to do competency testing or any  
 10 of the sort, so when a client comes on board  
 11 for observation, I'm there to serve whatever  
 12 needs that they need. So whatever she needed  
 13 to look at or whatever she wanted to evaluate,  
 14 I would certainly deal with her, I always  
 15 provide an overview of the department, just  
 16 going through the processes and the procedures  
 17 and all the documentation that we have just to  
 18 provide a well base of knowledge.  
 19 CHAYTOR, Q.C.:  
 20 Q. So she actually observed what you did in your  
 21 day-to-day job?  
 22 MS. WEGRYNOWSKI:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. And did she also review your documentation on

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1 how you record things?  
 2 MS. WEGRYNOWSKI:  
 3 A. Yes, she did.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and your SOP's?  
 6 MS. WEGRYNOWSKI:  
 7 A. She had the opportunity to read our SOP's,  
 8 yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, and what did you understand--what was  
 11 the purpose of Ms. Butler being there?  
 12 MS. WEGRYNOWSKI:  
 13 A. I would just say just to look at how the IHC  
 14 lab was run at Mount Sinai Hospital.  
 15 CHAYTOR, Q.C.:  
 16 Q. And by the time that she left then there, did  
 17 you have a sense that her understanding had  
 18 progressed in terms of the theory and how the  
 19 lab is run, how it's set up and the importance  
 20 of documentation?  
 21 MS. WEGRYNOWSKI:  
 22 A. Could you rephrase that for me please?  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. I'm just wondering whether or not by  
 25 the time that Ms. Butler left, had there been



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1 progress in terms of her understanding of the  
 2 processes and the documentation that go along  
 3 with the processes?  
 4 MS. WEGRYNOWSKI:  
 5 A. I wouldn't say great strides.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and what did you think then needed  
 8 further work?  
 9 MS. WEGRYNOWSKI:  
 10 A. I had tried to sit with Mary to assist her in  
 11 writing some standard operating procedures and  
 12 I don't think this was what she was most  
 13 comfortable doing.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So the actual development of the  
 16 standard operating procedures, there was a  
 17 level of discomfort for her in doing that?  
 18 MS. WEGRYNOWSKI:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. And if we could look please at P-1766? I'll  
 22 come back to this one, Registrar, so if you  
 23 just want to diminish it. And this is  
 24 indicated to be a Mount Sinai document, ER/PR  
 25 immunohistochemistry standard operating

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1 procedure.  
 2 MS. WEGRYNOWSKI:  
 3 A. Uh-hm.  
 4 CHAYTOR, Q.C.:  
 5 Q. Special histology, hard tissue procedure  
 6 manual. Can you identify this document for us  
 7 and tell us what this is?  
 8 MS. WEGRYNOWSKI:  
 9 A. This document would be seen on the other side  
 10 of the lab, this is not part of the service  
 11 laboratory and it's indicated by the  
 12 terminology there, the special hard tissue  
 13 procedure manual, it's not the  
 14 immunohistochemistry procedure manual,  
 15 although it is an operating procedure for  
 16 immunohistochemistry. The supervisor, the  
 17 written bio dates are all present. The Table  
 18 of Contents are there. The Table of Contents  
 19 always must be prefaced by a flow chart in  
 20 which it is.  
 21 CHAYTOR, Q.C.:  
 22 Q. So this is from the research side of the lab,  
 23 is it?  
 24 MS. WEGRYNOWSKI:  
 25 A. Yes, it is.

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1 CHAYTOR, Q.C.:  
 2 Q. This is a sample of one of your SOP's that  
 3 have been given to us, we understand.  
 4 MS. WEGRYNOWSKI:  
 5 A. Okay. So it's just walking through the  
 6 process in a schematic, that you receive the  
 7 slides in HNE, in the laboratory, it was run  
 8 on the auto-stainer, they do separate their  
 9 runs according to antibody pretreatment  
 10 detection system. They run their antibodies  
 11 with controls, positive for antibody, negative  
 12 for each--should be each test, each case in  
 13 the detection system, and then of course they  
 14 collate the slides and send them on up with  
 15 the HNE.  
 16 CHAYTOR, Q.C.:  
 17 Q. And so I won't take you through the whole  
 18 document, but this is the type of--it's a  
 19 typical, I take it, SOP, is it?  
 20 MS. WEGRYNOWSKI:  
 21 A. It's a little bit different than mine, but  
 22 yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. And if we could go back then please to P-1748?  
 25 And by the way, were you contacted to offer

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1 any further training to either Ms. Butler or  
 2 anyone else?  
 3 MS. WEGRYNOWSKI:  
 4 A. No, I was not.  
 5 CHAYTOR, Q.C.:  
 6 Q. And did anyone follow up with you from Eastern  
 7 Health or from the laboratory to inquire how  
 8 it had gone with Mary?  
 9 MS. WEGRYNOWSKI:  
 10 A. Not to my memory, no.  
 11 CHAYTOR, Q.C.:  
 12 Q. And this is the meeting of February 8th, 2006  
 13 and it appears from this meeting that Ms.  
 14 Butler has already been to Mount Sinai, it's a  
 15 meeting regarding an update on the  
 16 implementation of ER/PR and there's a number  
 17 of people present, including pathologists  
 18 Cook, Ejeckam, Carter, Fontaine, Mr. Gulliver  
 19 and Mr. Dyer are present, so are three techs,  
 20 Mr. Simms, Mr. Green and Ms. Butler. And the  
 21 meeting started with both Ken Green and Mary  
 22 giving written reports of their experiences in  
 23 Mount Sinai for Mary, and Montreal Jewish  
 24 General for Ken. "Ken brought back  
 25 information from Montreal on types of

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1 antibodies used and protocols. Mary brought  
 2 forth the issue on QA. She brought back  
 3 document on PA's, pathology assistants and  
 4 fixation protocols. Mary was not allowed to  
 5 bring back documents on immuno peroxidase  
 6 protocols from Mount Sinai. Both agreed on  
 7 the need for documentation of activities in  
 8 the lab and the establishment of manuals." so  
 9 it looks like she--Mary did bring back  
 10 documents on pathology assistants and fixation  
 11 protocols.  
 12 MS. WEGRYNOWSKI:  
 13 A. Uh-hm.  
 14 CHAYTOR, Q.C.:  
 15 Q. And this referenced that she was not allowed  
 16 to bring back documents on immuno peroxidase  
 17 protocols from Mount Sinai. Can you speak to  
 18 that?  
 19 MS. WEGRYNOWSKI:  
 20 A. We do not give out our standard operating  
 21 procedure manuals. We don't give them out to  
 22 paying clients either. Protocols are needed  
 23 to be developed on site by your own people. I  
 24 provided Mary with an opportunity to write  
 25 them. I saw with her. In the lecture that I

