

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">July 9, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. . . . . Commission Co-counsel Sandra Chaytor, Q.C. . . . . Commission Co-counsel</p> <p>Jackie Brazil . . . . . Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al</p> <p>Daniel Simmons . . . . . Eastern Regional Integrated . . . . . Health Authority</p> <p>Darlene Russell. . . . . Members of the Breast Cancer . . . . . Testing Class Action</p> <p>Mark Pike . . . . . NL Medical Association Jennifer Newbury . . . . . Canadian Cancer Society (NL Division) Blair Pritchett. . . . . Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-2158 THROUGH P-2173 . . . . . Pg. 5</p> <p>EXHIBITS P-2178 AND P-2179 . . . . . Pg. 110</p> <p>EXHIBITS P-2181 AND P-2182 . . . . . Pg. 110</p> <p>EXHIBIT P-2190 . . . . . Pg. 178</p> <p>EXHIBIT P-2174 . . . . . Pg. 357</p> <p>EXHIBIT P-2224 . . . . . Pg. 357</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>MR. KENNETH GREEN - SWORN</p> <p>Examination by Sandra Chaytor, Q.C. . . . . Pgs. 4 - 358</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 THE COMMISSIONER: 2 Q. Ms. Chaytor. 3 CHAYTOR, Q.C.: 4 Q. Good morning, Commissioner. The next witness 5 is Kenneth Green. 6 MR. KENNETH GREEN, SWORN, EXAMINATION BY SANDRA CHAYTOR, 7 Q.C. 8 REGISTRAR: 9 Q. Would you please state and spell your complete 10 name for the Commission? 11 MR. GREEN: 12 A. Ken Green, K-E-N G-R-E-E-N. 13 REGISTRAR: 14 Q. Thank you. 15 CHAYTOR, Q.C.: 16 Q. Good morning, Mr. Green. 17 MR. GREEN: 18 A. Good morning. 19 CHAYTOR, Q.C.: 20 Q. Commissioner, there are a number of new 21 exhibits which I would ask, please, to have 22 entered this morning. They are numbered P- 23 2158 through to P-2173 inclusive. 24 THE COMMISSIONER: 25 Q. Entered.</p>

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1 CHAYTOR, Q.C.:

2 Q. Thank you.

3 EXHIBITS ENTERED AND MARKED EXHIBITS P-2158 THROUGH P-

4 2173

5 CHAYTOR, Q.C.:

6 Q. Mr. Green, perhaps you could begin by telling

7 us about your educational and professional

8 background?

9 MR. GREEN:

10 A. I was born in Carbonear and finished my high

11 school education at St. Francis in Harbour

12 Grace. Attended Memorial University for a

13 year, went to College of Trades and Technology

14 and did the three-year program for general

15 laboratory, graduated in 1979. I wrote

16 national certification exams for the Canadian

17 Society of Laboratory Technologists and became

18 a registered technologist in laboratory

19 medicine. Currently registered member of the

20 Canadian Society of Medical Laboratory

21 Science, current member of the Newfoundland

22 and Labrador Society of Laboratory

23 Technologists, past president of Newfoundland

24 Society of Laboratory Technologists, committee

25 member for CSLT National Congress 1986 and a

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1 committee member for the CSMLS National

2 Congress 2009.

3 CHAYTOR, Q.C.:

4 Q. Okay.

5 MR. GREEN:

6 A. After graduating from the medical lab program,

7 I went to work at St. Clare's Mercy Hospital

8 in June of 1979, stayed there for 23 years and

9 applied for a job at the Health Sciences in

10 April 2002, where I presently work.

11 CHAYTOR, Q.C.:

12 Q. Okay. The general laboratory technologist

13 program that you did in the--I guess it would

14 have been the late 1979?

15 MR. GREEN:

16 A. Yeah.

17 CHAYTOR, Q.C.:

18 Q. You graduated in 1979?

19 MR. GREEN:

20 A. Yeah.

21 CHAYTOR, Q.C.:

22 Q. So the late 1970s.

23 MR. GREEN:

24 A. Yes.

25 CHAYTOR, Q.C.:

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1 Q. Was there any particular focus or any

2 particular area of laboratory technology that

3 you've personally focused on?

4 MR. GREEN:

5 A. Well, it's a general lab program and covered

6 all disciplines.

7 CHAYTOR, Q.C.:

8 Q. Okay, and I assume that included pathology?

9 MR. GREEN:

10 A. Pathology, yes.

11 CHAYTOR, Q.C.:

12 Q. Okay, and at that time, of course, there would

13 not have been any study for

14 immunohistochemistry?

15 MR. GREEN:

16 A. No, it was not included in the syllabus of

17 studies.

18 CHAYTOR, Q.C.:

19 Q. And the societies that you said you belong to,

20 could you just repeat that for us, please?

21 MR. GREEN:

22 A. The Canadian Society of Laboratory Technology,

23 which is now known as the Canadian Society of

24 Medical Labrador Science. That's the national

25 certification society. And the provincial

Page 8

1 branch of the CSLT is also a professional

2 society.

3 CHAYTOR, Q.C.:

4 Q. And is that the one that you are past

5 president of?

6 MR. GREEN:

7 A. Yes.

8 CHAYTOR, Q.C.:

9 Q. Okay, and when was that? When were you the

10 president?

11 MR. GREEN:

12 A. That would be in the 80s.

13 CHAYTOR, Q.C.:

14 Q. 1980s.

15 MR. GREEN:

16 A. 80s, the whole decade of the 80s, I served as

17 past president--vice president, president and

18 past president.

19 CHAYTOR, Q.C.:

20 Q. Okay, and what's the purpose of the provincial

21 society?

22 MR. GREEN:

23 A. Provincial society is to promote professional

24 development and education.

25 CHAYTOR, Q.C.:

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1 Q. And is there anything you have to do to  
 2 maintain your national certification?  
 3 MR. GREEN:  
 4 A. At present, no, it's not mandatory.  
 5 CHAYTOR, Q.C.:  
 6 Q. And I take it then the provincial organization  
 7 or provincial branch of the society  
 8 concentrates on continuing education for its  
 9 members?  
 10 MR. GREEN:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And is it a voluntary membership or is it  
 14 mandatory?  
 15 MR. GREEN:  
 16 A. It's voluntary.  
 17 CHAYTOR, Q.C.:  
 18 Q. Voluntary, and do you know how many current  
 19 members there are in Newfoundland?  
 20 MR. GREEN:  
 21 A. I would estimate between five and six hundred.  
 22 CHAYTOR, Q.C.:  
 23 Q. And how would that compare in terms of  
 24 percentage to the overall number of laboratory  
 25 technologists in the province?

Page 10

1 MR. GREEN:  
 2 A. I would say it would be approximately 90  
 3 percent.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. So most laboratory technologists would  
 6 be part of the society?  
 7 MR. GREEN:  
 8 A. Yeah.  
 9 CHAYTOR, Q.C.:  
 10 Q. When you began your position at St. Clare's in  
 11 June of 1979, were you assigned to a  
 12 particular area of the lab?  
 13 MR. GREEN:  
 14 A. Pathology. I worked in pathology--I finished  
 15 at the College on Friday and started on Monday  
 16 at St. Clare's in pathology.  
 17 CHAYTOR, Q.C.:  
 18 Q. So you were 23 years at St. Clare's in the  
 19 pathology lab?  
 20 MR. GREEN:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. And your position then in coming to the Health  
 24 Sciences Centre in 2002, you continued on in  
 25 the pathology lab?

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1 MR. GREEN:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. And was there any section then or any  
 5 particular area that you concentrated on at  
 6 the Health Sciences?  
 7 MR. GREEN:  
 8 A. The position I applied for at the Health  
 9 Sciences was a laboratory technologist two  
 10 position, and the duties included one week  
 11 rotation in immunohistochemistry, one week  
 12 rotation in gross pathology, one week rotation  
 13 in general lab. Other duties included  
 14 pediatric pathology gross assisting, muscle  
 15 histochemistry, frozen sections when required,  
 16 kidney biopsy collection, cryostat cutting,  
 17 immuno fluorescence, and finally aspiration  
 18 collection and preparation at the Janeway.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. So it was full gamut of pathology  
 21 services with a one-week rotation in the IHC  
 22 portion of the lab?  
 23 MR. GREEN:  
 24 A. Yeah. Well, when I moved over to the Health  
 25 Science, there was no IHC lab. IHC was part

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1 of anatomic pathology.  
 2 CHAYTOR, Q.C.:  
 3 Q. So IHC services is probably a better way for  
 4 me to state it?  
 5 MR. GREEN:  
 6 A. Yes.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. So you would concentrate one week--you  
 9 were on a rotation. I understand at the time  
 10 there were two other technologists there,  
 11 Peggy Welsh and Mary Butler?  
 12 MR. GREEN:  
 13 A. That's correct.  
 14 CHAYTOR, Q.C.:  
 15 Q. So you would, every three weeks, rotate  
 16 through IHC services?  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. When you were at St. Clare's, in the pathology  
 21 lab there, how much interaction would you have  
 22 with the pathologists?  
 23 MR. GREEN:  
 24 A. We interacted hourly and daily. It was a  
 25 constant interaction.

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<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. And how did that compare to the amount,</p> <p>3 frequency of contact with the pathologists</p> <p>4 then at the Health Sciences?</p> <p>5 MR. GREEN:</p> <p>6 A. Pathologists at the Health Sciences, it wasn't</p> <p>7 as--there was a different atmosphere at the</p> <p>8 Health Science than it was at St. Clare's.</p> <p>9 During that time, there was an amalgamation in</p> <p>10 progress and earlier you would have the Grace</p> <p>11 Hospital, the St. Clare's Hospital, the</p> <p>12 Janeway and the Health Science. All of them</p> <p>13 had their own identity, and during the</p> <p>14 amalgamation, all these people came together</p> <p>15 to form a new culture and it was a mix of</p> <p>16 different cultures which were now coming</p> <p>17 together. It wasn't until I became familiar</p> <p>18 with the pathologists at the Health Science</p> <p>19 that I had more interaction with them.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Okay, and that was 2002 that you went there?</p> <p>22 MR. GREEN:</p> <p>23 A. Yes.</p> <p>24 CHAYTOR, Q.C.:</p> <p>25 Q. So the merger would have taken place back in</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. In your position at St. Clare's, was there a</p> <p>3 period of time when St. Clare's embarked upon</p> <p>4 immunohistochemistry?</p> <p>5 MR. GREEN:</p> <p>6 A. At one brief period, we tried some kit</p> <p>7 methods.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. I'm sorry?</p> <p>10 MR. GREEN:</p> <p>11 A. Some kits.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. Kits, yes.</p> <p>14 MR. GREEN:</p> <p>15 A. We tried some kits on an experimental basis,</p> <p>16 but we found that it was too time consuming</p> <p>17 and costly and eventually the General Hospital</p> <p>18 took over all immunohistochemistry. We never</p> <p>19 did any diagnostic work with IHC.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. So did you ever--so you never did ER/PR</p> <p>22 testing?</p> <p>23 MR. GREEN:</p> <p>24 A. No.</p> <p>25 CHAYTOR, Q.C.:</p>
Page 14	Page 16
<p>1 1995/96 of the Health Care Corporation?</p> <p>2 MR. GREEN:</p> <p>3 A. Yeah, and then after the Grace Hospital</p> <p>4 closed, some employees from the Grace moved</p> <p>5 over to the Health Science. The Janeway new</p> <p>6 building was created, but the lab was</p> <p>7 incorporated into the General Hospital lab and</p> <p>8 the full merger was scheduled to take place</p> <p>9 where St. Clare's would eventually move to the</p> <p>10 Health Science.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. Yes, and then in 2005, of course, there's the</p> <p>13 further amalgamation or the creation of</p> <p>14 Eastern Health and did you notice any change</p> <p>15 at that point in time, in terms of the culture</p> <p>16 and environment that you're referring to?</p> <p>17 MR. GREEN:</p> <p>18 A. Those were rough times for people within the</p> <p>19 laboratory and within the hospital in general.</p> <p>20 Finances were limited and people who were used</p> <p>21 to having defined roles in their own hospitals</p> <p>22 now were put into situations where the roles</p> <p>23 weren't quite as clear any more. So it took</p> <p>24 time for people to mesh and to come together</p> <p>25 as a single unit.</p>	<p>1 Q. Okay, and do you recall what time period it</p> <p>2 was that St. Clare's had that brief stint in</p> <p>3 IHC?</p> <p>4 MR. GREEN:</p> <p>5 A. I can't recall right now.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. Would it have been the 80s, 90s?</p> <p>8 MR. GREEN:</p> <p>9 A. Probably late 80s.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Okay, and at that point in time, who trained</p> <p>12 you or how were you trained to do IHC testing?</p> <p>13 MR. GREEN:</p> <p>14 A. We basically trained ourselves to do it. We</p> <p>15 got the instructions from the manufacturer and</p> <p>16 we followed the instructions that we had.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. And I take it the test was done--or those</p> <p>19 tests, at that point in time, were done</p> <p>20 manually, were they?</p> <p>21 MR. GREEN:</p> <p>22 A. Yes, they were manual.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. There was no machine such as the DAKO machine</p> <p>25 when you went to the Health Science?</p>

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1 MR. GREEN:  
 2 A. No, all manual.  
 3 CHAYTOR, Q.C.:  
 4 Q. All manual, and do you recall how long did--  
 5 how long were you involved in carrying out IHC  
 6 testing at that point in time?  
 7 MR. GREEN:  
 8 A. No longer than maybe a month, and the kits  
 9 were so expensive and the time so consuming  
 10 that it was not feasible.  
 11 CHAYTOR, Q.C.:  
 12 Q. And did you--I take it then any IHC testing  
 13 that was required by the pathologists in St.  
 14 Clare's from that point in time was then  
 15 carried out at the Health Sciences Centre?  
 16 MR. GREEN:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay, and would you have been involved then in  
 20 arranging that testing?  
 21 MR. GREEN:  
 22 A. The request would come from the pathologist  
 23 for IHC and we would forward the wax blocks to  
 24 the General Hospital for cutting and staining.  
 25 CHAYTOR, Q.C.:

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1 Q. So the requisition would come through your  
 2 lab, through you or whichever technologist?  
 3 MR. GREEN:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. And you would be involved in the preparation  
 7 of the block? Is that correct?  
 8 MR. GREEN:  
 9 A. At first, we would prepare--cut slides and  
 10 send them to the General Hospital. Later on  
 11 in the process, the General Hospital took over  
 12 completely and just requested the wax blocks,  
 13 which we would send to the General Hospital.  
 14 CHAYTOR, Q.C.:  
 15 Q. So at one point in time, you were involved in  
 16 actually doing it to the stage of the slides?  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. And then ultimately just blocks and they'd  
 21 prepare the slides and sent them back?  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay. So do you recall that in terms of time

Page 19

1 periods? When were you actually sending your  
 2 own slides?  
 3 MR. GREEN:  
 4 A. Most of the requests for IHC for St. Clare's  
 5 would be for ER/P/RS because St. Clare's was  
 6 the breast centre and they would have the  
 7 bigger number of breast cases. I don't recall  
 8 the time frame, but it was a continuous  
 9 process.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, and so you don't know when--what period  
 12 of time you stopped sending slides and began  
 13 sending blocks?  
 14 MR. GREEN:  
 15 A. No.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay.  
 18 MR. GREEN:  
 19 A. Knowing what I know now, I would assume that  
 20 they were using specialized slides at the  
 21 Health Science for IHC and they would have  
 22 those slides. Those slides were treated with  
 23 an adhesive to secure the tissue to the  
 24 slides, which would end up in a better  
 25 product. So knowing what I know now, I would

Page 20

1 assume that's why they were brought over to  
 2 the Health Science for cutting.  
 3 CHAYTOR, Q.C.:  
 4 Q. So I take it that at St. Clare's you weren't  
 5 using those special slides?  
 6 MR. GREEN:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. But at the time, nobody explained that to you  
 10 that there were a certain type of slide that  
 11 were preferable to use, that wasn't explained  
 12 or the reasons for stopping St. Clare's  
 13 preparing their own slides and having them  
 14 prepared at Health Sciences?  
 15 MR. GREEN:  
 16 A. No, the reason was never told. At St.  
 17 Clare's, we would use an adhesive on all  
 18 slides, an albumin adhesive, to adhere the  
 19 sections to the slide. Knowing what I know  
 20 now, I know that those slides would have  
 21 resulted in a background staining on  
 22 immunohistochemistry. So that could have been  
 23 a factor also.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay. So the adhesive that was being used in

Page 21

1 the creation of your slides may not have been  
 2 the best for the IHC testing?  
 3 MR. GREEN:  
 4 A. True.  
 5 CHAYTOR, Q.C.:  
 6 Q. And how have you come to learn that since?  
 7 MR. GREEN:  
 8 A. Since I've moved over to Health Science, I've  
 9 had the opportunity to receive continuing  
 10 education and go to conferences. It's been an  
 11 ongoing learning experience.  
 12 CHAYTOR, Q.C.:  
 13 Q. And is there anything else, in terms of when  
 14 the slides were being prepared in house at St.  
 15 Clare's and shipped over to the Health  
 16 Sciences Centre for staining, is there  
 17 anything else about the preparation of the  
 18 slides at St. Clare's, with the knowledge you  
 19 have today, you think may have been a concern  
 20 or a factor?  
 21 MR. GREEN:  
 22 A. Breast tissue has always been an issue, as far  
 23 as I know, with all pathology labs, the nature  
 24 of the specimen itself. You've got a tissue  
 25 which has tumour which is hard, fatty tissue,

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1 soft fatty tissue which surrounds it. It is  
 2 technically difficult to cut.  
 3 CHAYTOR, Q.C.:  
 4 Q. So after you get to the stage that you're  
 5 sending the blocks over and the slides are  
 6 being prepared and sent back to St. Clare's,  
 7 prepared at Health Science and sent back to  
 8 St. Clare's, was there--would you have  
 9 interaction with the laboratory technologist  
 10 at the Health Science, would you be in contact  
 11 with them? How would you actually, I guess,  
 12 get the requisition over to them and would you  
 13 sometimes be on the phone speaking to them  
 14 about the test?  
 15 MR. GREEN:  
 16 A. Pathologists would request that the slides be  
 17 sent. We would gather blocks and they would  
 18 go over by--we had an in-house driver whose  
 19 job was to go back and forth between Health  
 20 Science and St. Clare's. They would drop them  
 21 off to the laboratory over there. If there  
 22 was a problem with blocks, Peggy or Mary would  
 23 pick up the phone and call over and ask us  
 24 about it.  
 25 CHAYTOR, Q.C.:

Page 23

1 Q. And were there ever concerns expressed by the  
 2 pathologist or did you yourself notice  
 3 anything about the slides that were coming  
 4 back from the Health Sciences? Over the  
 5 years, did you hear any concerns expressed  
 6 about the quality of the slides?  
 7 MR. GREEN:  
 8 A. As technologists, we would not see the slides  
 9 that returned from the Health Science. They  
 10 would go directly to the pathologist for  
 11 interpretation.  
 12 CHAYTOR, Q.C.:  
 13 Q. And did you ever hear any discussion or hear  
 14 any comments or feedback from the pathologist  
 15 as to the quality of the slides? For example,  
 16 would they come back and ever ask that things  
 17 be repeated?  
 18 MR. GREEN:  
 19 A. I would imagine from time to time they would  
 20 ask for repeats, but it wouldn't be uncommon  
 21 for a pathologist to ask for re-cuts on normal  
 22 breast tissue because in order to request an  
 23 ER/PR on the tissue, pathologists would need  
 24 the routine stain, which is a hematoxylin and  
 25 eosin stain. They would need to look at those

Page 24

1 slides to assess the quality before they would  
 2 order the ER/PR.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay, and perhaps you can just explain that  
 5 then a bit more for us?  
 6 MR. GREEN:  
 7 A. In pathology, every specimen receives a  
 8 routine stain which is hematoxylin and eosin.  
 9 It's the work horse stain of the lab. It is  
 10 the stain that the pathologist would look at  
 11 to make a diagnosis. It is the slide that the  
 12 pathologist will review to order specialized  
 13 tests. Usually the pathologist will know by  
 14 looking at the H & E slide, they will have a  
 15 fair idea what the diagnosis would be. They  
 16 will request these other tests to confirm what  
 17 they suspect. In the case of ER/PR, a  
 18 pathologist would look at the slides that we  
 19 had prepared, the H & E slides. They would  
 20 determine the appropriate -- most appropriate  
 21 slide to send for IHC, and in ER/PR, in  
 22 particular, they would want to send a slide  
 23 which had normal tissue and tumour tissue.  
 24 CHAYTOR, Q.C.:  
 25 Q. And did you know that at the time?

Page 25

1 MR. GREEN:  
 2 A. No.  
 3 CHAYTOR, Q.C.:  
 4 Q. And was that something -- when did you come to  
 5 realize that, that they would try to pick a  
 6 slide that had normal tissue and tumour  
 7 tissue?  
 8 MR. GREEN:  
 9 A. When I moved to Health Science and became  
 10 involved in IHC.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay.  
 13 MR. GREEN:  
 14 A. I knew from sitting with the pathologists at  
 15 the gross bench that they wanted to identify  
 16 the tumour and they wanted to identify how far  
 17 the tumour moved out into the tissue so they  
 18 could find margins to see how far it had  
 19 advanced.  
 20 CHAYTOR, Q.C.:  
 21 Q. So this idea we've heard talked about here at  
 22 the Commission regarding internal controls, is  
 23 that something that you were aware of during  
 24 your time at St. Clare's?  
 25 MR. GREEN:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. Is that something you ever heard pathologists  
 4 discuss or mention?  
 5 MR. GREEN:  
 6 A. No.  
 7 CHAYTOR, Q.C.:  
 8 Q. So the idea of picking a block or a slide that  
 9 had both the normal and tumour tissue, that's  
 10 something that came to your knowledge after  
 11 you moved in 2002?  
 12 MR. GREEN:  
 13 A. That's true.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. I understand then that the slides would  
 16 be sent back and you would not see them, but  
 17 there may be times when pathologists would  
 18 request a repeat?  
 19 MR. GREEN:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. Was there ever anything brought to your  
 23 attention that they had any particular  
 24 concerns about the quality of the slide other  
 25 than, you know, yes, there's a repeat

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1 requested from time to time? Was there ever  
 2 anything that was brought to your attention  
 3 that they weren't pleased with what they were  
 4 receiving back from the Health Sciences?  
 5 MR. GREEN:  
 6 A. Not for IHC slides coming back, but there  
 7 would be requests for re-cuts, what we call  
 8 re-cuts on breast tissue. That was a normal  
 9 request. After the pathologist had looked at  
 10 the H & E slides, if they weren't pleased with  
 11 the slides they had, they had two choices.  
 12 One was to go back and ask for re-cuts on the  
 13 original blocks, and the other choice was to  
 14 go back to the specimen itself and take  
 15 additional blocks.  
 16 CHAYTOR, Q.C.:  
 17 Q. And was there ever any discussion, for  
 18 example, about fixation issues?  
 19 MR. GREEN:  
 20 A. Breast tissue was probably the biggest  
 21 specimens that we had a problem with. From a  
 22 technical point of view, from the cutting,  
 23 those would be hard to cut because some of  
 24 them would not be optimally fixed or  
 25 processed. I think the problem would be more

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1 processing than fixation.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay.  
 4 MR. GREEN:  
 5 A. Because any problem that occurs after fixation  
 6 can be rectified, but fixation, if it's not  
 7 fixed properly, that is the only step which we  
 8 cannot go back and redo. So at one stage we  
 9 had a doctor, Dr. Tadross --  
 10 CHAYTOR, Q.C.:  
 11 Q. I'm sorry, what's the name.  
 12 MR. GREEN:  
 13 A. Dr. Tadross who had moved from Ontario;  
 14 Kingston, Ontario, and as he rotated through  
 15 the lab, he would have problem with some of  
 16 the breast tissues and he said why don't you  
 17 reprocess those blocks, and we had never heard  
 18 of reprocessing, so we said what do you mean  
 19 "reprocess". He said take the blocks and  
 20 remove the excess wax, put them on the tissue  
 21 processor, process them the next day and  
 22 they'll be fine. So we tried those, and sure  
 23 enough, when they were reprocessed, they cut  
 24 much better and the pathologist had a better  
 25 section.

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1 CHAYTOR, Q.C.:

2 Q. And when was that suggestion made by that

3 pathologist?

4 MR. GREEN:

5 A. I'm not exactly sure of the year Dr. Tadross

6 was there but it had to be late 80s.

7 CHAYTOR, Q.C.:

8 Q. How long then did reprocessing remain a

9 procedure carried out at St. Clare's?

10 MR. GREEN:

11 A. From that point onward, reprocessing was

12 routinely carried out on blocks that we

13 considered sub-optimal until the time I left

14 St. Clare's to move to the Health Science.

15 CHAYTOR, Q.C.:

16 Q. Are you able to give us any indication as to

17 the percentage of blocks that would have been

18 considered sub-optimal?

19 MR. GREEN:

20 A. No, I can't give a percentage. It would vary

21 by case, case to case. Some breast specimens

22 would be processed and they would be cut

23 routinely with no problems. Another specimen

24 may be cut and it would have problems.

25 CHAYTOR, Q.C.:

Page 30

1 Q. And was there -- well, I guess, then a

2 different way to ask the same question would

3 be, was it a common thing to reprocess blocks

4 or was it fairly infrequent?

5 MR. GREEN:

6 A. Depending on the surgeries that happened that

7 week, if there were a lot of breast specimens

8 that went through that week, sometimes there

9 would be a fair amount of breast tissue

10 reprocessed.

11 CHAYTOR, Q.C.:

12 Q. So do I take it from what you're telling us

13 that it was more common to reprocess for

14 breast tissue?

15 MR. GREEN:

16 A. Breast tissue is the only tissue that I can

17 recall reprocessing.

18 CHAYTOR, Q.C.:

19 Q. And in terms of the amount of those that would

20 have been reprocessed, was it a common thing

21 to reprocess breast tissue blocks?

22 MR. GREEN:

23 A. After we started reprocessing, we would

24 reprocess blocks every week.

25 CHAYTOR, Q.C.:

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1 Q. Every week?

2 MR. GREEN:

3 A. Yes.

4 COMMISSIONER:

5 Q. Excuse me, Mr. Green, but the question of

6 whether there would be a reprocessing, was

7 that something you as a technologist assessed

8 or was that something that a pathologist might

9 direct you to do?

10 MR. GREEN:

11 A. At first the pathologist -- we would mention

12 to the pathologist and they had no problem

13 with it, and after it became common practice

14 to reprocess, we would know when specimens

15 came off the processor in the morning if they

16 had to be reprocessed because some of them you

17 could tell -- we would not even try to cut

18 those blocks because we knew we would not be

19 able to get a technically good section from

20 those blocks. So we would just take those

21 blocks and reprocess them ourselves.

22 COMMISSIONER:

23 Q. So you -- when they came off the processor, is

24 it?

25 MR. GREEN:

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1 A. Yes.

2 COMMISSIONER:

3 Q. You would assess whether or not it was a block

4 from which in your view you could get a good

5 slide effectively?

6 MR. GREEN:

7 A. Yes.

8 COMMISSIONER:

9 Q. Make a good cut.

10 MR. GREEN:

11 A. Yeah.

12 COMMISSIONER:

13 Q. Okay, thank you.

14 CHAYTOR, Q.C.:

15 Q. Thank you, Commissioner. What was it then,

16 Mr. Green, about the processing, the tissue

17 processor, what was causing this issue?

18 MR. GREEN:

19 A. It's a combination of factors. The tissue

20 itself, most tissues that went through on the

21 processor were fine. The majority of specimens

22 that we did on a daily basis, we had no

23 problems with. It would only be the breast

24 tissue and those were the ones that we had to

25 reprocess.



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<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. Did anyone make any inquiries as to why that</p> <p>3 would be, why there were problems with the</p> <p>4 breast tissue?</p> <p>5 MR. GREEN:</p> <p>6 A. It seemed to be the school of thought that it</p> <p>7 was the nature of the specimen, a lot of fatty</p> <p>8 tissue, which doesn't process well at any</p> <p>9 time, plus a lot of -- since St. Clare's had</p> <p>10 the distinction of doing most of the breast</p> <p>11 surgery, we would have a larger volume of</p> <p>12 breast blocks. So it probably would not even</p> <p>13 be apparent at the Health Science who</p> <p>14 processed very little breast. So we processed</p> <p>15 -- it was a combination of processing a lot of</p> <p>16 specimens that were of this nature. So when</p> <p>17 they were processed a second time, it means</p> <p>18 that the alcohols had a chance to go in and</p> <p>19 dehydrate the specimen for to process them.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. And when you say it seemed to be the school of</p> <p>22 thought, whose school of thought? Was that</p> <p>23 just discussed amongst the technologist, or</p> <p>24 was that something that was brought to the</p> <p>25 attention of the pathologist?</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. And what do you now understand to be some of</p> <p>3 the shortcomings of reprocessing for IHC</p> <p>4 testing?</p> <p>5 MR. GREEN:</p> <p>6 A. I don't know if anybody knows what the results</p> <p>7 of reprocessing are. Knowing what I know now</p> <p>8 with my training in IHC, I know that in order</p> <p>9 to demonstrate the antigen antibody reaction</p> <p>10 we need to expose the antigen sites. What</p> <p>11 damage the reprocessing did to these sites, I</p> <p>12 couldn't -- I don't want to guess, but it may</p> <p>13 or may not affect it. I don't know if there's</p> <p>14 any -- if there's any research to show that it</p> <p>15 can or cannot affect it.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. Dr. Tadross, was it, from Kingston?</p> <p>18 MR. GREEN:</p> <p>19 A. Yes, Tadross.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. And he's the person who suggested to you</p> <p>22 reprocessing?</p> <p>23 MR. GREEN:</p> <p>24 A. Reprocess.</p>
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<p>1 MR. GREEN:</p> <p>2 A. Both pathologists and the technologists were</p> <p>3 aware of the problems with breast tissue, and</p> <p>4 after we started the practice of reprocessing,</p> <p>5 it was policy.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. It was policy?</p> <p>8 MR. GREEN:</p> <p>9 A. Yes.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And was anyone aware or was it brought to your</p> <p>12 attention as a technologist of any particular</p> <p>13 pitfalls or dangers in reprocessing the</p> <p>14 tissue?</p> <p>15 MR. GREEN:</p> <p>16 A. No, because the -- knowing now what I know, I</p> <p>17 know that looking down the road for future</p> <p>18 test for IHC, it could have been a problem,</p> <p>19 but our goal was to produce the best H &amp; E</p> <p>20 sections for the pathologist to make a</p> <p>21 diagnosis. So that was our job. We didn't</p> <p>22 look at the secondary testing of the block</p> <p>23 because if the pathologist couldn't make the</p> <p>24 primary diagnosis, had no H &amp; E slides to work</p> <p>25 with, he wouldn't be able to order IHC stains.</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. Did he have any particular area of expertise?</p> <p>3 MR. GREEN:</p> <p>4 A. As far as I know, it was general pathology.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. Was he -- how much experience had he had? Was</p> <p>7 he a fairly senior pathologist or fairly new?</p> <p>8 MR. GREEN:</p> <p>9 A. I'm not sure. I didn't think he had a -- he</p> <p>10 wasn't a senior pathologist, but he had some</p> <p>11 experience, and from talking with him, he told</p> <p>12 us that this was accepted practice in a</p> <p>13 hospital he had been in before.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. And that was back again in the 1980s?</p> <p>16 MR. GREEN:</p> <p>17 A. Yes.</p> <p>18 CHAYTOR, Q.C.:</p> <p>19 Q. And whether or not that hospital had been</p> <p>20 engaged in IHC, would you know that?</p> <p>21 MR. GREEN:</p> <p>22 A. I have no way of knowing.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Or whether he had any experience with IHC?</p> <p>25 MR. GREEN:</p>

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1 A. No, I don't.

2 CHAYTOR, Q.C.:

3 Q. But this was accepted then and known by the

4 other pathologists at St. Clare's that

5 reprocessing was taking place?

6 MR. GREEN:

7 A. Yes.

8 CHAYTOR, Q.C.:

9 Q. In terms of the fact that certain blocks had

10 to be reprocessed or it was felt necessary to

11 reprocess them to get adequate H & E slides as

12 you're describing, was there any investigation

13 or inquiries made as to how better the

14 processing -- initial processing could be

15 carried out to avoid having to reprocess?

16 MR. GREEN:

17 A. The processor that we used, it was changed --

18 regularly changed. I'm not sure of the

19 schedule now. I think it was changed every

20 second day, fully changed, and each day in

21 between the solutions would be topped up.

22 CHAYTOR, Q.C.:

23 Q. So it was undergoing regular cleaning and

24 maintenance?

25 MR. GREEN:

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1 A. Yes, and we weren't -- we were not having a

2 problem with all the other specimens. So if

3 there was only one specimen that's causing a

4 problem with fixation and processing, you

5 would attribute it to that specimen and not to

6 the processor which processed hundreds of

7 other specimens from all organs which we

8 didn't -- as a rule, we did not have a problem

9 with.

10 CHAYTOR, Q.C.:

11 Q. Okay. When the reprocessing took place on

12 various blocks, was there any record kept as

13 to which blocks had been reprocessed?

14 MR. GREEN:

15 A. We would have a book which we used to record

16 the gross specimens every day, and we would

17 have a total number of blocks so we know how

18 many to put on the processor, and I think the

19 processor took 150 blocks. So if we had, say,

20 140 blocks that day and we had ten reprocessed

21 blocks, we would write on the sheet for that

22 day, "ten reprocessed blocks". Sometimes we

23 would put the surgical number and other times

24 we would just put "ten reprocessed blocks".

25 CHAYTOR, Q.C.:

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1 Q. And would that record still exist?

2 MR. GREEN:

3 A. I'm not sure how long the yearly -- we would

4 probably generate maybe one of those books per

5 month. I'm not sure how long those books were

6 kept.

7 CHAYTOR, Q.C.:

8 Q. And where were those books generally kept?

9 MR. GREEN:

10 A. It would be kept at -- the ones at St. Clare's

11 were kept in the gross room at St. Clare's,

12 and the gross room would have a set of drawers

13 in there and they would be put in there.

14 CHAYTOR, Q.C.:

15 Q. And in your 23 years there, did it seem to you

16 that all those books were still in existence

17 and kept in those drawers?

18 MR. GREEN:

19 A. I don't think so. We would have generated

20 probably twelve books a year, and I can't see

21 keeping those books for an extended period of

22 time.

23 CHAYTOR, Q.C.:

24 Q. Okay. Would there have been -- I take it,

25 other than those books, no other record or

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1 means of identifying which blocks may have

2 been reprocessed?

3 MR. GREEN:

4 A. No, you can't physically tell by looking at

5 the blocks once they've been reprocessed.

6 CHAYTOR, Q.C.:

7 Q. I'm going to take you to -- eventually today

8 we'll get to the current processes, and

9 whether or not reprocessing is still

10 continuing. So we'll pick up that theme again

11 later with you. In keeping then with your

12 time at St. Clare's, were there ever any other

13 concerns expressed about the quality then of

14 the work product coming back from the Health

15 Sciences Centre?

16 MR. GREEN:

17 A. No.

18 CHAYTOR, Q.C.:

19 Q. So you move over then to the Health Sciences

20 in 2002?

21 MR. GREEN:

22 A. Yes.

23 CHAYTOR, Q.C.:

24 Q. And when you go there, you told us that you

25 weren't dedicated as such to IHC, that was

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<p>1 once every three weeks you would be doing the</p> <p>2 IHC testing?</p> <p>3 MR. GREEN:</p> <p>4 A. Yes.</p> <p>5 CHAYTOR, Q.C.:</p> <p>6 Q. And the other two weeks doing all of your</p> <p>7 other duties?</p> <p>8 MR. GREEN:</p> <p>9 A. Yes.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Was there a pathologist in charge of the IHC</p> <p>12 portion of services?</p> <p>13 MR. GREEN:</p> <p>14 A. Not a dedicated pathologist. Dr. Robb had</p> <p>15 experience in IHC. You could go to him if you</p> <p>16 had problems. Dr. Chittal seemed to be quite</p> <p>17 knowledgeable in IHC, and I gathered talking</p> <p>18 to Peggy and Mary that he had initiated a lot</p> <p>19 of the protocols that were there and set it up</p> <p>20 initially.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. I'm sorry, that was Doctor?</p> <p>23 MR. GREEN:</p> <p>24 A. Dr. Chittal.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 the gross, but we did not do any of the gross</p> <p>2 specimens ourselves. So at the Health</p> <p>3 Science, we were trained to process small</p> <p>4 specimens, which means that we would describe</p> <p>5 and dictate the specimens and put those in --</p> <p>6 make sure they were numbered, and put in</p> <p>7 cassettes for whatever pathologist was on the</p> <p>8 gross that day.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. So you had to learn that too?</p> <p>11 MR. GREEN:</p> <p>12 A. Yeah.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. And actually did it. I take it when you say</p> <p>15 "small specimens", you weren't involved,</p> <p>16 however, in grossing breast tissue?</p> <p>17 MR. GREEN:</p> <p>18 A. No, they were done by the pathologists or the</p> <p>19 pathologist residents at the time.</p> <p>20 CHAYTOR, Q.C.:</p> <p>21 Q. Okay, all right. So not only did you have to</p> <p>22 learn IHC and everything that I'll take you</p> <p>23 through that that entailed, you also had to</p> <p>24 learn to do this grossing?</p> <p>25 MR. GREEN:</p>
<p>Page 42</p> <p>1 Q. Dr. Chittal, yes. Okay. So when you went to</p> <p>2 the Health Sciences in 2002, what initiation</p> <p>3 or training did you receive in IHC?</p> <p>4 MR. GREEN:</p> <p>5 A. For the first two weeks, I kind of shadowed</p> <p>6 Peggy Welsh. She was the lead person in the</p> <p>7 IHC department, and for the next two weeks</p> <p>8 after that, I would do the IHC and Peggy would</p> <p>9 observe me, and that was the on the job</p> <p>10 training that we received.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. Okay. So I take it your other job duties, you</p> <p>13 were quite familiar with, the other things</p> <p>14 that you had to do weren't for the most part</p> <p>15 new to you over the past 23 years?</p> <p>16 MR. GREEN:</p> <p>17 A. On the contrary, most of the duties were new</p> <p>18 to me.</p> <p>19 CHAYTOR, Q.C.:</p> <p>20 Q. Okay, so what training did you receive? So</p> <p>21 how was it different, tell us how was your job</p> <p>22 then different when you arrived at the Health</p> <p>23 Sciences?</p> <p>24 MR. GREEN:</p> <p>25 A. At St. Clare's, we assisted the pathologist on</p>	<p>Page 44</p> <p>1 A. Yeah.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. What else was new for you?</p> <p>4 MR. GREEN:</p> <p>5 A. Muscle histochemistry. Muscle histochemistry</p> <p>6 at that time was far more challenging than the</p> <p>7 IHC for me to learn.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. And why was that?</p> <p>10 MR. GREEN:</p> <p>11 A. Muscle histochemistry is approximately a two</p> <p>12 day process where the first day you have to</p> <p>13 cut fresh muscle biopsies, and the muscle</p> <p>14 biopsies had to be cut in sequence. They had</p> <p>15 to be cut into five tier (phonetic) fresh</p> <p>16 tissue, if it had to be a cut in the cryostat</p> <p>17 and they had to be consecutive, and they have</p> <p>18 to be technically perfect when doing those</p> <p>19 specimens. The stains that you would do the</p> <p>20 following day, there were 14 stains. They</p> <p>21 were pH sensitive, temperature sensitive,</p> <p>22 weight sensitive and time sensitive, and they</p> <p>23 were quite demanding. So those were -- that</p> <p>24 was a bigger challenge to me at that time than</p> <p>25 IHC, running the IHC system.</p>

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1 CHAYTOR, Q.C.:

2 Q. Okay. So you had to learn all that as well,

3 and so in terms of the two week job shadowing

4 Ms. Welsh, was that just for IHC or was that

5 for all of your duties?

6 MR. GREEN:

7 A. That was for IHC, and Barry Dyer taught me the

8 muscle histochemistry. He had done that

9 procedure at the Janeway. He was quite

10 familiar with that.

11 CHAYTOR, Q.C.:

12 Q. How much time did you spend learning that

13 aspect?

14 MR. GREEN:

15 A. It was probably about a month learning that

16 procedure, and then you would have to do the

17 procedure several times to become proficient

18 in it.

19 CHAYTOR, Q.C.:

20 Q. Okay. So then in terms of IHC, you spent two

21 weeks watching Peggy Welsh do what needed to

22 be done in the IHC portion of the services,

23 and then you said you spent two weeks doing it

24 while she watched you?

25 MR. GREEN:

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1 A. That's correct.

2 CHAYTOR, Q.C.:

3 Q. And then I take it the next time you were in

4 the IHC lab, you were in there alone?

5 MR. GREEN:

6 A. Yeah.

7 CHAYTOR, Q.C.:

8 Q. Or in the IHC portion of the lab, I should

9 say?