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1 provided to and I gave you this morning, there  
 2 are also templates in there about the antibody  
 3 data sheets and the historical data sheets.  
 4 Manuals are--the whole purpose of a manual is  
 5 to scribe the process at your site. What I do  
 6 at my site may not necessarily to be at your  
 7 site. We don't even use the same equipment.  
 8 So her manuals would have to--the manuals for  
 9 Eastern Health would have to be how Eastern  
 10 Health worked with the equipment and worked  
 11 with the actual patient samples. Your  
 12 protocols would have to include that you are a  
 13 multi site; we are a single site. There are  
 14 many differences, but I certainly did assist  
 15 her in allowing her--well I shouldn't use that  
 16 term, she certainly had the opportunity to  
 17 read our procedure manual and see what was  
 18 required in it and I would have been certainly  
 19 able there to assist it, had she asked.  
 20 CHAYTOR, Q.C.:  
 21 Q. And I take it that with those standard  
 22 operating procedures, one size doesn't fit  
 23 all, obviously.  
 24 MS. WEGRYNOWSKI:  
 25 A. Not at all.

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1 CHAYTOR, Q.C.:  
 2 Q. And it has to be then, from what you're  
 3 saying, it has to be created and developed  
 4 according to the variations in each lab?  
 5 MS. WEGRYNOWSKI:  
 6 A. Yes. They refer to standard operating  
 7 procedures and manuals as being living  
 8 breathing documents to reflect your own needs.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay. And so you provided templates and you  
 11 provided other information, but the idea of  
 12 giving the standard operating procedure which  
 13 pertains to Mount Sinai, you didn't think that  
 14 would be prudent because it might not -  
 15 MS. WEGRYNOWSKI:  
 16 A. That's not our procedure, no.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. It's not what should or would be  
 19 relevant to St. John's.  
 20 MS. WEGRYNOWSKI:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. In these notes, Dr. Cook writes, "it  
 24 was agreed to test 30 - 40 case concurrently  
 25 with Mount Sinai and our system in respect to

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1 ER and PRS and also Montreal General for  
 2 correlation". In getting ready for St. John's  
 3 to start up again, we understand in February  
 4 of 2007, so it's a year after this is actually  
 5 being written, ER/PR was initiated again here  
 6 in St. John's. And were you involved at all  
 7 in helping them with the correlation and  
 8 having -  
 9 MS. WEGRYNOWSKI:  
 10 A. No.  
 11 CHAYTOR, Q.C.:  
 12 Q. No, okay. And if that did happen, do you  
 13 think you'd be aware of it, if Mount Sinai had  
 14 been used to help correlate results?  
 15 MS. WEGRYNOWSKI:  
 16 A. Only if I had been involved in it. No, I was  
 17 not.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. And if we could look please at P-1753.  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay.  
 22 CHAYTOR, Q.C.:  
 23 Q. And perhaps then you could tell us, we have  
 24 this two page document and it's entitled  
 25 "Optimized IHC staining condition validation"

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1 and perhaps you can tell us what those  
 2 documents are.  
 3 MS. WEGRYNOWSKI:  
 4 A. Okay. This is from the same group that made  
 5 the first document. It's very similar to the  
 6 template that I gave Mary and very similar to  
 7 the template that I use as well. It states on  
 8 it again, the antibody and what the clone is,  
 9 the catalogue number, the lot numbers that's  
 10 presently in use and the expiry date. It says  
 11 that it's a monoclonal antibody and who  
 12 manufacturers this produce. It tells us what  
 13 the isotype is. They haven't gone forward to  
 14 get the protein concentration, but that  
 15 certainly is available if you were to go to  
 16 the manufacturer. It came in a concentrated  
 17 form. They've given you what the primary  
 18 dilution is under the testing conditions, what  
 19 they used for it. So, they tested at 1:50-  
 20 1:100 and the final results was 1:75. They  
 21 gave me the name of the diluent, what the  
 22 pretreatments were and what the detection  
 23 system and chromogens are. It tells you the  
 24 technologist's name, the pathologist's name,  
 25 the date and the initial date of use and when

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1 it was reviewed.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. And those templates were given, you're  
 4 saying, to -  
 5 MS. WEGRYNOWSKI:  
 6 A. That was in that lecture and I left it for  
 7 Mary when I was here, yes, very similar, their  
 8 own.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay. Now, we understand that you had a trip  
 11 back in the spring then of 2006.  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Perhaps you could tell us, how did that come  
 16 about? Who contacted you?  
 17 MS. WEGRYNOWSKI:  
 18 A. I received a phone call from Dr. Williams  
 19 asking me to come back to re-review what I had  
 20 done originally.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. And what was to be the purpose in doing  
 23 a further review?  
 24 MS. WEGRYNOWSKI:  
 25 A. If I recall correctly, it was to look at what

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1 I had recommended and where they were coming  
 2 through the process.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. And if we could look please P-1749.  
 5 And this is an e-mail exchange between Ms.  
 6 Dunn, who I believe worked as an assistant for  
 7 Dr. Williams, March 6, 2006 to Dr. Cook, Mr.  
 8 Gulliver, Mr. Dyer and Ms. Predham and you're  
 9 the subject. "I want to advise you that Trish  
 10 Wegrynowski will be coming to visit us again  
 11 to review our program. She will be arriving  
 12 late on the evening of March 29 and staying  
 13 until March 31, 2006" and he's going to follow  
 14 up on that. And then a further e-mail at 3:34  
 15 p.m. on the same day, "further to my e-mail  
 16 below, Terry, I wonder if you would follow up  
 17 with her directly as she would like to have  
 18 some information to update her on our progress  
 19 prior to her arrival. I advised her that we  
 20 have a spreadsheet of issues we are working on  
 21 in an updated format. Once you have talked to  
 22 her, they may be sufficient to help her  
 23 prepare for her visit". So, this indicate  
 24 that you are looking for more information or  
 25 looking for some information as to where they