10 MR. GREEN:

11 A. Yeah.

12 CHAYTOR, Q.C.:

13 Q. And then you ran your own tests?

14 MR. GREEN:

15 A. Yes. Now like I said earlier, the IHC portion

16 of the lab at the Health Science was the next

17 bench, so if you had a problem, Peggy was

18 probably about the same distance you are from

19 me, or Mary, so there would be no problem

20 contacting them.

21 CHAYTOR, Q.C.:

22 Q. And they were available then for you to be

23 able to consult with?

24 MR. GREEN:

25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And did you find in those early days that you

3 frequently had to ask them questions?

4 MR. GREEN:

5 A. There were many times when questions would

6 arise, yeah.

7 CHAYTOR, Q.C.:

8 Q. And what kinds of questions? What was it that

9 you would have to seek further advice or

10 instruction on?

11 MR. GREEN:

12 A. It would depend on the antibodies that were

13 requested, the controls that were used, which

14 control to use. We had a list of controls,

15 plus a list of the antibodies which required

16 antigen retrieval, and a list of ones which

17 didn't require antigen retrieval. So if you

18 were in doubt about an antibody that required

19 antigen retrieval, you'd check with Peggy or

20 Mary.

21 CHAYTOR, Q.C.:

22 Q. Okay, and other than job shadowing Peggy, were

23 you given anything to read to familiarize

24 yourself with how to do IHC?

25 MR. GREEN:

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1 A. There were no formal textbooks except there

2 was a textbook there by Leon & Leon (phonetic)

3 on all the antibodies with the characteristics

4 of the antibodies.

5 CHAYTOR, Q.C.:

6 Q. And the purpose, I hear, of the antibodies?

7 MR. GREEN:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. But no actual textbooks, for example, as to

11 the theory of IHC, anything like that?

12 MR. GREEN:

13 A. No.

14 CHAYTOR, Q.C.:

15 Q. And were there other resources available to

16 you, such as the internet, journals, articles,

17 anything like that?

18 MR. GREEN:

19 A. The internet was not down in our part of the

20 lab, but it was available in the main lab.

21 CHAYTOR, Q.C.:

22 Q. Okay.

23 MR. GREEN:

24 A. And like I said earlier, the main lab is not a

25 long distance away.

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<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. So that was one computer, I take it, for</p> <p>3 everybody to be able to access?</p> <p>4 MR. GREEN:</p> <p>5 A. Yeah, and the Health Science had the library</p> <p>6 over in the next corridor, so if you're</p> <p>7 inclined, you could go over to the library and</p> <p>8 check out information there, plus we had the</p> <p>9 data sheets that came from the manufacturer.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Okay. So did you take it upon yourself to do</p> <p>12 any of those things, to go on the internet and</p> <p>13 study, or go to the library, or obtain other</p> <p>14 reading material?</p> <p>15 MR. GREEN:</p> <p>16 A. At St. Clare's, I would go in at 7 o'clock and</p> <p>17 I would leave at 2. I would work through</p> <p>18 lunch. So when I went to the Health Science,</p> <p>19 I would take a lunch period and in the</p> <p>20 beginning I would go over to the library at</p> <p>21 the Health Science here and look up various</p> <p>22 information.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. And, in particular, I'm wondering what</p> <p>25 information would have been available or did</p>	<p>1 A. Yes.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. And I guess you would refer to them as need</p> <p>4 be?</p> <p>5 MR. GREEN:</p> <p>6 A. Yeah.</p> <p>7 CHAYTOR, Q.C.:</p> <p>8 Q. When you were doing particular antibodies.</p> <p>9 MR. GREEN:</p> <p>10 A. Yes.</p> <p>11 CHAYTOR, Q.C.:</p> <p>12 Q. There were no other standard operating</p> <p>13 procedures, I understand, available?</p> <p>14 MR. GREEN:</p> <p>15 A. No.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. And in terms of anything else then in terms of</p> <p>18 you familiarizing yourself through any</p> <p>19 articles at that point in time or reading on</p> <p>20 the internet, or referencing textbooks, do you</p> <p>21 recall whether or not you did that in</p> <p>22 2002/2003 time frame?</p> <p>23 MR. GREEN:</p> <p>24 A. We would check out the PubMed site. That was</p> <p>25 a site for immunohistochemistry.</p>
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<p>1 you avail of regarding IHC?</p> <p>2 MR. GREEN:</p> <p>3 A. It would be articles mostly, but the DABB's</p> <p>4 book was at the library over there. I didn't</p> <p>5 use that, but then Maurice Larkin told me that</p> <p>6 she had told Dr. Ejeckam about the DABBS,</p> <p>7 which he got for us after.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. And when was that conversation with Dr.</p> <p>10 Maurice Larkin?</p> <p>11 MR. GREEN:</p> <p>12 A. It was probably recently after we had been</p> <p>13 discussing the ER/PR episode, and Dr. Ejeckam</p> <p>14 had referred to DABBS as his Bible, and she</p> <p>15 said -- well, she said I had told him about</p> <p>16 that. So I was familiar with it before.</p> <p>17 CHAYTOR, Q.C.:</p> <p>18 Q. So in terms of what you had available to you</p> <p>19 or what knowledge, that's what I'm trying to</p> <p>20 ascertain, what knowledge you had in 2002 when</p> <p>21 you started doing IHC testing, and you've told</p> <p>22 us about job shadowing Peggy and Peggy</p> <p>23 observing you do the work, and you had the</p> <p>24 data spec sheets from the manufacturers?</p> <p>25 MR. GREEN:</p>	<p>1 CHAYTOR, Q.C.:</p> <p>2 Q. So from time to time if you had any questions,</p> <p>3 you would go on that site?</p> <p>4 MR. GREEN:</p> <p>5 A. Yes.</p> <p>6 CHAYTOR, Q.C.:</p> <p>7 Q. Okay.</p> <p>8 MR. GREEN:</p> <p>9 A. And sometimes the pathologists would bring us</p> <p>10 articles from that site that they had looked</p> <p>11 up.</p> <p>12 CHAYTOR, Q.C.:</p> <p>13 Q. And, Mr Green, by the time you finished your</p> <p>14 four weeks of training with Peggy in the IHC</p> <p>15 portion, how comfortable did you feel about</p> <p>16 then being able to run that testing on your</p> <p>17 own with having them available to consult if</p> <p>18 necessary?</p> <p>19 MR. GREEN:</p> <p>20 A. The comfort level increased as I obtained more</p> <p>21 experience. It was kind of a daunting task at</p> <p>22 first, but it was a challenge, and after a few</p> <p>23 month there, I was quite confident in running</p> <p>24 the procedure itself.</p> <p>25 CHAYTOR, Q.C.:</p>

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1 Q. How many antibodies would have been in use at  
 2 that time?  
 3 MR. GREEN:  
 4 A. Probably in excess of 100.  
 5 CHAYTOR, Q.C.:  
 6 Q. And I take it they all had separate spec  
 7 sheets?  
 8 MR. GREEN:  
 9 A. They did.  
 10 CHAYTOR, Q.C.:  
 11 Q. And those -- were those at that time already  
 12 programmed into the computer?  
 13 MR. GREEN:  
 14 A. When I had arrived at the Health Science, all  
 15 the programs were programmed into the  
 16 computer, all the protocols were developed,  
 17 and all the validations had been done.  
 18 CHAYTOR, Q.C.:  
 19 Q. Had already been done on those antibodies, and  
 20 did you have the experience then of having to  
 21 introduce a new antibody?  
 22 MR. GREEN:  
 23 A. No, in my time there in the first year if  
 24 there was a new antibody, Peggy would take  
 25 care of that because even though I had 23

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1 years experience in pathology, I still only  
 2 had one year in IHC, and they would be the  
 3 senior people to put new antibodies into the  
 4 system.  
 5 CHAYTOR, Q.C.:  
 6 Q. How about a situation where a current antibody  
 7 in your inventory ran out or became low and a  
 8 new batch of that antibody had to be ordered,  
 9 were you involved in that?  
 10 MR. GREEN:  
 11 A. Not at first, but later on as I gained more  
 12 experienced, I would order the antibodies too.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and then what process of validation  
 15 would be undertaken in receiving a new batch  
 16 of a particular antibody?  
 17 MR. GREEN:  
 18 A. If there was a different clone, you had to  
 19 revalidate the antibody. If it was the same  
 20 clone, but of a different batch, it was not  
 21 revalidated. There was no lot to lot  
 22 validation.  
 23 CHAYTOR, Q.C.:  
 24 Q. No lot to lot validation?  
 25 MR. GREEN:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. So as long as it was the same clone  
 4 that you'd been using all along, and I take it  
 5 would you change your clones very frequently?  
 6 MR. GREEN:  
 7 A. Very rarely the clones were changed, and the  
 8 dilution of the antibody would be written on  
 9 the specification sheet, the dilution of the  
 10 antibody would be written on the antibody vial  
 11 itself, and the dilution of the antibody would  
 12 be written on the solution that we use on the  
 13 DAKO system.  
 14 CHAYTOR, Q.C.:  
 15 Q. And in terms of revalidation if a new clone  
 16 came along, what would that process entail?  
 17 MR. GREEN:  
 18 A. If you had a new antibody or a new clone, you  
 19 would read the manufacturers specifications  
 20 and you would take some of your known controls  
 21 that you have, and you would run the  
 22 manufacturers recommended protocol and you  
 23 would -- the dilution was usually -- you would  
 24 get a range of dilutions probably from 1 in  
 25 100, 1 in 200, could be 1 in 10, 1 in 50. We

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1 usually took the most concentrated antibody  
 2 and worked backwards. Those slides would be  
 3 brought to the pathologist. They would tell  
 4 us which one they like best and that one would  
 5 be used.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and I take it what you're trying to do  
 8 then is optimize the stain?  
 9 MR. GREEN:  
 10 A. Yes.  
 11 CHAYTOR, Q.C.:  
 12 Q. And the pathologist then ultimately would make  
 13 that call based on what they're seeing?  
 14 MR. GREEN:  
 15 A. Yes.  
 16 CHAYTOR, Q.C.:  
 17 Q. And the dilution range then, was it always  
 18 within the range provided by the manufacturer  
 19 on the spec sheet?  
 20 MR. GREEN:  
 21 A. To the best of my knowledge, it would be, but  
 22 each antibody has to be optimized for each  
 23 laboratory. So if you had an antibody which  
 24 did not work well with your fixation and  
 25 process tissues, you would have to adapt that

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<p>1 antibody to work in your laboratory because</p> <p>2 the guidelines that the manufacturer would</p> <p>3 give would be guidelines, and they would</p> <p>4 always specify that these should be optimized</p> <p>5 with your laboratory. There's not one size</p> <p>6 fits all philosophy, so each laboratory would</p> <p>7 be different.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. So it could be outside the range provided or</p> <p>10 suggested by the manufacturer?</p> <p>11 MR. GREEN:</p> <p>12 A. Yes, because those were recommended dilutions.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. If we could have, please, 2177, page seven.</p> <p>15 Actually, page five first, please. These are</p> <p>16 the specification sheets that we've been</p> <p>17 provided from Eastern Health, and this one has</p> <p>18 the date of June 13, 2001, written on it.</p> <p>19 Come down under -- I don't see anything</p> <p>20 written on that particular one in terms of --</p> <p>21 anything handwritten in terms of what dilution</p> <p>22 may be used. So would I take it from that</p> <p>23 that it would have been somewhere within the</p> <p>24 range of what the manufacturer was suggesting.</p> <p>25 It's quite the large range, though. It's an</p>	<p>1 MR. GREEN:</p> <p>2 A. That looks familiar.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. So, that looks familiar? Is this your</p> <p>5 handwriting?</p> <p>6 MR. GREEN:</p> <p>7 A. Looks a bit neat for my handwriting.</p> <p>8 CHAYTOR, Q.C.:</p> <p>9 Q. Okay. And again, in terms of the dilution</p> <p>10 suggested by the manufacturer, may be used at</p> <p>11 a dilution of 1 to 35 when performing IHC as</p> <p>12 in DAKO EnVision.</p> <p>13 MR. GREEN:</p> <p>14 A. Um-hm.</p> <p>15 CHAYTOR, Q.C.:</p> <p>16 Q. And DAKO EnVision double stain or DAKO LSAB2</p> <p>17 detection system. So, I take it you were</p> <p>18 using which of those -</p> <p>19 MR. GREEN:</p> <p>20 A. They were using the EnVision at the time.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. The EnVision at the time, okay. And at this</p> <p>23 point in time was suggesting 1 to 35. So, I</p> <p>24 take it there would have been a revalidation</p> <p>25 that took place at this point in time?</p>
<p>1 optimal staining and dilution of 1 to 50 to 1</p> <p>2 to 100. Do you remember when you -- in terms</p> <p>3 of ER/PR when you first arrived in 2002, what</p> <p>4 dilution was being used?</p> <p>5 MR. GREEN:</p> <p>6 A. I can't really specifically recall the</p> <p>7 dilution that we used. It was probably in the</p> <p>8 range of 150. 150 seems to ring a bell.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. Okay. This talks about the LSAB methods?</p> <p>11 MR. GREEN:</p> <p>12 A. The Labelled Streptavidin Biotin Method.</p> <p>13 CHAYTOR, Q.C.:</p> <p>14 Q. And is that what was being used?</p> <p>15 MR. GREEN:</p> <p>16 A. They put the EnVision on the DAKO system, that</p> <p>17 was the EnVision which they used for that</p> <p>18 system, yes. It was the detection system that</p> <p>19 they used. On the Ventana system we also used</p> <p>20 the Streptavidin Biotin Method.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. Okay. And then on the next page, the next</p> <p>23 specification sheet, at page seven, has the</p> <p>24 date of April 3, 2003 and it looks like one</p> <p>25 over fifty written here.</p>	<p>1 MR. GREEN:</p> <p>2 A. Most likely, yeah.</p> <p>3 CHAYTOR, Q.C.:</p> <p>4 Q. And if we go forward then to page 11, later</p> <p>5 that month, April 28, 2003 we see a 1 to 20 or</p> <p>6 1 in 20.</p> <p>7 MR. GREEN:</p> <p>8 A. Yeah, seems that the concentration is</p> <p>9 increasing.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. Okay. Now, do you remember anything in that</p> <p>12 time period then in April of 2003 as to why it</p> <p>13 would have changed from 1 to 50 to 1 to 20?</p> <p>14 MR. GREEN:</p> <p>15 A. I wasn't involved in the revalidation of the</p> <p>16 antibody at that time because I would have</p> <p>17 been the junior employee in the IHC</p> <p>18 department. Peggy was probably gone or pretty</p> <p>19 close to going, could have been Mary. It may</p> <p>20 be at time that Dr. Ejeckam had problems with</p> <p>21 some of the antibodies which I didn't realize</p> <p>22 until after.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Yes, and I'll take you through that as to when</p> <p>25 you became aware of Dr. Ejeckam and anything</p>

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1 he was doing to tweak the system at this point  
 2 in time. So, the fact that it had changed  
 3 from 1 to 50 to 1 to 20 in that month, would  
 4 you have been aware of that?  
 5 MR. GREEN:  
 6 A. If it was not my week on the machine, I'd  
 7 probably be two weeks without being in that  
 8 part of the lab. It's possible that other--  
 9 not only possible, it's factual that I was not  
 10 aware that it was not happening.  
 11 CHAYTOR, Q.C.:  
 12 Q. You didn't know that the change had taken  
 13 place in the dilutions?  
 14 MR. GREEN:  
 15 A. No.  
 16 CHAYTOR, Q.C.:  
 17 Q. How then when you next ran the machine would  
 18 you be aware that the dilution had changed?  
 19 MR. GREEN:  
 20 A. Because we went to re-dilute the antibody for  
 21 that run, it would have been changed on the  
 22 bottle, on the vial that the antibody would  
 23 come in, it would have been changed to  
 24 indicate 1 in 20. If it had not been changed  
 25 to indicate 1 in 20, there would be no way of

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1 knowing.  
 2 CHAYTOR, Q.C.:  
 3 Q. And do you know whether or not it had been  
 4 changed on the vial?  
 5 MR. GREEN:  
 6 A. I don't recall.  
 7 CHAYTOR, Q.C.:  
 8 Q. You don't recall?  
 9 MR. GREEN:  
 10 A. No. Because I had not been aware that there  
 11 had been work done on the antibodies. So, I  
 12 would have no way in knowing.  
 13 CHAYTOR, Q.C.:  
 14 Q. So, unless it was written on the vial and,  
 15 unless it was written on the vial and you  
 16 checked it, you would have no way in knowing?  
 17 MR. GREEN:  
 18 A. You would have to check in the vial in order  
 19 to make the antibody because in the ER/PRs we  
 20 would run most of them in batches. And on a  
 21 DAKO system, the amount of antibody needed to  
 22 run the tests would come up on the machine  
 23 before we ran a test. We made up the antibody  
 24 fresh. I think it took 250 microlitres per  
 25 slide and so on millilitre, we would need--

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1 would cover four slides. We very seldom had a  
 2 run of four slides on ER/PR, wouldn't be much  
 3 more than that. So, you would have to make up  
 4 approximately 10 mills of antibody for that  
 5 run. So, you would have to look at the -  
 6 CHAYTOR, Q.C.:  
 7 Q. You'd have to check the vial.  
 8 MR. GREEN:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. And so no other form of communication  
 12 of the information to you other than what may  
 13 or may not have been written on the vial. So,  
 14 no memo would go out, for example, or nothing  
 15 posted into the lab to advise when there have  
 16 been change in dilutions?  
 17 MR. GREEN:  
 18 A. No. And 1 in 20 dilution from a 1 in 50  
 19 dilution would suggest that you're trying to  
 20 increase the primary antibody. So, you're  
 21 trying to increase the expression of the  
 22 antibody.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay.  
 25 MR. GREEN:

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1 A. As opposed to going in the opposite direction  
 2 which means it would be too strong. So, it  
 3 would indicate that it was too weak.  
 4 CHAYTOR, Q.C.:  
 5 Q. It was too weak, yes, okay. And so the  
 6 concern being that, I take it, that the  
 7 antibody wasn't expressing, primary antibody  
 8 wasn't expressing itself enough on the test.  
 9 MR. GREEN:  
 10 A. It wouldn't be as sensitive as you wanted it  
 11 to be.  
 12 THE COMMISSIONER:  
 13 Q. Mr. Green, I just want to make sure that I  
 14 understand precisely what occurred here when  
 15 there was a change made. So, am I  
 16 understanding you to say that you realized a  
 17 change had been made because when you actually  
 18 went to take the solution, there was a changed  
 19 marked on the bottle of the solution or the  
 20 container in which the solution was kept.  
 21 MR. GREEN:  
 22 A. Yes, the practice at the Health Science IHC  
 23 paraffin lab was to write the dilutions on the  
 24 bottle which came from the manufacturer, write  
 25 it on the specification sheet that went in the



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1 file and to write it on the working dilution  
 2 bottle which you would put on the machine.  
 3 THE COMMISSIONER:  
 4 Q. Okay, but do I--now, I'm making an assumption  
 5 here which is maybe incorrect, so you should  
 6 tell me--I'm assuming that once you were  
 7 comfortable with doing this test, you probably  
 8 didn't look at the specification sheet every  
 9 day?  
 10 MR. GREEN:  
 11 A. Well, you wouldn't have to go back to the  
 12 specification sheet unless you had a problem.  
 13 THE COMMISSIONER:  
 14 Q. All right.  
 15 MR. GREEN:  
 16 A. Because their protocol would have been written  
 17 and the protocol is--and you would not change  
 18 a protocol. Once a protocol is set, it  
 19 wouldn't be changed and shouldn't be changed  
 20 unless you got a problem.  
 21 THE COMMISSIONER:  
 22 Q. Okay. Coming back to the dilution, when you  
 23 went to get the solution from the refrigerator  
 24 as -  
 25 MR. GREEN:

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1 A. Yes, it was kept in the refrigerator.  
 2 THE COMMISSIONER:  
 3 Q. - then the way you knew that there was a  
 4 change was because the numbers on the side -  
 5 MR. GREEN:  
 6 A. Would have Changed.  
 7 THE COMMISSIONER:  
 8 Q. - would have changed.  
 9 MR. GREEN:  
 10 A. Yes.  
 11 THE COMMISSIONER:  
 12 Q. Now, would somebody take out all the old  
 13 solution, perhaps I'm incorrect, would there  
 14 have been around a container with the same  
 15 solution with a different number on it?  
 16 MR. GREEN:  
 17 A. No.  
 18 THE COMMISSIONER:  
 19 Q. Would they, sort of, cross it out on the vial  
 20 and put on another number?  
 21 MR. GREEN:  
 22 A. The manufacturer would send a concentrated  
 23 solution. From that concentrated solution we  
 24 would make up a working dilution to use.  
 25 THE COMMISSIONER:

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1 Q. Would you make it up each occasion that you  
 2 used it as opposed to -  
 3 MR. GREEN:  
 4 A. Each time you ran the machine.  
 5 THE COMMISSIONER:  
 6 Q. All right.  
 7 MR. GREEN:  
 8 A. So, depending on the number of slides that you  
 9 ran, if you had to run two slides and you went  
 10 and you got your antibody to put on the  
 11 machine and you looked and you had two loads  
 12 of antibody, you will have no reason to add  
 13 antibody to that solution, but if you had a  
 14 run of 10, 20, 30, 40 which wasn't unusual,  
 15 you would have to make sure you had sufficient  
 16 antibody to cover all--you would have to make  
 17 up your antibody. And in the case with ER/PR,  
 18 they were batched. So you would have to make  
 19 up your antibody.  
 20 THE COMMISSIONER:  
 21 Q. Okay. So, somebody in the system did the  
 22 tweaking, determined that that dilution should  
 23 be at a different rate than it had been prior  
 24 to this and that was recorded by changing what  
 25 was on the side of the bottle.

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1 MR. GREEN:  
 2 A. Yes.  
 3 THE COMMISSIONER:  
 4 Q. Okay. I'm saying bottle, it may not be a  
 5 bottle, but the container.  
 6 MR. GREEN:  
 7 A. Yeah, container.  
 8 THE COMMISSIONER:  
 9 Q. Which was kept in the fridge.  
 10 MR. GREEN:  
 11 A. Yes.  
 12 THE COMMISSIONER:  
 13 Q. All right, thank you.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And if that change, Mr. Green, had not  
 16 been made on the side of the vial, what would  
 17 you do? What would happen?  
 18 MR. GREEN:  
 19 A. If the change had not been made on the  
 20 (inaudible - coughing).  
 21 CHAYTOR, Q.C.:  
 22 Q. Yes.  
 23 MR. GREEN:  
 24 A. We would--if it was my turn to run the machine  
 25 I would take the vial from the refrigerator,

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1 check whatever was on the label and whatever  
 2 dilution is indicated would be the dilution  
 3 that would go on. There would be no reason to  
 4 change the dilution, if you weren't instructed  
 5 to do so. And I take it that the tests would  
 6 proceed as normal?  
 7 MR. GREEN:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. And there'd be no way of you knowing that that  
 11 was not the -  
 12 MR. GREEN:  
 13 A. Change had been made.  
 14 CHAYTOR, Q.C.:  
 15 Q. Right.  
 16 MR. GREEN:  
 17 A. There would be no way of knowing.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MR. GREEN:  
 21 A. The slide would go to the pathologist to read.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay. Now, you mentioned in terms of your  
 24 training and learning about the different  
 25 antibodies and there were about a hundred at

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1 the beginning, some of them required antigen  
 2 retrieval. What were you taught in terms of  
 3 why you needed to do antigen retrieval and how  
 4 you, in fact, went around doing antigen  
 5 retrieval?  
 6 MR. GREEN:  
 7 A. There was some information in the lab on  
 8 antigen retrieval. I remember it because in  
 9 the literature back then they referred to it  
 10 as unmasking and we don't refer to that  
 11 nomenclature. It's called antigen retrieval.  
 12 And we would have a list and the antigen  
 13 retrieval, ones that required antigen  
 14 retrieval were highlighted and the ones that  
 15 didn't, were not. They were already pre-  
 16 determined, which ones needed antigen  
 17 retrieval. If you had any doubts about that,  
 18 you would check the specification sheets and  
 19 all the protocols were already programmed into  
 20 the computer. So, unless there was a new  
 21 antibody, there would be--you would know it.  
 22 CHAYTOR, Q.C.:  
 23 Q. And was there anything then in particular told  
 24 to you in terms of caution to be taken with  
 25 respect to those antibodies?

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1 MR. GREEN:  
 2 A. I knew from the reading that was there that  
 3 antigen retrieval was needed because of  
 4 formalin fixation. I had read that the IHC  
 5 had been developed on fresh human tissue which  
 6 were done on frozen sections and they had  
 7 great success with the frozen sections and  
 8 somewhere along the process scientists had  
 9 discovered that they could use paraffin  
 10 sections. Paraffin sections, it was  
 11 breakthrough in IHC because when you used  
 12 frozen tissue, you had a limited amount of  
 13 frozen tissue and when the tissue was gone,  
 14 you had nothing to go back to. When they  
 15 discovered that you could use antigen  
 16 retrieval to, kind of, reverse the effects of  
 17 formalin fixation, it was a breakthrough in  
 18 IHC and a number of IHC antibodies expanded  
 19 that exponentially. And so they figured that  
 20 that--it's kind of a paradox that with the  
 21 antigen antibody reaction, you kind of got to  
 22 watch the temperatures. You don't want to  
 23 have your oven at a higher temperature because  
 24 the literature says that it can affect the  
 25 antigen antibody reaction. But with antigen

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1 retrieval, you would subject the tissue to a  
 2 citrate buffer between 95 and 100 degrees for  
 3 20 minutes. Take it from the water bath, let  
 4 it sit for another 30 minutes and then go and  
 5 perform the same peroxidase, anti-peroxidase  
 6 method that you used on tissues that didn't  
 7 require antigen retrieval. Not all antibodies  
 8 require antigen retrieval. Some antibodies  
 9 will work with the Labeled Streptavidin Method  
 10 quite well with no antigen retrieval. Some of  
 11 the antibodies that we ran worked better with  
 12 our proteolytic enzyme which was used in the  
 13 digestion process to do antigen retrieval.  
 14 But the ones like ER/PR, they require a heat  
 15 induced antigen retrieval which was needed to  
 16 be heated in a water bath. One of the reasons  
 17 for the ER/PR, heat induced antigen retrieval  
 18 was because it was a nuclear antibody and the  
 19 nuclear antibody being far deeper in the cell,  
 20 it required more unmasking to expose an  
 21 antibody, find primary antibody.  
 22 CHAYTOR, Q.C.:  
 23 Q. And Mr. Green, is that something you knew at  
 24 the time when you started doing the test in  
 25 2002 or is that knowledge you have gained over

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1 time?  
 2 MR. GREEN:  
 3 A. I've gained it over time.  
 4 CHAYTOR, Q.C.:  
 5 Q. Yes, okay. So, the importance of antigen  
 6 retrieval and the detail that you've just told  
 7 us, that's something you've learned, I take  
 8 it, since 2005?  
 9 MR. GREEN:  
 10 A. Sure.  
 11 CHAYTOR, Q.C.:  
 12 Q. And in terms of the importance of it,  
 13 specifically for ER/PR in that being a nuclear  
 14 antibody, is that something that you've also  
 15 learned since 2005?  
 16 MR. GREEN:  
 17 A. I knew that the ER/PR was a nuclear antibody  
 18 very soon after I moved over to the Health  
 19 Science because when you read the  
 20 specification sheet that it will clearly tell  
 21 you which elements are supposed to be  
 22 demonstrated and the purpose of the stain. By  
 23 reading the sheet you would know that it was  
 24 nuclear antibody and by my general lab  
 25 knowledge, I knew that nuclear antibodies were

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1 deeper in the cell than the cytoplasmic  
 2 antibodies.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. And in terms of then anything, any  
 5 special precautions for ER/PR, were you aware  
 6 of those at the time?  
 7 MR. GREEN:  
 8 A. I learned when I went to Health Science that  
 9 since every antibody that needed antigen  
 10 retrieval had to be put on a special slide  
 11 which used the histogrip adhesive because  
 12 breast tissue was known to come off the slides  
 13 in normal pathology. And being exposed to  
 14 antigen retrieval complicated the matter. So,  
 15 it was even--you needed to take more  
 16 precautions. You wanted every help that you  
 17 could get to get that piece of tissue to stay  
 18 on the slide during the process.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. And in doing antigen retrieval then,  
 21 and were all the antibodies that required  
 22 antigen retrieval subjected to the same  
 23 process, the sam temperature, the same amount  
 24 of time?  
 25 MR. GREEN:

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1 A. Yes. There were two--on the DAKO system,  
 2 there were two antigen retrieval solutions.  
 3 The one we used for the ER/PR was a citrate  
 4 buffer which was pH 6. There was a higher  
 5 antigen retrieval solution of pH 8 which was  
 6 used very infrequently. Most of the  
 7 antibodies used the citrate buffer.  
 8 CHAYTOR, Q.C.:  
 9 Q. I'm sorry, so was it a different pH?  
 10 MR. GREEN:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. For ER.  
 14 MR. GREEN:  
 15 A. Citrate bugger of pH 6 we used for ER.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay. And who would have told you that so  
 18 that you would know that?  
 19 MR. GREEN:  
 20 A. It would have some on the manufacturer's -  
 21 CHAYTOR, Q.C.:  
 22 Q. On the spec sheet?  
 23 MR. GREEN:  
 24 A. On the spec sheet.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And in terms of the length of time and  
 2 the temperature, how long would the--to what  
 3 temperature would you heat the water bath and  
 4 for how long?  
 5 MR. GREEN:  
 6 A. It was between 95 and 100 degrees centigrade.  
 7 It would be heated for 20 minutes.  
 8 CHAYTOR, Q.C.:  
 9 Q. Twenty?  
 10 MR. GREEN:  
 11 A. Twenty. And the slides would be removed from  
 12 the water bath, still in the antigen retrieval  
 13 solution and placed on the bench for another  
 14 30 minutes so that they would actually cool  
 15 down so that they could be handled and put on  
 16 the machine. And all the tissues that had  
 17 antigen retrieval were treated in the same  
 18 way. They're all 20 minutes in the water  
 19 bath, 30 minutes on the bench.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. And is there anything--and I realize  
 22 now with Ventana, it's an automated process in  
 23 terms of antigen retrieval, I'm just wondering  
 24 in terms of any of the extensive reading and  
 25 you've had some substantial training since

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1 2005 in IHC, is there anything then that's  
 2 come to your attention regarding the antigen  
 3 retrieval process you were using with the DAKO  
 4 system that now causes you to look back and  
 5 question or concern?  
 6 MR. GREEN:  
 7 A. Hindsight is 20/20.  
 8 CHAYTOR, Q.C.:  
 9 Q. Yes, fair enough.  
 10 MR. GREEN:  
 11 A. And looking back now, when we set up the--I  
 12 worked for a little over a year on the DAKO  
 13 system, so I had the advantages of working on  
 14 both the DAKO system and the Ventana system.  
 15 When we introduced the Ventana system, we  
 16 transferred the protocols from the DAKO over  
 17 to the Ventana and we had protocols from other  
 18 institutions which we checked at the same  
 19 time. And the specs from Ventana suggested  
 20 that we use antigen retrieval standard which  
 21 was on--there a quite a few differences  
 22 between the DAKO system and the Ventana  
 23 system. On the DAKO system, the antigen  
 24 retrieval was done as a manual method and on  
 25 the Ventana system it was what we call

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1 onboard. And on the Ventana system, we could  
 2 choose an antigen retrieval of short which was  
 3 eight minutes. And if you pick the short, it  
 4 was eight minutes each time and every time.  
 5 We could pick mild which was 30 minutes and if  
 6 you picked 30 minutes, it was 30 minutes every  
 7 time with no variation. If you picked  
 8 standard, it was 60 minutes with no variation.  
 9 And if you pick extended, it was 90 minutes  
 10 with no variation. The protocol that we  
 11 decided to run on the Ventana was called CC1  
 12 mild. CC1 is the manufacturer's name for  
 13 antigen retrieval. The solution is an EDTA  
 14 borate solution with a pH of 8. That one we  
 15 used on the Ventana system and I think the  
 16 primary antibody time was probably 24 minutes,  
 17 24, 28, one or the other for ER and one for  
 18 PR. We ran those protocols on our controls on  
 19 the Ventana system and the results were  
 20 exceptional.  
 21 CHAYTOR, Q.C.:  
 22 Q. So, that's when you were doing--brought in  
 23 the Ventana and did the validation in terms of  
 24 which would be the optimal time for antigen  
 25 retrieval, I take it.

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1 MR. GREEN:  
 2 A. Yes. Compared to the DAKO system, the Ventana  
 3 system had a higher pH antigen retrieval and a  
 4 longer time and is controlled precisely by a  
 5 machine. The other differences in the Ventana  
 6 system, the antigen retrieval was done  
 7 onboard. We brought in what we called pre-  
 8 dilute antibodies which means that the  
 9 antibodies were optimized by the manufacturer  
 10 and they weren't meant to be tampered with.  
 11 You could control your antigen retrieval and  
 12 you could control your antibody incubation  
 13 time, but you could not control your antibody  
 14 dilution.  
 15 CHAYTOR, Q.C.:  
 16 Q. So, your understanding was the pre-diluted  
 17 antibodies, that's it, there's no validation  
 18 or optimization of those.  
 19 MR. GREEN:  
 20 A. No, by pre-diluted antibody it means that you  
 21 do not change dilution of the antibody.  
 22 CHAYTOR, Q.C.:  
 23 Q. You don't change the dilution under any  
 24 circumstances.  
 25 MR. GREEN:

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1 A. Or as far as the validation goes with the  
 2 antibody, validation is a different concept.  
 3 Validation is where you take your antibody and  
 4 adapt it to work in your lab. What you want  
 5 to achieve is optimal demonstration of the  
 6 antibody which you want to observe with  
 7 minimal background staining which is referred  
 8 to it as signal to noise ratio. You want it  
 9 optimized so that you demonstrate what you  
 10 want to demonstrate with the least amount of  
 11 antigen retrieval because antigen retrieval is  
 12 harsh on the tissue, but optimal results  
 13 demonstrating the elements that you want to  
 14 demonstrate and keeping at a minimum, the  
 15 elements that you don't want to demonstrate.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay. So, but in adapting it as you say to  
 18 your particular lab, you don't tamper at all  
 19 with the dilution of a pre-diluted antibody?  
 20 MR. GREEN:  
 21 A. On a pre-diluted antibody you do not touch the  
 22 dilution. It is optimized by the  
 23 manufacturer.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay. So, back to the issue of my question

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1 regarding antigen retrieval and how it was  
 2 done with the DAKO system. And I appreciate  
 3 how it's now change and what happened with  
 4 Ventana. So, with that knowledge and any  
 5 other knowledge that you've acquired, looking  
 6 back, is there anything about the antigen  
 7 retrieval system in the DAKO days that causes  
 8 you concern?  
 9 MR. GREEN:  
 10 A. It seemed to be working fine in the earlier  
 11 stage of the DAKO system, but the checks and  
 12 the balances that should have picked up low  
 13 expressors which would be the internal  
 14 controls which means that if the pathologist  
 15 read the slide, we run external batch  
 16 controls. And a batch control tells us that  
 17 the system worked and that the antibody was  
 18 applied when it was supposed to be applied and  
 19 the detection system was applied when it was  
 20 supposed to be applied. But an internal  
 21 control will tell you if the patient's tissue,  
 22 if the antibody in the patient's tissue, if it  
 23 was applied in the patient's tissue and had  
 24 worked--what I'm trying to say is that if the  
 25 proper piece of tissue had been submitted and

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1 the process had happened as it was supposed to  
 2 have happened, if the internal control was  
 3 positive, you would know that the system  
 4 worked. If there was no internal control and  
 5 the system didn't work, you would have no way  
 6 of knowing that the tissue itself was treated  
 7 properly.  
 8 CHAYTOR, Q.C.:  
 9 Q. So when you say a batch control, you're  
 10 referring, I take it, to the external  
 11 controls?  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. We've heard them called external controls.  
 16 MR. GREEN:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. So your external control would tell you that  
 20 the test itself had worked, the system had  
 21 worked?  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. But you see the internal control as being

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1 crucial to determining whether or not the test  
 2 worked for that particular patient?  
 3 MR. GREEN:  
 4 A. That patient.  
 5 CHAYTOR, Q.C.:  
 6 Q. Yes, okay. So if internal controls had not  
 7 worked or were absent, whether or not --  
 8 whether or not the test had been effective for  
 9 that particular patient, that would be the  
 10 key?  
 11 MR. GREEN:  
 12 A. That would be the key because if your internal  
 13 control works, which is normal ductal  
 14 epithelium which would -- if that was present  
 15 and had stained, you would know that that  
 16 patient's tissue had been treated.  
 17 CHAYTOR, Q.C.:  
 18 Q. And do you connect then -- my question had  
 19 been about the antigen retrieval. Do you  
 20 connect the antigen retrieval process to the  
 21 internal control, and whether or not the  
 22 internal control worked or not?  
 23 MR. GREEN:  
 24 A. No, not -- no.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MR. GREEN:  
 3 A. When I connected the antigen retrieval was  
 4 when the ER/PR episode unfolded, and I started  
 5 to ask questions and one of my first questions  
 6 was the specimens that were converting from  
 7 Mount Sinai, I said what protocol are they  
 8 using because from a technical point of view,  
 9 if we were running tests and we were getting a  
 10 negative result, and they were being retested  
 11 and getting a positive result, I would think  
 12 of -- I would want to know what was going on  
 13 because it would be -- that was my area. So I  
 14 wanted to know what protocols they were using,  
 15 what antibody they were using, the clone and  
 16 the dilution, and the antigen retrieval. I  
 17 found out subsequently that the antigen  
 18 retrieval that they were using was a pressure  
 19 cooker at 121 degrees. So our antigen  
 20 retrieval was at a water bath at 95 to 100  
 21 degrees, and I had experience with the Ventana  
 22 System, knowing that we were getting good  
 23 results with the Ventana, and the differences  
 24 between the DAKO, our DAKO and the Ventana,  
 25 was the antigen retrieval.

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1 CHAYTOR, Q.C.:

2 Q. Yes.

3 MR. GREEN:

4 A. So I connected the dots and the antigen

5 retrieval they were using to optimize our

6 specimens there was a factor.

7 CHAYTOR, Q.C.:

8 Q. So while Mount Sinai was using the DAKO

9 System, and for the vast majority of years

10 involved in the retrospective review St.

11 John's had been using the DAKO System, the

12 difference that you were able to determine was

13 that you were using water bath hash 95 to 100

14 degrees whereas the antigen retrieval process

15 at Mount Sinai involved the pressure cooker at

16 125 degrees?

17 MR. GREEN:

18 A. And the very chemistry behind it, you know, if

19 you increase the temperature, you're going to

20 increase the reaction rate.

21 CHAYTOR, Q.C.:

22 Q. Were the other -- when you made those

23 inquiries, Mr. Green, as to, for example, the

24 protocol and the antibodies they were using,

25 the clone and the dilution as you say, were

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1 all of those variables consistent?

2 MR. GREEN:

3 A. I didn't get that information.

4 CHAYTOR, Q.C.:

5 Q. Okay. The one thing that you were able to

6 determine was different was the antigen

7 retrieval process?

8 MR. GREEN:

9 A. Antigen retrieval.

10 CHAYTOR, Q.C.:

11 Q. I had asked you about difference in ER/PR in

12 terms of the antigen retrieval, or your

13 understanding of how ER/PR may be different,

14 and you did understand, of course, that it was

15 a nuclear antibody early on. Did you

16 understand when you first began doing ER/PR

17 tests the importance or significance of the

18 test?

19 MR. GREEN:

20 A. Yes.

21 CHAYTOR, Q.C.:

22 Q. So you knew what it was for, what the purpose

23 of the test --

24 MR. GREEN:

25 A. I knew what it was, a test that -- that was a

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1 subjective test, and that the results of that

2 test were used for patient treatment.

3 CHAYTOR, Q.C.:

4 Q. And if we just look back for a moment at 2177,

5 these specification sheets, where were those

6 kept within the lab?

7 MR. GREEN:

8 A. Those were kept in an accordion type folder

9 underneath the bench because the folder was

10 too big to -- we didn't have bench space, so

11 it was underneath the bench.

12 CHAYTOR, Q.C.:

13 Q. So it was underneath the bench in an accordion

14 folder?

15 MR. GREEN:

16 A. Yeah.

17 CHAYTOR, Q.C.:

18 Q. And were they in any particular order, if you

19 needed to consult and go back?

20 MR. GREEN:

21 A. Alphabetical order.

22 CHAYTOR, Q.C.:

23 Q. They were in alphabetical order in the

24 accordion folder?

25 MR. GREEN:

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1 A. Yeah.

2 CHAYTOR, Q.C.:

3 Q. So if you had taken out a specification sheet,

4 two or three out that day for whatever reason

5 and had to put them back, what order would

6 they go back in?

7 MR. GREEN:

8 A. The most recent would be put close to the

9 front.

10 CHAYTOR, Q.C.:

11 Q. Uh-hm.

12 MR. GREEN:

13 A. But we didn't necessarily throw out all the

14 old sheets. We kind of just added the newer

15 ones to the front.

16 CHAYTOR, Q.C.:

17 Q. And it's alphabetical according to -- for

18 example, we have monoclonal mouse, so this is

19 alphabetical and --

20 MR. GREEN:

21 A. Estrogen receptor would be under "E".

22 CHAYTOR, Q.C.:

23 Q. Okay, so it's under "E".

24 MR. GREEN:

25 A. Progesterone would be under "P".

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1 CHAYTOR, Q.C.:

2 Q. Okay, and when -- I'm going to ask you some

3 detail about your knowledge of when Ms.

4 Wegrynowski attended upon the lab and her

5 investigation there. We did hear her indicate

6 one of her findings that the specification

7 sheets and documentation being left somewhat

8 in random order in a drawer in the lab. What

9 do you say about that observation?

10 MR. GREEN:

11 A. They were not compiled in a binder in

12 alphabetical order but they were in the

13 accordion type folder.

14 CHAYTOR, Q.C.:

15 Q. So they weren't in a binder, they were in like

16 file folder?

17 MR. GREEN:

18 A. File folder, yes.

19 CHAYTOR, Q.C.:

20 Q. And they were in this drawer?

21 MR. GREEN:

22 A. Yes.

23 CHAYTOR, Q.C.:

24 Q. And were they always then in the file folder

25 or were some of these sheets in the drawer and

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1 outside of the folder?

2 MR. GREEN:

3 A. Periodically somebody would take it upon

4 themselves to take out some of the older ones

5 because the binder would start to get bigger

6 and bigger. So those would probably end up in

7 the drawer, they would not be thrown out, they

8 would be probably put in the drawer.

9 CHAYTOR, Q.C.:

10 Q. So I take it you could understand where that

11 particular observation may have come from?

12 MR. GREEN:

13 A. Yes, I can see where somebody could make that

14 observation.

15 CHAYTOR, Q.C.:

16 Q. Overall in terms of other record keeping then

17 within the lab, and again this is up until

18 this issue arises in 2005 -- so from when you

19 get there in 2002 up until that point in time

20 in 2005, what was happening in terms of

21 keeping track of what you were doing on any

22 ER/PR test or on any IHC testing?

23 MR. GREEN:

24 A. You would create a daily run sheet which would

25 be numbered 1 to 48. So the patient's surgical

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1 number would be on that sheet, plus the

2 antibody that we were going to run, and that

3 sheet would be entered into the computer and

4 it would generate a -- the computer would

5 generate a grid and we would match our slides

6 to the grid and the run sheet was the sheet

7 that we kept the -- that was our

8 documentation.

9 CHAYTOR, Q.C.:

10 Q. And what would happen to your run sheet at the

11 end of the day?

12 MR. GREEN:

13 A. At the end of the day, we would enter into the

14 computer the number of slides that we ran, and

15 that sheet would be filed.

16 CHAYTOR, Q.C.:

17 Q. And would you keep them, would your run sheets

18 be kept for a period of time?

19 MR. GREEN:

20 A. They were probably kept for maybe a year. I

21 don't think we had a specified time they were

22 supposed to be kept, not that I was aware of.

23 CHAYTOR, Q.C.:

24 Q. And in going back and looking for run sheets

25 for the period of time, for example, that the

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1 commission is involved with, I take it those

2 run sheets would not exist any longer?

3 MR. GREEN:

4 A. I doubt very much if those sheets would be

5 kept.

6 CHAYTOR, Q.C.:

7 Q. So what about in terms of then any

8 documentation about quality control that may

9 have been happening in the lab, documentation

10 as to, for example, maintenance or cleaning of

11 equipment, was there anything happening?

12 MR. GREEN:

13 A. The equipment -- the DAKO machine was set up

14 so that after you ran 200 slides, the machine

15 would shut down and you would have to clean it

16 before it -- before you could run it again,

17 but we didn't keep a record of that

18 maintenance.

19 CHAYTOR, Q.C.:

20 Q. So what then, broadly speaking in terms of

21 quality control, was happening with respect to

22 the IHC tests?

23 MR. GREEN:

24 A. We would run an external control which would

25 be checked by the pathologist, and -- our

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1 biggest quality control in IHC, and the  
 2 pathology lab in general, is the fact that  
 3 every slide that we sent out would be checked  
 4 by the pathologist.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay, and in terms of quality assurance,  
 7 ongoing quality assurance measures, and the  
 8 equipment maintenance, what you're telling me  
 9 is that after 200 slides, that the machine  
 10 would have to be -- there would be a  
 11 maintenance procedure then for the machine?  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Was there anything happening in terms of daily  
 16 check of the machine?  
 17 MR. GREEN:  
 18 A. No. The only check would be the pre-run  
 19 check, so that before you ran a batch of  
 20 slides, you would generate what we call a map.  
 21 A map would show the relationship of the  
 22 patient's slides to the grid on the machine,  
 23 and we would generate a map of the reagents  
 24 that we're going to use, the detection system,  
 25 plus the antibodies that we would run. On

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1 that grid, it would show you the volume of  
 2 antibody that you needed to put in each  
 3 container.  
 4 CHAYTOR, Q.C.:  
 5 Q. Now I know we have the reagent map. I don't  
 6 know if we have a copy of the patient's  
 7 slides, the grid that you're referring to. I  
 8 don't know if we have a sample of that or not,  
 9 but if not, that might be helpful for us when  
 10 I go through your questions on that aspect.  
 11 So perhaps we can look into that. I take it  
 12 then in terms of anything else that was  
 13 happening in terms of quality assurance or  
 14 quality control, is there anything else that  
 15 you can think of that was taking place?  
 16 MR. GREEN:  
 17 A. No.  
 18 CHAYTOR, Q.C.:  
 19 Q. And we've heard that there was no external  
 20 quality assurance as such for the IHC portion  
 21 of the lab in that time period?  
 22 MR. GREEN:  
 23 A. Not in that time period. That would come  
 24 later.  
 25 CHAYTOR, Q.C.:

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1 Q. That comes after 2005, and I believe you've  
 2 been involved in that yourself?  
 3 MR. GREEN:  
 4 A. Yeah, that was initiated by Dr. Ejeckam.  
 5 CHAYTOR, Q.C.:  
 6 Q. And I'll take you through that when we talk  
 7 about the present situation.  
 8 MR. GREEN:  
 9 A. Okay.  
 10 CHAYTOR, Q.C.:  
 11 Q. You indicated the location of the lab, which  
 12 we understand there's also been some changes  
 13 in terms of the physical setup now of the IHC  
 14 portion, that it was part of the main  
 15 pathology lab. Was there ever any discussion  
 16 prior to 2005 that you're aware of as to  
 17 concerns about the IHC lab being part of the  
 18 overall general lab or the location of it?  
 19 MR. GREEN:  
 20 A. I was not aware -- I assumed that all IHC labs  
 21 were part of the general anatomic pathology  
 22 lab.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you didn't hear anyone voice any concern  
 25 or any issue regarding its location?

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1 MR. GREEN:  
 2 A. No.  
 3 CHAYTOR, Q.C.:  
 4 Q. The refrigerator that you kept your antibodies  
 5 in, you would go to the fridge to get the  
 6 antibodies and you've described that to us.  
 7 Was the refrigerator at that period of time  
 8 equipped with an alarm?  
 9 MR. GREEN:  
 10 A. No.  
 11 CHAYTOR, Q.C.:  
 12 Q. And is it currently equipped with an alarm?  
 13 MR. GREEN:  
 14 A. Yes.  
 15 CHAYTOR, Q.C.:  
 16 Q. Do you know when that change came about?  
 17 MR. GREEN:  
 18 A. That change came about when we moved the IHC  
 19 lab to its -- we now have a separate section  
 20 for the IHC lab. We got a -- we purchased a  
 21 refrigerator which was dedicated to IHC only,  
 22 and then it was set up with an external alarm.  
 23 CHAYTOR, Q.C.:  
 24 Q. And in looking at the label on a given vial, a  
 25 given antibody for the dilution, you'd have to



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1 do that you've explained to us. Would there  
 2 be anything else on the label that you would  
 3 check?  
 4 MR. GREEN:  
 5 A. The expiry date and the clone.  
 6 CHAYTOR, Q.C.:  
 7 Q. The expiry date and the clone, okay. How in  
 8 the days of DAKO when you're diluting your own  
 9 antibodies, how would you come up with an  
 10 expiration date?  
 11 MR. GREEN:  
 12 A. The expiration date was supplied by the  
 13 manufacturer.  
 14 CHAYTOR, Q.C.:  
 15 Q. And in terms of making up a quantity of the  
 16 antibody, would you tend to make enough for a  
 17 given period of time?  
 18 MR. GREEN:  
 19 A. You would make enough for that particular run.  
 20 CHAYTOR, Q.C.:  
 21 Q. Just per run?  
 22 MR. GREEN:  
 23 A. Per run.  
 24 CHAYTOR, Q.C.:  
 25 Q. And so why would there be any then -- so you

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1 would take -- what you would take and dilute  
 2 for that day would just be for that run?  
 3 MR. GREEN:  
 4 A. Yeah.  
 5 CHAYTOR, Q.C.:  
 6 Q. And then you'd put the vial back with whatever  
 7 was remaining?  
 8 MR. GREEN:  
 9 A. Yeah.  
 10 CHAYTOR, Q.C.:  
 11 Q. Did you ever have experience of noting that  
 12 antibodies had been expired?  
 13 MR. GREEN:  
 14 A. An antibody like ER/PR or all the antibodies  
 15 which we used on a regular basis, it would  
 16 never expire because we did so many tests that  
 17 -- the bigger problem was making sure that you  
 18 had sufficient antibody on hand and you didn't  
 19 run out.  
 20 CHAYTOR, Q.C.:  
 21 Q. So you never had the experience particularly  
 22 with ER/PR that an expired antibody would be  
 23 on hand?  
 24 MR. GREEN:  
 25 A. No, because like -- the dilution that I

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1 remember, in particular, was 1 in 50. The  
 2 vials that we would order would come in 1 mil  
 3 or 2 mil size. So they wouldn't last very  
 4 long.  
 5 CHAYTOR, Q.C.:  
 6 Q. And the -- do you ever remember any comment or  
 7 discussion about using up an antibody because  
 8 of the cost of the antibody?  
 9 MR. GREEN:  
 10 A. I have never had a problem with cost of  
 11 procuring antibody.  
 12 CHAYTOR, Q.C.:  
 13 Q. So that's not anything that's ever said within  
 14 your earshot?  
 15 MR. GREEN:  
 16 A. We were aware that antibodies were expensive,  
 17 but it was never a factor in our using  
 18 antibodies, the cost.  
 19 CHAYTOR, Q.C.:  
 20 Q. So you were cognizant of the cost, but it was  
 21 never an issue in term of -- if it had to be  
 22 thrown out, for example, at the end of its  
 23 expiry date, that was never an issue?  
 24 MR. GREEN:  
 25 A. Never.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. I want to turn now then and concentrate  
 3 a little more on external controls, and how  
 4 external controls were first of all created.  
 5 What did you understand would be used to  
 6 create a bank of external controls?  
 7 MR. GREEN:  
 8 A. We would use in-house tissues which were --  
 9 patients which were known positive.  
 10 CHAYTOR, Q.C.:  
 11 Q. And --  
 12 MR. GREEN:  
 13 A. Pathologists would supply those tissues.  
 14 CHAYTOR, Q.C.:  
 15 Q. So the pathologists would be involved in  
 16 supplying the tissue.  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. Would there be any particular tissue for ER/PR  
 21 tests for an external control?  
 22 MR. GREEN:  
 23 A. It would be known positive breast tissue.  
 24 CHAYTOR, Q.C.:  
 25 Q. Known positive breast tissue, okay, and for

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1 other IHC tests, are other things sometimes  
 2 used, like, for example, tonsils, things like  
 3 that, sometimes used for your external  
 4 controls?  
 5 MR. GREEN:  
 6 A. Most of the other IHC tests have their own  
 7 individual controls. All the CD markers, the  
 8 CD3s, the CD5s, all the lymphoma markers would  
 9 be tonsils.  
 10 CHAYTOR, Q.C.:  
 11 Q. And for -- however, for ER/PR test, the  
 12 external control is always breast tissue?  
 13 MR. GREEN:  
 14 A. Always breast tissue and progesterone. A lot  
 15 of them were breast tissues.  
 16 CHAYTOR, Q.C.:  
 17 Q. And in terms of identifying then the need for  
 18 more controls, for example, if your control  
 19 bank is getting low, whose responsibility  
 20 would that be to ensure you have a healthy  
 21 supply?  
 22 MR. GREEN:  
 23 A. When the supply would start to run low, we  
 24 would check with the pathologists and they  
 25 would suggest blocks to use.

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1 CHAYTOR, Q.C.:  
 2 Q. And did you ever have any difficulty in  
 3 receiving assistance from the pathologists in  
 4 that regard?  
 5 MR. GREEN:  
 6 A. No, most of the pathologists were very  
 7 approachable.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay.  
 10 MR. GREEN:  
 11 A. Now controls were always a challenge because  
 12 you ran so many tests, that we always needed  
 13 controls, but when we asked, there was never a  
 14 problem getting controls.  
 15 CHAYTOR, Q.C.:  
 16 Q. And when you brought on the Ventana System in  
 17 terms of setting up control banks then -- I  
 18 take it first of all for DAKO, there was  
 19 already a supply of control slides in use.  
 20 MR. GREEN:  
 21 A. We used the same controls.  
 22 CHAYTOR, Q.C.:  
 23 Q. There was already control blocks already  
 24 created, and then on the Ventana, did you use  
 25 the same blocks that had been used on the DAKO

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1 machine?  
 2 MR. GREEN:  
 3 A. Yeah. When we started in the switch over, we  
 4 ran parallel runs on the DAKO and on the  
 5 Ventana System. We would use the same  
 6 controls.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay.  
 9 CHAYTOR, Q.C.:  
 10 Q. And in doing then ER/PR tests, for example, if  
 11 you had a request for an ER/PR test from St.  
 12 Clare's, some for other outside hospitals,  
 13 some for within, how many external controls  
 14 would you run?  
 15 MR. GREEN:  
 16 A. Depending on how your run is set up for that  
 17 day, if three pathologists at St. Clare's--  
 18 three different pathologists at St. Clare's  
 19 requested an ER/PR, most times they would get  
 20 one control and they would have to share that  
 21 control at St. Clare's. If three pathologists  
 22 at the Health Science requested an ER/PR, they  
 23 got one control and they had to share that  
 24 control. If we had one going to Carbonear,  
 25 Grand Falls, Gander, Corner Brook, they each

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1 would get their control, which would be sent,  
 2 an external control which would be sent to  
 3 those. They would have to interpret the  
 4 control and their own slides.  
 5 CHAYTOR, Q.C.:  
 6 Q. So from the time that you arrived in 2002, the  
 7 practice was one external control per  
 8 institution?  
 9 MR. GREEN:  
 10 A. Yes.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, and the in house, what would happen to  
 13 the external control in house? Where would  
 14 that go, within the Health Science I mean?  
 15 MR. GREEN:  
 16 A. Pathologists at the Health Science would read  
 17 their slides in what we call the reading room,  
 18 which was a slide which was equipped with  
 19 several microscopes, plus a multi-headed  
 20 microscope, and there was a shelf marked  
 21 controls. We would bring the controls for  
 22 that day, we would mark if it was June 15th,  
 23 we would write June 15th, bring the controls  
 24 for that day, put them on a shelf in the  
 25 reading room.

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1 CHAYTOR, Q.C.:

2 Q. So I take it they would be marked with a

3 particular antibody, as well as the date?

4 MR. GREEN:

5 A. Yes, each antibody, the ER control would be

6 written ER control and the date. PR, PR

7 control and the date.

8 CHAYTOR, Q.C.:

9 Q. And they'd be put on a particular--in a

10 particular spot within the reading room?

11 MR. GREEN:

12 A. Yeah, in the same spot.

13 CHAYTOR, Q.C.:

14 Q. And what then would happen in terms of once

15 the pathologists are finished with the control

16 slides, how would they end back into the

17 system or being filed?

18 MR. GREEN:

19 A. We would not necessarily get those slides back

20 in the IHC lab. They would be filed when all

21 the slides were filed in the general pathology

22 lab. They may or may not be filed with that

23 specific case.

24 CHAYTOR, Q.C.:

25 Q. Okay, and would you do anything with the

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1 external controls prior to putting them out in

2 the reading room or sending them out to the

3 other hospitals?

4 MR. GREEN:

5 A. Sometimes we would look at the external

6 controls to make sure that the antibody had

7 been applied.

8 CHAYTOR, Q.C.:

9 Q. And what in particular were you looking for?

10 MR. GREEN:

11 A. We were looking for--in my particular case, I

12 would be looking for brown diaminobenzadine

13 staining in the tissue.

14 CHAYTOR, Q.C.:

15 Q. And was it any particular area of the tissue

16 that you would be looking to see had stained?

17 MR. GREEN:

18 A. No, it wasn't until later that Dr. Ejeckam

19 took the time to teach us, in detail, the

20 controls.

21 CHAYTOR, Q.C.:

22 Q. Okay, and so Dr. Ejeckam some time--was that

23 after 2005 that that happened or before that?

24 MR. GREEN:

25 A. Around 2005 when he took control of the IHC

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1 lab.

2 CHAYTOR, Q.C.:

3 Q. Okay. I take it when he more formally took -

4 MR. GREEN:

5 A. Yes.

6 CHAYTOR, Q.C.:

7 Q. Yes, okay, and did you ever have occasion--

8 does anything stick out in your mind as to the

9 external controls not having worked, you,

10 yourself, in looking at them?

11 MR. GREEN:

12 A. No, I never had occasion and if the controls

13 didn't work, the pathologists would come back

14 and if they had a problem, they would say.

15 CHAYTOR, Q.C.:

16 Q. Okay, and I take it you do have recollections

17 of that happening, where the pathologist would

18 come out and come back to you and say an

19 external control hadn't worked?

20 MR. GREEN:

21 A. From time to time with any particular

22 antibody, if there was a problem with the

23 control, pathologist would come back and say

24 that the controls is not working the way we

25 would like. He'll ask for a repeat and we

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1 would do a repeat.

2 CHAYTOR, Q.C.:

3 Q. And what would happen? Would you just repeat

4 that particular test?

5 MR. GREEN:

6 A. Yeah, we would repeat the test, using the same

7 protocol we used before. If there was a

8 problem at this point, then we would go back

9 and troubleshoot and find out what the problem

10 was.

11 CHAYTOR, Q.C.:

12 Q. So if you repeated the test, then it still

13 wasn't satisfactory, then you would make

14 further investigation?

15 MR. GREEN:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. But in terms of the other, for example, ER/PR

19 test that had also run that day, if a

20 pathologist comes back and has noticed that

21 the external control hadn't worked, would

22 there be any efforts undertaken to ascertain

23 all other tests which had ER/PR carried out,

24 all other patients which had ER/PR tests that

25 day so that their tests could be rerun?

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1 MR. GREEN:  
 2 A. No, because it would be the pathologists  
 3 responsibility to check their patient's tissue  
 4 and it would be their responsibility to pick  
 5 the appropriate--to submit the appropriate  
 6 block with the appropriate internal control.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. So there was no policy to automatically  
 9 rerun all ER/PR tests with that batch -  
 10 MR. GREEN:  
 11 A. No.  
 12 CHAYTOR, Q.C.:  
 13 Q. - in the event that an external--it had been  
 14 brought to your attention the external control  
 15 hadn't worked?  
 16 MR. GREEN:  
 17 A. No.  
 18 THE COMMISSIONER:  
 19 Q. Ms. Chaytor, wherever you can find a spot,  
 20 we'll break for the morning break.  
 21 CHAYTOR, Q.C.:  
 22 Q. Actually, this would be a good place,  
 23 Commissioner.  
 24 THE COMMISSIONER:  
 25 Q. 15 minutes.

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1 CHAYTOR, Q.C.:  
 2 Q. Thank you.  
 3 (RECESS)  
 4 THE COMMISSIONER:  
 5 Q. Please be seated. Ms. Chaytor.  
 6 CHAYTOR, Q.C.:  
 7 Q. Thank you, Commissioner. Commissioner, there  
 8 are four other exhibits that I believe Mr.  
 9 Green will be referring to. We had intended  
 10 to put them in under another witness later,  
 11 but if we could instead have them entered  
 12 through Mr. Green.  
 13 THE COMMISSIONER:  
 14 Q. And they are?  
 15 CHAYTOR, Q.C.:  
 16 Q. They are P-2178 through P-2182 inclusive.  
 17 REGISTRAR:  
 18 Q. Excuse me, Ms. Chaytor, 2180 is (inaudible).  
 19 CHAYTOR, Q.C.:  
 20 Q. 21--oh, I'm sorry, yes, thank you, Registrar.  
 21 It's 2178, 2179, 2181 and 2182.  
 22 THE COMMISSIONER:  
 23 Q. Entered.  
 24 EXHIBITS ENTERED AND MARKED EXHIBITS P-2178 AND P- 2179  
 25 EXHIBITS ENTERED AND MARKED EXHIBITS P-2181 AND P- 2182

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1 CHAYTOR, Q.C.:  
 2 Q. And all counsel would already have received  
 3 those.  
 4 THE COMMISSIONER:  
 5 Q. Thank you.  
 6 CHAYTOR, Q.C.:  
 7 Q. Thank you. Mr. Green, just sticking with  
 8 external controls for a moment, external  
 9 controls in particular for ER/PR slides, would  
 10 those controls have been subjected to the same  
 11 antigen retrieval process as the patient  
 12 tissues?  
 13 MR. GREEN:  
 14 A. Yes.  
 15 CHAYTOR, Q.C.:  
 16 Q. So in terms of using though the DAKO or slides  
 17 which would--or blocks which would have been--  
 18 slides, sorry, which would have been prepared  
 19 through the DAKO system for the Ventana  
 20 system?  
 21 MR. GREEN:  
 22 A. It would go through the same fixation and  
 23 processing.  
 24 CHAYTOR, Q.C.:  
 25 Q. Would it go through the same antigen retrieval

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1 process? Would those slides have--those  
 2 external slides under the DAKO system, which  
 3 were used for controls under the Ventana  
 4 system, have been put through the same antigen  
 5 retrieval process?  
 6 MR. GREEN:  
 7 A. No, the antigen retrieval process on the  
 8 Ventana was different than the antigen  
 9 retrieval on the DAKO.  
 10 CHAYTOR, Q.C.:  
 11 Q. And were there ever any concerns or issues  
 12 raised in relation to that, that the slides--  
 13 the control slides may not have been put  
 14 through the same process as the patient slide?  
 15 MR. GREEN:  
 16 A. I don't know if I'm misunderstanding you. The  
 17 slides that were run on the DAKO system, they  
 18 were put through the same system as the DAKO  
 19 slides.  
 20 CHAYTOR, Q.C.:  
 21 Q. Yes.  
 22 MR. GREEN:  
 23 A. The ones that were run on the Ventana, were  
 24 run through the same as the ones on the  
 25 Ventana slides.

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1 CHAYTOR, Q.C.:

2 Q. Yes, now my question is geared more towards

3 then when the Ventana system came on, the

4 control slides were controls slides--sorry,

5 blocks, not--blocks which had been used

6 through the old system versus the new?

7 MR. GREEN:

8 A. They would be the same blocks.

9 CHAYTOR, Q.C.:

10 Q. Okay, all right. That's it. Thank you. When

11 you would look at external controls, when you

12 would look at--look through and I understand

13 what you said this morning that you learned a

14 little more about that through Dr. Ejeckam

15 later on in the process.

16 MR. GREEN:

17 A. Yes.

18 CHAYTOR, Q.C.:

19 Q. But when you would look at the external

20 controls, would you be looking for any

21 particular intensity in staining?

22 MR. GREEN:

23 A. No, not particularly, as long as it was

24 positive.

25 CHAYTOR, Q.C.:

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1 Q. Okay. In terms of just sticking again with

2 the external controls for a moment, if there

3 were any request for a slide to be redone,

4 would there be any record kept of that?

5 MR. GREEN:

6 A. The only way that you could tell is when we

7 went into the computer to put in what we call

8 units, you would go in and if you went in on

9 Tuesday and put in the surgical number,

10 surgical number 1000-2003, you would put in

11 ER, if there's one block ER1 or ER2, PR1. If

12 you went back the following day and you

13 repeated that test, you would go back under

14 the same surgical number and you would now go

15 in and change the one to a two. So that you

16 would know that there were two ERs done on

17 that one and two PRs.

18 CHAYTOR, Q.C.:

19 Q. Okay. So in terms of keeping a log of any

20 particular problems, that wasn't happening in

21 that time, I take it?

22 MR. GREEN:

23 A. No.

24 CHAYTOR, Q.C.:

25 Q. Okay. So for example, if you kept track and

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1 then you would know, over a given period of

2 time, how many repeats and whether or not that

3 would cause you then to make any adjustments

4 in your procedure, nothing like that was

5 happening?

6 MR. GREEN:

7 A. We didn't keep any statistics on repeats.

8 CHAYTOR, Q.C.:

9 Q. And no log whatsoever in terms of any problems

10 encountered with the testing?

11 MR. GREEN:

12 A. No, we didn't have a corrective action log.

13 CHAYTOR, Q.C.:

14 Q. Okay, and that's something, I understand, that

15 you do currently have?

16 MR. GREEN:

17 A. That's true.

18 CHAYTOR, Q.C.:

19 Q. And that's something that's come in recently?

20 MR. GREEN:

21 A. Yes.

22 CHAYTOR, Q.C.:

23 Q. Into use, okay. If we could look, please, at

24 P-2149, and I believe it's page 24, please,

25 Registrar? This is a--this Exhibit 2149 is a

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1 series of these special procedure request

2 forms and this one in particular has your name

3 as the histotech, and the date completed, it's

4 a little difficult to see, but I think it's

5 June 26th, 2002. If we look at the date up

6 here, it's June 21st, 2002, in which Dr.

7 Dalton would have ordered the test, and Dr.

8 Dalton, we understand, is from outside Eastern

9 Health region. Perhaps you could tell us, on

10 the side here, it's written "controls checked

11 KG." Is this your handwriting?

12 MR. GREEN:

13 A. That would be mine.

14 CHAYTOR, Q.C.:

15 Q. It's your handwriting, and this here as well,

16 "slides and block returned"?

17 MR. GREEN:

18 A. Yes.

19 CHAYTOR, Q.C.:

20 Q. And what's this here?

21 MR. GREEN:

22 A. That says "diagnosis and sign out." That

23 means that when we send a slide out of town to

24 a out-of-town site, we'd go into the computer

25 and we would go under diagnosis and we would

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1 says "slides returned to"--in this case, it  
 2 would be "slides returned to Gander for  
 3 reporting" and then you would go down and  
 4 bring up the next screen and you would sign it  
 5 out saying that we had finished with it here  
 6 and it was gone.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. So this indicates that it's gone back  
 9 to Dr. Dalton?  
 10 MR. GREEN:  
 11 A. Yeah.  
 12 CHAYTOR, Q.C.:  
 13 Q. And does a copy of the form go back to Dr.  
 14 Dalton?  
 15 MR. GREEN:  
 16 A. Yes, we would photocopy the form. We would  
 17 keep a sheet in our files and one would go out  
 18 with the slides.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and the slides would go out, okay. And  
 21 again, it says "controls checked KG." What  
 22 does that mean? Did you -  
 23 MR. GREEN:  
 24 A. That means I would have physically checked the  
 25 control under the microscope to see that it

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1 was indeed positive.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and so that would--so was that your  
 4 practice, to always note that on the form?  
 5 MR. GREEN:  
 6 A. Probably for out of town, it may have been a  
 7 practice. I really can't say for sure.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and if I could have then, the same  
 10 exhibit, page 49 please? And this is also one  
 11 that goes out to Dr. Dalton and it's a little  
 12 further along in 2002. September 16th, 2002  
 13 he ordered the test and on the bottom we see  
 14 date completed, your signature as the  
 15 histotech and September 18th 2002, and then  
 16 there's another date underneath there which is  
 17 a little difficult. I think it does say  
 18 though October 4th, 2002? Would you agree  
 19 with that?  
 20 MR. GREEN:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. And there's some writing along the side. Is  
 24 this your writing?  
 25 MR. GREEN:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. And it appears to be neat, neater.  
 4 MR. GREEN:  
 5 A. Yes, too neat for mine.  
 6 CHAYTOR, Q.C.:  
 7 Q. And it says here, "received" and then  
 8 unfortunately cut off, but then "return to  
 9 Health Science Centre, ER" looks like  
 10 "control" and it says--little bit of the word  
 11 missing, but I think it's "control  
 12 unsatisfactory. October 1/02" and then  
 13 there's--do you recognize those initials?  
 14 MR. GREEN:  
 15 A. No.  
 16 CHAYTOR, Q.C.:  
 17 Q. No? It looks like an ES maybe, can you think  
 18 who that might--or is it an EJ? Don't know,  
 19 okay. So you didn't write this on the side?  
 20 MR. GREEN:  
 21 A. No.  
 22 CHAYTOR, Q.C.:  
 23 Q. "Test was run September 18th" and it's  
 24 indicated here that it appears the ER control  
 25 was unsatisfactory and October 1/02, so

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1 perhaps that came back from Dr. Dalton's -  
 2 MR. GREEN:  
 3 A. I would say. That's what it looks like, yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. Yes, okay, perhaps that came from Gander, and  
 6 then October 4th '02, it appears that the test  
 7 was rerun. Is that what that would mean?  
 8 MR. GREEN:  
 9 A. Repeated and sent again, yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. So on this particular occasion, it  
 12 appears that the controls and the--control  
 13 slide and the test were sent out to Dr.  
 14 Dalton, but he determined that the control was  
 15 unsatisfactory. Do you recall--I take it you  
 16 don't recall this specific incident, or does  
 17 it stand out in your mind in any way?  
 18 MR. GREEN:  
 19 A. It doesn't, no.  
 20 CHAYTOR, Q.C.:  
 21 Q. And what would happen then in terms of that?  
 22 The test would just be rerun and sent back out  
 23 or would there be any investigation into the  
 24 cause of why the first control was  
 25 unsatisfactory or what Dr. Dalton may have

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1        been looking for in the control?  
 2 MR. GREEN:  
 3     A. We would just repeat it and most likely we  
 4        would check with a pathologist before we sent  
 5        it out again?  
 6 CHAYTOR, Q.C.:  
 7     Q. So check with a pathologist in terms of having  
 8        a pathologist look then -  
 9 MR. GREEN:  
 10    A. Look at the control, yes.  
 11 CHAYTOR, Q.C.:  
 12    Q. At the control, so a pathologist within the  
 13        Health Sciences to make sure that it was  
 14        satisfactory?  
 15 MR. GREEN:  
 16    A. When Dr. Ejeckam took over running the IHC  
 17        lab, all out-of-town IHC would have to go  
 18        through him first.  
 19 CHAYTOR, Q.C.:  
 20    Q. So Dr. Ejeckam, once he took over, would check  
 21        all of the controls before they went back out  
 22        to -  
 23 MR. GREEN:  
 24    A. Yeah, we would check them together.  
 25 CHAYTOR, Q.C.:

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1     Q. You would look at them with him, and I take it  
 2        that's the time period when you learned more  
 3        about what to look for?  
 4 MR. GREEN:  
 5     A. Yes.  
 6 CHAYTOR, Q.C.:  
 7     Q. So was that some time then after this time  
 8        period, this September -  
 9 MR. GREEN:  
 10    A. It would be after that time, yes.  
 11 CHAYTOR, Q.C.:  
 12    Q. So some time into 2003, I take it?  
 13 MR. GREEN:  
 14    A. Yes.  
 15 CHAYTOR, Q.C.:  
 16    Q. So in terms of any investigation as to what  
 17        Dr. Dalton would have been looking for or what  
 18        concern he may have had, there would have been  
 19        no inquiry made?  
 20 MR. GREEN:  
 21    A. No. Sometimes they will submit an alternate  
 22        block, but that says block number four there  
 23        and it's probably the same block as previous.  
 24 CHAYTOR, Q.C.:  
 25    Q. Yes, probably, okay, and I assume if he wanted

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1        a different block chosen, then he would  
 2        indicate it up here?  
 3 MR. GREEN:  
 4     A. Yes, because we usually return the blocks when  
 5        we send the slides.  
 6 CHAYTOR, Q.C.:  
 7     Q. So the blocks and the slides would go out to  
 8        the regions?  
 9 MR. GREEN:  
 10    A. Yes.  
 11 CHAYTOR, Q.C.:  
 12    Q. And again, I take it with respect to this type  
 13        of an issue, this is something that currently,  
 14        in the current system, a corrective action  
 15        would be noted?  
 16 MR. GREEN:  
 17    A. A corrective action would be noted and no  
 18        slide would leave the lab unless we knew that  
 19        the control was working.  
 20 CHAYTOR, Q.C.:  
 21    Q. Okay. So if a similar situation were to  
 22        happen, you know, today or next week, you  
 23        would note that a repeat had been run?  
 24 MR. GREEN:  
 25    A. Yeah.

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1 CHAYTOR, Q.C.:  
 2     Q. And would then--now, would any inquiry be made  
 3        of the pathologist requesting the repeat as to  
 4        what the issue was?  
 5 MR. GREEN:  
 6     A. If we were asked for a repeat like that now,  
 7        we would go ahead and do the repeat. We would  
 8        show it to Dr. Ford Elms, who would come over--  
 9        he comes over every day from St. Clare's and  
 10        we go over all the controls and he would be  
 11        made aware of it.  
 12 CHAYTOR, Q.C.:  
 13    Q. Okay, so -  
 14 MR. GREEN:  
 15    A. And he may take it upon himself, most likely  
 16        he would call out and ask what the situation  
 17        was.  
 18 CHAYTOR, Q.C.:  
 19    Q. Okay. So that would be up to Dr. Elms to make  
 20        any inquiry he deemed appropriate?  
 21 MR. GREEN:  
 22    A. Yeah.  
 23 CHAYTOR, Q.C.:  
 24    Q. And I will take you to that policy a little  
 25        later. In terms of then repeating any other

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1 ER/PR tests which were run on September 18th,  
 2 2002, would that have happened?  
 3 MR. GREEN:  
 4 A. No.  
 5 CHAYTOR, Q.C.:  
 6 Q. Today would it happen?  
 7 MR. GREEN:  
 8 A. Today, we would not run a batch control. Each  
 9 would have its own control.  
 10 CHAYTOR, Q.C.:  
 11 Q. On the slide?  
 12 MR. GREEN:  
 13 A. On each slide. We would have a negative  
 14 control with each patient and we would have a  
 15 triple batch control with each run to show  
 16 that--the triple batch control will have a  
 17 negative expresser, a low expresser and an  
 18 intermediate expresser and a high expresser  
 19 for the whole run.  
 20 CHAYTOR, Q.C.:  
 21 Q. And that, I understand, is on the patient  
 22 slide now, your controls?  
 23 MR. GREEN:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

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1 Q. So there would be--would there be--there would  
 2 certainly be less concern, I guess, if one  
 3 particular slide had a problem, but would  
 4 there still be a possibility that if one slide  
 5 had a problem that others may have had as  
 6 well?  
 7 MR. GREEN:  
 8 A. We would check each patient individually. So  
 9 if one slide were to have a problem, it would  
 10 be confined to that one slide only.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay. If we could look, please, at P-1886?  
 13 And this is another immunoperoxidase request  
 14 form. This one is a little further along,  
 15 January 28th, 2003 and Dr. Cook is the  
 16 requesting pathologist for ER/PR tests and  
 17 this one is also signed by you, date  
 18 completed, January 30th, 2003 and then it's  
 19 indicated received January 31st, 2003. And  
 20 we've seen a lot of Dr. Cook's handwriting and  
 21 that appears to be his.  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. What about this writing here "PR negative, PR

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1 negative"?)  
 2 MR. GREEN:  
 3 A. I don't recognize it.  
 4 CHAYTOR, Q.C.:  
 5 Q. You don't know that? That's not your  
 6 handwriting, is it?  
 7 MR. GREEN:  
 8 A. It's bad, it could be.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, fair enough. Up in the corner here,  
 11 there's some other things written. Do you  
 12 know what that is or what that indicates?  
 13 MR. GREEN:  
 14 A. That means, UT means units taken and 18, that  
 15 would be the code in the computer which says  
 16 that they would go in the computer and I would  
 17 say slides returned to St. Clare's and a  
 18 certain date.  
 19 MR. BROWNE:  
 20 Q. Commissioner, sorry, is it possible if he  
 21 could lean into the mike, we're having  
 22 difficulty hearing back here.  
 23 CHAYTOR, Q.C.:  
 24 Q. Me or the witness?  
 25 MR. BROWNE:

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1 Q. No, the witness.  
 2 CHAYTOR, Q.C.:  
 3 Q. Thank you. Sorry, so perhaps you could repeat  
 4 that for everybody in the room please?  
 5 MR. GREEN:  
 6 A. UT would say units taken and 18 would be the  
 7 reference to the computer which says "patient  
 8 comments". We would go into that section of  
 9 the computer and I would say, in this case  
 10 would say immunoperoxidase slides ordered on  
 11 January 28th, then I would go in and say what  
 12 date do you have a returned. So that there  
 13 would be a record in the computer that they  
 14 were ordered and they were completed.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and there's other writing here at the  
 17 top of the page and it appears to say "ER/PR  
 18 controls are okay, checked by Dr. Chittal."  
 19 MR. GREEN:  
 20 A. That would be my writing.  
 21 CHAYTOR, Q.C.:  
 22 Q. That's your writing? And what would you be  
 23 indicating by that?  
 24 MR. GREEN:  
 25 A. It would be, I would have shown the slides to



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1 Dr. Chittal and he would have checked them and  
 2 said the controls are fine.  
 3 CHAYTOR, Q.C.:  
 4 Q. And so Dr. Chittal at this point in time is at  
 5 the Health Sciences, is he?  
 6 MR. GREEN:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. And why would that be written on this when  
 10 it's going to Dr. Cook?  
 11 MR. GREEN:  
 12 A. We probably would not have had a control to  
 13 send over with his slides.  
 14 CHAYTOR, Q.C.:  
 15 Q. So there were times when there may not have  
 16 been a control available to send out to all of  
 17 the other hospitals?  
 18 MR. GREEN:  
 19 A. That's true and there was a time when Dr.  
 20 Parai was assigned to read the controls, so  
 21 that if a control was not sent to St. Clare's,  
 22 one of the pathologists at St. Clare's would  
 23 have to call over and ask who checked the  
 24 controls.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay, so--and we heard a bit of that from Ms.  
 2 Welsh yesterday, I believe you were here for  
 3 her evidence in terms of them being checked,  
 4 if you didn't have enough or sufficient  
 5 controls to go around, then a pathologist in-  
 6 house would do it.  
 7 MR. GREEN:  
 8 A. One of the major reasons you would not run a  
 9 lot of controls would be space. We would  
 10 probably have a hundred antibodies to run, you  
 11 could run 48 antibodies per machine. We ran a  
 12 control with every antibody, but if you had 10  
 13 ERs to run, you would run one--if they were  
 14 confined, say to the Health Science and St.  
 15 Clare's, no out of town ER/PRs, we would  
 16 probably put one or two controls on there. In  
 17 this case, we probably put one control on for  
 18 the whole batch. So that control would have  
 19 to be shared. If we had to put ten controls  
 20 on for the ten ERs that were there, that would  
 21 mean that ten other patients would be dropped  
 22 from the list and they could not be done that  
 23 day.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and in terms of Dr. Parai reading the

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1 controls, do you recall what time period that  
 2 was?  
 3 MR. GREEN:  
 4 A. I don't, no.  
 5 CHAYTOR, Q.C.:  
 6 Q. At this point in time it appears Dr. Chittal,  
 7 did he have any responsibility or was he just  
 8 the pathologist you happened to contact that  
 9 day?  
 10 MR. GREEN:  
 11 A. He, I probably had slides for Dr. Chittal that  
 12 day and if I went out with his slides in the  
 13 reading room and he was there, I figure it was  
 14 a good time to get him to check my controls.  
 15 CHAYTOR, Q.C.:  
 16 Q. And so it was always one control, though, per  
 17 antibody?  
 18 MR. GREEN:  
 19 A. Yes, one ER; one PR.  
 20 CHAYTOR, Q.C.:  
 21 Q. And those, of course, were positive controls.  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. Were negative controls being used at that

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1 point in time?  
 2 MR. GREEN:  
 3 A. They weren't, they were not.  
 4 CHAYTOR, Q.C.:  
 5 Q. And today are negative controls used?  
 6 MR. GREEN:  
 7 A. They are.  
 8 CHAYTOR, Q.C.:  
 9 Q. And when did that come in?  
 10 MR. GREEN:  
 11 A. That came in after we revalidated the, after  
 12 we started sending slides to Mount Sinai for  
 13 ER/PR testing and revalidated our whole ER/PR  
 14 system, we decided to run negative controls  
 15 with each patient.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, so I take it once testing resumed in  
 18 February of 2007, that was the first time that  
 19 Health Sciences started using negative  
 20 controls?  
 21 MR. GREEN:  
 22 A. Yes. A negative control is treated in--uses  
 23 the same protocol as we used with the patient,  
 24 all the steps are identical, except when it  
 25 comes time to put the primary antibody, we

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1 take the--in place of the primary antibody,  
 2 there's a buffer applied, antibody diluting  
 3 buffer and so that we stain that patient with  
 4 the same protocol with no antibody, and if we  
 5 get any staining in the patient's tissue, we  
 6 know that there's no antibody applied, so it's  
 7 non-specific staining and the test would be  
 8 invalid.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay. And within the Health Sciences when the  
 11 controls went to the reading room to be shared  
 12 by whatever pathologist may have had ER/PR  
 13 test that day, did you ever observe any build  
 14 up of control slides over a period of time?  
 15 MR. GREEN:  
 16 A. Control slides, each day they would build up  
 17 until they got to the point where there was no  
 18 space left, then we would take those out for  
 19 filing and start again.  
 20 CHAYTOR, Q.C.:  
 21 Q. So there could be a period of time where ER/PR  
 22 control slides for a couple of weeks, two or  
 23 three weeks, could be in the reading room  
 24 altogether?  
 25 MR. GREEN:

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1 A. That's possible.  
 2 CHAYTOR, Q.C.:  
 3 Q. And in that situation, the pathologist would  
 4 have to look through or dig through the slides  
 5 and figure out the correct dates for their  
 6 tests?  
 7 MR. GREEN:  
 8 A. He would have to check the date on the slide.  
 9 CHAYTOR, Q.C.:  
 10 Q. And you said then you would take the control  
 11 slides out of there. How would you know when  
 12 it was okay to remove the control slides that  
 13 they had been read or referred to by the  
 14 pathologist?  
 15 MR. GREEN:  
 16 A. We had no way of knowing, when we would notice  
 17 it when we went out to bring more control  
 18 slides out and we were starting to run out of  
 19 space.  
 20 CHAYTOR, Q.C.:  
 21 Q. Would there be an area where they would  
 22 actually then physically move the control  
 23 slides, when they were done, was there a tick  
 24 off sheet or anything which would indicate for  
 25 various pathologists to mark off that they had

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1 read anything to keep track of it?  
 2 MR. GREEN:  
 3 A. Not that I was aware of.  
 4 CHAYTOR, Q.C.:  
 5 Q. And in terms of then where the control slides  
 6 ended up, and I appreciate earlier you said  
 7 that you didn't file away the control slides,  
 8 do you know if there was any record keeping,  
 9 any central registry as to what patients had  
 10 tests done together on a particular batch?  
 11 MR. GREEN:  
 12 A. I'm not aware of any way to link a particular  
 13 patient to a batch. The only way you could  
 14 link that would be to have the run sheet and  
 15 the date of the run sheet.  
 16 CHAYTOR, Q.C.:  
 17 Q. So to be able to figure out, for example, who  
 18 else on this particular date, January 30th,  
 19 2003, also had an ER/PR test run that day,  
 20 there'd be no way of doing it, except to pull  
 21 these and figure out who else and then go  
 22 looking for the control slide, should be filed  
 23 with one or the other patients.  
 24 MR. GREEN:  
 25 A. Yeah, that's the only way.