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1 were in their progress prior to arriving in  
 2 St. John's.  
 3 MS. WEGRYNOWSKI:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. Did Mr. Gulliver follow up with you?  
 7 MS. WEGRYNOWSKI:  
 8 A. I can't remember who called me, but I do  
 9 recall getting the spreadsheet. I know if it  
 10 was by phone or e-mail, but I did have a  
 11 spreadsheet prior to arriving back at St.  
 12 John's.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. And other than the spreadsheet, did you  
 15 receive anything else?  
 16 MS. WEGRYNOWSKI:  
 17 A. Not that I recall.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. And the spreadsheet that you received,  
 20 do you recall did it have all of your  
 21 recommendations on it?  
 22 MS. WEGRYNOWSKI:  
 23 A. No, it did not.  
 24 CHAYTOR, Q.C.:  
 25 Q. It did not. If we could look please at P-

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1 1757. Could we make that a little bigger,  
 2 Registrar? Thank you, it's getting late in  
 3 the day. And this spreadsheet is dated,  
 4 updated March 10, 2006. And if we scroll down  
 5 through we'll see that there's a total, I  
 6 believe, of 30 recommendations on this sheet.  
 7 So, there's a total of 30 recommendations and  
 8 you'll see that it's recommended by either  
 9 yourself and/or Dr. Banerjee. So, there's 30  
 10 recommendations here. Does this look like the  
 11 spreadsheet that you were provided?  
 12 MS. WEGRYNOWSKI:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And if we could look then, please, at--  
 16 I think it's P-0050. And this is the same  
 17 spreadsheet--I don't think that's the right  
 18 one though. We can look at it. This one is  
 19 updated; it's been updated several times. So,  
 20 this one is updated April 26, 2007 and if we  
 21 scroll down through we see that there are 52  
 22 recommendations on this spreadsheet. Ms.  
 23 Wegrynowski, after you came back to St. John's  
 24 the second time, did you have further  
 25 recommendations?

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1 MS. WEGRYNOWSKI:  
 2 A. Yes, there was a second report generated.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. And so there were new recommendations  
 5 plus other recommendations that had originated  
 6 from your first report?  
 7 MS. WEGRYNOWSKI:  
 8 A. I don't know about new recommendations, but  
 9 certainly what my premise was to do was to  
 10 look at what they had done and if things had  
 11 been done or not done to clarify it. There  
 12 may be.  
 13 CHAYTOR, Q.C.:  
 14 Q. Yes, and perhaps I'll take you through that.  
 15 MS. WEGRYNOWSKI:  
 16 A. Okay.  
 17 CHAYTOR, Q.C.:  
 18 Q. And you may then be able to identify whether  
 19 or not there, in fact, are additional  
 20 recommendations.  
 21 MS. WEGRYNOWSKI:  
 22 A. Okay. And if we could look, please, at P-  
 23 1751? And this is an e-mail from yourself to  
 24 Dr. Williams. The subject is IHC quality  
 25 review, March 23, 2006. "Dr. Williams, I will

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1 be arriving" and you say when you're arriving  
 2 and where you're staying. "If there are any  
 3 protocols or paperwork that you would like me  
 4 review prior to my arrival" and you indicate  
 5 that can be faxed to you. "I do ask however  
 6 that you let me know prior to sending them  
 7 because it's a common fax machine" and you  
 8 "look forward to reviewing your laboratory  
 9 again". And you're asking about snow in March  
 10 in Newfoundland which I can't understand. And  
 11 then Dr. Williams forwards this onto Dr.  
 12 Denic, Mr. Gulliver, Mr. Dyer, "do we have  
 13 anything to send to Trish. Thanks." And then  
 14 Dr. Denic replies, "can we give her our  
 15 spreadsheets so she will know in advance what  
 16 has been accomplished? Signed, Nash". Other  
 17 than the spreadsheet, did you receive any  
 18 other documentation?  
 19 MS. WEGRYNOWSKI:  
 20 A. Nothing else?  
 21 CHAYTOR, Q.C.:  
 22 Q. And were you expecting or anticipating that  
 23 there might be more available?  
 24 MS. WEGRYNOWSKI:  
 25 A. I was hopeful, I believe, that is why I asked

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1 for the protocols, if there are any protocols  
 2 or paperwork for me to review because it had  
 3 been several months since I had originally  
 4 been there.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay. Yes, I think it's about six months  
 7 later. So you are specifically asking for  
 8 protocols or paperwork. So do I take it from  
 9 that that you were anticipating being able to  
 10 see standards of operating procedure?  
 11 MS. WEGRYNOWSKI:  
 12 A. Something, yes.  
 13 CHAYTOR, Q.C.:  
 14 Q. And do you know, did they exist at that time,  
 15 six months after you had been here the first  
 16 time?  
 17 MS. WEGRYNOWSKI:  
 18 A. I only found that out when I came on site.  
 19 CHAYTOR, Q.C.:  
 20 Q. And what then did you learn when you came on  
 21 site?  
 22 MS. WEGRYNOWSKI:  
 23 A. They still weren't on site.  
 24 CHAYTOR, Q.C.:  
 25 Q. There was still no standards operating

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1 procedure?  
 2 MS. WEGRYNOWSKI:  
 3 A. No.  
 4 CHAYTOR, Q.C.:  
 5 Q. When you came back in March of 2006, the end  
 6 of March 2006, what specifically were you  
 7 asked to do? Was it anything different than  
 8 what you had been asked to do before? And  
 9 were you restricted in any way?  
 10 MS. WEGRYNOWSKI:  
 11 A. I came back doing what I thought I was going  
 12 to do before, but the second time that I came  
 13 back to Eastern Health, I was restricted. I  
 14 was only allowed to go to the  
 15 immunohistochemistry department and I was not  
 16 interviewing the same--not given the same  
 17 latitude to interview the pathologists and to  
 18 go and look at the different sites again.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and was any explanation given to you as  
 21 to why that would be?  
 22 MS. WEGRYNOWSKI:  
 23 A. No, I didn't ask.  
 24 CHAYTOR, Q.C.:  
 25 Q. And what then, overall, and I'll take you to

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1 your report, but overall then, what was your  
 2 impression of the progress that had been made  
 3 in those six months?  
 4 MS. WEGRYNOWSKI:  
 5 A. They had certainly listened to the  
 6 recommendations and that they had started to  
 7 implement some of the recommendations, but  
 8 they were a long, long, long way to completing  
 9 them.  
 10 CHAYTOR, Q.C.:  
 11 Q. And in terms of the progress then, being a  
 12 long way from where they had to go, were you  
 13 surprised by that?  
 14 MS. WEGRYNOWSKI:  
 15 A. I would have thought that there would have  
 16 been much more documentation in place at that  
 17 point because it was six months out, and at  
 18 least a start on the standard operating  
 19 procedures.  
 20 CHAYTOR, Q.C.:  
 21 Q. Were there even drafts of those procedures?  
 22 MS. WEGRYNOWSKI:  
 23 A. Not that I saw.  
 24 CHAYTOR, Q.C.:  
 25 Q. Were they doing any pHing?