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1 CHAYTOR, Q.C.:  
 2 Q. With their slides.  
 3 MR. GREEN:  
 4 A. It's not the system we have now because each  
 5 patient has its own control on the slide, so  
 6 it's filed with the patient.  
 7 CHAYTOR, Q.C.:  
 8 Q. Yes, so it's not an issue today with the  
 9 current -  
 10 MR. GREEN:  
 11 A. Not an issue.  
 12 THE COMMISSIONER:  
 13 Q. Mr. Green, do I take it there was only one  
 14 batch run per day then?  
 15 MR. GREEN:  
 16 A. Usually only one batch run per day because a  
 17 run would take approximately three and a half  
 18 hours.  
 19 THE COMMISSIONER:  
 20 Q. Uh-hm.  
 21 MR. GREEN:  
 22 A. And we would have probably--it would be  
 23 possible to have two runs per day, but what  
 24 you would try to do, you would try to group  
 25 all of your antibodies together, like you

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1 would run all your ERs together, all your PRs,  
 2 all the CK-7s, CK-20s.  
 3 THE COMMISSIONER:  
 4 Q. So in that way eliminate the possibility that  
 5 one might get confused by the control--I'm  
 6 sitting here thinking, well if you run two or  
 7 three batches a day and you identify the  
 8 control by the date on it, you're saying that  
 9 wouldn't happen because you would run all -  
 10 MR. GREEN:  
 11 A. All similar antibodies together.  
 12 THE COMMISSIONER:  
 13 Q. At the same time, so there would be only one  
 14 control -  
 15 MR. GREEN:  
 16 A. Per batch.  
 17 THE COMMISSIONER:  
 18 Q. And one run of a particular kind.  
 19 MR. GREEN:  
 20 A. Yes,  
 21 THE COMMISSIONER:  
 22 Q. All right, thank you.  
 23 CHAYTOR, Q.C.:  
 24 Q. Mr. Green, did this process of sending out  
 25 control slides to other hospitals or one

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1 control slide being shared within the Health  
 2 Science by the pathologists there, did a  
 3 pathologist, any pathologist ever complain  
 4 that they hadn't received control slides or  
 5 weren't satisfied with having to share the  
 6 controls?  
 7 MR. GREEN:  
 8 A. The only time that would come up was when,  
 9 usually St. Clare's when one of the  
 10 pathologists from St. Clare's would call over  
 11 and say they didn't have a control that day  
 12 and they wanted somebody to check the control,  
 13 so they wanted to know who to speak with to  
 14 check the controls. And it was probably more  
 15 of an inconvenience than, because I guess they  
 16 were fairly busy and take the time out to look  
 17 for the control.  
 18 CHAYTOR, Q.C.:  
 19 Q. And so the onus would be on them to come look  
 20 to see if the control had been checked. So in  
 21 those circumstances if no control went, are  
 22 you saying there were times that no comment,  
 23 such as what we see here on 1886, that the  
 24 form would go without such a comment on it,  
 25 indicating that a pathologist had checked the

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1 control?  
 2 MR. GREEN:  
 3 A. It's possible.  
 4 CHAYTOR, Q.C.:  
 5 Q. And on the form that I showed you earlier  
 6 where it said that you had checked the  
 7 control, remember that one, KG, would there--  
 8 in that particular circumstance, would there  
 9 also have been a check done by the  
 10 pathologist?  
 11 MR. GREEN:  
 12 A. Most likely at that stage, I was fairly new  
 13 there, so I would have checked with a  
 14 pathologist.  
 15 CHAYTOR, Q.C.:  
 16 Q. Was there ever an occasion where it was the  
 17 technologist checking the controls to see if  
 18 they had worked, as opposed to pathologists?  
 19 MR. GREEN:  
 20 A. It's possible.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. And if we could just go back to that  
 23 exhibit, please, I think it was P-2149, page  
 24 24? And this is going back to Dr. Dalton,  
 25 controls check, KG?

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1 MR. GREEN:  
 2 A. Yeah.  
 3 CHAYTOR, Q.C.:  
 4 Q. Would Dr. Dalton understand that it's you who  
 5 checked--KG is you, you're the person who  
 6 checked the control, as opposed to a  
 7 pathologist?  
 8 MR. GREEN:  
 9 A. I have no way of knowing if he would have  
 10 known, unless he probably knew the pathologist  
 11 at the Health Sciences and knew there wasn't a  
 12 KG, but I would have no way of knowing if he  
 13 knew.  
 14 CHAYTOR, Q.C.:  
 15 Q. And then this particular case, perhaps you  
 16 were the person who checked the control, as  
 17 opposed to a pathologist?  
 18 MR. GREEN:  
 19 A. Most likely.  
 20 CHAYTOR, Q.C.:  
 21 Q. Most likely, okay. Did that happen very  
 22 often? And why would that happen, why would  
 23 it be you and not a pathologist?  
 24 MR. GREEN:  
 25 A. Probably if there was no pathologist available

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1 at that time.  
 2 CHAYTOR, Q.C.:  
 3 Q. And at this point in time, Mr. Green, in terms  
 4 of your knowledge, this June of 2002, does  
 5 this predate the additional knowledge you  
 6 acquired from Dr. Ejeckam in terms of how to  
 7 interpret external controls?  
 8 MR. GREEN:  
 9 A. My knowledge would be minimal.  
 10 CHAYTOR, Q.C.:  
 11 Q. Minimal at this point in time.  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. So you would not have understood looking at  
 16 nuclear staining verses any other staining at  
 17 this particular point in time?  
 18 MR. GREEN:  
 19 A. Probably not.  
 20 CHAYTOR, Q.C.:  
 21 Q. If we could have, please, P-1853, page 13?  
 22 And this is called a reagent layout map and  
 23 the date up in the corner, I'm not sure if  
 24 that's July or September, would you know which  
 25 this is?

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1 MR. GREEN:  
 2 A. No.  
 3 CHAYTOR, Q.C.:  
 4 Q. It's either July of 2002 or September of 2002,  
 5 I take it. So this would be after you came on  
 6 at the Health Sciences, and it's written that  
 7 it's DAKO auto stainer setup. We heard from--  
 8 Ms. Welsh gave some explanation yesterday as  
 9 to how this actually worked, and I understand  
 10 from your evidence this morning there's also  
 11 another grid map, and I haven't been able to  
 12 locate that. I don't know if Mr. Simmons  
 13 would know if we have one; if not, perhaps we  
 14 could get one, a copy.  
 15 MR. SIMMONS:  
 16 Q. No, I don't have one.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. So perhaps you could just explain a bit  
 19 to us your understanding when you first came  
 20 on, how you would have--how this worked, how  
 21 this was explained to you, and how you  
 22 understood you would use the reagent layout  
 23 map?  
 24 MR. GREEN:  
 25 A. The left hand portion of the screen would show

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1 the detection system that you were going to  
 2 use that day. The first solution would be  
 3 EnVision, and you would need 2.6 millilitres--  
 4 a minimum of 2.6. Then there would be a  
 5 protein blocker. You would need a minimum of  
 6 2.6 millilitres. The next one would be  
 7 Trypsn, which you would need .5 millilitres,  
 8 and hydrogen peroxide, which you would need  
 9 2.6 mil, and diaminobenzadine, you would need  
 10 2.6 mil. Those are the minimum volumes that  
 11 you would need for this run.  
 12 CHAYTOR, Q.C.:  
 13 Q. And how would you draw up those volumes?  
 14 MR. GREEN:  
 15 A. By pipette.  
 16 CHAYTOR, Q.C.:  
 17 Q. By pipette, okay. Then the--you can just  
 18 continue on, please.  
 19 MR. GREEN:  
 20 A. On your right of your screen are the  
 21 antibodies that we were running that day.  
 22 It's set up in A, B, C, and D. A is the top  
 23 horizontal line. A4 would be Vimentin, A5  
 24 would be KI67, A6 S100, A7 GFAP, and A8 Actin.  
 25 The second horizontal roll starting with B4,

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1 that's CD34 antibody of Qbend, and the other  
 2 is Ubiqtn, which is--and volumes underneath  
 3 are the minimum volumes required to run those  
 4 antibodies. On that run that day, you would  
 5 have, one, two, three, four, five, six, seven  
 6 antibodies. You may have more than seven  
 7 slides. You may have different patients who  
 8 are having that antibody done.  
 9 CHAYTOR, Q.C.:  
 10 Q. And is there any particular reason or magic as  
 11 to where it's placed? Like, we see some gaps  
 12 here. There's nothing in A3, B2, B3. Is there  
 13 any reason for that?  
 14 MR. GREEN:  
 15 A. The machine had the capability of running all  
 16 those circles that you see that are  
 17 unoccupied.  
 18 CHAYTOR, Q.C.:  
 19 Q. And you can use the mouse, if you wish, Mr.  
 20 Green, to point out anything to us.  
 21 MR. GREEN:  
 22 A. Okay.  
 23 CHAYTOR, Q.C.:  
 24 Q. Don't click it, though.  
 25 MR. GREEN:

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<p>1 A. All these spaces here are blanks.</p> <p>2 CHAYTOR, Q.C.:</p> <p>3 Q. Yes.</p> <p>4 MR. GREEN:</p> <p>5 A. We could put additional antibodies into those</p> <p>6 spaces. So if you want to run an ER, you</p> <p>7 could put an ER in B6. If you wanted to run a</p> <p>8 PR, you could put a PR in B7, and any other</p> <p>9 antibody you wanted to run, you could put it</p> <p>10 in those. It wouldn't - that is a very small</p> <p>11 run that was run that day. That was an easy</p> <p>12 day. Usually this grid would be pretty well</p> <p>13 filled.</p> <p>14 CHAYTOR, Q.C.:</p> <p>15 Q. So, for example, why do we have A4 filled in</p> <p>16 and not A3? Any reason?</p> <p>17 MR. GREEN:</p> <p>18 A. Whoever set up the grid, it looks like Mary,</p> <p>19 you would choose to put your antibodies to the</p> <p>20 right, far away from your other solutions.</p> <p>21 CHAYTOR, Q.C.:</p> <p>22 Q. Why would that be?</p> <p>23 MR. GREEN:</p> <p>24 A. Less chance of mixing the anti--the solutions.</p> <p>25 CHAYTOR, Q.C.:</p>	<p>1 any system, for example, to have someone come</p> <p>2 over and double check or check off with you,</p> <p>3 or was there any requirement for you to do</p> <p>4 that, to actually --</p> <p>5 MR. GREEN:</p> <p>6 A. That would be your responsibility to check and</p> <p>7 to double check to make sure that you put the</p> <p>8 correct reagent in the correct slot on the</p> <p>9 machine.</p> <p>10 CHAYTOR, Q.C.:</p> <p>11 Q. And was there any requirement for you to</p> <p>12 document that you, in fact, had checked and</p> <p>13 indeed double checked?</p> <p>14 MR. GREEN:</p> <p>15 A. No.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. So no--was there a practice that you would, in</p> <p>18 fact, do that, that you would not only check</p> <p>19 it, you would double check it?</p> <p>20 MR. GREEN:</p> <p>21 A. If you're on the machine, it would be your</p> <p>22 responsibility to check and double check, and</p> <p>23 triple check if you had to, to make sure that</p> <p>24 you put the right reagent in the right slot.</p> <p>25 The problem is that if you put the wrong</p>
<p>Page 146</p> <p>1 Q. Okay.</p> <p>2 MR. GREEN:</p> <p>3 A. Inadvertently putting one next to the other.</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. And your--so then if we could, this would then</p> <p>6 we used, this is your layout map. You would</p> <p>7 use this to know where to place things on the</p> <p>8 machine?</p> <p>9 MR. GREEN:</p> <p>10 A. This layout map is a representation of the</p> <p>11 slide of the reagent holder that you use on</p> <p>12 the machine. The reagent holder had the same</p> <p>13 number of slots as the map. So you would</p> <p>14 physically put these reagents that you see</p> <p>15 here in their respective slots on the holder.</p> <p>16 CHAYTOR, Q.C.:</p> <p>17 Q. Okay, and was there any--we spoke, and I think</p> <p>18 you were here yesterday when this was asked of</p> <p>19 Ms Welsh about the potential for human error</p> <p>20 if the wrong reagent--or the reagent is put on</p> <p>21 the wrong spot, and that being a potential</p> <p>22 error. Was there any way of double checking?</p> <p>23 I understand that you would have been working</p> <p>24 yourself in the lab, but the other</p> <p>25 technologist would be nearby. So was there</p>	<p>Page 148</p> <p>1 reagent in one slot, you would also have to</p> <p>2 put the wrong reagent in another slot, so you</p> <p>3 would have to make two mistakes because -</p> <p>4 CHAYTOR, Q.C.:</p> <p>5 Q. You mix a couple up.</p> <p>6 MR. GREEN:</p> <p>7 A. Yeah, you just can't mix one up, you had to</p> <p>8 mix up at least two.</p> <p>9 CHAYTOR, Q.C.:</p> <p>10 Q. Right, okay, or I guess if your slots aren't</p> <p>11 filled, like this day, you could just put one</p> <p>12 in the wrong place.</p> <p>13 MR. GREEN:</p> <p>14 A. That's possible, but I think if you put one in</p> <p>15 the wrong, like this grid is also programmed</p> <p>16 into the computer and the robotic arm would</p> <p>17 come over and go down and dispense it, would</p> <p>18 aspirate the volume that it needed and then it</p> <p>19 would dispense it on the slide. And I wasn't</p> <p>20 aware of it until recently that there was an</p> <p>21 alarm on the DAKO system which said that if</p> <p>22 the volume wasn't there, it will alarm.</p> <p>23 CHAYTOR, Q.C.:</p> <p>24 Q. Yes, because I believe when we spoke</p> <p>25 initially, you didn't know that there was such</p>

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1 an alarm.  
 2 MR. GREEN:  
 3 A. I wasn't aware of it and all the time that I  
 4 used the DAKO system, I had never heard it  
 5 alarm, so I can only assume that I made sure  
 6 that the right solution was in the right spot.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. Do you recall any difficulties with the  
 9 DAKO machine?  
 10 MR. GREEN:  
 11 A. In the time that I worked with it, the machine  
 12 was probably six or seven years old. We were  
 13 starting to have problems with the robotic  
 14 arm, we had to get the biomedical people to,  
 15 you know, repair or replace it at one  
 16 particular time.  
 17 CHAYTOR, Q.C.:  
 18 Q. I'm just going to ask, if you could lean in  
 19 again into the microphone to make sure  
 20 everybody is hearing. So, Mr. Green, some  
 21 problems with the robotic arm, what exactly  
 22 were the problems? What was happening and how  
 23 did you become aware of it?  
 24 MR. GREEN:  
 25 A. It would just refuse to move. It would lock

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1 in one position and stay there and you  
 2 couldn't run the machine.  
 3 CHAYTOR, Q.C.:  
 4 Q. And when that happened, no alarm triggered?  
 5 MR. GREEN:  
 6 A. It wouldn't alarm because the--and not only if  
 7 you were there, it just would not start up or  
 8 if it started and stopped, it would alarm.  
 9 CHAYTOR, Q.C.:  
 10 Q. I just wanted to, I had understood you said  
 11 that the entire time you never heard the alarm  
 12 go off.  
 13 MR. GREEN:  
 14 A. I never heard the alarm for a reagent volume.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, for reagent volume.  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. So there may not be an alarm triggered if the  
 21 robotic arm failed?  
 22 MR. GREEN:  
 23 A. It's possible.  
 24 CHAYTOR, Q.C.:  
 25 Q. There may not have been?

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1 MR. GREEN:  
 2 A. There may not have been  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay, so there was an alarm for reagent volume  
 5 if the volumes were wrong or insufficient  
 6 amount of reagent was applied.  
 7 MR. GREEN:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. But there may not have been an alarm for any  
 11 difficulties with the robotic arm and I  
 12 understand the robotic arm is dispensing the  
 13 reagent, was that correct?  
 14 MR. GREEN:  
 15 A. Yes, that's true.  
 16 CHAYTOR, Q.C.:  
 17 Q. But if that's the case and there's a problem  
 18 with the robotic arm and such that no reagent  
 19 is applied, you would expect the alarm to be  
 20 triggered?  
 21 MR. GREEN:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. So when you became aware that there was some  
 25 issue with the robotic arm going so far and

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1 stopping, did you actually observe that or how  
 2 did it come to your attention?  
 3 MR. GREEN:  
 4 A. You would observe that it would either try to  
 5 move and couldn't move, that would be what you  
 6 would observe, it was actually trying to do  
 7 what it's supposed to do, but it wouldn't  
 8 move.  
 9 CHAYTOR, Q.C.:  
 10 Q. And if the robotic arm went a certain  
 11 distance, I understand it took two or three  
 12 hours to run the test?  
 13 MR. GREEN:  
 14 A. Approximately three and a half hours per run.  
 15 CHAYTOR, Q.C.:  
 16 Q. Three and a half? Okay, depending, I guess,  
 17 how many -  
 18 MR. GREEN:  
 19 A. How many antibodies.  
 20 CHAYTOR, Q.C.:  
 21 Q. That particular day or that particular run.  
 22 So if the robotic arm were to go a certain  
 23 distance, correct itself and continue on,  
 24 would you have any way of knowing that?  
 25 MR. GREEN:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. In putting the slides then onto, and we don't  
 4 have the map to look at, but the grids, so  
 5 perhaps you can explain it to us, there's 48  
 6 slots on the DAKO, we understood, which would  
 7 include--which would have to include your  
 8 patient slides as well as your control slides.  
 9 So in putting those on the machine, what  
 10 precautions would you use to make sure the  
 11 patient slides were put in the right place?  
 12 MR. GREEN:  
 13 A. The grid that I was referring to would be  
 14 numbered two to 48. In the initial set up,  
 15 you would have put your patient number, SS2000  
 16 in slot No. 1 and next to it you would write  
 17 the antibody that you were using, CK7, and you  
 18 would progressively go down the sheet and put  
 19 all your slides there. You would have to  
 20 physically take your slides and sort them out  
 21 in your tray before you started and as you put  
 22 those slides on, you would either look--you  
 23 would either print off your run sheet or you  
 24 would look at the screen in front of you and  
 25 the identical map of the 48 slides would be

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1 there and it was your responsibility to ensure  
 2 that the patient that was listed on No. 1 on  
 3 your list was put in slide No. 1 on the  
 4 machine and the same way down.  
 5 CHAYTOR, Q.C.:  
 6 Q. And again, in terms of rechecking or double  
 7 checking that that happened, was there any  
 8 record of that kept?  
 9 MR. GREEN:  
 10 A. No, the only record would be the run sheet  
 11 that you had which indicated the order that  
 12 you had there.  
 13 CHAYTOR, Q.C.:  
 14 Q. Would you have to sign off or initial that to  
 15 indicate that you had in fact verified that  
 16 the slides were placed in the right slots?  
 17 MR. GREEN:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. And no policy - sorry, go ahead.  
 21 MR. GREEN:  
 22 A. I was going to say and you would also have to  
 23 mix up two slides, so that if you misplace  
 24 slide one in slot one, that means that the  
 25 slid that you were supposed to put there had

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1 to go somewhere else, so you would have to  
 2 make the same mistake twice.  
 3 CHAYTOR, Q.C.:  
 4 Q. You'd have to mix a couple - right. And would  
 5 you then, say for example in this case, I  
 6 don't know, you only have like a dozen or less  
 7 than a dozen, would you always go from one to  
 8 ten, one to twelve or would you skip slots on  
 9 the machine as well?  
 10 MR. GREEN:  
 11 A. Not usually, usually you went in order,  
 12 numerical order, one -  
 13 CHAYTOR, Q.C.:  
 14 Q. And if, in terms of your control slides, were  
 15 they always placed in a certain place on the  
 16 machine?  
 17 MR. GREEN:  
 18 A. We usually put the controls at the end.  
 19 CHAYTOR, Q.C.:  
 20 Q. And was that a policy or a procedure that  
 21 required that they always be put at the end?  
 22 MR. GREEN:  
 23 A. No, it was just that's the way that Peggy  
 24 taught me to do it, so -  
 25 CHAYTOR, Q.C.:

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1 Q. So that was, tended to be your own personal  
 2 practice?  
 3 MR. GREEN:  
 4 A. Yeah, you could put them wherever you wanted,  
 5 as long as you told the computer you were  
 6 going to put them in that spot, but we usually  
 7 put them at the end.  
 8 CHAYTOR, Q.C.:  
 9 Q. And when you say "the end" you mean the very  
 10 end, so if you've got 40 patient slides, then  
 11 41 through 48 are your control slides?  
 12 MR. GREEN:  
 13 A. Usually, yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. What about if you do ER/PR and put the control  
 16 slide for ER/PR immediately after ER/PR and  
 17 then go on with your others, grouping your  
 18 patients, I guess, in terms of what tests  
 19 they're having done, would that happen?  
 20 MR. GREEN:  
 21 A. We would try to group your antibodies, either  
 22 antibodies close--slides as close as you  
 23 could, so that when the--you would make the  
 24 run longer if you were to put your slides at  
 25 random all over the area. It means the

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1 robotic arm would have to take longer to go  
 2 all around. So it make sense, when you could,  
 3 to group your--if you're going to run a batch,  
 4 to group your slides together because it's  
 5 three and a half hours, you may extent your  
 6 run a little bit longer. Now depending on how  
 7 busy you are that day, you could put--if a  
 8 patient had four different antibodies, you  
 9 could run those four together. You didn't  
 10 have to group them all.

11 THE COMMISSIONER:  
 12 Q. And they're grouped by antibody, not by  
 13 patient?

14 MR. GREEN:  
 15 A. You could do either, but like in the case of  
 16 ER/PR, we would usually group all the ERs  
 17 together and all the PRs together, because you  
 18 got a larger volume.

19 THE COMMISSIONER:  
 20 Q. Okay.

21 CHAYTOR, Q.C.:  
 22 Q. And so but it wasn't normally the practice to  
 23 group all--if you grouped all your ER/PRs, for  
 24 example, to then put your ER/PR controls  
 25 immediately after the grouping or immediately

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1 before for that matter?

2 MR. GREEN:  
 3 A. You could. It didn't--from a technical point  
 4 of view, it made no difference where you put  
 5 your controls on the run.

6 CHAYTOR, Q.C.:  
 7 Q. Okay, and if there were though to be a problem  
 8 with the machine, in terms of the robotic arm  
 9 dispensing the antibody, and your controls  
 10 came before your patient slides, you could  
 11 have a situation where the control was exposed  
 12 to the antibody but not the patient slide?

13 MR. GREEN:  
 14 A. That's true.

15 CHAYTOR, Q.C.:  
 16 Q. That could happen?

17 MR. GREEN:  
 18 A. Yeah.

19 CHAYTOR, Q.C.:  
 20 Q. And do you know whether or not any maintenance  
 21 was ever carried out on the alarm system for  
 22 the DAKO machine?

23 MR. GREEN:  
 24 A. Not that I'm aware of.

25 CHAYTOR, Q.C.:

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1 Q. Whether there was any checks as to whether or  
 2 not it in fact was working?

3 MR. GREEN:  
 4 A. Not that I'm aware of. I don't know if the  
 5 hospital had a service contract with the  
 6 manufacturer and how long that it went for. I  
 7 know on the Ventana system, we have a service  
 8 contract and there's--the company will come in  
 9 once a year to do an annual preventive  
 10 maintenance.

11 CHAYTOR, Q.C.:  
 12 Q. And on the occasions when you noticed that the  
 13 robotic arm hadn't completed the run, would  
 14 the entire run be repeated or just the -

15 MR. GREEN:  
 16 A. If the run had started, the entire run would  
 17 have to be repeated. If the run didn't start,  
 18 then they would--the slides would only be  
 19 covered in buffers, so that would be fine, but  
 20 if there was a malfunction midway through a  
 21 run, they would have to be repeated.

22 CHAYTOR, Q.C.:  
 23 Q. So that would mean taking all of your slides  
 24 off, even though some of them may have worked,  
 25 they would all be taken off and redone?

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1 MR. GREEN:  
 2 A. Yes.

3 CHAYTOR, Q.C.:  
 4 Q. And in the situation that the hypothetical  
 5 that I was giving you about your controls  
 6 coming before your patients tests and if the  
 7 robotic arm worked up to a certain point, such  
 8 that your control slides stained but not  
 9 before--but then it stopped before it got to  
 10 the patient slides, but somehow it fixed  
 11 itself or continued on after that, you could  
 12 have a situation where your controls, external  
 13 controls worked, your patient slides had not  
 14 been exposed to the antibody and you wouldn't  
 15 know it?

16 MR. GREEN:  
 17 A. That's true.

18 CHAYTOR, Q.C.:  
 19 Q. Okay, and -

20 MR. GREEN:  
 21 A. That's why a positive external control on  
 22 every patient is the optimal -

23 CHAYTOR, Q.C.:  
 24 Q. Having the control on the patient slide?

25 MR. GREEN:



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1 A. Yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. Yes, so in your current system, that shouldn't  
 4 be an issue?  
 5 MR. GREEN:  
 6 A. No, that's true.  
 7 THE COMMISSIONER:  
 8 Q. Mr. Green, I just want to make sure I fully  
 9 understood what you had said about your  
 10 practice at this period of time of putting the  
 11 controls on the end and then you talked about  
 12 putting them after like things, so that the  
 13 ER/PR controls would be next to the ER/PR  
 14 slides, as it were. So when you mean at the  
 15 end, you mean not at--towards 46, 47, 48, you  
 16 mean at the end of the like -  
 17 MR. GREEN:  
 18 A. Well, it could happen either way. You could  
 19 put the control at the end of all the ERs.  
 20 THE COMMISSIONER:  
 21 Q. Um-hm.  
 22 MR. GREEN:  
 23 A. Or if you--when you sat down to make up your  
 24 list of which slides you were going to run, if  
 25 you're running an ER and a PR, if you run just

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1 an ER and PR, it wouldn't be a problem, you'd  
 2 just put those controls at the end. If you  
 3 were running an ER and a PR and a CK7 and a  
 4 CK20 and an S-100 and a GFAP, an Actin, you  
 5 would figure out how many slides you needed.  
 6 So you could keep adding patients until you  
 7 got to the point where you had to add all your  
 8 controls and then you would have to stop with  
 9 your patients. So that's why the controls  
 10 could usually go at the latter numbers.  
 11 THE COMMISSIONER:  
 12 Q. Okay.  
 13 CHAYTOR, Q.C.:  
 14 Q. And also, I take it, if there was insufficient  
 15 reagent used, so an insufficient volume used,  
 16 and the machine were to run out of reagent  
 17 then prior to it reaching all of the patient  
 18 slides, if that were to happen and the alarm  
 19 system wasn't working, what would be the  
 20 result, in particular, with respect to an  
 21 ER/PR test?  
 22 MR. GREEN:  
 23 A. What would happen, if there was a certain time  
 24 frame that you had, you had a window of time  
 25 there to add that antibody. Say in this case

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1 right here, on A6--if the S-100 there on A6--  
 2 if the S-100, if there wasn't enough volume in  
 3 that, the alarm went off, you had maybe two or  
 4 three minutes to add more volume to that one  
 5 there. If that didn't happen, the machine  
 6 would continue on its way and assume that you  
 7 had put something in there or it would not  
 8 have any antibody to dispense on that slide.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, so just explain that to us again. So  
 11 even if the alarm were to work, if you didn't  
 12 respond to it within those two or three  
 13 minutes, then the machine would assume that  
 14 you had corrected the problem, continue on and  
 15 insufficient antibody may in fact have been  
 16 dispensed to the particular slides in  
 17 question?  
 18 MR. GREEN:  
 19 A. Yeah, that's my understanding, but like I said  
 20 before, I can't be completely clear on that  
 21 point because during my time running the DAKO  
 22 system, I can never remember the alarm for  
 23 insufficient volume going off while I ran the  
 24 machine.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. So whether that's because the alarm  
 2 system wasn't working or because there was no  
 3 reason for the alarm to go off, you don't  
 4 know?  
 5 MR. GREEN:  
 6 A. I would hope that there was no reason for the  
 7 alarm to go off.  
 8 CHAYTOR, Q.C.:  
 9 Q. I hope too. But in terms of even if the alarm  
 10 went off and the person running the machine is  
 11 not within earshot, the machine would continue  
 12 on?  
 13 MR. GREEN:  
 14 A. That's my understanding.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and the result then, in terms if that  
 17 were to happen, and inadequate amount of  
 18 reagent having been applied, what would be the  
 19 result with respect to an ER/PR test?  
 20 MR. GREEN:  
 21 A. Well, we're talking--these reagents, we're  
 22 talking primary antibody, is an antigen  
 23 antibody reaction. If no primary antibodies  
 24 are applied, there will be no reaction.  
 25 CHAYTOR, Q.C.:

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1 Q. So I take it the test would be negative?  
 2 MR. GREEN:  
 3 A. It would be negative. It would be a false  
 4 negative.  
 5 CHAYTOR, Q.C.:  
 6 Q. It would be a false negative.  
 7 MR. GREEN:  
 8 A. Oh, assuming that it was -  
 9 CHAYTOR, Q.C.:  
 10 Q. Meant to be a positive.  
 11 MR. GREEN:  
 12 A. - positive to begin with.  
 13 CHAYTOR, Q.C.:  
 14 Q. Yes, right.  
 15 THE COMMISSIONER:  
 16 Q. Do you know whether if that occurred your  
 17 computer would tell you that there had been an  
 18 alarm?  
 19 MR. GREEN:  
 20 A. I'm not aware of it. I can't tell you for  
 21 sure.  
 22 CHAYTOR, Q.C.:  
 23 Q. And that particular issue or the potential for  
 24 that as being a pitfall, does that exist with  
 25 the Ventana machine?

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1 MR. GREEN:  
 2 A. No. The Ventana machine, every reagent that  
 3 we use on the machine--it's got a microchip  
 4 and it's scanned into the system. For the  
 5 pre-diluted antibodies, we would--as in the  
 6 case of an ER/PR, we would get the antibody,  
 7 you would get lots of 250. When you register  
 8 in the machine, the computer notes that there  
 9 are 250 tests. As you run your ER/PRs, the  
 10 computer will subtract the number of tests  
 11 that it's running and it will keep a tally of  
 12 the volume that's in the container. After  
 13 you've run 250 tests, if you add slides on  
 14 there, it would alarm and say "sorry, you  
 15 can't run these slides. There's insufficient  
 16 volume to proceed" and it would not let you  
 17 run the test.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay, and what about the issue of potential  
 20 for slide placement error? Does that exist as  
 21 a pitfall with the Ventana machine?  
 22 MR. GREEN:  
 23 A. No, the Ventana system has a bar code system.  
 24 All the protocols are entered into the system  
 25 and each protocol--a protocol is simply a

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1 recipe. Each antibody has its own recipe and  
 2 the recipe will, like all recipes, will tell  
 3 you the steps that are involved in this  
 4 process. So the bar code system, when you bar  
 5 code your--when you enter your slides into the  
 6 system, it generates a bar code. The bar code  
 7 will go on the patient's slide and you can put  
 8 that slide in any position on the machine and  
 9 it doesn't matter.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. So then from a technical point of view,  
 12 with the DAKO system, slide placement, reagent  
 13 placement and volume of the reagent could all  
 14 potentially lead to errors?  
 15 MR. GREEN:  
 16 A. Those are all areas where you have manual  
 17 manipulation, so human interaction, yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay.  
 20 MR. GREEN:  
 21 A. And the antigen retrieval is also automated on  
 22 the Ventana system, as well as the  
 23 counterstaining of the slides after, so you  
 24 don't physically touch the slides. With the  
 25 Ventana system, the slide is taken from the

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1 oven, put on the machine. It is not touched  
 2 any more until the process is complete and  
 3 ready to be cover slipped.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and with respect to any of those, so the  
 6 slide placement, reagent placement, the volume  
 7 of your reagent and the antigen retrieval,  
 8 there was no procedure or policy in place  
 9 which required documentation of what was  
 10 happening and/or any requirement to document  
 11 or have someone else do a second check as to  
 12 what you were doing?  
 13 MR. GREEN:  
 14 A. There was no second check, no.  
 15 CHAYTOR, Q.C.:  
 16 Q. No second check, and no requirement for the  
 17 technologist doing those procedures to  
 18 document what in fact they had done?  
 19 MR. GREEN:  
 20 A. No, the only requirement was the due diligence  
 21 on the part of the person who ran the  
 22 procedure.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, and if I could look at, please, 2190?  
 25 That's not entered yet, is it?

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1 REGISTRAR:  
 2 Q. It's not entered yet.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay, thank you.  
 5 REGISTRAR:  
 6 Q. (Inaudible).  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, all right, well then perhaps we'll come  
 9 back to that one after lunch and we can have  
 10 it entered. If we could go back then please to  
 11 the Exhibit I had, 1853? There we go. Up in  
 12 the top corner here, Mr. Green, it indicates  
 13 24 slides, four cases. What does that mean?  
 14 MR. GREEN:  
 15 A. That means that there were 24 slides on that  
 16 run that day. Four cases, it means there were  
 17 four patients.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay. The issue that you spoke about earlier  
 20 today at St. Clare's, issue with the tissue  
 21 processor, did you--and tissue processor in  
 22 particular with respect to the breast tissue,  
 23 did you notice any similar issue at the Health  
 24 Sciences laboratory?  
 25 MR. GREEN:

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1 A. No, I didn't have a lot of opportunity to load  
 2 slides on the processor at the Health Science  
 3 because my duties had changed since I went  
 4 over to the Health Science and other people  
 5 took care of that.  
 6 CHAYTOR, Q.C.:  
 7 Q. So in the two weeks that you weren't in the  
 8 IHC portion of services, you wouldn't be  
 9 involved in the tissue processing aspect?  
 10 MR. GREEN:  
 11 A. I wouldn't be involved in the changing of the  
 12 solutions or with the processor, no.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, and do you know whether or not, other  
 15 than personal firsthand knowledge, whether or  
 16 not there were any issues identified with the  
 17 tissue processor at the Health Sciences?  
 18 MR. GREEN:  
 19 A. It wasn't a common practice to reprocess  
 20 blocks at the Health Science.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay, so that wasn't a common practice?  
 23 MR. GREEN:  
 24 A. No, I don't know if they have ever reprocessed  
 25 blocks at the Health Science.

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1 CHAYTOR, Q.C.:  
 2 Q. When did that come to your attention, and did  
 3 you make any inquiries as to why that would be  
 4 the case?  
 5 MR. GREEN:  
 6 A. No, I knew we reprocessed blocks at St.  
 7 Clare's. I knew that we had a lot of breast  
 8 specimens at St. Clare's. I knew that the  
 9 Health Science didn't have a lot of breast  
 10 specimens. I probably made the assumption  
 11 because they didn't have a lot of breast  
 12 specimens, they didn't need to reprocess  
 13 blocks.  
 14 CHAYTOR, Q.C.:  
 15 Q. But they were doing breast specimens as well?  
 16 MR. GREEN:  
 17 A. Yes.  
 18 CHAYTOR, Q.C.:  
 19 Q. But perhaps not the same quantity?  
 20 MR. GREEN:  
 21 A. Not the volume that -  
 22 CHAYTOR, Q.C.:  
 23 Q. Not the same volume as St. Clare's?  
 24 MR. GREEN:  
 25 A. No.

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1 CHAYTOR, Q.C.:  
 2 Q. But was it your understanding that they  
 3 weren't doing much, if any, reprocessing in  
 4 any event, regardless of the type of specimen?  
 5 MR. GREEN:  
 6 A. Reprocessing didn't seem to be an issue at the  
 7 Health Science.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, all right. And when did you learn that?  
 10 MR. GREEN:  
 11 A. Probably--I was probably over there a while  
 12 and I'm not sure when I--I would have--because  
 13 it wasn't an issue over there, so -  
 14 CHAYTOR, Q.C.:  
 15 Q. But did it--were you curious about that,  
 16 "well, why isn't that an issue here? Why  
 17 don't they do reprocessing?"  
 18 MR. GREEN:  
 19 A. Not really because I was so concerned with  
 20 learning all the new techniques and that that  
 21 I had to learn that I just didn't give it any  
 22 thought.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. What would happen to the DAKO machine  
 25 if there were a power outage?

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1 MR. GREEN:  
 2 A. The DAKO machine would just stop.  
 3 CHAYTOR, Q.C.:  
 4 Q. And what would have to happen to your run?  
 5 MR. GREEN:  
 6 A. You would have to repeat the whole run.  
 7 CHAYTOR, Q.C.:  
 8 Q. And what would happen to your tissue processor  
 9 if there were a power outage? Tissue  
 10 processing, I understand, was run overnight,  
 11 is that right?  
 12 MR. GREEN:  
 13 A. Yeah, it usually takes approximately 11 and a  
 14 half hours, somewhere between 11 hours 15  
 15 minutes, 11 hours and 30, depending,  
 16 approximately 11 hours.  
 17 CHAYTOR, Q.C.:  
 18 Q. And what would happen if you had a power  
 19 outage which interfered with your tissue  
 20 processing?  
 21 MR. GREEN:  
 22 A. If you had a power outage, as far as I know,  
 23 right now, the processors are under back up  
 24 power and they're hooked up to an alarm, and I  
 25 don't know how long they've been like that.