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1 MS. WEGRYNOWSKI:  
 2 A. You know, I would feel more comfortable if we  
 3 went through the report. I would prefer,  
 4 because I have it documented there and I don't  
 5 want to work off memory, if that's at all  
 6 possible?  
 7 CHAYTOR, Q.C.:  
 8 Q. Sure, okay, we can do that. And what about  
 9 the issue of not having interviews with  
 10 anyone, did you meet with anyone? Did you  
 11 have discussions with anyone?  
 12 MS. WEGRYNOWSKI:  
 13 A. I met with the technologists, the three  
 14 technologists. I met with Catherine Parnell  
 15 and Barry Dyer.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, and who did you understand Catherine  
 18 Parnell to be?  
 19 MS. WEGRYNOWSKI:  
 20 A. To be taking over or to begin with the QA.  
 21 CHAYTOR, Q.C.:  
 22 Q. And did Ms. Parnell have any particular  
 23 concerns or issues that she addressed with  
 24 you?  
 25 MS. WEGRYNOWSKI:

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1 A. She had mentioned to me that prior to the  
 2 amalgamation that they had been doing quality  
 3 assurance and that she had been rather  
 4 frustrated that it hadn't been continued on  
 5 and that she was very pleased to see that it  
 6 was being looked at.  
 7 CHAYTOR, Q.C.:  
 8 Q. So that prior to the amalgamation back in 1996  
 9 or the one that had just happened in 2005?  
 10 MS. WEGRYNOWSKI:  
 11 A. I don't know that.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, and did you understand, was she a lab  
 14 technologist herself?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes, she had told me that she and Barry had  
 17 applied for the same position and Barry had  
 18 been successful in it, so that she had had  
 19 many years of experience in the area as well.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and which site did you understand or  
 22 which hospital did she come from? Did you  
 23 know that?  
 24 MS. WEGRYNOWSKI:  
 25 A. I don't recall.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and when you met with Ms. Parnell, did

3 you make any observation as to the tools or

4 equipment that she had available to her to be

5 able to do her job?

6 MS. WEGRYNOWSKI:

7 A. Yes, I do. She had some relic of a computer

8 and I remember at the exit interview telling

9 Dr. Williams that that needed to be rectified

10 because she needed something that certainly

11 had some capacity to hold the information that

12 was required. I wasn't quite sure where the

13 lines of communication went with that.

14 CHAYTOR, Q.C.:

15 Q. And your discussions then with Mr. Dyer, the

16 second time around, what did you discuss with

17 him?

18 MS. WEGRYNOWSKI:

19 A. It was more to do with what had happened, the

20 advances that they had made, the

21 recommendations that they had looked at and

22 where they were going with that.

23 CHAYTOR, Q.C.:

24 Q. Okay, and were there any particular concerns

25 voiced by him at that point in time?

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1 MS. WEGRYNOWSKI:

2 A. Not that I recall.

3 CHAYTOR, Q.C.:

4 Q. And your meeting then with the technologists,

5 you were in St. John's from the 29th to the

6 afternoon of the 31st?

7 MS. WEGRYNOWSKI:

8 A. It was a very short visit. It was like one

9 and a half days.

10 CHAYTOR, Q.C.:

11 Q. Okay, and when did you meet with the

12 technologists?

13 MS. WEGRYNOWSKI:

14 A. On the first day, I had--it was Barry,

15 Catherine Parnell, and then I met with the

16 technologists. I remember one of them taking

17 me over to the Janeway to look at their frozen

18 section room and we came back. I remember

19 looking at their paperwork. They had been

20 enrolled in the UK NEQAS. That's basically -

21 CHAYTOR, Q.C.:

22 Q. So they had been enrolled then in external

23 proficiency?

24 MS. WEGRYNOWSKI:

25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. So that was obviously a very positive

3 improvement?

4 MS. WEGRYNOWSKI:

5 A. Very positive.

6 CHAYTOR, Q.C.:

7 Q. Okay, and what did you discuss with the

8 technologists? Were those the same three

9 technologists that you had met with the first

10 time?

11 MS. WEGRYNOWSKI:

12 A. Yes.

13 CHAYTOR, Q.C.:

14 Q. And had their jobs or their roles changed in

15 any way?

16 MS. WEGRYNOWSKI:

17 A. Yes, they were now permanently

18 immunohistochemistry. They had taken the

19 antibody spec sheets out of the cupboard and

20 put them into alphabetical order. I don't

21 recall there being validation sheets attached

22 to them, but they had certainly compiled them.

23 The antibodies were at least in the

24 refrigerator now in alphabetical order, so

25 that they could certainly find them much

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1 easier. They had talked about that they were

2 cleaning the Ventana, and we talked about

3 firming up the documentation on that. That

4 they need to, you know, fill it out every day

5 that they were doing that.

6 CHAYTOR, Q.C.:

7 Q. Okay, and I take it at this point in time,

8 they still had not resumed their ER/PR

9 testing. So this would be with respect to

10 other IHC testing, but you were also there to

11 observe what was in place on a go-forward

12 basis, presumably to get ready for re-

13 instituting the ER/PR.

14 MS. WEGRYNOWSKI:

15 A. Okay.

16 CHAYTOR, Q.C.:

17 Q. Did you have an exit interview this time?

18 MS. WEGRYNOWSKI:

19 A. Yes, I did.

20 CHAYTOR, Q.C.:

21 Q. And that was, I think you said, with Dr.

22 Williams?

23 MS. WEGRYNOWSKI:

24 A. Yes, it was.

25 CHAYTOR, Q.C.:

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1 Q. And what else did you discuss with Dr.  
 2 Williams besides Ms. Parnell's computer?  
 3 MS. WEGRYNOWSKI:  
 4 A. We were talking about external quality  
 5 assurance and we were talking about with the  
 6 UK NEQAS and we were talking about with CAP,  
 7 the College of American Pathologists, and I  
 8 asked him if he was interested in knowing what  
 9 the differences were, and he said yes, and I  
 10 explained the differences of the two to him.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, and do you recall meeting with Drs.  
 13 Denic, Fontaine, Cook, Mr. Dyer, Mr. Gulliver?  
 14 Do you recall -  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes, I met with them prior to going to see Dr.  
 17 Williams.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. So you had a meeting with--this would  
 20 be the lab people or the senior management of  
 21 the lab, I take it?  
 22 MS. WEGRYNOWSKI:  
 23 A. Um-hm.  
 24 CHAYTOR, Q.C.:  
 25 Q. So you met with them and what did you discuss

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1 with them?  
 2 MS. WEGRYNOWSKI:  
 3 A. We were talking about just some of the  
 4 recommendations that had gone on and I  
 5 remember mentioning to them that there still  
 6 weren't refrigerators in the quick section  
 7 rooms and there was a discussion that went on  
 8 why there wasn't, and they need to -  
 9 CHAYTOR, Q.C.:  
 10 Q. And what was the explanation as to why?  
 11 MS. WEGRYNOWSKI:  
 12 A. There wasn't. There just was a lot of people  
 13 saying "how come they're not there?" So I  
 14 don't know.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and did you discuss anything else with  
 17 them other than the refrigerators?  
 18 MS. WEGRYNOWSKI:  
 19 A. Just going over what I was going to be saying,  
 20 but nothing stands out.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. So going over what you had observed and  
 23 what you saw having--the progress had been  
 24 made on?  
 25 MS. WEGRYNOWSKI:

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1 A. Yes, and that some -  
 2 CHAYTOR, Q.C.:  
 3 Q. And other things that still needed to be done?  
 4 MS. WEGRYNOWSKI:  
 5 A. Absolutely.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. So basically, I take it, you reviewed  
 8 with them what ultimately ended up in your  
 9 second report?  
 10 MS. WEGRYNOWSKI:  
 11 A. For the most part, yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And if we could look at, please, P-1752, page  
 14 13?  
 15 MS. WEGRYNOWSKI:  
 16 A. Okay.  
 17 CHAYTOR, Q.C.:  
 18 Q. These are notes--I think these are some of  
 19 your notes and it indicates at the top that--  
 20 you've got Terry, Barry, Dr. Cook, Dr. Denic,  
 21 Dr. Dan Fontaine.  
 22 MS. WEGRYNOWSKI:  
 23 A. Um-hm.  
 24 CHAYTOR, Q.C.:  
 25 Q. And actually, if I take you back, there's also

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1 reference back here to Ms. Parnell as well.  
 2 MS. WEGRYNOWSKI:  
 3 A. Okay.  
 4 CHAYTOR, Q.C.:  
 5 Q. Here we go, at page eight of the exhibit  
 6 there's reference to Ms. Parnell. I don't  
 7 know if there's anything there that jogs your  
 8 memory. These are fairly scant notes.  
 9 MS. WEGRYNOWSKI:  
 10 A. Yes. Controls, tech to read the external  
 11 controls for the day. Path to determine  
 12 validity of the stain if the patient negative  
 13 or not done, patient negative, slide  
 14 designated patient negative. Yeah.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, so these are things that you were  
 17 reviewing again on your second trip, I take  
 18 it?  
 19 MS. WEGRYNOWSKI:  
 20 A. Uh-hm. Processing at St. Clare, all  
 21 processing at--yeah, the cutting was going on  
 22 there, the slides and block storage, three  
 23 month there and then going back to St. Clare's  
 24 for storage. They had an enhanced courier  
 25 system, they had a stacked courier system

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1 coming four times a day. They said they had  
 2 documentation for the courier. Surgical  
 3 reports, they wanted to use Eastern Health  
 4 standard. They still weren't amalgamated.  
 5 Interpretation and diagnosis, one side wanted  
 6 one and one side, the other. Even in the  
 7 Ventana handout themselves, I showed them that  
 8 they too talk about using the negative and  
 9 positive controls and that they were available  
 10 at the universal controls from that particular  
 11 company, that they could purchase. I believe  
 12 this is from their NEQAS, their antigen was  
 13 assessed, the number of participating labs,  
 14 the sections circulated, assessment of slides,  
 15 score staining patterns, features optimal  
 16 slide sub-groups, yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and then this was the page I originally  
 19 brought you to.  
 20 MS. WEGRYNOWSKI:  
 21 A. Okay.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay, and it says I believe "Control bank IHC  
 24 beginning with documented."  
 25 MS. WEGRYNOWSKI:

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1 A. Yeah, so they were already starting to get  
 2 together different, for some controls for IHC,  
 3 you're required diseased processes to be in  
 4 place, so they were getting that control bank  
 5 established so that they would always have a  
 6 wealth of tissue. They had involved  
 7 themselves in UK and NEQAS and that there was  
 8 a journal, so it was assessed, the number of  
 9 labs that were participating, assessment of  
 10 the staining, so we had an in-house tumors,  
 11 there was an introduction guidelines used in  
 12 the validation. The score staining pattern,  
 13 features of--the NEQAS would tell them what  
 14 the features of the optimal staining was,  
 15 features of sub-optimal, importance of good  
 16 fixation, antigen retrieval and the conclusion  
 17 from the data, there would have been  
 18 references.  
 19 CHAYTOR, Q.C.:  
 20 Q. And did you understand they're participating  
 21 in UK NEQAS, were they actually running ER/PR  
 22 tests?  
 23 MS. WEGRYNOWSKI:  
 24 A. I don't recall what it was on.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MS. WEGRYNOWSKI:  
 3 A. This would have been taken right out of their  
 4 handbook, out of NEQAS' handbook, so the  
 5 primary antibody, the list of clones, the  
 6 number of participants, suppliers, yeah.  
 7 CHAYTOR, Q.C.:  
 8 Q. So these would have been the main topics  
 9 discussed with the doctors and Mr. Gulliver  
 10 and Mr. Dyer that day, I take it?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yeah, uh-hm.  
 13 CHAYTOR, Q.C.:  
 14 Q. So the concentration being on the external  
 15 proficiency?  
 16 MS. WEGRYNOWSKI:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. And again your discussion that you had in your  
 20 exit interview with Dr. Williams there was  
 21 discussion about which of the two programs  
 22 that you preferred or the differences between  
 23 the two programs.  
 24 MS. WEGRYNOWSKI:  
 25 A. The differences between them, yes.