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1 But if it wasn't hooked up to the external  
 2 alarm and the--if it happened the alarm would  
 3 go off, if it went off in the middle of the  
 4 night, nobody is going to hear it because  
 5 there is nobody in the lab at that time of the  
 6 night. So the tissues would remain in  
 7 whichever reagent that they were in until  
 8 somebody came in at maybe 6:30-7:00 and would  
 9 find that the run had been interrupted.  
 10 CHAYTOR, Q.C.:  
 11 Q. And if the power had come back on overnight,  
 12 would the person coming in at 6:30 in the  
 13 morning or 6:00 in the morning know there had  
 14 been an interruption?  
 15 MR. GREEN:  
 16 A. From what I understand, if the run had been  
 17 interrupted, it would not start again. It  
 18 would stay in that station that it was in, and  
 19 what you would end up doing, after you found  
 20 out what the problem was, you would have to  
 21 resume your processing from that point, which  
 22 probably meant that if it shut off at three or  
 23 four a.m., which would be two or three hours  
 24 before it's final completion time, your blocks  
 25 would be delayed by that time.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. So there was--to your knowledge, was  
 3 this ever an issue, power failure? Was it  
 4 ever an issue in running either at St. Clare's  
 5 or -  
 6 MR. GREEN:  
 7 A. It has happened, yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. And it's come to the knowledge of the  
 10 technologists and appropriate corrective  
 11 action was taken, I take it?  
 12 MR. GREEN:  
 13 A. What would happen then, you would resume your  
 14 processing. In the processors that we have  
 15 today, they are designed--they are closed  
 16 systems and what happens, the tissues are in a  
 17 retort or a holding block and solutions are  
 18 pumped in and pumped out. So if there was a  
 19 malfunction, the tissues would be kept in one  
 20 of the solutions until it restarted. In the  
 21 older type systems which were not enclosed,  
 22 the tissues would lift up and physically move  
 23 into each station. So that would be more of a  
 24 concern in the older days because it's  
 25 possible that your--if a malfunction could

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1 happen, your sections would be high and dry.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay. So would you have to then start the  
 4 whole process over, that -  
 5 MR. GREEN:  
 6 A. You would start the process where it stopped.  
 7 Now if it happened at any time after the  
 8 fixation, there would be no damage to the  
 9 tissue. Fixation is the critical stage in the  
 10 tissue processing. Fixation is the only stage  
 11 that cannot be reversed.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, and so what would happen if it happened  
 14 after the fixation stage?  
 15 MR. GREEN:  
 16 A. If it happened after the fixation, you would  
 17 just resume the processing schedule and the  
 18 only ill effects would be that your blocks  
 19 would be delayed.  
 20 CHAYTOR, Q.C.:  
 21 Q. And what if it happened before the fixation  
 22 stage?  
 23 MR. GREEN:  
 24 A. Well, fixation starts from the time the  
 25 specimen is taken at surgery and goes through

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1 the whole process. The last fixation stage  
 2 takes place on the processor. I think there  
 3 are two one-hour fixation stages before the  
 4 alcohols. If it happened when a processor  
 5 starts up, it starts up in formalin. So  
 6 fixation is already started. The only danger  
 7 would be if it happened before the next  
 8 formalin.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay, and what would the result be in that  
 11 case?  
 12 MR. GREEN:  
 13 A. For a tissue processor, enclosed system, there  
 14 would be no problem because the solutions are  
 15 still confined inside the machine. Had it  
 16 been one of the older machines, all the  
 17 tissues could dry out.  
 18 CHAYTOR, Q.C.:  
 19 Q. And again, in terms of documenting any issues  
 20 in that regard, was there any corrective  
 21 action log taken for any issues around the  
 22 tissue processor?  
 23 MR. GREEN:  
 24 A. At that time, there was not.  
 25 CHAYTOR, Q.C.:

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1 Q. I'm being told that we can now, please, enter  
 2 2190, Commissioner.  
 3 THE COMMISSIONER:  
 4 Q. Okay.  
 5 REGISTRAR:  
 6 Q. 2190.  
 7 THE COMMISSIONER:  
 8 Q. Entered.  
 9 CHAYTOR, Q.C.:  
 10 Q. Thank you.  
 11 EXHIBIT ENTERED AND MARKED EXHIBIT P-2190  
 12 CHAYTOR, Q.C.:  
 13 Q. And if we could bring up--I'm sorry, if we  
 14 could bring up 2190, please? And do you  
 15 recognize what type of form this is?  
 16 MR. GREEN:  
 17 A. That looks like the sheet I was referring to  
 18 earlier, the run log with the 48.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, so this is a run log, and we see the 48  
 21 here.  
 22 MR. GREEN:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and so, for example, in--we have a

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1 number, antibody, comments?  
 2 MR. GREEN:  
 3 A. Yeah.  
 4 CHAYTOR, Q.C.:  
 5 Q. Three columns, and so the numbers coming down  
 6 the side, I take it that's the slide position  
 7 on the machine? Is that correct?  
 8 MR. GREEN:  
 9 A. It is, yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, and then your antibody, of course,  
 12 speaks for itself, and what's the comment  
 13 section?  
 14 MR. GREEN:  
 15 A. This one here, in particular, looks like  
 16 somebody was doing a validation on the  
 17 antibodies and because they don't have a  
 18 surgical number in there, what they have in  
 19 there is a dilution, and it got like tonsils,  
 20 skin lesion, thymus, and one in ten, one in  
 21 20. It looks like somebody was running a run  
 22 and they were checking control.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. So in this one, we see one in 50, these  
 25 dilutions, one in 100. So that's someone

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1 running a validation?  
 2 MR. GREEN:  
 3 A. It looks like number one, two and three. It  
 4 looks like they were using one in 50 dilution  
 5 on a L26 antibody and they probably used three  
 6 different blocks and they were trying to  
 7 determine which block would be the best for  
 8 the control, or if they could use all three  
 9 for a control. Next one is the--they're using  
 10 a skin lesion to do--try on the L26 antibody  
 11 and the next one, they're using a tonsil for  
 12 control, looks like.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay.  
 15 MR. GREEN:  
 16 A. And CD79A, which is another lymphoma marker,  
 17 probably doing different -  
 18 CHAYTOR, Q.C.:  
 19 Q. So they're trying different dilutions as well  
 20 as different control tissues?  
 21 MR. GREEN:  
 22 A. Controls.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, and if we could -  
 25 MR. GREEN:

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1 A. Probably trying to--it looks like they're  
 2 trying to get a control bank.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay, and that, I take it, that's not your  
 5 handwriting?  
 6 MR. GREEN:  
 7 A. No.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay. If we could have page 24, please? Now  
 10 on this particular one, we'll see under the  
 11 comments sections, we have what appears to be  
 12 surgical numbers?  
 13 MR. GREEN:  
 14 A. Yeah.  
 15 CHAYTOR, Q.C.:  
 16 Q. So I take it normally the comments section -  
 17 MR. GREEN:  
 18 A. Yeah, normally it would be a surgical number  
 19 in that area.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and so on this particular one then, it  
 22 appears that you had up to 44 for that day?  
 23 MR. GREEN:  
 24 A. Yeah.  
 25 CHAYTOR, Q.C.:

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1 Q. 44 of your slide slots used or whoever, who's  
 2 doing this run, and again, I take it it's not  
 3 your handwriting, or it might be? Do you  
 4 know?  
 5 MR. GREEN:  
 6 A. Looks a little too neat for mine.  
 7 CHAYTOR, Q.C.:  
 8 Q. Little bit too neat, okay. And this one here,  
 9 if we come down to 24, we see ER and a  
 10 surgical number. So I take it that on slide  
 11 slot 24, we would expect -  
 12 MR. GREEN:  
 13 A. Yes, it would be -  
 14 CHAYTOR, Q.C.:  
 15 Q. - this patient's slide and that ER will be the  
 16 antibody?  
 17 MR. GREEN:  
 18 A. That's true.  
 19 CHAYTOR, Q.C.:  
 20 Q. And then 25 PR?  
 21 MR. GREEN:  
 22 A. Yes.  
 23 CHAYTOR, Q.C.:  
 24 Q. And nothing written in, so what does that tell  
 25 me in terms of the surgical number?

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1 MR. GREEN:  
 2 A. That would be the same patient carried over  
 3 from the previous. This would be ER and that  
 4 would be the PR on that patient.  
 5 CHAYTOR, Q.C.:  
 6 Q. So this is the PR now on that same patient?  
 7 MR. GREEN:  
 8 A. Yeah, and like -  
 9 CHAYTOR, Q.C.:  
 10 Q. And 26?  
 11 MR. GREEN:  
 12 A. Yeah, and number 26, 27 would be the ER and PR  
 13 on that surgical number. 28, 29 would be the  
 14 surgical number, that patient. Looks like  
 15 cases one to nine would be--would be all 94-  
 16 21.  
 17 CHAYTOR, Q.C.:  
 18 Q. All on the same patient, from one to nine,  
 19 inclusive?  
 20 MR. GREEN:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay, and then starting at 30, we have MN-  
 24 F116, is that right, and control?  
 25 MR. GREEN:

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1 A. Controls, yeah.  
 2 CHAYTOR, Q.C.:  
 3 Q. And then do I understand from this that from  
 4 30 through to 44 are all control slides.  
 5 MR. GREEN:  
 6 A. Controls.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, and so in this particular case, your  
 9 ER/PR controls are 41 through 44 inclusive?  
 10 MR. GREEN:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. And so there were two ERs and two PRs run that  
 14 day?  
 15 MR. GREEN:  
 16 A. Controls, yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. Controls, I'm sorry, yes, controls, and there  
 19 were three patients -  
 20 MR. GREEN:  
 21 A. Three patients.  
 22 CHAYTOR, Q.C.:  
 23 Q. - who had ER/PR tests?  
 24 MR. GREEN:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And then these are more pages of the same, and

3 on this particular day then, page 26, and

4 there's no date on this particular--is this is

5 the date--no, is this a date, do you know, and

6 it's got a B after it, so perhaps it's a date

7 and a separate batch? Do you know any

8 significance to 03/11/17B? Would you use a

9 letter, for example, if you ran more than one

10 batch on the same day?

11 MR. GREEN:

12 A. It's possible.

13 CHAYTOR, Q.C.:

14 Q. Okay. You don't recall that being your

15 practice?

16 MR. GREEN:

17 A. I don't recall, no.

18 CHAYTOR, Q.C.:

19 Q. Okay. All right. Then on this particular day

20 then, we see a number of ER/PR tests from slot

21 nine. So there appears to be 1-2-3-4-5

22 patients who had ER/PR tests and then we had

23 1-2-3, three controls.

24 MR. GREEN:

25 A. Three sets of controls.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and they appeared to be have been placed

3 at the end of your run?

4 MR. GREEN:

5 A. At the end of the run.

6 CHAYTOR, Q.C.:

7 Q. Okay.

8 MR. GREEN:

9 A. And most likely in a situation like this, you

10 would have--you wouldn't have a control for

11 each case because maybe two cases were Health

12 Science and that control would be shared.

13 CHAYTOR, Q.C.:

14 Q. Right, okay. Now we spoke briefly about a

15 situation if a pathologist wasn't satisfied

16 with a slide or a particular test and asking

17 to have a repeat done. Did it--was it ever

18 brought to your attention that a pathologist

19 wasn't satisfied and looking for a retest

20 because the result wasn't what the pathologist

21 was expecting?

22 MR. GREEN:

23 A. We would have no way of knowing, you know.

24 Lots of times you would--they would ask for a

25 repeat and just say repeat, you know, and they

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1 would not necessarily specify what the problem

2 was. It could be that they wanted a better

3 section. Maybe when they looked at the slide,

4 it wasn't what they needed, so they would ask

5 for a--maybe it was because that it didn't

6 work. But they would not always--but usually,

7 if it didn't work, you would know because they

8 would tell you it didn't work.

9 CHAYTOR, Q.C.:

10 Q. Okay, so would tell you that the control

11 hadn't worked.

12 MR. GREEN:

13 A. The control hadn't worked or they were

14 expecting a different result.

15 CHAYTOR, Q.C.:

16 Q. Yes, and that's what I was wondering, was that

17 ever articulated to you that they were

18 expecting a different result, the control may

19 have worked, but they were expecting a

20 different result, so they were requesting a

21 repeat?

22 MR. GREEN:

23 A. That has happened, yes.

24 CHAYTOR, Q.C.:

25 Q. That happened?

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1 MR. GREEN:

2 A. Yes.

3 CHAYTOR, Q.C.:

4 Q. Okay, and in those particular instances, do

5 you know if, when the repeat then happened,

6 was there ever any communication as to whether

7 a different result had been obtained the

8 second time around?

9 MR. GREEN:

10 A. Usually there wouldn't be any follow up, you

11 would have no way of knowing the second time

12 around if the result had changed or not. And

13 as with all these antibodies and you're

14 dealing with human tissue, although there's

15 always the chance that, for some reason a

16 particular biological specimen will not react,

17 as you think it will react.

18 CHAYTOR, Q.C.:

19 Q. So there were occasions, though, that you

20 recall a pathologist looking for a repeat

21 because he or she didn't get the result they

22 had anticipated.

23 MR. GREEN:

24 A. They had anticipated, yes.

25 CHAYTOR, Q.C.:

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1 Q. Okay, and then the test was repeated, I take  
 2 it?  
 3 MR. GREEN:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. And was there ever any, in that situation, any  
 7 follow up as to why the test needed to be  
 8 repeated?  
 9 MR. GREEN:  
 10 A. I would assume that after the repeat if the  
 11 problem wasn't resolved, you would know about  
 12 it and we would have to do work in a  
 13 particular antibody.  
 14 CHAYTOR, Q.C.:  
 15 Q. What do you mean, though, with the problem  
 16 resolved, because perhaps the second time  
 17 round the pathologist got the answer he or she  
 18 was expecting.  
 19 MR. GREEN:  
 20 A. Then the problem would be solved.  
 21 CHAYTOR, Q.C.:  
 22 Q. And the problem was solved.  
 23 MR. GREEN:  
 24 A. Because then you would have to put it down to  
 25 that particular antibody and that particular

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1 specimen.  
 2 CHAYTOR, Q.C.:  
 3 Q. Or perhaps in getting a second or different  
 4 result the second time around, the problem is  
 5 identified, as opposed to resolved?  
 6 MR. GREEN:  
 7 A. Yes, and maybe the second time around the  
 8 pathologist, it wouldn't be uncommon to ask  
 9 for a testing on a different block on the same  
 10 patient.  
 11 CHAYTOR, Q.C.:  
 12 Q. But you're not aware then of in those  
 13 situations anyone coming to make further  
 14 inquiry of your processes as to if a changed  
 15 result had occurred, coming to make further  
 16 inquiries of your processes?  
 17 MR. GREEN:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. And it wasn't brought to your attention  
 21 whether or not changed results had occurred?  
 22 MR. GREEN:  
 23 A. No.  
 24 CHAYTOR, Q.C.:  
 25 Q. For example, and I'm sure you're aware, you've

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1 heard about the index case or what's referred  
 2 to as the index case, Mrs. Dean's case.  
 3 MR. GREEN:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. And a different result coming in her situation  
 7 and we understand that's because after a  
 8 consult in the United States, it was felt that  
 9 that was a negative ER in that situation was  
 10 unusual. So whether or not there were prior  
 11 patients who had repeats done with changed  
 12 results, whether or not that happened, you're  
 13 not aware of that?  
 14 MR. GREEN:  
 15 A. I'm not aware of it, it was probably before my  
 16 time at the Health Science to IHC.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay.  
 19 THE COMMISSIONER:  
 20 Q. Ms. Chaytor, whenever you can find a spot -  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. If we could look, please, at P-2149?  
 23 And in particular, page 23? And this  
 24 particular form, Mr. Green, you're the  
 25 histotech indicated and it's June 25th, 2002,

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1 it was a test ordered by Dr. Cook in June  
 2 21st, 2002 and it's not circled what the test  
 3 was, but over here it says "repeat ER".  
 4 MR. GREEN:  
 5 A. Repeat.  
 6 CHAYTOR, Q.C.:  
 7 Q. So on this particular occasion for whatever  
 8 reason, Dr. Cook was looking for a repeat on  
 9 the ER. The wording on the bottom here of the  
 10 form, "For a complete listing of  
 11 immunoglobulins available in our laboratory,  
 12 consult the bound collection and the product  
 13 monographs in the reporting room." Are you  
 14 aware of a bound collection of--well first of  
 15 all, what would you understand product  
 16 monographs to be?  
 17 MR. GREEN:  
 18 A. I'm not familiar with that.  
 19 CHAYTOR, Q.C.:  
 20 Q. Might that be the specification sheets for the  
 21 various antibodies?  
 22 MR. GREEN:  
 23 A. Unless they're referring to these requisitions  
 24 come in a pad of 50 or 100.  
 25 CHAYTOR, Q.C.:



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1 Q. Oh, okay, so it may be the listing of all the  
 2 various stains that you can request?  
 3 MR. GREEN:  
 4 A. Yes, and that's usually the way they came, I  
 5 guess that was the way they were printed and  
 6 bound.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, and so there was a bound volume of that  
 9 in the reporting room, was there?  
 10 MR. GREEN:  
 11 A. There will be stacks of blank requisitions.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, so other than that, you're not able to  
 14 shed any light on what that might be?  
 15 MR. GREEN:  
 16 A. That's the only thing that I can allude to  
 17 what it means. It doesn't mean anything else  
 18 to me.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. If we could look at page 39, please, of  
 21 this document? And this form looks a little  
 22 bit different, do you know when this form or  
 23 was this form used for a different purpose or  
 24 when would this form be used, as opposed to  
 25 the type I just showed you?

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1 MR. GREEN:  
 2 A. This is probably just a different update of  
 3 the same form. As the amount of antibodies  
 4 increased, they went to a form all of their  
 5 own.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, so this might be the later version of  
 8 this sheet.  
 9 MR. GREEN:  
 10 A. Probably.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, and this one was a request by Dr. Denic  
 13 and it was on August 28th, '08, and again,  
 14 sorry, August 28th, '02 and up here it says  
 15 "repeat". What does 18 plus negative, this  
 16 writing over here mean?  
 17 MR. GREEN:  
 18 A. 18 means that I went into the computer and  
 19 probably under patient comments, today that  
 20 these slides were returned to St. Clare's.  
 21 CHAYTOR, Q.C.:  
 22 Q. And it looks then like a repeat was carried  
 23 out a few days later or, sorry, it was  
 24 originally completed September 3rd and then  
 25 the repeat was carried out, September 4th.

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1 MR. GREEN:  
 2 A. 4th, yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. And written here is "tissue washed off  
 5 slides"? Is that your handwriting?  
 6 MR. GREEN:  
 7 A. That is.  
 8 CHAYTOR, Q.C.:  
 9 Q. And so what would the problem have been on  
 10 that particular day?  
 11 MR. GREEN:  
 12 A. That would mean that the block that we had to  
 13 work with was probably suboptimal, which means  
 14 that we had--there was probably a problem with  
 15 fixation and/or processing and we had to, we  
 16 had to work with the block that you had and it  
 17 probably didn't have a lot of tissue on it,  
 18 and then it had to be subjected to the antigen  
 19 retrieval solution in the ER process and it's  
 20 possible that some of the tissue would have  
 21 washed off.  
 22 CHAYTOR, Q.C.:  
 23 Q. So are you indicating tissue washed off the  
 24 slides with respect to the repeat test or a  
 25 reason for why the test may have had to be

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1 repeated?  
 2 MR. GREEN:  
 3 A. That would be a reason why that there was a  
 4 poor slide to begin with.  
 5 CHAYTOR, Q.C.:  
 6 Q. And do I take it then if you were able to  
 7 identify a problem with other cases for  
 8 repeat, would we expect to see that documented  
 9 on the form?  
 10 MR. GREEN:  
 11 A. Not necessarily, that was probably put there  
 12 if you had had a bad day and you just had to  
 13 repeat a test because you didn't have a good  
 14 block to work with.  
 15 CHAYTOR, Q.C.:  
 16 Q. And if we could look at, please, I think that  
 17 might be it for this particular document, for  
 18 you. Okay, this is a good place then,  
 19 Commissioner, if it's convenient please?  
 20 THE COMMISSIONER:  
 21 Q. Yes, we'll take the luncheon break, meet again  
 22 at 2:05.  
 23 (LUNCH BREAK)  
 24 THE COMMISSIONER:  
 25 Q. Please be seated. Ms. Chaytor.

1 CHAYTOR, Q.C.:

2 Q. Thank you, Commissioner, good afternoon Mr.

3 Green.

4 MR. GREEN:

5 A. Good afternoon.

6 CHAYTOR, Q.C.:

7 Q. Mr. Green, did any pathologist up until 2005

8 ever suggest any change in your protocols or

9 your way of doing IHC testing?

10 MR. GREEN:

11 A. Not to my knowledge.

12 CHAYTOR, Q.C.:

13 Q. Was there ever any discussion, for example, as

14 to changing or altering antigen retrieval

15 times?

16 MR. GREEN:

17 A. Not to my knowledge.

18 CHAYTOR, Q.C.:

19 Q. Did you, yourself, ever prior to 2005, ever

20 express any concerns to anyone about the

21 testing procedures?

22 MR. GREEN:

23 A. No, I had no way of knowing that there was a

24 problem.

25 CHAYTOR, Q.C.:

1 A. That's correct.

2 CHAYTOR, Q.C.:

3 Q. Were you involved in that? Were you involved

4 in the change over between the two machines?

5 MR. GREEN:

6 A. Yes, I was.

7 CHAYTOR, Q.C.:

8 Q. Perhaps you could tell us then about that?

9 What was your involvement?

10 MR. GREEN:

11 A. I worked with Barry Dyer in setting up the

12 Ventana system and we ran parallel runs on

13 patient's tissue and on controls with the

14 various protocols until the Ventana system was

15 able to take over and run on its own.

16 CHAYTOR, Q.C.:

17 Q. And do you know how many--so you ran parallel

18 tests on both DAKO and Ventana for both

19 controls and -

20 MR. GREEN:

21 A. And patients.

22 CHAYTOR, Q.C.:

23 Q. And actual patients. And do you know how many

24 tests you ran?

25 MR. GREEN:

1 Q. And were you aware of whether or not anyone

2 else may have expressed any concerns?

3 MR. GREEN:

4 A. I wasn't, no.

5 CHAYTOR, Q.C.:

6 Q. So from your perspective, everything seemed to

7 be going along fine and if there was a

8 problem, you were unaware of it?

9 MR. GREEN:

10 A. That's true.

11 CHAYTOR, Q.C.:

12 Q. So I take it other than things we've talked

13 about that sometimes there'd be requests for

14 retests, sometimes there were problems with

15 the DAKO machine, as it aged, I take it.

16 Other than those types of issues that we

17 discussed this morning, were you aware of any

18 other difficulties with the IHC testing?

19 MR. GREEN:

20 A. No.

21 CHAYTOR, Q.C.:

22 Q. Now we understand that the DAKO machine was

23 replaced with the Ventana machine in early

24 2004?

25 MR. GREEN:

1 A. I don't recall exactly but we were, we worked

2 on the machine for close to maybe a month, so

3 on a daily basis we would run the machine, so

4 quite a number, and we would take the slides

5 to the pathologists to critique.

6 CHAYTOR, Q.C.:

7 Q. And so was there any particular pathologist

8 involved in that?

9 MR. GREEN:

10 A. All the pathologists at the Health Science

11 would be involved.

12 CHAYTOR, Q.C.:

13 Q. So it wasn't one particular pathologist, it

14 was whoever was available at the time?

15 MR. GREEN:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. And so you would bring then, I would take it

19 you would run the test, for example, on the

20 DAKO and on the Ventana, would you bring both

21 lots of slides then to the pathologist?

22 MR. GREEN:

23 A. Yes, usually if whatever pathologist requested

24 the stains, would request the stains, the IHC

25 stains, that would be the pathologist that we

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1 would show the slides to.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, so it would be the current tests which  
 4 were being requested and you would run the  
 5 test on both DAKO and Ventana?  
 6 MR. GREEN:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. And you would bring it to--okay, now were  
 10 there any differences between the two? Were  
 11 there times when the tests weren't coming out  
 12 comparable?  
 13 MR. GREEN:  
 14 A. I can't recall any differences between  
 15 patients, but the stain itself seemed to be  
 16 crisper and of better quality.  
 17 CHAYTOR, Q.C.:  
 18 Q. So the stain on which machine?  
 19 MR. GREEN:  
 20 A. On the Ventana machine.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay, so the staining itself appeared to be  
 23 crisper and you observed that yourself by  
 24 looking at the external controls?  
 25 MR. GREEN:

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1 A. Yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. And but you don't recall any discussion or  
 4 issue as to one test result being different  
 5 from another, one patient being positive and  
 6 one negative?  
 7 MR. GREEN:  
 8 A. No major discrepancies in testing, no.  
 9 CHAYTOR, Q.C.:  
 10 Q. No major discrepancies brought to your  
 11 attention?  
 12 MR. GREEN:  
 13 A. No, not that I was aware of.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay, and would you and Mr. Dyer keep track of  
 16 that then? Would you keep track of, not only  
 17 that you had run these tests, but the outcomes  
 18 after bringing it to the pathologist?  
 19 MR. GREEN:  
 20 A. I'm not sure if Barry kept a spreadsheet or  
 21 not, he may have.  
 22 CHAYTOR, Q.C.:  
 23 Q. And do you know what time period this took  
 24 place? I guess this is a concordance study,  
 25 is it?

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1 MR. GREEN:  
 2 A. Yeah, it would be probably January, February,  
 3 March of 2003.  
 4 CHAYTOR, Q.C.:  
 5 Q. 2004 perhaps?  
 6 MR. GREEN:  
 7 A. 2004, yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. And if we could look, please, at P-2178? Mr.  
 10 Green, do you recognize this document?  
 11 MR. GREEN:  
 12 A. Yes, I do.  
 13 CHAYTOR, Q.C.:  
 14 Q. And perhaps you could tell us then what this  
 15 is? This a four-page document.  
 16 MR. GREEN:  
 17 A. These are protocols used by other hospitals  
 18 across Canada who are using the Ventana system  
 19 and these are their protocols, their antibody  
 20 dilutions, the antigen retrieval required and  
 21 the type of antibody, the antibody supplier.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay, so for example, on P-2178 we see Toronto  
 24 General written at the top here?  
 25 MR. GREEN:

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1 A. That's true.  
 2 CHAYTOR, Q.C.:  
 3 Q. Now when would this information be acquired?  
 4 MR. GREEN:  
 5 A. This information was given to us when we set  
 6 up the Ventana system by the company  
 7 representative, the Canadian representative  
 8 who came in to help us install the equipment.  
 9 CHAYTOR, Q.C.:  
 10 Q. So is this your writing on the document?  
 11 MR. GREEN:  
 12 A. No.  
 13 CHAYTOR, Q.C.:  
 14 Q. That's the writing of the representative, is  
 15 it?  
 16 MR. GREEN:  
 17 A. It could be the writing of the representative,  
 18 it could be the writing of the technologist at  
 19 that institution.  
 20 CHAYTOR, Q.C.:  
 21 Q. Oh, okay. So this was given to you so that  
 22 you could use the same protocols from Toronto  
 23 General, is that right?  
 24 MR. GREEN:  
 25 A. So that we could have a reference point to

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1 compare.  
 2 CHAYTOR, Q.C.:  
 3 Q. And if we could have P-2179 please? Actually,  
 4 I'm sorry, can we go back to 2178 for a  
 5 moment? Perhaps you can just tell me, it says  
 6 here slide number and then case number,  
 7 antibody number and antibody, dispensing  
 8 pattern and comments. What were those  
 9 categories intended to represent?  
 10 MR. GREEN:  
 11 A. These sheets will tell us all the information  
 12 about this particular antibody and it's used,  
 13 this particular hospital here using this  
 14 particular sheet to have a spreadsheet of all  
 15 their antibodies and the antigen retrieval  
 16 required, antibody dilution, as you can see,  
 17 they've got dispensing pattern there?  
 18 CHAYTOR, Q.C.:  
 19 Q. Yes  
 20 MR. GREEN:  
 21 A. In that column, they just put the manufacturer  
 22 there.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, so for example down on No. 17 we see ER  
 25 and what's then written here?

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1 MR. GREEN:  
 2 A. It says "CC1/mild/32, one in fifty, nova  
 3 6F11", that means that it's the estrogen  
 4 receptor antibody. CC1 mild refers to the  
 5 antigen retrieval. CC1 is the Ventana company  
 6 trademark name for antigen retrieval, that is  
 7 the EDTA citrate for a buffer pH 8. Mild  
 8 refers to the time in antigen retrieval, mild  
 9 would equate to 30 minutes. And 32 minutes  
 10 right here would be the time in primary  
 11 antibody, the incubation time in primary  
 12 antibody. Let's see, it's from Novacastra,  
 13 that would be the company and the clone would  
 14 be 6F11.  
 15 CHAYTOR, Q.C.:  
 16 Q. And what's the one over fifty.  
 17 MR. GREEN:  
 18 A. That would be the dilution, this antibody  
 19 would not be a pre-dilute, it would come in  
 20 concentrated from Novacastra and diluted one  
 21 in fifty.  
 22 CHAYTOR, Q.C.:  
 23 Q. So for the Ventana system, you can have an ER  
 24 antibody that's not pre-diluted?  
 25 MR. GREEN:

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1 A. Yes, you can use any manufacturer's antibody  
 2 on that system as long as you use Ventana's,  
 3 what's called a prep kit, which is an empty  
 4 container which is programmed into the Ventana  
 5 system. The clone and the manufacturer would  
 6 be programmed in and the Ventana system then  
 7 would put an expiry date on the system for one  
 8 year.  
 9 CHAYTOR, Q.C.:  
 10 Q. So once the Ventana became operationalized in,  
 11 we believe it's April of 2004, were pre-  
 12 diluted antibodies always used for ER and PR?  
 13 MR. GREEN:  
 14 A. We would have used up all the antibodies that  
 15 we had left from the DAKO system and when  
 16 those antibodies were used up, we would have  
 17 went to pre-dilutes from Ventana.  
 18 CHAYTOR, Q.C.:  
 19 Q. So for a period of time you would have been  
 20 still continuing to dilute.  
 21 MR. GREEN:  
 22 A. We would have run the DAKO antibody, yeah.  
 23 CHAYTOR, Q.C.:  
 24 Q. And do you know how long that lasted? Do you  
 25 know, was that a period of months or a couple

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1 of years?  
 2 MR. GREEN:  
 3 A. It would have been weeks, it wouldn't have  
 4 been very long.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay.  
 7 MR. GREEN:  
 8 A. Our goal was to switch over all antibodies  
 9 that we could to the pre-diluted antibodies.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, and here we have then at 25, we have PR  
 12 and perhaps you can take us through that  
 13 information?  
 14 MR. GREEN:  
 15 A. Yeah, PR is the name of the antibody,  
 16 progesterone CC1/mild/32. CC1 mild refers to  
 17 the antigen retrieval, again mild, it's ED-  
 18 CC1 is the EDTA borate pH 8. Mild is 30  
 19 minutes and 32 minutes refers to the primary  
 20 antibody incubation time, that was diluted one  
 21 in fifty, that's a DAKO antibody and the clone  
 22 is P6R, 636.  
 23 CHAYTOR, Q.C.:  
 24 Q. So did you just take this information and  
 25 program it into the Ventana machine, or did

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1 you make any adjustments?  
 2 MR. GREEN:  
 3 A. We looked at these here and we found a common  
 4 denominator to those and that's the way we  
 5 decided the protocols to run, to try our  
 6 controls and if I remember correctly, I think  
 7 the ER was probably CC1 standard, 24 or 28  
 8 minutes.  
 9 CHAYTOR, Q.C.:  
 10 Q. Sorry, it was, if we just look at the ER here,  
 11 so it was CC1, was it mild or -  
 12 MR. GREEN:  
 13 A. That one there is mild, yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. But yours, the protocol you came up with was  
 16 which?  
 17 MR. GREEN:  
 18 A. We used standard.  
 19 CHAYTOR, Q.C.:  
 20 Q. Standard.  
 21 CHAYTOR, Q.C.:  
 22 Q. Which would be, a standard would be 60 minutes  
 23 in antigen retrieval as opposed to mild, which  
 24 would be 30.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay.  
 2 MR. GREEN:  
 3 A. We use these protocols as a guideline and  
 4 different hospitals will use different  
 5 protocols, which ever works better in their  
 6 laboratory.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay. And if I could go back then, please, to  
 9 P-2179? And do you recognize this document?  
 10 MR. GREEN:  
 11 A. I do.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, and is this your handwriting?  
 14 MR. GREEN:  
 15 A. Probably, yeah.  
 16 CHAYTOR, Q.C.:  
 17 Q. All of this, three page document.  
 18 MR. GREEN:  
 19 A. Well this handwriting here is not, this  
 20 sloppy handwriting on the left is mine.  
 21 CHAYTOR, Q.C.:  
 22 Q. This is yours, right, okay.  
 23 MR. GREEN:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

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1 Q. And do you know who wrote the rest of this?  
 2 MR. GREEN:  
 3 A. No, I would imagine it's probably this person  
 4 on the top which is probably the technologist  
 5 at this hospital.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and do we know which hospital is this?  
 8 MR. GREEN:  
 9 A. I'm pretty sure it's in Quebec.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, that's the name here, Protocole, I  
 12 guess.  
 13 CHAYTOR, Q.C.:  
 14 Q. Protocole, I think that's French for protocol.  
 15 CHAYTOR, Q.C.:  
 16 Q. Protocol, oh, okay, so do you know the name  
 17 for the hospital? This is a French hospital,  
 18 though, is it?  
 19 MR. GREEN:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. And again this was provided to you by the  
 23 Ventana rep?  
 24 MR. GREEN:  
 25 A. It was, yes, and it gives basically the same

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1 information, it tells the antibody, the  
 2 dilution and the clone and company where it  
 3 was purchased. It can also give the antigen  
 4 retrieval and the primary antibody incubation  
 5 time.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and so then you use this as well as a  
 8 guide, I take it?  
 9 MR. GREEN:  
 10 A. Yes. And you would also, along with these,  
 11 you would also use the package inserts from  
 12 the antibodies that you were putting in there  
 13 too.  
 14 CHAYTOR, Q.C.:  
 15 Q. I'm sorry?  
 16 MR. GREEN:  
 17 A. We would also--in addition to these here we  
 18 would also cross check against the package  
 19 inserts or the datasheets from the antibody to  
 20 see what the manufacturer recommended.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay, and so you used the spec sheets and you  
 23 used those two hospitals, their protocols?  
 24 MR. GREEN:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. Did you have any others or is that it?

3 MR. GREEN:

4 A. There's one more that seems to be missing from

5 that list.

6 CHAYTOR, Q.C.:

7 Q. Okay, maybe we have it, 2181?

8 MR. GREEN:

9 A. From Vancouver probably.

10 CHAYTOR, Q.C.:

11 Q. Let's just see, is this it?

12 MR. GREEN:

13 A. No, that's not it. That's a sheet from Cell

14 Marque company which gives some of their

15 suggested protocols or new Cell Marque

16 antibodies.

17 CHAYTOR, Q.C.:

18 Q. Okay.

19 MR. GREEN:

20 A. And it gives the same type of information,

21 except that would be limited to the Cell

22 Marque antibodies only.

23 CHAYTOR, Q.C.:

24 Q. Yes, I don't see ER on this list.

25 MR. GREEN:

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1 A. No, Cell Marque has some kind of agreement

2 with Ventana, they supply a lot of their

3 antibodies.

4 CHAYTOR, Q.C.:

5 Q. Okay, I think maybe then it's 2182, that might

6 be the Vancouver St. Paul's Hospital? This

7 one?

8 MR. GREEN:

9 A. Yes, that's it.

10 CHAYTOR, Q.C.:

11 Q. And so again, this is the same thing you would

12 have received this from the Ventana rep as a -

13 MR. GREEN:

14 A. Those were all protocols which they had in use

15 at that time.

16 CHAYTOR, Q.C.:

17 Q. Okay, and for example under ER at St. Paul's

18 Hospital, the clone is CF11 and the antigen

19 retrieval is CC1 mild.

20 MR. GREEN:

21 A. Mild 16.

22 CHAYTOR, Q.C.:

23 Q. And 16, what does the 16 mean?

24 MR. GREEN:

25 A. CC1 mild is the same thing again, CC1 is

Page 215

1 antigen retrieval solution, mild means 30

2 minutes and 16 is the primary antibody

3 incubation time.

4 CHAYTOR, Q.C.:

5 Q. Okay, and BF110, what's that?

6 MR. GREEN:

7 A. These are the fixatives that this column right

8 here, BF is buffer formalin, the others Bouins

9 B5 are carnoys, so if any of the tissues were

10 fixed in those, those are codes they would

11 have for those.

12 CHAYTOR, Q.C.:

13 Q. Okay, and then we have progesterone down here

14 and -

15 MR. GREEN:

16 A. CC1 mild, 32, so that progesterone, 16 is the

17 clone on that one in the first column on the

18 left and then the other one is the antigen

19 retrieval, mild, which is 30 minutes. 32

20 minutes is primary antibody incubation time.

21 Primary antibody incubation time is the time

22 that the tissue would be exposed to the

23 primary antibody.

24 CHAYTOR, Q.C.:

25 Q. And I take it you used those three hospitals,

Page 216

1 their protocols as a guide, along with the

2 spec sheets, but you and Mr. Dyer did your own

3 -

4 MR. GREEN:

5 A. We did -- we ran our own variations of these

6 until we came to a protocol that the

7 pathologists were happy with.

1 CHAYTOR, Q.C.:

2 Q. Okay, and do you recall was Dr. Ejeckam

3 involved at all in the process?

4 MR. GREEN:

5 A. Dr. Ejeckam was there when the process was

6 going on. I'm sure he would have seen some of

7 the slides.

8 CHAYTOR, Q.C.:

9 Q. Was there any one pathologist at that point in

10 time who was considered to be overseeing IHC?

11 MR. GREEN:

12 A. I think Dr. Ejeckam was probably the man to go

13 to. I don't know if he had an official title

14 at that time, but if he was there, we would

15 have certainly went to him.

16 CHAYTOR, Q.C.:

17 Q. Okay. So it wasn't a situation based on this

18 information. You didn't just take the

1 -- this tweaking of protocols took place in

2 any event, you didn't just use up those

3 antibodies and then do the tweaking, the

4 tweaking took place before the Ventana was

5 brought on stream?

6 MR. GREEN:

7 A. It would have -- it would have been done while

8 the DAKO was still there, and once we used up

9 all the antibodies, then we brought in the

10 predilutes from Ventana.

11 CHAYTOR, Q.C.:

12 Q. So this -- that's what I'm wondering. This

13 process of what you went through here and

14 comparing to other hospitals, did that happen

15 before Ventana was brought on stream or was

16 this used, the protocols changed, or any

17 tweaking to the protocols after?

18 MR. GREEN:

19 A. No, this was in the initial setup.

20 CHAYTOR, Q.C.:

21 Q. This was the initial setup, okay. Did you

22 receive any additional training on the Ventana

23 machine prior to it being operationalized?

24 MR. GREEN:

25 A. Yes, in February of 2004, or was it -- early

1 protocols that you had used in your DAKO

2 system and input those into your Ventana

3 System?

4 MR. GREEN:

5 A. We didn't go verbatim, no.

6 CHAYTOR, Q.C.:

7 Q. So you know with respect to the ER antibody,

8 any change that took place to the protocol

9 from the DAKO System to the Ventana?

10 MR. GREEN:

11 A. The biggest change would have been the antigen

12 retrieval. We would have worked with a

13 standard antigen retrieval. On the CCI, which

14 would be EETA 48 solution, which was Ph8 as

15 opposed to the one which was used on the DAKO

16 which was pH -- which was citrate buffer Ph6,

17 and that one went for 20 minutes between 95

18 and 100 degrees, an extra 30 minutes on the

19 bench. It's still an antigen retrieval, but

20 the temperature was cooling down. That would

21 be the biggest change.

22 CHAYTOR, Q.C.:

23 Q. So even for the time period when you were

24 continuing to use the antibodies that you had

25 in your supply or in your inventory, you still

1 2004, I went to Tucson, Arizona, to Ventana's

2 data training and a production area there. We

3 went there for -- myself and Barry Dyer went

4 there for a week to get hands-on training as

5 well as classroom training.

6 CHAYTOR, Q.C.:

7 Q. And what was involved in the classroom

8 training?

9 MR. GREEN:

10 A. The classroom training would be theory,

11 immunoperoxidase basics, and theory, how to

12 set up a protocol, which antigen retrievals to

13 use, the significance of antigen retrieval,

14 significance of antibody incubation time.

15 CHAYTOR, Q.C.:

16 Q. And this is February, 2004?

17 MR. GREEN:

18 A. Yes.

19 CHAYTOR, Q.C.:

20 Q. And were there things that you learned in that

21 process that you didn't know before?

22 MR. GREEN:

23 A. Every day was a learning process for me at

24 this point because this whole IHC area was

25 fairly new, so my knowledge increased greatly

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1 starting with the Ventana training.

2 CHAYTOR, Q.C.:

3 Q. So I take it that was an helpful process for

4 you, not only just in terms of how to

5 operationalize the machine, but how to

6 understand the theory behind IHC?

7 MR. GREEN:

8 A. It's invaluable background into not just how

9 to do something, but why to do it, how to

10 troubleshoot, what to go wrong -- when

11 something goes wrong, how to trace back and

12 find the problem.

13 CHAYTOR, Q.C.:

14 Q. And you say Mr. Dyer also went on that

15 training exercise with you?

16 MR. GREEN:

17 A. That's true.

18 CHAYTOR, Q.C.:

19 Q. You spent some time in the classroom and the

20 rest you spent actually learning how to use

21 the machine?

22 MR. GREEN:

23 A. They had several machines set up there, maybe

24 12/14 machines, and they had classroom

25 sessions set up, week sessions, for all over

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1 the country. So you would interact with

2 people. There were people there from Florida,

3 people from Texas, mostly from different parts

4 of the US, so -- who were buying their

5 equipment and they were getting training, and

6 you would also get to interact with these

7 people and learn how their hospitals work, how

8 their laboratories work. So that was a good

9 aspect too.