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1 CHAYTOR, Q.C.:  
 2 Q. Is there anything else then that you recall  
 3 about your visit to St. John's or will we--I  
 4 can take you right to your report?  
 5 MS. WEGRYNOWSKI:  
 6 A. I don't recall anything in addition to this.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, if we could look then, please, at P-  
 9 0048? And you sent along four copies of your  
 10 report to the leadership team again. And your  
 11 report this time is dated May 2nd, 2006. And  
 12 you indicate under your executive summary, "In  
 13 September, 2005, the pathology laboratory's  
 14 practices and procedures were evaluated. The  
 15 i n c o n s i s t e n c i e s i d e n t i f i e d i n  
 16 immunohistochemistry and the total lack of  
 17 standard operating procedures throughout the  
 18 entire pathology laboratory for both the  
 19 technical and professional staff, directly  
 20 contributed to the lack of reproducibility  
 21 associated with the ER/PR receptor status."  
 22 So that's similar to the conclusion that you  
 23 drew from your first report as well?  
 24 MS. WEGRYNOWSKI:  
 25 A. Right.



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1 CHAYTOR, Q.C.:

2 Q. And then under "Background" you indicate that

3 "two of the registered technologists assigned

4 to the immunohistochemistry service had been

5 sent to other institutions to view their

6 processes."

7 MS. WEGRYNOWSKI:

8 A. Uh-hm.

9 CHAYTOR, Q.C.:

10 Q. And that's referenced, I take it, to Mary

11 having come to Mount Sinai and Ken having gone

12 to Jewish General. "A reassessment of the

13 immunohistochemistry laboratory occurred from

14 March 30th to 31st at the request of Dr.

15 Williams and a recommendation spreadsheet was

16 reviewed prior to." And it was the one

17 compiled December 16th, 2005, the updated

18 version I showed you was March 10th, 2006, so

19 that appears to be the document you would have

20 had with thirty recommendations?

21 MS. WEGRYNOWSKI:

22 A. Yes.

23 CHAYTOR, Q.C.:

24 Q. And your objective this time around was to

25 evaluate the current practices and procedure,

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1 comment on the progress of the

2 immunohistochemistry laboratory and provide

3 recommendations. And your scope this time, as

4 you have indicated, "focus on

5 immunohistochemistry laboratory, in particular

6 in pathology in general." Ms. Wegrynowski, if

7 you had--if you could have done what you

8 deemed appropriate or necessary to do, what

9 would you have done when you came back to St.

10 John's the second time round?

11 MS. WEGRYNOWSKI:

12 A. I would have looked at the process in the

13 beginning as I did the previous visit. I

14 would have looked to see whether or not there

15 was standard operating procedures for their

16 specimens. I would have looked at their

17 standard operating procedures for the fixation

18 and as well, as for the processing. I would

19 have gone right back down to the basics to

20 make sure that those corner stones were in

21 place before we moved on with

22 immunohistochemistry.

23 CHAYTOR, Q.C.:

24 Q. And the methodology, you've indicated that

25 "the immunohistochemistry laboratory

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1 technologist's processes were assessed in that

2 time period. The process assessment was

3 evaluated by interviews, the review of written

4 material and observation. A brief discussion

5 also took place with Mr. Barry Dyer and Ms.

6 Catherine Parnell."

7 MS. WEGRYNOWSKI:

8 A. Uh-hm.

9 CHAYTOR, Q.C.:

10 Q. What written material, other than the

11 spreadsheet, what other written material did

12 you review?

13 MS. WEGRYNOWSKI:

14 A. It would have been definitely the UK NEQAS,

15 back that they sent me back.

16 CHAYTOR, Q.C.:

17 Q. Okay, so the results of the UK NEQAS.

18 MS. WEGRYNOWSKI:

19 A. Yes, that I definitely recall.

20 CHAYTOR, Q.C.:

21 Q. Okay, and do you recall reviewing any other

22 documentation?

23 MS. WEGRYNOWSKI:

24 A. Not at this point in time.

25 CHAYTOR, Q.C.:

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1 Q. And are there any other pertinent observations

2 that you made?

3 MS. WEGRYNOWSKI:

4 A. No.

5 CHAYTOR, Q.C.:

6 Q. And I've already asked you about your

7 discussions with Ms. Parnell and Mr. Dyer.

8 "The histology laboratory fixation and

9 grossing, the fixation and grossing of the

10 surgical pathology specimen has remained site

11 dependent." So I take it that's St. Clare's

12 and the Health Science are still doing things

13 independently?

14 MS. WEGRYNOWSKI:

15 A. Independently.

16 CHAYTOR, Q.C.:

17 Q. "The majority of the breast cases still

18 originate from St. Clare's site, this review

19 did not include a visit to St. Clare's site

20 and did not review any processes or

21 documentation associated with the fixation or

22 specimens at either site." And again that was

23 because you were restricted in what, the

24 mandate that you were given?

25 MS. WEGRYNOWSKI:

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1 A. Correct.  
 2 CHAYTOR, Q.C.:  
 3 Q. "Frozen sections continue to be performed at  
 4 both sites. I had an opportunity to inspect  
 5 the quick section room at Health Science  
 6 Centre. Refrigeration storage is still not  
 7 available for large or own fixed specimens."  
 8 And again you indicated there was some  
 9 discussion in your meeting with the doctors  
 10 around that issue?  
 11 MS. WEGRYNOWSKI:  
 12 A. Yes.  
 13 CHAYTOR, Q.C.:  
 14 Q. "Four pathology assistant positions have been  
 15 recently created. This shall provide an  
 16 opportunity to ensure that all fixation and  
 17 grossing procedures at both sites are  
 18 consistent and standardized. Very informal  
 19 protocols and documentation exist. Standard  
 20 operating procedure manuals do not exist."  
 21 And then your recommendation regarding that,  
 22 number one recommendation is the same as  
 23 previous.  
 24 MS. WEGRYNOWSKI:  
 25 A. Absolutely.