10 CHAYTOR, Q.C.:

11 Q. Did you actually bring down slides from the

12 Health Sciences Centre?

13 MR. GREEN:

14 A. We did.

15 CHAYTOR, Q.C.:

16 Q. You did?

17 MR. GREEN:

18 A. We brought down slides so that we could stain

19 our slides on their equipment down there.

20 CHAYTOR, Q.C.:

21 Q. And do you know how many slides you brought

22 down?

23 MR. GREEN:

24 A. Not specifically. I know Barry carried the

25 slides himself, and they were probably in one

Page 222

1 of our plastic slide containers, probably 40

2 or 50 slides.

3 CHAYTOR, Q.C.:

4 Q. Forty or fifty slides?

5 MR. GREEN:

6 A. I'm just guessing. I really don't know.

7 CHAYTOR, Q.C.:

8 Q. Yes, okay, and -- so then you used your own

9 slides that you had processed in-house back in

10 St. John's and used those for staining while

11 you were in Arizona?

12 MR. GREEN:

13 A. Yes.

14 CHAYTOR, Q.C.:

15 Q. And was there any feedback given -- was anyone

16 interacting with you on that from Ventana in

17 terms of the quality of the staining of those

18 slides?

19 MR. GREEN:

20 A. The quality of our stains were just as good or

21 better than the quality of the other people

22 who were there who had brought slides.

23 CHAYTOR, Q.C.:

24 Q. Okay, and would pathologists be involved in

25 this training exercise?

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1 MR. GREEN:

2 A. They -- not to my knowledge, not that I know.

3 They had a person who was -- that was her job.

4 CHAYTOR, Q.C.:

5 Q. So she wasn't a pathologist?

6 MR. GREEN:

7 A. I don't think so.

8 CHAYTOR, Q.C.:

9 Q. So in terms of looking at the quality of the

10 slides, was there any feedback given to you

11 regarding any issues about the quality of the

12 slides that you brought down?

13 MR. GREEN:

14 A. No.

15 CHAYTOR, Q.C.:

16 Q. Were you taught how to maintain the Ventana

17 machine, how to clean it and what would be

18 necessary?

19 MR. GREEN:

20 A. That would be part of the training.

21 CHAYTOR, Q.C.:

22 Q. And what did you understand in terms of how

23 frequently cleaning and maintenance were

24 supposed to take place?

25 MR. GREEN:



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1 A. There's daily maintenance on the Ventana  
 2 machine, and there's monthly maintenance, and  
 3 quarterly maintenance, and the company will do  
 4 the annual preventive maintenance.  
 5 CHAYTOR, Q.C.:  
 6 Q. And you came back to St. John's. How did you  
 7 feel in terms of your comfort level after that  
 8 week in being able to operate the Ventana  
 9 machine?  
 10 MR. GREEN:  
 11 A. It was -- the comfort level had increased  
 12 greatly because by that time we had been  
 13 learning the machine for a couple of months,  
 14 so we knew some parts of running it, but this  
 15 gave us a much greater comfort level in  
 16 operating the machine.  
 17 CHAYTOR, Q.C.:  
 18 Q. And in terms of the other technologists then,  
 19 I guess, Mary and Peggy, how did they then  
 20 learn how to use the Ventana machine?  
 21 MR. GREEN:  
 22 A. Peggy was left by this time.  
 23 CHAYTOR, Q.C.:  
 24 Q. Peggy was -- right, yes, Peggy is gone in '03,  
 25 that's right.

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1 MR. GREEN:  
 2 A. Yeah, the Ventana system --  
 3 CHAYTOR, Q.C.:  
 4 Q. So it's Les and Mary.  
 5 MR. GREEN:  
 6 A. It would be Les and Mary, and so -- basically  
 7 I trained Mary and Les how to operate the  
 8 machine, brought back the training manual that  
 9 I had there and discussed with them the  
 10 procedures and the knowledge that I had  
 11 brought back.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, and how long did that take for you to  
 14 train them?  
 15 MR. GREEN:  
 16 A. It was ongoing. It probably took place over  
 17 the following month after I returned because  
 18 we were still taking turns on the machine. So  
 19 when it was Mary's turn on the machine, I  
 20 would tell -- pass on the information to her,  
 21 and when it was Les' turn, I would pass on the  
 22 information to him.  
 23 CHAYTOR, Q.C.:  
 24 Q. So when it was Mary's week to operate --  
 25 MR. GREEN:

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1 A. Operate the machine.  
 2 CHAYTOR, Q.C.:  
 3 Q. The IHC, the DAKO, I guess, was still in  
 4 operation?  
 5 MR. GREEN:  
 6 A. By this point the DAKO was probably winding  
 7 down, but when myself and Barry were working  
 8 on the Ventana system, Mary and Les  
 9 concentrated on running the DAKO.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. So while you and Barry were using the  
 12 Ventana to do the concordant study, they would  
 13 be doing the tests on the DAKO?  
 14 MR. GREEN:  
 15 A. On the DAKO.  
 16 CHAYTOR, Q.C.:  
 17 Q. So at some period then, I take it, it would be  
 18 Mary, though --  
 19 MR. GREEN:  
 20 A. Yeah.  
 21 CHAYTOR, Q.C.:  
 22 Q. Or Les. So both of you then would have been  
 23 in the IHC lab at the same -- a portion of the  
 24 lab at the same time?  
 25 MR. GREEN:

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1 A. Yeah, and what we would do, I would set up  
 2 runs and then Les or Mary would set up runs  
 3 after, and if they had any questions, they  
 4 would ask.  
 5 CHAYTOR, Q.C.:  
 6 Q. And I'm just thinking in terms of the amount  
 7 of training then that they received and you  
 8 came back and taught them how to do this, that  
 9 was done, I take it, while the Ventana machine  
 10 was up and running, you would work with them  
 11 for a period of time?  
 12 MR. GREEN:  
 13 A. Yes, yeah, that's true.  
 14 CHAYTOR, Q.C.:  
 15 Q. And how long did that last? For example, if it  
 16 was a week on -- you were still on your weekly  
 17 rotations at that point, were you?  
 18 MR. GREEN:  
 19 A. It was shortly after that that once we moved  
 20 down -- we had moved down to our new location  
 21 by that time, and we had our separate area.  
 22 So by that time we were starting to move away  
 23 from the general lab and most of our time  
 24 would be spent down in Immunohistochemistry.  
 25 CHAYTOR, Q.C.:

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1 Q. Now this would be April, 2004, I take it?

2 MR. GREEN:

3 A. Yes.

4 CHAYTOR, Q.C.:

5 Q. So that's when you started your training of

6 Mary and Les. How many slides would fit on

7 the Ventana machines? We heard that it's 48

8 on the DAKO. How many were on the new

9 Ventana?

10 MR. GREEN:

11 A. We had two Ventana machines, two bench marks,

12 and they would accommodate 20 slides each.

13 CHAYTOR, Q.C.:

14 Q. And did you have two from the beginning in

15 April, 2004?

16 MR. GREEN:

17 A. Yes, we had two.

18 CHAYTOR, Q.C.:

19 Q. So you had two machines, so you were able to

20 do 40?

21 MR. GREEN:

22 A. Forty slides.

23 CHAYTOR, Q.C.:

24 Q. And in terms of the validation exercises or

25 concordance studies that you and Mr. Dyer

Page 229

1 carried out, that had to be done on two

2 machines then?

3 MR. GREEN:

4 A. Yes.

5 CHAYTOR, Q.C.:

6 Q. So that period of time, there were two

7 machines that actually had to be validated?

8 MR. GREEN:

9 A. Yes.

10 CHAYTOR, Q.C.:

11 Q. Do you know what happened to the DAKO machine?

12 MR. GREEN:

13 A. After the DAKO machine was taken out of

14 service, it was stored in the back of the lab

15 for a while, maybe five or six months, and as

16 far as I know, it was sold to a person -- one

17 of the people who does repairs on equipment in

18 the hospital.

19 CHAYTOR, Q.C.:

20 Q. Do you know who that person is?

21 MR. GREEN:

22 A. Probably Joe White.

23 CHAYTOR, Q.C.:

24 Q. Joe White?

25 MR. GREEN:

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1 A. Yeah.

2 CHAYTOR, Q.C.:

3 Q. And do you know what he used the machine for

4 or why he would have acquired it?

5 MR. GREEN:

6 A. He probably would have sold it.

7 CHAYTOR, Q.C.:

8 Q. Sold it again?

9 MR. GREEN:

10 A. Resold it.

11 CHAYTOR, Q.C.:

12 Q. Resold it, yes. You say it was about five or

13 six months after. So by the time these issues

14 arose in the spring of 2005, the ER/PR issues

15 that we're dealing with, was the DAKO machine

16 already gone out of the hospital by then?

17 MR. GREEN:

18 A. It was long gone by then.

19 CHAYTOR, Q.C.:

20 Q. Okay.

21 MR. GREEN:

22 A. It was shortly after we had the two Ventana

23 machines that we realized that we had a

24 problem with running controls, and if we --

25 the Ventana machine with only 20 slides, if we

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1 ran a control for each patient, we would cut

2 our volume by 50 percent. So Barry had been

3 in Montreal, some part of Quebec, Montreal, I

4 think, and he had visited a hospital there and

5 they had used controls on their slides. So he

6 proposed that we cut our controls and put them

7 on individual slide. That way we could -- not

8 only would be have a positive control on each

9 slide, but we would increase our volume of

10 slides. It would double the volume of slides

11 that we could run. On the DAKO system, the

12 slide was divided into three zones, three drop

13 zones, and you had to pick a zone. If you

14 picked all three zones, you would need three

15 times as much antibody. On the Ventana

16 system, it was designed to use 100 microlitres

17 of antibody per slide, and the machine didn't

18 care if there was one piece of tissue on a

19 slide or two or three, it didn't matter. So

20 we could have some quality control and some

21 cost savings by running the control slide --

22 control on top of the slide.

23 CHAYTOR, Q.C.:

24 Q. And when that -- so that decision was made

25 before any issue arose in 2005?

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1 MR. GREEN:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. That was already the practice by the time  
 5 May/June of 2005 came around?  
 6 MR. GREEN:  
 7 A. Yeah, and shortly after we started doing that,  
 8 then we would show the slides to Dr. Ejeckam  
 9 and he kind of liked that idea too, put the  
 10 control on top of the slide. Dr. Ejeckam was  
 11 very knowledgeable in the DAKO System. The  
 12 Ventana was new to him also. So he was  
 13 starting to come around and take a liking to  
 14 the machine by that time.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, so I take it he didn't initially embrace  
 17 it?  
 18 MR. GREEN:  
 19 A. He was comfortable with the DAKO machine  
 20 because that's what he knew.  
 21 CHAYTOR, Q.C.:  
 22 Q. Yes.  
 23 MR. GREEN:  
 24 A. Even after we had the Ventana up and running,  
 25 and we would run into a problem with an

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1 antibody, he would come and he would say we're  
 2 going to have to change the dilution of this  
 3 antibody, this is not working well enough for  
 4 me. I would check out which antibody we were  
 5 using and if it was a pre-diluted, I'd say,  
 6 no, we can't alter the dilution of the  
 7 antibody, but we can change the antigen  
 8 retrieval or we can change the primary  
 9 antibody incubation time, and after he got  
 10 past that stage, he was quite receptive to it.  
 11 CHAYTOR, Q.C.:  
 12 Q. The idea that Barry had to put the control  
 13 slide on the patient slide, initially when  
 14 that was done, or that decision was made, was  
 15 that decision or was that idea discussed? Do  
 16 you know if any pathologist had any input into  
 17 that decision?  
 18 MR. GREEN:  
 19 A. Not that I know of, but from hearing Dr.  
 20 Ejeckam's testimony, I think he wanted to take  
 21 credit for that too. Usually when you do  
 22 something good, everybody wants to take credit  
 23 for it, and when you do something bad, nobody  
 24 wants to take credit for it.  
 25 CHAYTOR, Q.C.:

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1 Q. And I'm just thinking in terms of how much of  
 2 a control was put on the slide at that point  
 3 in time? Was it just -- because I understand  
 4 now there's more than one control, there's --  
 5 MR. GREEN:  
 6 A. At that time, the control -- we would have  
 7 used the controls that we had which were  
 8 larger. After we started to develop our  
 9 control bank, we would make smaller sections  
 10 of control so that we could use -- I can show  
 11 you a positive control, if you wish.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, that would be great. So you've brought  
 14 some slides with you?  
 15 MR. GREEN:  
 16 A. Yeah, this one here is a positive control,  
 17 which is a small tissue on the top. The  
 18 patient's tissue would be put on the bottom.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay.  
 21 MR. GREEN:  
 22 A. And these are what we call triple controls.  
 23 These are ER/PR controls. There are three  
 24 pieces of tissue on that. So when we run an  
 25 ER/PR now, it'll have the ER positive on the

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1 top, patient's tissue will be on the bottom.  
 2 We will run an adjacent slide with the  
 3 patient's tissue only, which will be a  
 4 negative control, and for each patient gets  
 5 treated like that, and for the batch, we will  
 6 run a triple control, which is there will be  
 7 ER negative on this one here. There'll be an  
 8 ER intermediate and there'll be an ER  
 9 positive, and the same will apply to the PR.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, and when did that become your practice?  
 12 MR. GREEN:  
 13 A. That became the practice after we resumed  
 14 ER/PR.  
 15 CHAYTOR, Q.C.:  
 16 Q. In February 2007?  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and Mr. Dyer's initial idea to have the  
 21 control tissue on the patient slide, I take  
 22 it, was only one control placed at that time,  
 23 was that?  
 24 MR. GREEN:  
 25 A. Yes, one positive control.

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1 CHAYTOR, Q.C.:

2 Q. One positive control.

3 MR. GREEN:

4 A. Because not only ER/PR. We run a positive

5 control on all antibodies on all slides now.

6 CHAYTOR, Q.C.:

7 Q. Okay, and at the time when it was just one

8 external control being used, who--what type of

9 control--because I know now you're talking

10 about, you know, a strongly positive or what -

11 MR. GREEN:

12 A. That would be -

13 CHAYTOR, Q.C.:

14 Q. So what was used?

15 MR. GREEN:

16 A. This is a positive control, strong positive.

17 CHAYTOR, Q.C.:

18 Q. A strong positive?

19 MR. GREEN:

20 A. Yes.

21 CHAYTOR, Q.C.:

22 Q. Okay, so the tissue that was chosen for your

23 controls, when it was only one, was a strong

24 positive?

25 MR. GREEN:

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1 A. Yeah.

2 CHAYTOR, Q.C.:

3 Q. Okay.

4 THE COMMISSIONER:

5 Q. Okay, let me make sure I now understand what

6 the current practice is. So that if you are

7 doing an ER, for example, you will have a

8 piece of patient tissue, which, as I

9 understand it, will contain the internal

10 control and the tumour?

11 MR. GREEN:

12 A. Yes.

13 THE COMMISSIONER:

14 Q. And in addition, on that same slide, there

15 will be a strongly positive control which is

16 know to you?

17 MR. GREEN:

18 A. That's correct.

19 THE COMMISSIONER:

20 Q. And in the next spot over, there will be a

21 separate slide which will have--I'm not sure

22 I've got the order right, but there will be

23 another slide with three controls on it?

24 MR. GREEN:

25 A. Yes.

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1 THE COMMISSIONER:

2 Q. And there will be also the piece of--a

3 separate slide with a piece of tissue which is

4 the negative control?

5 MR. GREEN:

6 A. Yes, the negative will be the patient's

7 tissue, which is subjected to the same

8 protocol as the ER protocol, except a primary

9 antibody will be omitted.

10 THE COMMISSIONER:

11 Q. All right.

12 MR. GREEN:

13 A. And the theory being that the antigen antibody

14 reaction should not take place if you don't

15 have the primary antibody there to begin with.

16 So this will show any staining that's in the

17 tissue.

18 THE COMMISSIONER:

19 Q. Okay. So effectively for each patient, there

20 are two slides which are unique to that

21 patient?

22 MR. GREEN:

23 A. Correct.

24 THE COMMISSIONER:

25 Q. And then there is the third one which is

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1 relevant which would--but is for the batch?

2 MR. GREEN:

3 A. Yes, that's correct.

4 THE COMMISSIONER:

5 Q. And that same thing--and if someone orders

6 both ER and PR to be done, then you multiple

7 that by two because the same process -

8 MR. GREEN:

9 A. Same process for the PR, yes, exactly.

10 THE COMMISSIONER:

11 Q. Okay, thank you.

12 MR. GREEN:

13 A. And then on the ER/PR, when these slides are

14 run, those were--they were sent to the St.

15 Clare's Hospital, to the Breast Group, and the

16 Breast Group would read the slides and we

17 would run a duplicate control, which we would

18 keep in the lab and we would print from the

19 Ventana machine the run reports which shows

20 all the antigens used, the antibodies used,

21 the reagents used, their expiry dates, their

22 lot numbers, and the total run report with all

23 the patients, that would go with the slides to

24 the Breast Group to read.

25 CHAYTOR, Q.C.:

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1 Q. Okay, and you'd also retain a copy for your  
2 records?

3 MR. GREEN:

4 A. For our records, yes.

5 CHAYTOR, Q.C.:

6 Q. And those slides that you were just using to  
7 demonstrate, are those just blank slides?

8 MR. GREEN:

9 A. No, those are real slides.

10 CHAYTOR, Q.C.:

11 Q. They are real slides with actual tissue on  
12 them, are they?

13 MR. GREEN:

14 A. Yes.

15 CHAYTOR, Q.C.:

16 Q. Okay, and no, I was thinking they were just--I  
17 couldn't see from here that they were blank,  
18 but written on them, which controls they would  
19 be.

20 MR. GREEN:

21 A. Yeah, what we do, we also--the date of the  
22 batch control is on the top and we will put  
23 the run number on the slide. The run number,  
24 every run that the machine does is  
25 sequentially numbered, so we can go back into

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1 the computer on the machine and call up that  
2 run number at any time and print that out.

3 CHAYTOR, Q.C.:

4 Q. Okay. I don't know if it's useful to you,  
5 Commissioner, if you would actually want to  
6 see those slides?

7 THE COMMISSIONER:

8 Q. I think it probably resembles a slide which  
9 I've had an opportunity to see already, but I  
10 will, during the break, have a look.

11 CHAYTOR, Q.C.:

12 Q. Okay, and Mr. Green, I'm going to ask you more  
13 about the current process too in a minute. I  
14 just want to reflect back on the DAKO days for  
15 a moment, or actually, any time period, I  
16 guess, with--I'm wondering if there were any  
17 other interruptions in the work of the lab  
18 during your time there, from 2002 forward?

19 MR. GREEN:

20 A. Not that I'm aware of. I know from listening  
21 to the Commission about the letter from Dr.  
22 Ejeckam.

23 CHAYTOR, Q.C.:

24 Q. Yes, and I'll ask you about that, yes. What  
25 about labour strikes or labour interruptions?

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1 MR. GREEN:

2 A. Part of the last labour dispute, I was--we had  
3 the Ventana system then.

4 CHAYTOR, Q.C.:

5 Q. The Ventana was in operation?

6 MR. GREEN:

7 A. Yeah.

8 CHAYTOR, Q.C.:

9 Q. So sometime after April 2004?

10 MR. GREEN:

11 A. Yes.

12 CHAYTOR, Q.C.:

13 Q. Okay, and who ran any IHC testing that was  
14 required during the labour strike?

15 MR. GREEN:

16 A. I was designated as essential. I'm pretty  
17 well sure Les was designated as essential, and  
18 Mary. Barry would have ran the first couple,  
19 maybe the first day. After that, we would be  
20 called in as necessary to run the machine.

21 CHAYTOR, Q.C.:

22 Q. So Mr. Dyer ran for -

23 MR. GREEN:

24 A. Probably the first day of the strike,  
25 probably, and after that we were designated

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1 essential.

2 CHAYTOR, Q.C.:

3 Q. You were called back to work?

4 MR. GREEN:

5 A. We were called back as needed.

6 CHAYTOR, Q.C.:

7 Q. Okay, and we've heard that there was a flood  
8 at some point in the lab. Do you recall that?

9 MR. GREEN:

10 A. Yes.

11 CHAYTOR, Q.C.:

12 Q. When did that take place?

13 MR. GREEN:

14 A. I don't know specifically. I just know that  
15 there were workers doing work on the floor  
16 above and somebody hit a pipe with a  
17 sledgehammer and the fire alarm, sprinklers,  
18 flooded the lab.

19 CHAYTOR, Q.C.:

20 Q. Okay, and was that after the Ventana was  
21 brought in or still in DAKO days?

22 MR. GREEN:

23 A. I'm pretty well sure that was DAKO.

24 CHAYTOR, Q.C.:

25 Q. Okay, and what happened to--did this affect

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1 the IHC portion of the lab?

2 MR. GREEN:

3 A. The only thing it probably would have affected

4 would have been any paperwork that we had

5 around.

6 CHAYTOR, Q.C.:

7 Q. Okay, so you lost some paperwork?

8 MR. GREEN:

9 A. Yeah. Antibodies wouldn't be affected. They

10 would be in the fridge. I'm not aware of any

11 ill effects from it.

12 CHAYTOR, Q.C.:

13 Q. Okay, and what about the machinery itself?

14 Were they--was that affected? Was there any

15 water -

16 MR. GREEN:

17 A. As far as I know, it wasn't affected.

18 CHAYTOR, Q.C.:

19 Q. Okay. Did the lab have to relocate for a

20 period of time?

21 MR. GREEN:

22 A. We did. We moved over to the medical school.

23 CHAYTOR, Q.C.:

24 Q. So the entire pathology lab?

25 MR. GREEN:

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1 A. I'm pretty well sure the whole lab was closed

2 down.

3 CHAYTOR, Q.C.:

4 Q. And how long did that last?

5 MR. GREEN:

6 A. Probably a couple of weeks.

7 CHAYTOR, Q.C.:

8 Q. So the DAKO machine would have been moved out

9 and moved back?

10 MR. GREEN:

11 A. I'm not really clear on which machine was

12 there and what time it was.

13 CHAYTOR, Q.C.:

14 Q. But whatever machine was there doing the IHC

15 testing, the machinery was physically moved to

16 the medical school?

17 MR. GREEN:

18 A. I don't recall the IHC equipment being moved.

19 CHAYTOR, Q.C.:

20 Q. Okay. So perhaps Mr. Dyer would have a better

21 recollection of that?

22 MR. GREEN:

23 A. He probably would, yeah.

24 CHAYTOR, Q.C.:

25 Q. You indicated earlier this morning, in your

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1 time at St. Clare's, there was a fairly close

2 working relationship between the technical

3 staff and the pathologists and you had fairly

4 frequent interaction and at Health Science, it

5 wasn't quite the same amount of interaction.

6 MR. GREEN:

7 A. No.

8 CHAYTOR, Q.C.:

9 Q. Was there any issues though of any tension

10 between medical technologists and the medical

11 staff?

12 MR. GREEN:

13 A. No, I've always had a good relationship with

14 all the pathologists there, and as I spent

15 more time at the Health Science and got to

16 know the pathologists, the same kind of

17 relationship developed that I've had at St.

18 Clare's.

19 CHAYTOR, Q.C.:

20 Q. And are you aware whether or not there was, in

21 general, any issues between the technical side

22 of the staff and the medical side?

23 MR. GREEN:

24 A. From a technologist's point of view, I'm not

25 aware of any. There may have been some issues

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1 between management and pathologists, but

2 that's kind of -

3 CHAYTOR, Q.C.:

4 Q. Nothing at your level, nothing--all right.

5 MR. GREEN:

6 A. Nothing that I can speak to.

7 CHAYTOR, Q.C.:

8 Q. Okay.

9 MR. GREEN:

10 A. But from a technologist's point of view,

11 there's always been a great relationship

12 between the pathologists at St. Clare's and at

13 the Health Science. I've never had--

14 personally, I've never had a problem with

15 pathologists.

16 CHAYTOR, Q.C.:

17 Q. Okay, and if there were any issues or

18 questions that you needed to ask regarding

19 your processes, the pathologists were

20 approachable to answer any questions you may

21 have?

22 MR. GREEN:

23 A. More than willing to help at any time.

24 CHAYTOR, Q.C.:

25 Q. Okay, and with respect to Dr. Ejeckam, did he

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1 take a particular interest in trying to train  
 2 the technologists?  
 3 MR. GREEN:  
 4 A. Yeah, he did. He would--after we had the  
 5 Ventana system up and operating, we would go  
 6 to him for controls and he developed a--he got  
 7 us to set up a control bank where he would--so  
 8 we would have controls to draw from. He would  
 9 set up sessions on the multi-headed scope so  
 10 that we could review the controls and the  
 11 patient's tissue and that's where I first  
 12 learned about internal controls, from Dr.  
 13 Ejeckam, and we were particularly interested  
 14 in the breast tissue at that time and that was  
 15 the time that he would show us the internal  
 16 controls, the ductal epithelium to explain  
 17 that it should be--it should normally be  
 18 positive, but not necessarily 100 percent of  
 19 the time. There are times when it won't be,  
 20 but as a general rule. So before that, we  
 21 weren't aware of those.  
 22 CHAYTOR, Q.C.:  
 23 Q. Okay, and how knowledgeable did Dr. Ejeckam  
 24 appear to you to be in IHC?  
 25 MR. GREEN:

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1 A. From my perspective, he was probably the most  
 2 knowledgeable pathologist for IHC that I knew.  
 3 CHAYTOR, Q.C.:  
 4 Q. Was there a point in time where you sensed  
 5 from Dr. Ejeckam that he was becoming  
 6 frustrated?  
 7 MR. GREEN:  
 8 A. He didn't hide his feelings. When he was  
 9 frustrated, you knew he was frustrated, and  
 10 there were times when he was. He had a  
 11 particular vision in mind for the laboratory.  
 12 One was he wanted a separate space. He wanted  
 13 dedicated technologists full time and when  
 14 things didn't move fast enough for him, he  
 15 would be upset.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, and you -  
 18 MR. GREEN:  
 19 A. But he would be upset at us, but he would be  
 20 upset at the system.  
 21 CHAYTOR, Q.C.:  
 22 Q. And he'd voice that to you?  
 23 MR. GREEN:  
 24 A. On many occasions, yes.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. So things weren't--the changes he  
 2 wanted to see happening in IHC weren't taking  
 3 place quickly enough for him?  
 4 MR. GREEN:  
 5 A. They weren't taking place quickly enough for  
 6 him. He had been used to working, I think it  
 7 was in Dohar.  
 8 CHAYTOR, Q.C.:  
 9 Q. Yes.  
 10 MR. GREEN:  
 11 A. And I think things moved a bit faster there,  
 12 and he had--he brought a copy of the manual  
 13 that they used in Dohar, so he wanted us to  
 14 prepare a manual that was similar to that one.  
 15 CHAYTOR, Q.C.:  
 16 Q. So a manual like a standard operating  
 17 procedure manual?  
 18 MR. GREEN:  
 19 A. Yeah, like a manual procedures for IHC. So he  
 20 gave me that manual which we read over and I  
 21 took that one and adapted it to--because that  
 22 one had DAKO information and I adapted it to  
 23 the Ventana system, and we used a lot of the  
 24 information from that. I revised it and  
 25 brought it back to him and he said "it's a

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1 good start," but that's the way he was, you  
 2 know. He always wanted us to do better and he  
 3 told us that we could be the best and he was  
 4 on his way to teaching us to go that route.  
 5 CHAYTOR, Q.C.:  
 6 Q. So the manual that you did an initial draft  
 7 for, would that contain things like--was that  
 8 policies and procedures like we see in what  
 9 you've prepared now?  
 10 MR. GREEN:  
 11 A. It was more of a technical manual.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay.  
 14 MR. GREEN:  
 15 A. It's a step A, B and C to doing procedures and  
 16 procedures, say, for immuno fluorescence, the  
 17 procedures they ran with the DAKO system,  
 18 dilutions and technical like that, not a  
 19 standard operating procedures manual.  
 20 CHAYTOR, Q.C.:  
 21 Q. So did you ultimately get that technical  
 22 manual developed?  
 23 MR. GREEN:  
 24 A. I believe, we did a clone of the one that he  
 25 had, yeah.

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1 CHAYTOR, Q.C.:

2 Q. And when was that? When did you -

3 MR. GREEN:

4 A. That would have been around 2005, I would say,

5 at the same time he started teaching us to

6 read controls.

7 CHAYTOR, Q.C.:

8 Q. Okay.

9 MR. GREEN:

10 A. And he would--he'd set up lectures so that all

11 the staff could be involved. He'd give

12 lectures on formalin fixation and tissue

13 processing, slide preparation,

14 troubleshooting, defects in tissue, especially

15 defects in lymph node tissues and stuff like

16 that. So he was proactive in that sense.

17 CHAYTOR, Q.C.:

18 Q. And I take it you learned a lot through Dr.

19 Ejeckam?

20 MR. GREEN:

21 A. That was when we started to take this IHC onto

22 its own and make it a separate department.

23 CHAYTOR, Q.C.:

24 Q. And after Dr. Ejeckam left, did another

25 pathologist take up his torch?

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1 MR. GREEN:

2 A. I think Dr. Makarla probably filled in for a

3 while. Dr. Makarla had come from the U.S. He

4 had spent time down in Arizona. Matter of

5 fact, he had worked with one of the

6 pathologists who designed the Ventana system

7 and he knew him quite well. So I figured,

8 great, we've got a person on the inside, and

9 he was quite willing to make his contact

10 there, but he didn't stay around long enough

11 to--he started to work with it, but he didn't

12 stay around that long.

13 CHAYTOR, Q.C.:

14 Q. And after Dr. Makarla, did somebody else step

15 up?

16 MR. GREEN:

17 A. I think Dr. Dan Fontaine stepped in for a

18 while. Dr. Fontaine would help us with any

19 problems we have in antibodies or any

20 questions that we had.

21 CHAYTOR, Q.C.:

22 Q. And was there anyone then after Dr. Fontaine?

23 He's there's for a while assisting, I take it.

24 MR. GREEN:

25 A. There was probably a gap in between and then

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1 Dr. Ford Elms took over.

2 CHAYTOR, Q.C.:

3 Q. Okay, and I understand that's after the issues

4 arise in 2005?

5 MR. GREEN:

6 A. Yes.

7 CHAYTOR, Q.C.:

8 Q. That Dr. Elms steps up?

9 MR. GREEN:

10 A. Yeah.

11 CHAYTOR, Q.C.:

12 Q. Okay, and so in terms of another pathologist

13 in that year or so after Dr. Ejeckam leaves

14 filling the gap, was there the same type of

15 interest shown to the staff, towards staff

16 training, by any other pathologist that Dr.

17 Ejeckam had displayed?

18 MR. GREEN:

19 A. Dr. Bev Carter took an interest in the

20 training and education. She set up the

21 academic pathology rounds, which would take

22 place every Friday. She encouraged all the

23 residents and the pathologists and the

24 technologists to, if they went to a conference

25 or went to a lecture, so they would come back,

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1 it was their responsibility to give that

2 information to your colleagues. So she

3 included us in that process.

4 CHAYTOR, Q.C.:

5 Q. And was that the first time technologists had

6 been invited to academic rounds?

7 MR. GREEN:

8 A. Yes.

9 CHAYTOR, Q.C.:

10 Q. And does that practice still continue today?

11 MR. GREEN:

12 A. They still go on every Friday.

13 CHAYTOR, Q.C.:

14 Q. And I'm going to ask you a little bit later

15 about some continuing education that you've

16 had. Did you have an opportunity to present

17 at those academic pathology rounds?

18 MR. GREEN:

19 A. Twice. The first time, after I came back from

20 Phoenix, Arizona to the NSH conference.

21 That's a conference where it's devoted solely

22 to pathology, in the U.S., so you get a lot of

23 exposure to pathology and IHC. So after I

24 came back, she wanted me to give a report and

25 kind of an overview of the lectures and that



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1 we went to. And later on, maybe in the same  
 2 year, she wanted me to give a lecture on the  
 3 basics of immunohistochemistry.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay, and if I could just go back then to Dr.  
 6 Ejeckam's time, and I'll ask you some more  
 7 about those conferences that you attended.  
 8 Dr. Ejeckam, the Commissioner has heard that  
 9 he did raise issues with certain stains in  
 10 April 2003 initially. Two of those stains  
 11 were ER and PR. Do you recall those issues at  
 12 the time that were raised by Dr. Ejeckam?  
 13 MR. GREEN:  
 14 A. I was not aware that there was a problem with  
 15 the stains and I was not involve in the  
 16 collective actions that took place during that  
 17 time. I'm pretty well sure that Dr. Ejeckam  
 18 worked with Barry and Mary on those.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay. Now, you weren't aware of the  
 21 corrective action that took place. Do you  
 22 recall at all that there was corrective action  
 23 taking place, that there was any testing  
 24 happening or any adjustments happening?  
 25 MR. GREEN:

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1 A. I was not even aware that it happened.  
 2 CHAYTOR, Q.C.:  
 3 Q. When did you first become aware of that?  
 4 MR. GREEN:  
 5 A. When the Commission set up and all these  
 6 documents started to appear; that's when I  
 7 first saw it.  
 8 CHAYTOR, Q.C.:  
 9 Q. That's when you first learned about any  
 10 adjustments that Dr. Ejeckam had made or any  
 11 issues he brought forward.  
 12 MR. GREEN:  
 13 A. Because I was surprised that the assumption  
 14 was made that the lab had shut down. As long  
 15 as I've been there, I was never aware that the  
 16 lab was shut down.  
 17 CHAYTOR, Q.C.:  
 18 Q. No.  
 19 MR. GREEN:  
 20 A. I'm sure somebody would have told me when I  
 21 showed up for work.  
 22 CHAYTOR, Q.C.:  
 23 Q. And what about the suspension of any testing  
 24 for those particular eight stains, were you  
 25 aware that had happened?

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1 MR. GREEN:  
 2 A. I was not aware.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay. And I take it you learned that too then  
 5 much later in 2007.  
 6 MR. GREEN:  
 7 A. So, obviously it happened on the two week  
 8 stint that I had been out of the IHC area.  
 9 CHAYTOR, Q.C.:  
 10 Q. But you weren't in there?  
 11 MR. GREEN:  
 12 A. No.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. If we could look at, please, P-0113 and  
 15 this is the first of Dr. Ejeckam's memos,  
 16 April 4, 2003 and this where he writes that,  
 17 "kindly note"--"this is sent to pathologists,  
 18 Health Sciences, St. Clare's and out of town  
 19 hospitals. Kindly note that  
 20 immunohistochemical stains with the following  
 21 antibodies" and there's a list which include  
 22 ER and PR have remained unreliable, erratic  
 23 and therefore unhelpful for diagnostic  
 24 purposes. Consequent, on the above staining  
 25 with these antibodies shall stop forthwith

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1 until we can solve the reliability,  
 2 sensitivity and specificity problems. Efforts  
 3 are underway and hopefully a solution will be  
 4 found within the next four to six weeks.  
 5 You'll be duly informed when such stains can  
 6 resume". And it's indicated to be copied to  
 7 Barry Dyer as well as all technical staff on  
 8 immunohistochemistry.  
 9 Mr. Green, did you receive a copy of this  
 10 memo?  
 11 MR. GREEN:  
 12 A. No.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay. Do you know of if any of the  
 15 technologists received a copy of this memo?  
 16 MR. GREEN:  
 17 A. Not that I'm aware of. I'm pretty sure if  
 18 Mary or Les had received a copy, that would  
 19 have shared that information with me.  
 20 CHAYTOR, Q.C.:  
 21 Q. You would have expected they would have -  
 22 MR. GREEN:  
 23 A. I would expect that they would.  
 24 CHAYTOR, Q.C.:  
 25 Q. Yes.

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1 MR. GREEN:  
 2 A. This is the second time I've seen it. The  
 3 first time I seen it was when Dan Simmons  
 4 showed it to me earlier the week.  
 5 CHAYTOR, Q.C.:  
 6 Q. Earlier this week?  
 7 MR. GREEN:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. Okay. And do you have any recollection at all  
 11 that there was any suspension of or any  
 12 adjustments made to any antibodies in this  
 13 time period?  
 14 MR. GREEN:  
 15 A. Not that I'm aware of.  
 16 CHAYTOR, Q.C.:  
 17 Q. Nothing involving lymphoma markers?  
 18 MR. GREEN:  
 19 A. Not that I'm aware of.  
 20 CHAYTOR, Q.C.:  
 21 Q. If we could have please, P-2173, page five.  
 22 And these are again, the request forms that we  
 23 were referring to earlier. And you are the  
 24 tech on this one and it's completed March 21,  
 25 2003 and then it's indicated M. Butler, April

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1 28, 2003. So, it's over a month later. And  
 2 on the bottom here we see written "checked by  
 3 Dr. Ejeckam".  
 4 MR. GREEN:  
 5 A. That would be my handwriting.  
 6 CHAYTOR, Q.C.:  
 7 Q. This is probably your handwriting?  
 8 MR. GREEN:  
 9 A. Yes.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay. And what would you mean by "checked by  
 12 Dr. Ejeckam"?  
 13 MR. GREEN:  
 14 A. That means that I would have brought the  
 15 slides over to him, the control slides along  
 16 with the patient slides and he would have  
 17 checked the controls and knowing Dr. Ejeckam,  
 18 he would have looked at the patient slides too  
 19 and probably knew what the diagnosis was  
 20 before it left his office.  
 21 CHAYTOR, Q.C.:  
 22 Q. Okay. Now, this says on the top, "Dr. Elms  
 23 has ER/PR control".  
 24 MR. GREEN:  
 25 A. That's probably the first--is this a repeat?

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1 CHAYTOR, Q.C.:  
 2 Q. It's certainly indicated that there's two  
 3 different dates.  
 4 MR. GREEN:  
 5 A. Two different dates.  
 6 CHAYTOR, Q.C.:  
 7 Q. Yes, but nothing written on it to say repeat.  
 8 So, whether it's a -  
 9 MR. GREEN:  
 10 A. If Dr. Ejeckam looked at the slide, if there  
 11 was no control, he wouldn't have needed a  
 12 control. He would tell from the patient's  
 13 tissue what he needed to know.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. And if we could look then please at--  
 16 this one is March 21st and April 28th and my  
 17 only reason really in this line of  
 18 questioning, showing you this document was  
 19 whether or not there was something else  
 20 happening here other than a regular repeat,  
 21 whether or not this, in fact, was part of what  
 22 may have happened in that time period.  
 23 MR. GREEN:  
 24 A. I think maybe Dr. Ejeckam was, probably luck  
 25 of the draw that he looked at those slides.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. And if we could look at then P-2155,  
 3 please. And this is not written to yourself,  
 4 but it is a letter from DAKO on April 22nd,  
 5 2003 to Mr. Dyer and to Mary Butler. And it  
 6 includes a reference to a number of stains  
 7 including ER/PR and he writes or this person  
 8 writes, "I have taken the time to review the  
 9 information that Mary provided me with and I  
 10 have provided you with comments and  
 11 suggestions for each of the antibodies. With  
 12 a little tweaking I am sure that we can have  
 13 this whole situation ironed out in no time.  
 14 As a general comment, it is going to be  
 15 important for the future of consistently  
 16 standardized results, that all tissues are  
 17 fixed and processes identically as possible.  
 18 Since your control tissues appear to be  
 19 staining acceptably, it is reasonable to think  
 20 that the variability in staining is due to a  
 21 variability in tissue preparation. Since you  
 22 are operating a regional testing centre and  
 23 you receive samples from hospitals all across  
 24 the province, I realize that it is difficult  
 25 to control the conditions under which tissue

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1 is prepared in all cases. However, it might  
 2 be a good idea to get some guidelines for the  
 3 other hospitals so that you will always know  
 4 what you are dealing with. For example, you  
 5 can send out a letter saying that all  
 6 specimens must be fixed between 18 to 24 hours  
 7 in 10 percent neutral buffered formalin. And  
 8 since this will not be possible in all cases,  
 9 ie. at the end of a work week, you could ask  
 10 the hospital to specify the precise fixation  
 11 conditions if they deviate from the  
 12 recommended ones. This will help you by  
 13 establishing a solid connection between IHC  
 14 results and condition that the tissue was  
 15 shipped to you in. I'm not sure how much of  
 16 this, if any, will be possible for you to  
 17 accomplish, given the practical and political  
 18 situation. The more the better though!" And  
 19 then a few specific comments and suggestions  
 20 on the various antibodies including ER/PR.  
 21 "And as discussed these three antibodies  
 22 extend all primary antibody dilutions to 60  
 23 minutes, perform antigen retrieval using  
 24 target retrieval solution S1699" and it goes  
 25 on from there.

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1 Any of this information brought to your  
 2 attention in April of 2003 or that this was -  
 3 MR. GREEN:  
 4 A. No, it wasn't.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay. And the suggestions here in terms of  
 7 changes to how to conduct the ER/PR, was this  
 8 information shared with you?  
 9 MR. GREEN:  
 10 A. No. I notice that the dilution has been  
 11 changed.  
 12 CHAYTOR, Q.C.:  
 13 Q. Yes, from 1 to 50 to 1 to 20.  
 14 MR. GREEN:  
 15 A. But the second statement is interesting. "If  
 16 the staining is still inadequate, you should  
 17 try using the high pH target retrieval  
 18 solution for antigen retrieval. The high pH  
 19 buffer produces best results for all three of  
 20 these antibodies. Although tissue damage or  
 21 loss can occur". So, you probably fix -  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, and why is that of interest to you?  
 24 MR. GREEN:  
 25 A. It's interesting because when we set up the

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1 Ventana system, we had used a higher pH target  
 2 retrieval system.  
 3 CHAYTOR, Q.C.:  
 4 Q. And this is April of 2003, so was this change  
 5 not made at that point in time and not made  
 6 until April 2004?  
 7 MR. GREEN:  
 8 A. I would seriously doubt if the higher pH  
 9 antigen retrieval was ever used on the ER/PR  
 10 on the DAKO system. I was not aware of it, if  
 11 it was.  
 12 CHAYTOR, Q.C.:  
 13 Q. And you were running the test every three  
 14 weeks.  
 15 MR. GREEN:  
 16 A. Yes.  
 17 CHAYTOR, Q.C.:  
 18 Q. So, you would expect to be aware if that had  
 19 changed.  
 20 MR. GREEN:  
 21 A. From my recollection, we didn't change the  
 22 antigen retrieval on the ER/PR on all the time  
 23 that I worked on the DAKO system. I can't say  
 24 what happened before I went there.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay. And if we could look at P-2177, please.  
 2 And these are the spec sheets again that I  
 3 showed you earlier. And if we just come  
 4 forward to page seven, we see-I believe I  
 5 showed you this earlier, April 3rd, 2003, it's  
 6 1 in 50. And then April 28th, 2003, 1 in 20.  
 7 MR. GREEN:  
 8 A. One in twenty.  
 9 CHAYTOR, Q.C.:  
 10 Q. So, that's consistent with the memo I showed  
 11 you from DAKO and the recommendation.  
 12 MR. GREEN:  
 13 A. Yeah, it is.  
 14 CHAYTOR, Q.C.:  
 15 Q. And do you recall this change yourself in the  
 16 -  
 17 MR. GREEN:  
 18 A. I was never officially made aware of it, no.  
 19 The only way I would have known is when my  
 20 turn came to run the slides, that when I made  
 21 up the antibody, it would have been changed on  
 22 the antibody concentrate.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay. So, the memo that I showed you, April  
 25 22nd, 2003 from DAKO, that was never

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1 distributed to you?

2 MR. GREEN:

3 A. No.

4 CHAYTOR, Q.C.:

5 Q. If I could have, please, P-1572 and this is a

6 meeting of Surgical Pathology Review

7 Committee, April 15th, 2003. So again, this

8 is in the same time period, April 2003. And

9 Dr. Ejeckam was the chair of that committee

10 and he's in attendance with a number of other

11 physicians, and Theresa Curtis, secretary.

12 And under "New Business, 3.1, ER and PR

13 receptors, Dr. G. Ejeckam stated that the ER

14 and PR receptors are not being performed for

15 the next six weeks due to a technical

16 problem". And again, this is April 15th. You

17 have no recollection of any suspension in ER

18 and PR in that time period?

19 MR. GREEN:

20 A. No recollection for stopping that service at

21 all.

22 CHAYTOR, Q.C.:

23 Q. Okay. And obviously if it went on for that

24 long or for this period of time, it would have

25 also been during your time in rotating -

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1 MR. GREEN:

2 A. In my general rotation -

3 MR. GREEN:

4 A. Because you would rotate through every third

5 week. "If a solution cannot be found, these

6 tests will be sent outside St. John's". I

7 take it you weren't aware that that was being

8 contemplated?

9 MR. GREEN:

10 A. No.

11 CHAYTOR, Q.C.:

12 Q. He stated, "it's being considered to send one

13 or two technologists to Halifax or Toronto for

14 training". Now, in April of 2003 was that

15 ever discussed with you, that there was

16 consideration to have your or any of your

17 colleagues sent outside the province for

18 training?

19 MR. GREEN:

20 A. Dr. Ejeckam did talk to me about going outside

21 the province for training, not sure of the

22 time line, but I think--let's see--January

23 2006 was the time I went to the Jewish

24 General. This is -

25 CHAYTOR, Q.C.:

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1 Q. This is 2003, January 2003.

2 MR. GREEN:

3 A. No, it wouldn't be in the same time line at

4 all.

5 CHAYTOR, Q.C.:

6 Q. So, the first time you received training

7 outside of the province other than the Ventana

8 machine and learning to use that, the first

9 time you received any training outside the

10 province was January 2006?

11 MR. GREEN:

12 A. Ventana in 2004 in Tucson and Fort Lauderdale

13 2005.

14 CHAYTOR, Q.C.:

15 Q. Okay. When in 2005?

16 MR. GREEN:

17 A. Fort Lauderdale, September 2005.

18 CHAYTOR, Q.C.:

19 Q. Okay. So, after the issues of ER/PR arose?

20 MR. GREEN:

21 A. Yes.

22 THE COMMISSIONER:

23 Q. Ms. Chaytor, wherever you can find a spot,

24 we'll take the afternoon break.

25 CHAYTOR, Q.C.:

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1 Q. Thank you. Mr. Green, the issue--we've been

2 calling it the ER/PR issue, just our

3 abbreviated way of referring to it--when did

4 you first learn that there was such an issue?

5 MR. GREEN:

6 A. I first learned on, I think it was August 8,

7 2005, when I received a letter from Dr. Cook.

8 CHAYTOR, Q.C.:

9 Q. Okay. And I'm going to refer you to that

10 memo. So, you heard nothing verbally before

11 that?

12 MR. GREEN:

13 A. Nothing officially up until that time, I had

14 no idea what was going on, but I knew

15 something was going on because we were getting

16 increased requests for ER/PR and tests for

17 older cases for ER/PR.

18 CHAYTOR, Q.C.:

19 Q. I'm sorry, tests for?

20 MR. GREEN:

21 A. Older cases. I mean, not current patients.

22 CHAYTOR, Q.C.:

23 Q. You could tell that from the surgical number,

24 I take it.

25 MR. GREEN:

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1 A. You could tell from the surgical numbers that-

2 -your regular work load would come in and you

3 would get the current workload. And then if

4 you got numbers that were right back, you

5 know, there's probably a reason for it. But

6 officially, nobody ever mentioned it to me.

7 CHAYTOR, Q.C.:

8 Q. So, I believe that was June and July of 2005

9 that there were a number of retests taken

10 place. So, those probably what you were

11 seeing through in terms of volume.

12 MR. GREEN:

13 A. Yes.

14 CHAYTOR, Q.C.:

15 Q. But nobody spoke to you to tell you why it was

16 happening or what was going on?

17 MR. GREEN:

18 A. No.

19 CHAYTOR, Q.C.:

20 Q. Okay. And was that the subject of discussion

21 amongst you and your colleagues?

22 MR. GREEN:

23 A. You could tell that there was something going

24 on, we just didn't know what was going on and

25 there were a lot of meetings going on. So, we

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1 never knew exactly what was going on or the

2 depth or the scope of it and in hindsight,

3 maybe not a lot of people knew the depth or

4 scope in the beginning.

5 CHAYTOR, Q.C.:

6 Q. And I take it then in that, you know,

7 May/June/July, 2005, well until August 8, 2005

8 when you received a memo, and even in

9 receiving the memo, you hadn't been told

10 anything in person?

11 MR. GREEN:

12 A. No, even the memo itself, which I guess we'll

13 get to read when you're ready, the memo

14 suggests that we are sending ER/PR specimens

15 outside the province, but we will continue to

16 do ER/PR. So, ER/PR was never suspended, from

17 my point of view, in the IHC lab. We

18 continued to do our specimens as usual using

19 the protocols we had in place.

20 CHAYTOR, Q.C.:

21 Q. Yes, and I'm going to take you to that. But

22 in terms of even then, someone coming to you

23 with the memo and sitting down and explaining

24 what it meant, did anyone do that?

25 MR. GREEN:

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1 A. I think Barry dropped off the memo and that

2 was the--knowing that background.

3 CHAYTOR, Q.C.:

4 Q. And throughout the spring, May/June and in the

5 summer, July of 2005, I take it, nobody--did

6 anyone come though and ask questions about

7 your process or come and observe what was

8 happening in the lab? Was there anything

9 unusual happening like that?

10 MR. GREEN:

11 A. Not that I can recall. Somewhere along the

12 way, I heard about a case that had been ER/PR

13 negative and had been retested and it was

14 ER/PR positive, but it was never officially

15 told to me.

16 CHAYTOR, Q.C.:

17 Q. Did you learn that after receiving the memo or

18 before.

19 MR. GREEN:

20 A. It would have been after.

21 CHAYTOR, Q.C.:

22 Q. After. If we could look, please, at P-0515

23 and I think the second page will be better to

24 read. And this is a meeting of July 21st,

25 2005 between Drs. Carter, Cook and Williams.

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1 And it's just some bullets, we understand

2 these are Dr. Williams' notes, a typed version

3 of his notes of that meeting. And Dr. Carter,

4 is written here, "feels there was a problem in

5 2002, some runs on retrospect were not normal.

6 Inconsistency from one batch to another,

7 current Ventana test is picking up too much.

8 Dr. Carter also doing some work on quality

9 control and use them as controls. Techs may

10 need to be retrained on immunoperoxidase and

11 need controlled access to the room. Training

12 of techs in the immunohistochemistry needs

13 separate service; need QA and proficiency

14 testing; need to have an external consultant

15 to come to the lab and do QA.

16 So, in terms of any training that you had

17 in immunohistochemistry, did anyone make any

18 inquiries as to that in this time period?

19 MR. GREEN:

20 A. No.

21 CHAYTOR, Q.C.:

22 Q. In terms of whether or not controls were being

23 run with all of your -- with all your tests,

24 was there any discussion regarding that?

25 MR. GREEN:

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1 A. No.  
 2 CHAYTOR, Q.C.:  
 3 Q. So any suggestion that Dr. Carter may have  
 4 expressed some concern as to whether or not  
 5 controls were run with every batch, was there  
 6 ever any discussion with that -- about that  
 7 with you?  
 8 MR. GREEN:  
 9 A. Never brought to my attention.  
 10 CHAYTOR, Q.C.:  
 11 Q. And, Mr. Green, how confident are you that a  
 12 control was run with every batch of ER/PR  
 13 testing?  
 14 MR. GREEN:  
 15 A. Quite confident. It was -- it was the normal  
 16 practice for us to run controls.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay. Thank you, Commissioner, this is a good  
 19 place.  
 20 COMMISSIONER:  
 21 Q. All right, we'll take the afternoon break.  
 22 (RECESS)  
 23 COMMISSIONER:  
 24 Q. Ms. Chaytor.  
 25 CHAYTOR, Q.C.:

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1 Q. Thank you, Commissioner. We were looking at  
 2 P-0515 when we broke and the second bullet  
 3 here I think I skipped over. Mr. Green, it  
 4 says, "Sentinel case-reviewed old slides.  
 5 Program would not always run a control". I  
 6 take it that's not correct, from your point of  
 7 view?  
 8 MR. GREEN:  
 9 A. From my perspective, that's not correct.  
 10 CHAYTOR, Q.C.:  
 11 Q. It's also indicated, "That the current  
 12 Ventana's test is picking up too much, have  
 13 sent out", and there's words here missing,  
 14 "results and sent to Mount Sinai", and again  
 15 this is July 21st, 2005. Did anyone bring to  
 16 your attention any concern that the Ventana  
 17 machine was too sensitive?  
 18 MR. GREEN:  
 19 A. No, the first indication I got that that had  
 20 been mentioned was in a report by maybe Dr.  
 21 Banerjee, who said in his report, "Is the  
 22 Ventana System too sensitive", and that was  
 23 the first idea that -- the first time I've  
 24 seen that.  
 25 CHAYTOR, Q.C.:

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1 Q. When did you see Dr. Banerjee's report?  
 2 MR. GREEN:  
 3 A. When it was released by the -- when the  
 4 Commission released the report.  
 5 CHAYTOR, Q.C.:  
 6 Q. So this year?  
 7 MR. GREEN:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. In February, 2008?  
 11 MR. GREEN:  
 12 A. Yeah, that was the first time I saw the  
 13 report.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay. So you never learned that anyone had  
 16 any suggestion about the Ventana machine being  
 17 too sensitive in 2005?  
 18 MR. GREEN:  
 19 A. No.  
 20 CHAYTOR, Q.C.:  
 21 Q. And who amongst the technologists would have  
 22 been seen to be most knowledgeable about the  
 23 Ventana machine?  
 24 MR. GREEN:  
 25 A. It would be me.

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1 CHAYTOR, Q.C.:  
 2 Q. So if there were a concern about the Ventana  
 3 machine, would you have expected it to be  
 4 brought to your attention?  
 5 MR. GREEN:  
 6 A. I would have, yes.  
 7 CHAYTOR, Q.C.:  
 8 Q. If we could look, please, at P-0552, and this  
 9 is a report from Carole -- I believe -- how do  
 10 you pronounce her name, Mr. Green?  
 11 MR. GREEN:  
 12 A. Quevillon.  
 13 CHAYTOR, Q.C.:  
 14 Q. Quevillon. We've been pronouncing that wrong.  
 15 August 5th, 2005, written to Mr. Gulliver.  
 16 Now do you recall -- I've forgotten already.  
 17 MR. GREEN:  
 18 A. Quevillon. Carole, yeah.  
 19 CHAYTOR, Q.C.:  
 20 Q. You recall her visiting the lab in the  
 21 beginning of August, 2005?  
 22 MR. GREEN:  
 23 A. I do.  
 24 CHAYTOR, Q.C.:  
 25 Q. And did you - what were you told about the

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1 reason for her visit at that time?  
 2 MR. GREEN:  
 3 A. That there were problems with some antibodies  
 4 and some of the pathologists were having --  
 5 were questioning the Ventana System.  
 6 CHAYTOR, Q.C.:  
 7 Q. So you were aware that there was some  
 8 questioning about the Ventana System at that  
 9 time?  
 10 MR. GREEN:  
 11 A. Yeah, I knew that's the reason Carole was  
 12 down.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay, but whether or not it was an issue of it  
 15 being too sensitive, you weren't aware of that  
 16 kind of detail?  
 17 MR. GREEN:  
 18 A. No, I think they were questioning the whole  
 19 Ventana platform.  
 20 CHAYTOR, Q.C.:  
 21 Q. Oh, is that right, the whole system?  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and was it regarding certain antibodies

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1 or the whole system?  
 2 MR. GREEN:  
 3 A. From what I recall, it was the ER/PR.  
 4 CHAYTOR, Q.C.:  
 5 Q. ER/PR, okay. So by the beginning of August,  
 6 2005, you were aware of that. Now this  
 7 predates -- her visit predates you actually  
 8 receiving the memo from Dr. Cook on August  
 9 8th?  
 10 MR. GREEN:  
 11 A. I would have -- like I say, not officially,  
 12 but I knew that Carole was down, that she had  
 13 checked out our protocols.  
 14 CHAYTOR, Q.C.:  
 15 Q. And I guess around -- shortly before that, you  
 16 would also seeing all the ER/PR retests from  
 17 the old system?  
 18 MR. GREEN:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. Did you meet with her while she was down on  
 22 this visit?  
 23 MR. GREEN:  
 24 A. Yes.  
 25 CHAYTOR, Q.C.:

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1 Q. What did she discuss with you?  
 2 MR. GREEN:  
 3 A. I don't remember the specifics. She just went  
 4 over the machine again, took protocols. I  
 5 think she printed out copies of all our  
 6 protocols when she was down so that we could  
 7 put them in a binder where we would have hard  
 8 copies.  
 9 CHAYTOR, Q.C.:  
 10 Q. So that's printed off from the computer on the  
 11 Ventana machine?  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. And were you present when she did that then  
 16 and whatever checks she carried out on the  
 17 system?  
 18 MR. GREEN:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. And were you advised of the outcome of her  
 22 assessment?  
 23 MR. GREEN:  
 24 A. I would assume that -- well, we didn't make  
 25 any changes, so I would assume that she found

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1 no problems with the protocols.  
 2 CHAYTOR, Q.C.:  
 3 Q. And this letter that we see here drafted to  
 4 Mr. Gulliver, did you ever receive a copy or  
 5 were you ever told the contents of the letter?  
 6 MR. GREEN:  
 7 A. I've never received a copy.  
 8 CHAYTOR, Q.C.:  
 9 Q. So you assumed the fact there were no changes  
 10 to the protocols after she was in, you assumed  
 11 that she found no problem?  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. Okay.  
 16 MR. GREEN:  
 17 A. And when we enrolled in the external  
 18 proficiency program for the ER/PR, I used  
 19 identical protocols that we had been running.  
 20 Those were the slides that I sent off for the  
 21 external proficiency testing.  
 22 CHAYTOR, Q.C.:  
 23 Q. So you used the same protocols. Those were  
 24 what -- did you actually send the protocols,  
 25 though, or just your slides?

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1 MR. GREEN:  
 2 A. We send -- you would send the information from  
 3 the protocol from NEQAS. They would ask you  
 4 what antibody you used, what clone you used,  
 5 what antigen retrieval you used, antibody  
 6 incubation time. You would have to provide  
 7 all this information.  
 8 CHAYTOR, Q.C.:  
 9 Q. And that information is the same as when you  
 10 set the system up in April of 2004?  
 11 MR. GREEN:  
 12 A. Yes, we didn't change the -- if I remember,  
 13 protocols 46 and 48 were the ones that we  
 14 sent, and those were the same ones that we  
 15 sent to NEQAS.  
 16 CHAYTOR, Q.C.:  
 17 Q. I don't know if we have copies of those  
 18 protocols. We got those, okay. You don't  
 19 know the number to put your hand on them?  
 20 MR. SIMMONS:  
 21 Q. It would be in Volume 14, I think.  
 22 CHAYTOR, Q.C.:  
 23 Q. That's okay. We'll come back to it. Thank  
 24 you. In this letter then, Mr. Green, it  
 25 indicates that as per your request, so

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1 presumably Mr. Gulliver's request, "I checked  
 2 the Ventana bench mark instruments, the  
 3 procedure and protocols used for the ER and  
 4 PGR stains, the knowledge and the capacity of  
 5 the technicians to troubleshoot and run the  
 6 instruments". Now did you know that you were  
 7 -- she was also making inquiries as to your  
 8 knowledge and capacity to troubleshoot?  
 9 MR. GREEN:  
 10 A. Yeah, I was aware of that.  
 11 CHAYTOR, Q.C.:  
 12 Q. And she says, "I performed a level one on both  
 13 instruments, level one being check instrument  
 14 levels, slide volumes, rinsing volumes, bar  
 15 code reader alignment. Both instruments are  
 16 within specifications". So she checked both  
 17 Ventana machines, I take it. "I ran a full  
 18 coverage Vimentin --  
 19 MR. GREEN:  
 20 A. Vimentin.  
 21 CHAYTOR, Q.C.:  
 22 Q. "On both instruments to validate the staining  
 23 of the instruments. Both gave good results. I  
 24 checked the protocols that you are using for  
 25 the ER and PGR antibodies, CC1 standard, and

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1 32 min primary incubation. These protocols  
 2 are used in many accounts in Canada and  
 3 recommended by Ventana Medical Systems Inc. I  
 4 checked the pH of the solutions, pH within  
 5 specifications. I asked questions to the  
 6 different technicians using the instruments.  
 7 They are properly trained and able to  
 8 troubleshoot if a problem occurs. I found out  
 9 that the recommended maintenance procedures  
 10 monthly and quarterly were never done on the  
 11 instruments. We did it monthly and quarterly  
 12 on one bench mark yesterday and they are doing  
 13 the second one today. A monthly and quarterly  
 14 maintenance will be put in place". So this  
 15 part here about the maintenance, she's  
 16 indicating that the recommended maintenance,  
 17 monthly and quarterly had never been done on  
 18 the instruments. Is that correct?  
 19 MR. GREEN:  
 20 A. That's true.  
 21 CHAYTOR, Q.C.:  
 22 Q. So did anyone advise you of that in August of  
 23 2005 that this needed to be done, and that a  
 24 monthly and quarterly maintenance schedule be  
 25 put in place?

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1 MR. GREEN:  
 2 A. I haven't seen this.  
 3 CHAYTOR, Q.C.:  
 4 Q. You haven't seen this letter, but were you  
 5 verbally told about this finding and that the  
 6 maintenance should be carried out on a monthly  
 7 and quarterly basis?  
 8 MR. GREEN:  
 9 A. We would have been aware of that after Carole  
 10 had come there, yeah.  
 11 CHAYTOR, Q.C.:  
 12 Q. So she discussed that with you?  
 13 MR. GREEN:  
 14 A. Yes.  
 15 CHAYTOR, Q.C.:  
 16 Q. And did it change after her visit in August,  
 17 2005?  
 18 MR. GREEN:  
 19 A. Yes, we do that regularly now.  
 20 CHAYTOR, Q.C.:  
 21 Q. And was that true as of August, 2005, after  
 22 her visit that you started doing monthly and  
 23 quarterly maintenance on the machines?  
 24 MR. GREEN:  
 25 A. Yes.



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1 CHAYTOR, Q.C.:

2 Q. And she concludes by saying that she feels

3 confident that the technicians know what they

4 are doing, they know how to use the

5 instruments, and that the bench mark

6 instruments are staining as they should be,

7 and I take it her conclusion that regard was

8 not communicated to you at the time?

9 MR. GREEN:

10 A. No.

11 CHAYTOR, Q.C.:

12 Q. But you were made aware of the issue regarding

13 maintenance procedures?

14 MR. GREEN:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. If we could look then, please, at P-0559.

18 This, I believe, is Dr. Cook's memo of August

19 8, 2005. It's written to Mr. Gulliver, Mr.

20 Dyer, Ms. Butler, Mr. Green, and -- yourself,

21 sorry, and Mr. Simms, "re: estrogen receptors

22 and progesterone receptors", and there's seven

23 points written out here, "First there will be

24 a hold on reporting of all ER and PRs by all

25 pathologists. Secondly, immunohistochemical

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1 form will continue to be filled out by our

2 pathologists. Thirdly, upon receipt of our

3 immunohistochemical form, fax a copy to Dr.

4 Carter at St. Clare's. Fourth, you will

5 continue to proceed with requests and return

6 stained ER and PR slides using the Ventana

7 System to the ordering pathologist. Fifth,

8 following this, the same paraffin block will

9 be forwarded to Dr. Carter at St. Clare's.

10 Sixth, Dr. Carter will forward the paraffin

11 blocks to Mount Sinai with the standardized

12 request, and seventh, the Mount Sinai report,

13 with the slides and paraffin block, will be

14 returned to the St. Clare's site", and it's

15 signed by Dr. Cook, Clinical Chief. How usual

16 was it for you to get a memo from the Clinical

17 Chief?

18 MR. GREEN:

19 A. That is the only memo that I've ever received

20 from the Clinical Chief.

21 CHAYTOR, Q.C.:

22 Q. And was this hand delivered to you?

23 MR. GREEN:

24 A. I think Barry probably would have delivered

25 that.

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1 CHAYTOR, Q.C.:

2 Q. And did Mr. Dyer elaborate upon the contents

3 of the memo or was there any discussion as to

4 why this was happening?

5 MR. GREEN:

6 A. Not in great detail, no.

7 CHAYTOR, Q.C.:

8 Q. What did you understand from this point

9 forward was to happen with respect to ER/PR

10 testing?

11 MR. GREEN:

12 A. At this point, I would have figured out that

13 there was a problem with previous ER/PRs, and

14 that there had been some conversions. By this

15 time, I probably would have been aware that

16 there had been an index case, and that it was

17 being investigated.

18 CHAYTOR, Q.C.:

19 Q. And what did you understand on a go forward

20 basis was to happen with respect to ER/PR

21 testing?

22 MR. GREEN:

23 A. I would -- I continued as usual doing the

24 ER/PR testing.

25 CHAYTOR, Q.C.:

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1 Q. So while you're being told there's going to be

2 a hold on the reporting of the ER/PRs by the

3 pathologists, from a technical point of view,

4 you continued on as per usual?

5 MR. GREEN:

6 A. Yeah.

7 CHAYTOR, Q.C.:

8 Q. And did the tests?

9 MR. GREEN:

10 A. Yeah.

11 CHAYTOR, Q.C.:

12 Q. And upon receipt of the form, did you fax a

13 copy of the request form -- did you fax a copy

14 to Dr. Carter at St. Clare's?

15 MR. GREEN:

16 A. Yes.

17 CHAYTOR, Q.C.:

18 Q. So I take it that was a change in your usual

19 procedure?

20 MR. GREEN:

21 A. Yes. Actually we had two stamps made up, one

22 with "ER/PR" written on it and the other

23 "Attention Dr. Bev Carter". We would stamp the

24 forms and faxed them over.

25 CHAYTOR, Q.C.:

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1 Q. And did you do this with respect to all ER/PR  
 2 tests, whether they were from within Eastern  
 3 Health or not?  
 4 MR. GREEN:  
 5 A. Yeah, they would all be faxed over to St.  
 6 Clare's.  
 7 CHAYTOR, Q.C.:  
 8 Q. And so you continued then -- it says, "To  
 9 proceed with the requests and return the  
 10 stained ER/PR slides using Ventana System to  
 11 the ordering pathologist". So you continued  
 12 to do the tests as per normal and send the  
 13 slides back to the ordering pathologist?  
 14 MR. GREEN:  
 15 A. That happened for maybe a month or two, and  
 16 after a month or two, somebody told us to stop  
 17 sending the slides to St. Clare's, they're all  
 18 being sent to Mount Sinai and they're being  
 19 read at Mount Sinai. So what we did, we just  
 20 cut the slides in duplicate, sent them -- sent  
 21 the blocks over to St. Clare's to be sent  
 22 away, and we would file the slides in our  
 23 refrigerator and when we had capacity on one  
 24 of the machines, we would run the slides and  
 25 just file it.

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1 CHAYTOR, Q.C.:  
 2 Q. Okay. So just let me understand that again  
 3 then. So for about a month after receiving  
 4 this memo, you continued to send the slides  
 5 out to the reporting pathologist?  
 6 MR. GREEN:  
 7 A. Yeah.  
 8 CHAYTOR, Q.C.:  
 9 Q. And what was being sent? It says here in the  
 10 memo you were to send the paraffin block, the  
 11 same paraffin block to Dr. Carter?  
 12 MR. GREEN:  
 13 A. Yes, that's true.  
 14 CHAYTOR, Q.C.:  
 15 Q. And she was then going to send the block on to  
 16 Mount Sinai, and then the Mount Sinai report,  
 17 with the slides and paraffin block, were going  
 18 to be returned to St. Clare's. So you  
 19 continued on for about a month after receiving  
 20 this memo, continued to send the slides out to  
 21 the reporting pathologist and the blocks over  
 22 to Dr. Carter?  
 23 MR. GREEN:  
 24 A. Yeah.  
 25 CHAYTOR, Q.C.:

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1 Q. And after a month, do you recall who told you  
 2 to stop doing that?  
 3 MR. GREEN:  
 4 A. I'm not sure who told us to stop sending them  
 5 over to St Clare's, but it had to be one of  
 6 the pathologists at St. Clare's because if  
 7 they were waiting to get their slides, their  
 8 ER/PR slides and they didn't show up, they  
 9 never looked for them. So if they were  
 10 waiting on ER/PR slides and ER/PR was the  
 11 topic of conversation at the time, I would be  
 12 very surprised if they didn't get ER/PR slides  
 13 for a few months, that they would wonder where  
 14 they went. So obviously the request to stop  
 15 sending the slides must have come from the  
 16 pathologist at St. Clare's.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and you said, though, that you then  
 19 continued with the slides. Can you just  
 20 explain that to us again?  
 21 MR. GREEN:  
 22 A. So when we get the request for an ER/PR, we  
 23 would cut our duplicates -- we would cut a set  
 24 of sections, ER/PR for ourselves, we would  
 25 take the block and the requisition and we

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1 would fax a copy to St. Clare's, and then we  
 2 would send it over by the courier system, and  
 3 the slides that we had saved for ourselves, we  
 4 stored in the same refrigerator that we stored  
 5 our antibodies. When we had extra capacity on  
 6 one of the machines, we would run the ER/PR  
 7 slides and we just filed them in the lab.  
 8 CHAYTOR, Q.C.:  
 9 Q. Filed those in the lab?  
 10 MR. GREEN:  
 11 A. Yes.  
 12 CHAYTOR, Q.C.:  
 13 Q. So were these requests for patient tests on  
 14 ER/PR?  
 15 MR. GREEN:  
 16 A. Yes. So and --  
 17 CHAYTOR, Q.C.:  
 18 Q. And they were still coming in from where?  
 19 MR. GREEN:  
 20 A. From the pathologists at St. Clare's mostly,  
 21 just the regular ER/PR requests. So we kept -  
 22 - we stained these slides with the intention  
 23 of comparing the results of those slides with  
 24 the results from Mount Sinai when they were  
 25 finished.

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1 CHAYTOR, Q.C.:

2 Q. Okay. So any requests that were coming in for

3 ER/PR were still being sent to you and you

4 continued to make the slides and stain the

5 slides?

6 MR. GREEN:

7 A. Yes.

8 CHAYTOR, Q.C.:

9 Q. When you got a chance?

10 MR. GREEN:

11 A. When we got a chance.

12 CHAYTOR, Q.C.:

13 Q. So when your workload permitted, you would

14 then repeat the tests, knowing they were also

15 taking place in Mount Sinai?

16 MR. GREEN:

17 A. Yeah, because we knew that the patients

18 themselves, those tests were being taken care

19 of, they were -- we know they were all going

20 to Mount Sinai.

21 CHAYTOR, Q.C.:

22 Q. And were those only St. Clare's cases that you

23 were doing that for?

24 MR. GREEN:

25 A. We were doing all requests that we would get.

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1 CHAYTOR, Q.C.:

2 Q. Uh-hm.

3 MR. GREEN:

4 A. And they all went to St. Clare's, to Dr. Bev

5 Carter, to be sent to Mount Sinai.

6 CHAYTOR, Q.C.:

7 Q. And for how long did you continue to create

8 slides on the same work that was going to

9 Mount Sinai?

10 MR. GREEN:

11 A. We never ever stopped creating the slides

12 right up until the time we revalidated the

13 ER/PR again, and the system started up with

14 the breast group in place. Then that system

15 took over again.

16 CHAYTOR, Q.C.:

17 Q. So every -- this is go forward basis,

18 obviously, not the ones which were part of the

19 retrospective study. You didn't do any work

20 on those, I take it?

21 MR. GREEN:

22 A. No.

23 CHAYTOR, Q.C.:

24 Q. So all the prospective cases, for all of those

25 that were sent to Mount Sinai between August,

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1 2005, and February, 2007, there were also

2 slides created in St. John's?

3 MR. GREEN:

4 A. Duplicates, yes.

5 CHAYTOR, Q.C.:

6 Q. There were duplicates, okay, and to your

7 knowledge, has anyone done any comparative

8 work between the work from Mount Sinai and the

9 work in St. John's?

10 MR. GREEN:

11 A. Not that I'm aware of.

12 CHAYTOR, Q.C.:

13 Q. And have you, yourself, had any occasion to

14 look at the slides created through your work

15 and those of Mount Sinai?

16 MR. GREEN:

17 A. I've never seen the Mount Sinai slides.

18 CHAYTOR, Q.C.:

19 Q. Have you looked at the slides that you created

20 yourself?

21 MR. GREEN:

22 A. Some of them we've looked at.

23 CHAYTOR, Q.C.:

24 Q. And in what context did you do that?

25 MR. GREEN:

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1 A. Just to check on -- if we see some slides that

2 are obviously positive, we will look at them

3 just from a curiosity point of view.

4 CHAYTOR, Q.C.:

5 Q. Okay. So just looking at them to determine

6 whether or not you were satisfied with the

7 quality?

8 MR. GREEN:

9 A. Yeah.

10 CHAYTOR, Q.C.:

11 Q. And has any pathologist been involved in that

12 process with you?

13 MR. GREEN:

14 A. No.

15 CHAYTOR, Q.C.:

16 Q. So have all of those slides now been stained?

17 MR. GREEN:

18 A. Yes.

19 CHAYTOR, Q.C.:

20 Q. So they're all completed, and where are those

21 slides?

22 MR. GREEN:

23 A. Those slides are in the pathology lab in the

24 IHC section at the General Hospital.

25 CHAYTOR, Q.C.:

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1 Q. You said at some point you became aware of the  
 2 index case. Who told you that, who told you  
 3 about the index case?  
 4 MR. GREEN:  
 5 A. I'm not really sure. Probably it might have  
 6 been Barry, probably Barry.  
 7 CHAYTOR, Q.C.:  
 8 Q. And is there anything else that you recall  
 9 being told about the index case?  
 10 MR. GREEN:  
 11 A. The information I was given was that it was a  
 12 patient with lobular carcinoma, ER/PR reported  
 13 as negative, patient had asked for a second  
 14 opinion or a consult, and they were sent away  
 15 to an outside laboratory and came back with a  
 16 change result. Now the -- I think the -- it  
 17 said that lobular carcinoma ER/PR should be  
 18 positive in 80 percent or more of the cases,  
 19 repeat ER/PR.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay. Before I leave this memo then, August  
 22 8th, 2005, the rerunning of or the  
 23 continuation of the test, the ER/PR testing  
 24 and the slides that were created, have you  
 25 ever had an opportunity to compare any of your

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1 work to the results from Mount Sinai?  
 2 MR. GREEN:  
 3 A. I haven't, no.  
 4 CHAYTOR, Q.C.:  
 5 Q. Do you know if anyone else has done that?  
 6 MR. GREEN:  
 7 A. I'm not aware of it.  
 8 CHAYTOR, Q.C.:  
 9 Q. And when you received this memo, being the  
 10 first time you ever -- and the only time you  
 11 received a memo from the Clinical Chief, was  
 12 that the subject of discussion amongst you and  
 13 Ms. Butler and Mr. Simms?  
 14 MR. GREEN:  
 15 A. Yes, it was.  
 16 CHAYTOR, Q.C.:  
 17 Q. And what was discussed at that time?  
 18 MR. GREEN:  
 19 A. Well, it was the first time that I was aware  
 20 of the suspension of the ER/PR antibodies. I  
 21 knew the significance of the ER/PR antibodies,  
 22 and I suspected that there was a problem.  
 23 CHAYTOR, Q.C.:  
 24 Q. And were there concerns expressed at that  
 25 point in time?

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1 MR. GREEN:  
 2 A. Pardon me?  
 3 CHAYTOR, Q.C.:  
 4 Q. Were there concerns expressed at that point in  
 5 time or was there anything in particular, for  
 6 example, in your mind as to what may have  
 7 caused this issue?  
 8 MR. GREEN:  
 9 A. Well, the first thing that would cross your  
 10 mind is, is this a technical problem, and if  
 11 this is a technical problem, how come nobody  
 12 has spoken to me about it, because this is  
 13 part of the work that I do.  
 14 CHAYTOR, Q.C.:  
 15 Q. Yes.  
 16 MR. GREEN:  
 17 A. So it would be a concern.  
 18 CHAYTOR, Q.C.:  
 19 Q. Okay, and did you bring that up with your  
 20 managers?  
 21 MR. GREEN:  
 22 A. We had discussed it with Barry.  
 23 CHAYTOR, Q.C.:  
 24 Q. And did he provide you with any answers?  
 25 MR. GREEN:

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1 A. From the information, my conversation with  
 2 Barry, I had the impression that the  
 3 oncologists were blaming the pathologists and  
 4 the pathologists were blaming technologists  
 5 and nobody really knew the depth or the  
 6 breadth of the problem.  
 7 CHAYTOR, Q.C.:  
 8 Q. Okay, and when did Mr. Dyer tell you that?  
 9 MR. GREEN:  
 10 A. It probably would have been after this became  
 11 common knowledge, when the ER/PRs were  
 12 stopped.  
 13 CHAYTOR, Q.C.:  
 14 Q. In August 2005, and so you continued on  
 15 business as usual and continued on with the  
 16 ER/PR testing. When did you next hear  
 17 anything about the ER/PR issue?  
 18 MR. GREEN:  
 19 A. This was August in 2005. By this time, some  
 20 of the information was starting to--I knew of  
 21 the index case. I knew there had been--they  
 22 were sending back cases out of province to be  
 23 tested, and shortly after that, I learned that  
 24 they were going back as far as 1997 and  
 25 looking at cases.

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1 CHAYTOR, Q.C.:

2 Q. And how did you learn that?

3 MR. GREEN:

4 A. I probably learnt it from Barry.

5 CHAYTOR, Q.C.:

6 Q. Okay. Were you asked--in this memo, August

7 8th, the fact of what was going to be

8 happening and then upon learning that there

9 was also going to be a retrospective study,

10 were you asked to keep any of that information

11 confidential or would it just be assumed that

12 that would be confidential?

13 MR. GREEN:

14 A. It would be assumed that it was confidential.

15 Any discussion about patients would be assumed

16 to be confidential.

17 CHAYTOR, Q.C.:

18 Q. So anything in terms of where testing is

19 taking place would be confidential. If I

20 could look, please, at P-2166? And this

21 appears to be September 10th and 15th, through

22 to the 15th, 2005, National Society for

23 Histotechnology, 31st Annual Symposium, Fort

24 Lauderdale, Florida, and I understand that you

25 attended this symposium?

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1 MR. GREEN:

2 A. Yes.

3 CHAYTOR, Q.C.:

4 Q. Okay, and there were workshops in

5 immunohistochemistry, mathematics in the

6 laboratory, introduction to

7 immunohistochemistry, lymphomas, the control

8 conundrum in histopathology, what can and

9 should be controlled. So did you attend all

10 of these workshops?

11 MR. GREEN:

12 A. Yes.

13 CHAYTOR, Q.C.:

14 Q. Okay, and how did it come about then, in

15 September 2005, that you attended this

16 symposium?

17 MR. GREEN:

18 A. Terry Gulliver asked me to go.

19 CHAYTOR, Q.C.:

20 Q. And do you know why you were chosen to go?

21 Did anyone else go?

22 MR. GREEN:

23 A. Barry was there, Barry Dyer.

24 CHAYTOR, Q.C.:

25 Q. Okay, and do you know why you were chosen to

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1 go in terms of technologists?

2 MR. GREEN:

3 A. Probably because I had taken the lead using

4 the Ventana system and immunoperoxidase.

5 CHAYTOR, Q.C.:

6 Q. And other than the training that you received

7 on the Ventana machine back in the winter of

8 2004, this is the first, I take it -

9 MR. GREEN:

10 A. Yeah, the first formal -

11 CHAYTOR, Q.C.:

12 Q. - education that you've received in

13 immunohistochemistry?

14 MR. GREEN:

15 A. Yes.

16 CHAYTOR, Q.C.:

17 Q. Okay, and did you find this helpful?

18 MR. GREEN:

19 A. It was very helpful, yes.

20 CHAYTOR, Q.C.:

21 Q. And when you came back, did you then

22 disseminate the information to the other

23 technologists or any learnings from the

24 seminar?

25 MR. GREEN:

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1 A. I brought back the paper copies of the

2 lectures, of the workshops, which we keep in

3 the lab, and this was some of the information

4 that I gave to the pathology academic

5 meetings.

6 CHAYTOR, Q.C.:

7 Q. Was there anything in particular that stood

8 out or that you learned, recall learning at

9 this first formal symposium that you attended,

10 something that you hadn't been aware of

11 before?

12 MR. GREEN:

13 A. Nothing in particular.

14 CHAYTOR, Q.C.:

15 Q. Were there things though, in general, that you

16 felt that -

17 MR. GREEN:

18 A. All the information that I got was very

19 useful.

20 CHAYTOR, Q.C.:

21 Q. Okay. Mr. Green, there was then, we

22 understand, Ms. Wegrynowski attended the lab

23 in St. John's in September 2005. Did you meet

24 with her when she came?