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1 CHAYTOR, Q.C.:  
 2 Q. You're again recommending the standard  
 3 operating procedures. Number two, regarding  
 4 the pathology assistants, I take it this is a  
 5 new recommendation now that they've created  
 6 those positions and you're indicating that  
 7 documentation must also exist as to the  
 8 performance of the PA's and they are to be  
 9 evaluated by the pathologists. Is that what  
 10 happens in Mount Sinai, the PA's are evaluated  
 11 by the pathologists?  
 12 MS. WEGRYNOWSKI:  
 13 A. Absolutely because every morning there are  
 14 rounds, so the pathologists go in to visit  
 15 with the pathologist assistants and Brendan  
 16 Mullen would probably be the better person to  
 17 ask about that.  
 18 CHAYTOR, Q.C.:  
 19 Q. And again, number three, is a refrigerator in  
 20 the operating room quick section at both  
 21 sites.  
 22 MS. WEGRYNOWSKI:  
 23 A. That's right.  
 24 CHAYTOR, Q.C.:  
 25 Q. And that, you indicate has not been addressed

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1 since the assessment. And you're suggesting a  
 2 time stamp for the receipt of specimens from  
 3 the courier to avoid any unforeseen  
 4 circumstances and I believe that might be a  
 5 new recommendation. And if we go on to the  
 6 processing section of your report, "the tissue  
 7 processors are now all located at the Health  
 8 Science Centre." So just explain that to us,  
 9 so what exactly is happening now in terms of  
 10 how the processing was taking place?  
 11 MS. WEGRYNOWSKI:  
 12 A. So if the grossing was being done at site  
 13 dependents, the actual blocks were being put  
 14 on a processor at one particular site. So  
 15 however they got from St. Clare's, I didn't  
 16 view this, so I don't know, but they would  
 17 have needed to come to the Health Sciences  
 18 Centre and then all the blocks would have been  
 19 put on the same tissue processor at the same  
 20 time and handled in the same way, and the  
 21 blocks created from that.  
 22 CHAYTOR, Q.C.:  
 23 Q. And you go on to say that "Procedure manuals  
 24 detailing standard operating procedures for  
 25 the tissue processors do not exist. I did not

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1 have an opportunity to review the processing  
 2 area, but was informed that temperature  
 3 monitoring and maintenance documentation has  
 4 begun. The St. Clare's site has five  
 5 pathologists who assess and evaluate the  
 6 surgical breast samples. All paraffin  
 7 embedded blocks are kept on the site at Health  
 8 Science Centre for three months and  
 9 subsequently stored at St. Clare's." And then  
 10 your recommendation is previous, "Standard  
 11 operating procedures are to be written for the  
 12 tissue processors, also written for the  
 13 embedding centres and embedding protocols for  
 14 all tissue types and procedures for the  
 15 handling of suboptimal specimens must be  
 16 developed and documented." And in the  
 17 immunohistochemistry lab under "IHC Staffing"  
 18 you note that "This section is now staffed  
 19 with three registered technologists dedicated  
 20 to perform the staining optimization and  
 21 validation." And "The staff have also  
 22 absorbed the"--help me with that word?  
 23 MS. WEGRYNOWSKI:  
 24 A. "Microtomy"  
 25 CHAYTOR, Q.C.:

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1 Q. Thank you, "function. One of the  
 2 technologists has been given the lead  
 3 position." So all that, I take it, was good  
 4 news and that's what you had recommended the  
 5 first time down?  
 6 MS. WEGRYNOWSKI:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. And "A medical section head has been  
 10 established for the immunohistochemistry  
 11 laboratory." And some note there that they  
 12 may need to be looking at a successor. You  
 13 indicate, "Lack of communication between  
 14 technical and professional staff still remains  
 15 an issue, for example, recently the marker Low  
 16 Molecular Weight Keratin was added to all  
 17 sentinel lymph node biopsy protocols. The  
 18 immunohistochemistry laboratory was not  
 19 apprised of this prior to implementation.  
 20 This has a direct impact on the laboratory,  
 21 not only regarding the amount of primarily  
 22 antibody and detection system required for  
 23 staining but on the workload in general." Ms.  
 24 Wegrynowski, what was that all about?  
 25 MS. WEGRYNOWSKI:

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1 A. They had just mentioned to me that they were  
 2 still a little bit frustrated because they  
 3 weren't sure where the lines of communication  
 4 were coming. So you find out, I can't recall  
 5 how they found out, but perhaps secondhand,  
 6 that this was going to be a change. This  
 7 change should have been--had there been a  
 8 procedure manual, it would have been  
 9 documented in that, as well. They have to  
 10 ensure that they have enough product on hand  
 11 to be able to maintain a fluid end product, so  
 12 they would want to ensure that they either had  
 13 enough lots in or whatever for their  
 14 validation process as well, and it's going to  
 15 impact their workload.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay. And these recommendations then about  
 18 the lines of communication, of course, are  
 19 carried forward. You certainly had mentioned  
 20 this in your previous report. In terms of--  
 21 and you describe briefly for us, though, a  
 22 little while ago about the lines of  
 23 communication in Mount Sinai.  
 24 MS. WEGRYNOWSKI:  
 25 A. Um-hm.

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1 CHAYTOR, Q.C.:  
 2 Q. And how the pathologists and the technologists  
 3 interact there. In terms of any new--anything  
 4 new happening within the laboratory, what kind  
 5 of consultation process takes place?  
 6 MS. WEGRYNOWSKI:  
 7 A. At Eastern Health?  
 8 CHAYTOR, Q.C.:  
 9 Q. No, at Mount Sinai.  
 10 MS. WEGRYNOWSKI:  
 11 A. At Mount Sinai. In respect to what?  
 12 CHAYTOR, Q.C.:  
 13 Q. Oh, for example, if a situation such as what  
 14 you've described here were to arise, how are  
 15 decisions made, what consultation -  
 16 MS. WEGRYNOWSKI:  
 17 A. Oh, if somebody was going to add, so if  
 18 something was going to be added to one of the  
 19 programs, the pathologist that was responsible  
 20 for that program, let's say, for example,  
 21 somebody was to come up with a protocol for a  
 22 specific tumor, they would come and they would  
 23 state that to us. We would make sure that we  
 24 had all the product that they needed. They  
 25 would either send up an e-mail to all their

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1 contemporaries or they would go through the  
 2 medical section head. It's very fluid.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. If you, at Mount Sinai if you encounter  
 5 a problem with a block, for example, we  
 6 discussed earlier today the issues around  
 7 fixation and if you encounter a problem, what  
 8 kind of communication can you have with the  
 9 pathologists?  
 10 MS. WEGRYNOWSKI:  
 11 A. Okay. If we receive a block, you have to  
 12 understand that more than half the work that  
 13 we do at Mount Sinai presently is consult  
 14 blocks, so we would be speaking about a block  
 15 from the outside, we have a particular sheet  
 16 that we've developed called a "Client  
 17 Satisfaction Form", but what it truly is is a  
 18 mechanism for the medical laboratory  
 19 technologists to inform the pathologist of any  
 20 concerns that they have with a particular  
 21 block. So on it would be the outside case  
 22 number, what their case number would be, and  
 23 what the issue would be. So for example, if  
 24 we got something in and it was far too small  
 25 and we were concerned that we wouldn't be able

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1 to get enough product out of it, we would send  
 2 that along, if there was staples in the block,  
 3 if there anything absolutely wrong with it.  
 4 One of the reasons that we do this is that as  
 5 professionals we want to ensure that the  
 6 pathologist recognizes that the product that  
 7 they're getting may not be of the best  
 8 standard. We have received blocks from all  
 9 over the places and sometimes, you know, they  
 10 get left out in the heat, so we get a block  
 11 that is completely deformed because it's been  
 12 mounted. We're not sure what that is going to  
 13 do to the actual antigen. So what we will do  
 14 is then we will then go ahead, we will do what  
 15 we need to do, we'll melt it down, but we will  
 16 give that direct information to the  
 17 pathologist on this form. When the case gets  
 18 signed out, we give it to the pathologist so  
 19 that they have a heads up prior to reading it  
 20 and then what they do, they should do, is they  
 21 sign it back and then we maintain all that  
 22 information in our laboratory.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. And then you have written documentation  
 25 outlining what the problem was with respect to

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1 any particular block?  
 2 MS. WEGRYNOWSKI:  
 3 A. That's correct.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. And how long has Mount Sinai, how long  
 6 has that been a practice?  
 7 MS. WEGRYNOWSKI:  
 8 A. Oh, we've been doing that for a number of  
 9 years now.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. And is that also done internally, the  
 12 Client Satisfaction Form, is that also done if  
 13 there's a problem with a block internal to  
 14 Mount Sinai?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes, we would do that, as well.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay.  
 19 COMMISSIONER:  
 20 Q. Ms. Chaytor, it's getting near the close of  
 21 the day, so I'm just going to invite you at a  
 22 convenient place to call the break.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. Thank you. Then the lines of  
 25 communication, again, we've talked about that,

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1 so that's still there. And page 10, the  
 2 documentation, "The process of documentation  
 3 has recently begun in immunohistochemistry.  
 4 Key areas identified," and again you talk  
 5 about "The assemblage of the procedure manual  
 6 has been initiated, however the manual is not  
 7 written in compliance with Clinic and  
 8 Laboratory Standard Institution Guidelines.  
 9 All antibody data sheets have been compiled.  
 10 However, formal documented validation is not  
 11 present. Templates of examples of validation  
 12 worksheets were provided during the initial  
 13 assessment." So you had given those templates  
 14 during the initial assessment?  
 15 MS. WEGRYNOWSKI:  
 16 A. Yes, I had.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. "Recorded maintenance records of  
 19 Ventana benchmark were present." And "No  
 20 pipette and thermometer calibration of  
 21 accuracy is documented."  
 22 MS. WEGRYNOWSKI:  
 23 A. None.  
 24 CHAYTOR, Q.C.:  
 25 Q. None. So they're still not calibrating the

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1 pipettes?  
 2 MS. WEGRYNOWSKI:  
 3 A. No. And I have no idea how old those pipettes  
 4 were.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay. "Reagent and detection system  
 7 validation initiated. Retirement of  
 8 procedures and antibodies documentation was  
 9 commenced." So those were positive, I would  
 10 take it, improvements?  
 11 MS. WEGRYNOWSKI:  
 12 A. Um-hm.  
 13 CHAYTOR, Q.C.:  
 14 Q. "Ensure documentation is evident in the  
 15 procedure manual as to the location of the  
 16 retired documents." And you're saying that  
 17 they need to "ensure that obsolete reagents  
 18 are removed and only currently authorized  
 19 reagents are available for use." And  
 20 "Incomplete corrective action and error log  
 21 was now present."?  
 22 MS. WEGRYNOWSKI:  
 23 A. Um-hm.  
 24 CHAYTOR, Q.C.:  
 25 Q. Or "Incomplete corrective action and log, and

1 error log was present." What does that mean?  
 2 MS. WEGRYNOWSKI:  
 3 A. I don't know.  
 4 CHAYTOR, Q.C.:  
 5 Q. "Incomplete corrective action".  
 6 MS. WEGRYNOWSKI:  
 7 A. I'll think about that.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. I'm not sure if that's a good thing or  
 10 a bad thing.  
 11 MS. WEGRYNOWSKI:  
 12 A. No, no.  
 13 CHAYTOR, Q.C.:  
 14 Q. "Retired procedures and antibodies information  
 15 has been gathered and maintain records for a  
 16 minimum of two years."  
 17 MS. WEGRYNOWSKI:  
 18 A. Um-hm.  
 19 CHAYTOR, Q.C.:  
 20 Q. And then you have a number of recommendations  
 21 flowing from there, which perhaps that's a  
 22 good place for us to pick it up tomorrow at  
 23 recommendation No. 10.  
 24 COMMISSIONER:  
 25 Q. All right, then. We'll break until 9:30 in

1 CERTIFICATE  
 2 I, Judy Moss, hereby certify that the foregoing is  
 3 a true and correct transcript in the matter of the  
 4 Commission of Inquiry on Hormone Receptor Testing,  
 5 heard on the 24th day of June, A.D., 2008 before  
 6 the Honourable Justice Margaret A. Cameron,  
 7 Commissioner, at the Commission of Inquiry, St.  
 8 John's, Newfoundland and Labrador and was  
 9 transcribed by me to the best of my ability by  
 10 means of a sound apparatus.  
 11 Dated at St. John's, Newfoundland and Labrador  
 12 this 24th day of June, A.D., 2008  
 13 Judy Moss

1 the morning. Thank you.  
 2 Upon conclusion at 4:57 p.m.

**Inquiry on Hormone Receptor Testing**

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Inquiry on Hormone Receptor Testing

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