25 MR. GREEN:

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1 A. Briefly, yes.  
 2 CHAYTOR, Q.C.:  
 3 Q. Okay, and what did you discuss with her?  
 4 MR. GREEN:  
 5 A. She went on a tour of the lab and she gave a  
 6 presentation of the immunohistochemistry and  
 7 the basics.  
 8 CHAYTOR, Q.C.:  
 9 Q. And what did you understand was the purpose of  
 10 her visit at the time?  
 11 MR. GREEN:  
 12 A. I assumed that she was checking out our  
 13 laboratory, with the help--with the idea of  
 14 finding any weaknesses that existed, so that  
 15 we could use that on a go-forward basis to  
 16 help us with any deficiencies that we had.  
 17 CHAYTOR, Q.C.:  
 18 Q. Okay, and we also understand that in the fall  
 19 of 2005, Dr. Banerjee visited the lab as well,  
 20 and St. Clare's lab. Did you have any  
 21 meetings or discussions with him?  
 22 MR. GREEN:  
 23 A. No.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay. If we could look at, please, 2172? And

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1 I meant to bring this to your attention  
 2 before, Mr. Green, because I think--do you  
 3 recognize this or what this involves?  
 4 MR. GREEN:  
 5 A. Yes.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay. Perhaps you could explain to us what  
 8 this document is? And there's several pages  
 9 here, so you can always click up here and go  
 10 through it for us.  
 11 MR. GREEN:  
 12 A. This is a grid that myself and Barry set up to  
 13 run ER/PRs on the Ventana system, checking out  
 14 different patients, using our protocol.  
 15 CHAYTOR, Q.C.:  
 16 Q. So this is when you're bringing the Ventana  
 17 online for the first time in 2004?  
 18 MR. GREEN:  
 19 A. Yes.  
 20 CHAYTOR, Q.C.:  
 21 Q. That's what this is?  
 22 MR. GREEN:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. Okay, and there's a note here, "Ken, a little

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1 bit rushed, but you get the idea. Bev, I'm on  
 2 holiday Friday, vacation," and then is this  
 3 your signature?  
 4 MR. GREEN:  
 5 A. That would be mine.  
 6 CHAYTOR, Q.C.:  
 7 Q. That's your signature, okay. So was Dr.  
 8 Carter involved in the process? What's this  
 9 about?  
 10 MR. GREEN:  
 11 A. Yes, she was.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay. So that was in, again, setting up the--  
 14 this is setting up the Ventana in 2004?  
 15 MR. GREEN:  
 16 A. I think that was--I just think that was  
 17 checking--we were checking our protocols  
 18 against surgicals, the ER/PR cases that were  
 19 there.  
 20 CHAYTOR, Q.C.:  
 21 Q. Do you know what time period this is?  
 22 MR. GREEN:  
 23 A. Not exactly, no. I know from the previous  
 24 page there--see all these antibodies here?  
 25 CHAYTOR, Q.C.:

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1 Q. Yes.  
 2 MR. GREEN:  
 3 A. A, E, K would be my initial in front of it. I  
 4 used those protocols so that I could separate  
 5 those protocols from the ones that we--our  
 6 normal protocols. So we were trying different  
 7 -  
 8 CHAYTOR, Q.C.:  
 9 Q. So this page is definitely you and Mr. Dyer  
 10 setting up the Ventana back in 2004? Is that  
 11 right?  
 12 MR. GREEN:  
 13 A. I would assume that's the time.  
 14 CHAYTOR, Q.C.:  
 15 Q. And this note from Dr. Carter, you're not sure  
 16 what this is?  
 17 MR. GREEN:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. Do you know -  
 21 MR. GREEN:  
 22 A. But I know Dr. Carter, she would be reviewing  
 23 the slides that we produced, because we had  
 24 set up a grid and she reviewed it.  
 25 CHAYTOR, Q.C.:

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1 Q. Okay, so that was still at the time that  
2 you're setting up the Ventana in 2004?  
3 MR. GREEN:  
4 A. I would assume that's -  
5 MR. SIMMONS:  
6 Q. Excuse me. Go ahead a few pages. There are  
7 some dates on some of the documents a little  
8 further along, on these (inaudible).  
9 CHAYTOR, Q.C.:  
10 Q. Okay, this one, this is in '05.  
11 MR. GREEN:  
12 A. Okay, this must be '05 then.  
13 CHAYTOR, Q.C.:  
14 Q. All right. So this is after the problem  
15 arose?  
16 MR. GREEN:  
17 A. Yeah, the Ventana would have been long set up  
18 by then.  
19 CHAYTOR, Q.C.:  
20 Q. Okay. So does that help then with your  
21 recollection as to what's going on here? And  
22 you can take the mouse and click on and go  
23 through the pages, if you wish. I just want  
24 you to be able to explain to us what these  
25 documents are about and what was happening in

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1 this process.  
2 MR. GREEN:  
3 A. We were running tissues using different  
4 protocols. All these are PRs. These are  
5 protocols. These are for a number of  
6 protocols and a different number in protocol -  
7 CHAYTOR, Q.C.:  
8 Q. Do you want to take the mouse and just point  
9 to what you're referring to, please?  
10 MR. GREEN:  
11 A. Okay.  
12 CHAYTOR, Q.C.:  
13 Q. So this has a date, a run started of August  
14 25th.  
15 MR. GREEN:  
16 A. These numbers here on the protocol number.  
17 CHAYTOR, Q.C.:  
18 Q. Yes, try not to click on it. Just move it  
19 around for us, and you want to scroll down, we  
20 can do this. Okay, all right.  
21 MR. GREEN:  
22 A. These are protocol numbers, and the other one  
23 is the PR antibody and these letters, D, F, H,  
24 and J, those would be numbers which we would  
25 have assigned to different surgical numbers.

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1 So it looks like we were kind of doing a blind  
2 test, so that when the slides were read, you  
3 would not know which patients they belonged  
4 to.  
5 CHAYTOR, Q.C.:  
6 Q. Okay, and this was going on in August 2005?  
7 MR. GREEN:  
8 A. Yeah.  
9 CHAYTOR, Q.C.:  
10 Q. Okay.  
11 MR. GREEN:  
12 A. That would be the 25th of August, 2005. We  
13 got that memo from Don on -  
14 CHAYTOR, Q.C.:  
15 Q. August 8th.  
16 MR. GREEN:  
17 A. - August 8th, 2005. So I guess the question  
18 of the Ventana machine and the ER/PR protocols  
19 were probably being checked out.  
20 CHAYTOR, Q.C.:  
21 Q. And then if we just go back to this here, is  
22 this your document?  
23 MR. GREEN:  
24 A. That would be Barry's.  
25 CHAYTOR, Q.C.:

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1 Q. That's Barry Dyer's?  
2 MR. GREEN:  
3 A. Yeah.  
4 CHAYTOR, Q.C.:  
5 Q. Okay, so perhaps we'll ask him then to explain  
6 what's happening. So I take it it was you and  
7 Barry Dyer and Dr. Carter involved in this  
8 process?  
9 MR. GREEN:  
10 A. Yes.  
11 CHAYTOR, Q.C.:  
12 Q. And how long did that go on into -  
13 MR. GREEN:  
14 A. It was probably, by the look of that note  
15 there, "going on vacation" I'd say it was  
16 handled fairly swiftly, and this -  
17 CHAYTOR, Q.C.:  
18 Q. And page--sorry?  
19 MR. GREEN:  
20 A. - this one right here, this looks like mine.  
21 CHAYTOR, Q.C.:  
22 Q. Page ten, that's your writing?  
23 MR. GREEN:  
24 A. That's my writing.  
25 CHAYTOR, Q.C.:

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1 Q. Okay, and can you explain what's going on  
 2 there then? We've got block -  
 3 MR. GREEN:  
 4 A. We were running different protocols, some with  
 5 blockers and some without blockers.  
 6 CHAYTOR, Q.C.:  
 7 Q. Blockers, okay.  
 8 MR. GREEN:  
 9 A. Blockers are used for endogenous peroxidase.  
 10 Blockers are used to pick up staining activity  
 11 which is not related to the antigen antibody  
 12 reaction, so those would be--we'd block those  
 13 so they wouldn't interfere with the reading of  
 14 the slides.  
 15 CHAYTOR, Q.C.:  
 16 Q. And your understanding is that this is testing  
 17 on the Ventana to see if the Ventana is  
 18 operating properly?  
 19 MR. GREEN:  
 20 A. Yes, yeah.  
 21 CHAYTOR, Q.C.:  
 22 Q. That's what was happening here, okay. And  
 23 then page 12, what's this document? And is  
 24 this your handwriting?  
 25 MR. GREEN:

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1 A. It is.  
 2 CHAYTOR, Q.C.:  
 3 Q. And this is--is this antigen retrieval, mild  
 4 and standard?  
 5 MR. GREEN:  
 6 A. Mild and standard, and this is primary  
 7 antibody incubation times on the left, and we  
 8 would have tried those, 28 minutes one with a  
 9 mild antigen retrieval and 28 minutes with a  
 10 standard, 24 mild and standard, 32 mild and  
 11 standard. We would have tried all those  
 12 protocols.  
 13 CHAYTOR, Q.C.:  
 14 Q. Okay.  
 15 MR. GREEN:  
 16 A. And the clone we're using is 6F11. The clone,  
 17 that clone would be a predilute clone, because  
 18 it would be from the Ventana.  
 19 CHAYTOR, Q.C.:  
 20 Q. And again, this is part of what you were doing  
 21 in August 2005 to -  
 22 MR. GREEN:  
 23 A. Yeah.  
 24 CHAYTOR, Q.C.:  
 25 Q. - validate the Ventana system? And page 14,

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1 this is your writing?  
 2 MR. GREEN:  
 3 A. No.  
 4 CHAYTOR, Q.C.:  
 5 Q. Okay. Is it Mr. Dyer's?  
 6 MR. GREEN:  
 7 A. Probably Bev's writing.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and this again, the same person?  
 10 MR. GREEN:  
 11 A. Probably.  
 12 CHAYTOR, Q.C.:  
 13 Q. None of this is yours, I take it? You  
 14 recognize the document? Do you know--can you  
 15 explain to us what's happening here?  
 16 MR. GREEN:  
 17 A. This document, those were--we would have run a  
 18 blind test, sent them over to Bev with the  
 19 protocols. Looks like she was reading the  
 20 slides and commenting on the different  
 21 protocols to see which way we were going,  
 22 trying to reach a optimum protocol.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, and this is just more of the same  
 25 document, I take it?

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1 MR. GREEN:  
 2 A. Yeah.  
 3 CHAYTOR, Q.C.:  
 4 Q. So is there anything else then about that that  
 5 you recall? For example, if we look at the  
 6 comments section, internal control weak,  
 7 internal control weak, poor--not sure what -  
 8 MR. GREEN:  
 9 A. Poor cover slipping.  
 10 CHAYTOR, Q.C.:  
 11 Q. - cover slipping, those comments, are these  
 12 being written in by--is that you or is that  
 13 Dr. Carter?  
 14 MR. GREEN:  
 15 A. That would be a pathologist.  
 16 CHAYTOR, Q.C.:  
 17 Q. Pathologist, okay. Were any of those issues  
 18 discussed with you at the time or did you see  
 19 this document with these comments filled in?  
 20 MR. GREEN:  
 21 A. I can't remember seeing it after we done the  
 22 work.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay, and was any issue of any problems with  
 25 controls or any other problems with the



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1 testing brought to your attention?  
 2 MR. GREEN:  
 3 A. No.  
 4 CHAYTOR, Q.C.:  
 5 Q. I just want to look at then, please, P-0637?  
 6 This is a letter, Mr. Green, October 13, 2005,  
 7 written by Dr. Cook and copied to Dr.  
 8 Fontaine, Mr. Gulliver, Dr. Williams, written  
 9 to Dr. Ejeckam. "As discussed, I appreciate  
 10 your continuing role in overseeing the  
 11 immunoperoxidase service. As you know, we are  
 12 in the process of developing a specialized  
 13 service with technologists solely dedicated in  
 14 immunohistochemical technique." So I take it  
 15 up to this point in time you weren't  
 16 dedicated, October of '05.  
 17 MR. GREEN:  
 18 A. No.  
 19 CHAYTOR, Q.C.:  
 20 Q. "As agreed, you will oversee all aspects of  
 21 the immunoperoxidase operation and have direct  
 22 supervision over the technologists involved in  
 23 the service." Mr. Green, was that told to you  
 24 at the time or to the technologists at the  
 25 time that Dr. Ejeckam would now have direct

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1 supervision over you?  
 2 MR. GREEN:  
 3 A. I thought he always had direct supervision  
 4 over us, that was the impression that he gave  
 5 us.  
 6 CHAYTOR, Q.C.:  
 7 Q. All right, so this would not have been seen as  
 8 a change to you.  
 9 MR. GREEN:  
 10 A. It would not be a shock. It would be a shock  
 11 if I saw it otherwise.  
 12 CHAYTOR, Q.C.:  
 13 Q. Okay, but in terms of--so in terms of him  
 14 being able to directly supervise you with  
 15 respect to IHC, did you see Dr. Ejeckam any  
 16 different than any other pathologist in that  
 17 regard?  
 18 MR. GREEN:  
 19 A. No, because when he was there, he was the man  
 20 to go to for IHC, so I just assumed that he  
 21 was always in that capacity.  
 22 CHAYTOR, Q.C.:  
 23 Q. If we could look, please, at P-0047? And, Mr.  
 24 Green, this is Ms. Wegrynowski's first report  
 25 on November 9th, 2005 and I understand you saw

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1 Dr. Banerjee's report after it was made  
 2 public, is that also true of this report?  
 3 MR. GREEN:  
 4 A. Same time.  
 5 CHAYTOR, Q.C.:  
 6 Q. So the first time you received a copy or were  
 7 able to read the report was in February of  
 8 this year, 2008?  
 9 MR. GREEN:  
 10 A. Yes.  
 11 CHAYTOR, Q.C.:  
 12 Q. Were you otherwise any time prior to that  
 13 advised of the content of the reports?  
 14 MR. GREEN:  
 15 A. About a year ago Dr. Denic had the report, had  
 16 a spreadsheet with the report with a list of  
 17 recommendations that we were to have put in  
 18 place.  
 19 CHAYTOR, Q.C.:  
 20 Q. So a spreadsheet with recommendations and  
 21 we've seen spreadsheets like that here in our  
 22 process, so those spreadsheets were--a  
 23 spreadsheet was shown to you at least about a  
 24 year ago?  
 25 MR. GREEN:

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1 A. Yes, I never, after the report, I think there  
 2 were only four copies of the report, but I  
 3 wasn't aware of the content of the report  
 4 before then.  
 5 CHAYTOR, Q.C.:  
 6 Q. Okay, and the spreadsheet, you saw that for  
 7 the first time in the summer of 2007?  
 8 MR. GREEN:  
 9 A. I think that's about the time, the date I'm  
 10 not exactly sure of.  
 11 CHAYTOR, Q.C.:  
 12 Q. Okay, and what was the purpose at that point  
 13 in time of Dr. Denic showing you the  
 14 spreadsheet?  
 15 MR. GREEN:  
 16 A. We were about to--there was a--we were  
 17 supposed to get a visit from the QMPLS people  
 18 in Ontario and they were going to do, I guess,  
 19 they were doing a consult on our laboratory  
 20 and Dr. Denic was checking to see what the  
 21 progress of these recommendations were.  
 22 CHAYTOR, Q.C.:  
 23 Q. And prior to that, even if a general sense,  
 24 were you made aware of what the  
 25 recommendations were? Did you have any idea

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1 what the outcome was of Ms. Wegrynowski's  
 2 report?  
 3 MR. GREEN:  
 4 A. Not in any real sense, no. I could read  
 5 between the lines some of the stuff that we  
 6 were doing, the external quality assurance, so  
 7 we had started to do that and so I figured  
 8 that would have been part of the report.  
 9 CHAYTOR, Q.C.:  
 10 Q. And we understand Ms. Wegrynowski had come  
 11 back in the spring of 2006. Did you meet with  
 12 her at that time as well?  
 13 MR. GREEN:  
 14 A. I cannot remember meeting with her when she  
 15 made her return visit.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, so you met with her when she was here in  
 18 September 2005.  
 19 MR. GREEN:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. And you had some brief discussion with her  
 23 then and when do you next hear anything about  
 24 Ms. Wegrynowski or her assessment of the lab?  
 25 MR. GREEN:

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1 A. Well when this--it would have been before the  
 2 QMPLS people came down, about a year ago, I  
 3 guess.  
 4 CHAYTOR, Q.C.:  
 5 Q. In 2007.  
 6 MR. GREEN:  
 7 A. Uh-hm.  
 8 CHAYTOR, Q.C.:  
 9 Q. And in terms of any--and you have seen the  
 10 report, I take it since and have had an  
 11 opportunity to read it.  
 12 MR. GREEN:  
 13 A. Yes.  
 14 CHAYTOR, Q.C.:  
 15 Q. I don't want to spend a whole lot of time  
 16 taking you through it, but in terms of the  
 17 recommendations in here, you did see a  
 18 spreadsheet of recommendations sometime in  
 19 2007.  
 20 MR. GREEN:  
 21 A. Yes.  
 22 CHAYTOR, Q.C.:  
 23 Q. But in terms of anything prior to that, you  
 24 know, in the almost two years prior to that in  
 25 terms of what needed to be done or done

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1 differently within IHC, did anyone have a  
 2 meeting with you or explain anything to you?  
 3 MR. GREEN:  
 4 A. Dr. Ford Elms, I worked with Dr. Ford Elms  
 5 probably before that, we were doing standard  
 6 operating procedures and we were doing  
 7 validation of antibodies, so I assume that all  
 8 this stuff was part of the report.  
 9 CHAYTOR, Q.C.:  
 10 Q. You assumed anything new that was happening  
 11 was part of a recommendation coming from -  
 12 MR. GREEN:  
 13 A. I figured that any improvements that were in  
 14 place or anything new, was probably part of  
 15 the report.  
 16 CHAYTOR, Q.C.:  
 17 Q. But in terms of anyone sitting down and asking  
 18 you for your input into the recommendations or  
 19 the changes that were taking place, did that  
 20 ever happen?  
 21 MR. GREEN:  
 22 A. No.  
 23 CHAYTOR, Q.C.:  
 24 Q. And you have had a chance to read through Ms.  
 25 Wegrynowski's report?

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1 MR. GREEN:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. And in general, what do you think of the  
 5 report?  
 6 MR. GREEN:  
 7 A. It's a good report, it has some valid  
 8 concerns. I think we can take that report  
 9 and, well a lot of the stuff that is there is  
 10 already implemented or it's partially been  
 11 implemented, it's all being worked on.  
 12 CHAYTOR, Q.C.:  
 13 Q. So it's all either implemented or currently  
 14 being -  
 15 MR. GREEN:  
 16 A. Implemented, yeah.  
 17 CHAYTOR, Q.C.:  
 18 Q. Being implemented. So I take it you see it as  
 19 having useful information in it?  
 20 MR. GREEN:  
 21 A. It's a positive approach and I take it as  
 22 constructive criticism and it's a way for us  
 23 to move on and to make, use this as a benefit  
 24 to us so that we can make a better lab.  
 25 CHAYTOR, Q.C.:

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1 Q. And are there any parts of it that, and in  
 2 fairness, but you know, take your time, is  
 3 there any parts in it or when you read it, did  
 4 you, was there anything in there you think is  
 5 not a fair criticism or in fact might not be  
 6 accurate?  
 7 MR. GREEN:  
 8 A. Criticism is never easy, you know, to take,  
 9 but constructive criticism is fine. For the  
 10 most part the recommendations that are there  
 11 are not out of our capacity to do and they are  
 12 things that should be done.  
 13 CHAYTOR, Q.C.:  
 14 Q. And again, now the first time you're seeing  
 15 this is in February, 2008, so two and a half  
 16 years after it's written and by that point in  
 17 time, as you say, many changes have already  
 18 been made.  
 19 MR. GREEN:  
 20 A. Uh-hm. And a lot of the changes in the  
 21 report, like pathologist assistants, that  
 22 would be out of my scope of work and like the  
 23 standard operating procedures for fixation and  
 24 grossing, although the results would affect  
 25 me, those procedures there themselves would

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1 probably not be written by me. And a lot of  
 2 the recommendations that would require  
 3 resources would be handled by management.  
 4 CHAYTOR, Q.C.:  
 5 Q. Yes, okay. And in terms of the processing  
 6 section, for example here, the points that she  
 7 comes up with there and in terms of the  
 8 immunohistochemistry laboratory, the  
 9 recommendations for dedicated staff, of  
 10 course, and that's something that I understand  
 11 you had heard Dr. Ejeckam was looking for,  
 12 before this?  
 13 MR. GREEN:  
 14 A. Yes.  
 15 CHAYTOR, Q.C.:  
 16 Q. And the idea of lines of authority or  
 17 communication, was that any issue that was  
 18 ever expressed? Did you hear that expressed  
 19 before?  
 20 MR. GREEN:  
 21 A. It might have been a problem between the  
 22 pathologists and the lab director.  
 23 CHAYTOR, Q.C.:  
 24 Q. Okay.  
 25 MR. GREEN:

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1 A. But it was never an issue for me.  
 2 CHAYTOR, Q.C.:  
 3 Q. Her recommendations regarding documentation.  
 4 MR. GREEN:  
 5 A. Yeah, we have no, we have our standard  
 6 operating procedures either in place or in  
 7 draft, manufacturer specification sheets are  
 8 not catalogued and in a binder. All  
 9 maintenance records are now done and posted on  
 10 the wall, our pipettes are now calibrated.  
 11 CHAYTOR, Q.C.:  
 12 Q. So you continue to use pipettes in your work?  
 13 MR. GREEN:  
 14 A. Yeah, and we now run lot to lot validations on  
 15 the antibodies, we have a requirement  
 16 procedures for antibodies, we keep our records  
 17 for two years. We have a correction action  
 18 log in place.  
 19 CHAYTOR, Q.C.:  
 20 Q. And that's fairly new, I take it, that's in  
 21 the past few months.  
 22 MR. GREEN:  
 23 A. Yes. So all these things are either in place  
 24 or in the process of being handled.  
 25 CHAYTOR, Q.C.:

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1 Q. And Mr Green, in terms of having had this  
 2 report or the contents of the report available  
 3 to you back in 2005, would that have been  
 4 helpful?  
 5 MR. GREEN:  
 6 A. It would have been helpful, it's pretty hard  
 7 to implement changes if you don't know what  
 8 they are.  
 9 CHAYTOR, Q.C.:  
 10 Q. I just want to continue, just quickly take you  
 11 through, though, if there's anything--and the  
 12 procedure manual outlining standard operating  
 13 procedure is to be created and I'll talk to  
 14 you about that probably next time we meet now,  
 15 because you've done some substantial work on  
 16 that.  
 17 MR. GREEN:  
 18 A. Yes.  
 19 CHAYTOR, Q.C.:  
 20 Q. The issue regarding the antibody data  
 21 specification sheet, I believe I've already  
 22 spoke to you about that previously in your  
 23 evidence and the equipment maintenance, I take  
 24 it you don't take exception to any of this?  
 25 MR. GREEN:

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1 A. No, it's all good laboratory practice and it  
 2 should be done in every laboratory.  
 3 CHAYTOR, Q.C.:  
 4 Q. Okay, and the guaranteed pipette and  
 5 temperature accuracy and calibration, did you  
 6 understand the importance of that before?  
 7 MR. GREEN:  
 8 A. The?  
 9 CHAYTOR, Q.C.:  
 10 Q. The importance of the accuracy of the volume  
 11 of the pipette?  
 12 MR. GREEN:  
 13 A. Yes, I understood the concept of accuracy.  
 14 CHAYTOR, Q.C.:  
 15 Q. Particularly when you're -  
 16 MR. GREEN:  
 17 A. With the volumes that we use and the  
 18 antibodies that we use, the one in fifty  
 19 dilution, if we did get our pipette  
 20 calibrated, I'm fairly sure that it came back  
 21 with a 98.5 percent accuracy rate. So on the  
 22 -  
 23 CHAYTOR, Q.C.:  
 24 Q. So it's since been calibrated, I take it?  
 25 MR. GREEN:

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1 A. Yeah, and on the one in fifty dilution of  
 2 ER/PR, if your pipette was out by one percent,  
 3 that means that the one in fifty dilution  
 4 would probably be now one in fifty, or if it  
 5 went the other way, it would be one in forty-  
 6 nine. The same dilution would be carried  
 7 through onto your control tissue as your  
 8 patient tissue. When you validate an  
 9 antibody, you usually go in increments of one  
 10 in twenty-five, one in fifty, one in seventy-  
 11 five, one in a hundred. I don't know of  
 12 anybody who validates an antibody using one in  
 13 forty-nine and one in fifty, one in fifty-one.  
 14 A broad spectrum of the antibodies that we  
 15 use, although it is the right thing to do, I  
 16 do not think that it would have affected the  
 17 overall accuracy of the test.  
 18 CHAYTOR, Q.C.:  
 19 Q. And that pipette, was it just one pipette that  
 20 you had calibrated?  
 21 MR. GREEN:  
 22 A. We've got all new pipettes and they're all  
 23 calibrated.  
 24 CHAYTOR, Q.C.:  
 25 Q. They're all new now?

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1 MR. GREEN:  
 2 A. Yeah, I spoke with the people from BioMed who  
 3 calibrated pipettes and I said how do you  
 4 calibrate your pipettes? He said, we've got a  
 5 laptop computer which we hook up and we take  
 6 the temperature and the barometric pressure.  
 7 We take the pipette and we take distilled  
 8 water, the computer is hooked up to a digital  
 9 scale and we will take the pipette and we will  
 10 dispense whatever the volume of the pipette is  
 11 calibrated for, if it's a hundred mil, we  
 12 dispense a hundred mils. We'll dispense it  
 13 ten times onto the scale and each time it's  
 14 weighed and that's the way the calibrate the  
 15 reproducibility of the pipette. I said, what  
 16 happens if the pipette doesn't meet the  
 17 calibration specifications? And he said, we  
 18 take it out of service. I said, do you repair  
 19 it or adjust it? And he said, no, it was  
 20 taken out of service.  
 21 CHAYTOR, Q.C.:  
 22 Q. And the pipette that you had adjusted here,  
 23 which was 98.5 percent accurate.  
 24 MR. GREEN:  
 25 A. That was the pipette that we used on the DAKO

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1 system.  
 2 CHAYTOR, Q.C.:  
 3 Q. On the DAKO, that was still in existence.  
 4 MR. GREEN:  
 5 A. Well it's also important to point out,  
 6 although it is the right thing to do and  
 7 nobody can argue with that, but on the Ventana  
 8 system and ER and PR antibodies which we used  
 9 come pre-dilute from the manufacturer, so  
 10 there is no pipetting of primary antibody.  
 11 CHAYTOR, Q.C.:  
 12 Q. Now, yes.  
 13 MR. GREEN:  
 14 A. Now.  
 15 CHAYTOR, Q.C.:  
 16 Q. And what if your dilution was one in twenty,  
 17 how would that affect -  
 18 MR. GREEN:  
 19 A. One in twenty would be a stronger dilution, so  
 20 if you're off by one percent -  
 21 CHAYTOR, Q.C.:  
 22 Q. 1.5 percent.  
 23 MR. GREEN:  
 24 A. 1.5 percent, depending if you were above or  
 25 below. In my opinion, if you use that same

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1 antibody dilution on your patient and on your  
 2 control, the same error would be carried  
 3 forward on both and I don't know of anybody  
 4 who runs antibody dilutions in one percent  
 5 increments.  
 6 CHAYTOR, Q.C.:  
 7 Q. Okay, and--sorry, were you finished?  
 8 MR. GREEN:  
 9 A. No, carry on.  
 10 CHAYTOR, Q.C.:  
 11 Q. Okay, No. 18, "documented evaluation must be  
 12 performed to ensure the sensitivity and  
 13 specificity of the test results" and there's a  
 14 number of things that she mentions along there  
 15 about validation.  
 16 MR. GREEN:  
 17 A. I don't have any problem with any of those -  
 18 CHAYTOR, Q.C.:  
 19 Q. With any of the rest, okay.  
 20 CHAYTOR, Q.C.:  
 21 Q. - those recommendations.  
 22 CHAYTOR, Q.C.:  
 23 Q. And there's issue of the quality assurance and  
 24 of course, recommending external proficiency  
 25 testing and external quality assurance, I take

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1 it you have no issue with that?  
 2 MR. GREEN:  
 3 A. No, we're involved in external QA with NEQAS,  
 4 United Kingdom, CAP, American Pathologists, we  
 5 are involved in QMPLS and now we're currently  
 6 looking at another place in Saskatoon in which  
 7 we are going to be involved in.  
 8 CHAYTOR, Q.C.:  
 9 Q. Okay, and where is that? It's in Saskatoon,  
 10 do you know which group?  
 11 MR. GREEN:  
 12 A. I'm not sure right now, but I know they're  
 13 doing tissue arrays. Doctor Ford Elms is  
 14 checking into it.  
 15 CHAYTOR, Q.C.:  
 16 Q. Okay, and on page 18, she refers to competency  
 17 testing, staff to be assessed for competence  
 18 to perform task following training, identify  
 19 requirements of task performed, GAP analysis  
 20 and develop action plans. Has that happened?  
 21 Have you had any competency testing carried  
 22 out?  
 23 MR. GREEN:  
 24 A. The only assessment I have done is from Barry  
 25 Dyer.

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1 CHAYTOR, Q.C.:  
 2 Q. I'm sorry, from Barry Dyer?  
 3 MR. GREEN:  
 4 A. Yes.  
 5 CHAYTOR, Q.C.:  
 6 Q. And was that happening before 2005?  
 7 MR. GREEN:  
 8 A. Yes.  
 9 CHAYTOR, Q.C.:  
 10 Q. Was that your regular performance evaluation?  
 11 MR. GREEN:  
 12 A. Yes.  
 13 CHAYTOR, Q.C.:  
 14 Q. And were you getting those regularly?  
 15 MR. GREEN:  
 16 A. I had one after I moved over to the Health  
 17 Science, after I finished my probationary  
 18 period and probably one a year after.  
 19 CHAYTOR, Q.C.:  
 20 Q. Okay, and did you have any while you were at  
 21 St. Clare's?  
 22 MR. GREEN:  
 23 A. Yes.  
 24 CHAYTOR, Q.C.:  
 25 Q. So you were having evaluations fairly

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1 routinely?  
 2 MR. GREEN:  
 3 A. Yes.  
 4 CHAYTOR, Q.C.:  
 5 Q. And referenced to, she recommended internet be  
 6 available at the work bench.  
 7 MR. GREEN:  
 8 A. Uh-hm.  
 9 CHAYTOR, Q.C.:  
 10 Q. And she didn't find any textbooks in the IHC.  
 11 MR. GREEN:  
 12 A. We have internet in our laboratory and we have  
 13 reference manuals, DABB's is the one that Dr.  
 14 Ejeckam recommended, so we have that one.  
 15 CHAYTOR, Q.C.:  
 16 Q. And the continuing education for the  
 17 technologists and I understand that you've had  
 18 substantial continuing education since?  
 19 MR. GREEN:  
 20 A. Yes.  
 21 CHAYTOR, Q.C.:  
 22 Q. If we could look, please, at P-2160? And Mr.  
 23 Green, I understand this is a list of the  
 24 continuing education courses taken by you over  
 25 the past three years and it's dated the first

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1 being your training on the Ventana in February  
 2 '04 and continues on down to November, 2007.  
 3 And in that time period is your trip to  
 4 Florida in September of '05, which we talked  
 5 about.  
 6 MR. GREEN:  
 7 A. Yes.  
 8 CHAYTOR, Q.C.:  
 9 Q. The Jewish General in January 2006, perhaps  
 10 you could tell us about that?  
 11 MR. GREEN:  
 12 A. It was Dr. Ejeckam's idea to, he wanted to  
 13 send us out for training at different  
 14 hospitals. The Jewish General was chosen for  
 15 me because it had the same equipment that we  
 16 had, it had the benchmark equipment. Mary  
 17 went to Mount Sinai to get training on  
 18 documentation, standards of practice. I spent  
 19 two weeks at the Jewish General, they took me  
 20 through the whole laboratory. I was given  
 21 free rein of all their protocols and  
 22 procedures, got to run their equipment, got to  
 23 stain our slides, got to look at their slides.  
 24 CHAYTOR, Q.C.:  
 25 Q. So you brought slides up from St. John's?

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1 MR. GREEN:  
 2 A. Yes, and they went through their protocols  
 3 with me, they gave me copies of their  
 4 protocols to take back, information on their  
 5 antibodies, the pathologists would call me  
 6 when they were grossing the breast specimens.  
 7 They have PA's up there and they would gross  
 8 the specimens, they would call me when they  
 9 were grossing the specimens to show how the  
 10 sections they took. So apparently they would  
 11 know up there which section that they were  
 12 going to submit for ER/PR from the gross  
 13 bench. If Section B would be a section that  
 14 they would take, they would know that it would  
 15 have normal tissue. They would have tumour  
 16 tissue and hopefully normal tissue. Of  
 17 course, it would go to the pathologist first  
 18 and the pathologist would specify which block,  
 19 but majority that they had, the pathologist  
 20 assistants would know in advance which block  
 21 they would suspect would go for ER/PR, so they  
 22 were very helpful, very accommodating, took  
 23 time out of their busy schedules to help me,  
 24 to answer all the questions that I had. It  
 25 was a very worthwhile experience.

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1 CHAYTOR, Q.C.:  
 2 Q. And perhaps we could look at P-2170 please?  
 3 And this is called a report on  
 4 immunoperoxidase staining, Jewish General,  
 5 Montreal, Quebec, January 16 through to 27,  
 6 2006. And it's prepared for the  
 7 Immunopathology Department at Eastern Health,  
 8 prepared by yourself. Who did you prepare  
 9 this report for?  
 10 MR. GREEN:  
 11 A. When I came back from the Jewish General, I  
 12 prepared it for Dr. Ejeckam.  
 13 CHAYTOR, Q.C.:  
 14 Q. And did you submit the report then to Dr.  
 15 Ejeckam, is that who this went to?  
 16 MR. GREEN:  
 17 A. Yes, and I gave--there was a meeting called  
 18 and I'm trying to remember who was at the  
 19 meeting, probably Dr. Cook, Dr. Ejeckam,  
 20 Barry, Mary, Les, myself.  
 21 CHAYTOR, Q.C.:  
 22 Q. And you brought back with you standard  
 23 operating procedures from the Jewish General?  
 24 MR. GREEN:  
 25 A. Copy of their protocols.

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1 CHAYTOR, Q.C.:  
 2 Q. And what did you, sorry, it was the protocols?  
 3 MR. GREEN:  
 4 A. Protocols that they used for their antibodies,  
 5 the dilutions that they use up there, the  
 6 suppliers for their antibodies.  
 7 CHAYTOR, Q.C.:  
 8 Q. And overall what was your sense in terms of  
 9 the lab at the Jewish General as compared to  
 10 the lab here in St. John's? Was it comparable  
 11 or -  
 12 MR. GREEN:  
 13 A. The Jewish General was a very well run  
 14 organized hospital. They had a lot of the  
 15 paperwork and the documentation which we  
 16 didn't have, which I could learn from that,  
 17 learn the documentation that they had. The  
 18 basic protocols and the running of the Ventana  
 19 system was very similar to ours.  
 20 CHAYTOR, Q.C.:  
 21 Q. Okay, and you say in your initial discussion,  
 22 "Edward", is that Edward Depestry, is that his  
 23 name?  
 24 MR. GREEN:  
 25 A. Yes.

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1 CHAYTOR, Q.C.:

2 Q. And that's Dr. Depestry, I guess, is it? "And

3 I felt that even though my prime focus would

4 be immunoperoxidase, some time devoted to

5 routine pathology would be beneficial. And

6 would you make notable differences from our

7 laboratory, gross attendance, gross using the

8 above classification and will call the

9 pathologist only for clarification purposes."

10 So I take it they had pathology assistants in

11 place?

12 MR. GREEN:

13 A. Pathology assistants, yes.

14 CHAYTOR, Q.C.:

15 Q. "And the Jewish General tends to use a

16 speciality system for specimen division.

17 Jewish General sort and fill their processing

18 baskets by colour code and classification and

19 their embedded cut and stain are sorted

20 accordingly. They generate a master gross

21 list to check off blocks and help with

22 embedding. There is no scraping of blocks, as

23 the embedders do not use excess wax. They had

24 5 millilitres of alcohol" -

25 MR. GREEN:

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1 A. Alcoholic eosin.

2 CHAYTOR, Q.C.:

3 Q. - eosin to the second alcohol on the tissue

4 processor to facilitate easier embedding and

5 orientation. White tissue/white wax, white

6 lens paper.

7 MR. GREEN:

8 A. The reason for that is that the eosin is a

9 pinkish colour. So when they would stain

10 their tissues, when you put them in a

11 cassette, you got white tissue on a white

12 background and white wax, so at least this

13 would give the person embedding a better sense

14 of the finding of tissue for orientation

15 purposes.

16 CHAYTOR, Q.C.:

17 Q. Was there any reprocessing happening in the--

18 reprocessing of the blocks happening at Jewish

19 General?

20 MR. GREEN:

21 A. I wasn't aware of any that they did there.

22 CHAYTOR, Q.C.:

23 Q. And then it says "the gross attendant and

24 pathologist specializing in breast pathology

25 spend considerable time explaining the breast

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1 dissection and the blocking sequence, in

2 particular areas where the blocks would be

3 used for ER/PR requests." So I take it they

4 had pathologists specializing in breast

5 pathology?

6 MR. GREEN:

7 A. They did. They had a pathologist that was her

8 specialty.

9 CHAYTOR, Q.C.:

10 Q. Okay, and then day two was spent in the

11 routine pathology lab where you observed a

12 typical day. "Cutting was very similar," you

13 note, "to our method. The next eight working

14 days were spent in the immunoperoxidase lab.

15 The immuno lab is a separate lab on its own."

16 So that was different from your lab at that

17 point in time?

18 MR. GREEN:

19 A. Yeah, they had a separate facility, yes.

20 CHAYTOR, Q.C.:

21 Q. Okay, and they used the Ventana system, using

22 two benchmarks as well, and two Nexus IHC

23 stainers. Is that the same as what you had?

24 MR. GREEN:

25 A. We used the Nexus IHC stainers for special

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1 stains. They had adapted two of those to use

2 for IHC.

3 CHAYTOR, Q.C.:

4 Q. Okay.

5 MR. GREEN:

6 A. But the benchmarks were identical to ours.

7 CHAYTOR, Q.C.:

8 Q. And the volume is obviously much more. They

9 have about four immuno runs per day?

10 MR. GREEN:

11 A. Yeah.

12 CHAYTOR, Q.C.:

13 Q. So that would be higher. The antibodies are

14 divided into two groups, one incubated at 37

15 degrees, the others at 56, and you've included

16 a list for future reference. What was that

17 about? That's okay. I'm sorry, you didn't

18 hear me, did you?

19 MR. GREEN:

20 A. No, I didn't. No.

21 CHAYTOR, Q.C.:

22 Q. I'm sorry. I thought you were in deep

23 thought.

24 MR. GREEN:

25 A. I was reading.

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1 CHAYTOR, Q.C.:

2 Q. What was this about the antibodies are divided

3 into two groups, one incubated at 37 degrees

4 and the other at 56 degrees?

5 MR. GREEN:

6 A. They had some antibodies which they would run

7 at 37 and some at 56, so they would--they

8 found that those temperatures, some antibodies

9 would work better at those temperatures.

10 CHAYTOR, Q.C.:

11 Q. Okay.

12 MR. GREEN:

13 A. And I brought back a list of those.

14 CHAYTOR, Q.C.:

15 Q. For future reference, yes, and have you used

16 that since?

17 MR. GREEN:

18 A. We haven't changed the temperature on the

19 antibodies.

20 CHAYTOR, Q.C.:

21 Q. Okay, and "I brought a list of our antibodies

22 and protocols to compare with those," and you

23 also said that you brought slides along?

24 MR. GREEN:

25 A. I brought slides which we stained.

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1 CHAYTOR, Q.C.:

2 Q. And was there any concern expressed as to the

3 quality of your slides at the Jewish General?

4 MR. GREEN:

5 A. No, they had no problem with the quality and

6 the stains we did, I think were mostly ER/PR

7 slides we stained.

8 CHAYTOR, Q.C.:

9 Q. Okay, and did you do a comparison? Did you

10 stain your slides as well as stains from--or

11 slides from the Jewish General?

12 MR. GREEN:

13 A. I would look at their slides up there that

14 they stained daily.

15 CHAYTOR, Q.C.:

16 Q. And "the most noticeable difference being

17 antibody supplier and dilution on some

18 antibodies. They used very few protocols with

19 block as they claim background staining

20 blushes easily, different from positive

21 staining. After each run, the technologist

22 would check the slide and show me the

23 controls, both internal and external." So in

24 terms of the most notable difference, "most of

25 the protocols being different, with the most

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1 notable difference being antibody supplier and

2 dilution," was there notable difference with

3 respect to the ER/PR antibody?

4 MR. GREEN:

5 A. No.

6 CHAYTOR, Q.C.:

7 Q. Antibodies, I should say.

8 MR. GREEN:

9 A. No, noticeable difference. They would use

10 very few blockers because they say the blush

11 that you would see in the background is blush

12 and it should be discounted. So like some

13 people run the immunoperoxidase stains and

14 they like to have a clear crisp background,

15 and it would give it this blush. But they'd

16 say don't worry about that blush. It's non-

17 specific, doesn't interfere. If it doesn't

18 interfere with the reading of the slides, it's

19 not a problem.

20 CHAYTOR, Q.C.:

21 Q. Okay, and the technologist there was looking

22 at both the internal and external controls?

23 MR. GREEN:

24 A. They would show--she would show me the breast

25 tissue. We looked at the internal controls.

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1 She would show S-100 stains and show the nerve

2 fibres for internal controls, or look at

3 factor eight stain and look at the blood

4 vessels.

5 CHAYTOR, Q.C.:

6 Q. And how did the knowledge level seem to be of

7 the technologist who was assisting you?

8 MR. GREEN:

9 A. The technologist there had approximately 30

10 years, most of it which was in IHC, and she

11 knew her material inside out and backwards and

12 forwards and a lot of times the pathologists

13 would come to her with questions on the IHC.

14 CHAYTOR, Q.C.:

15 Q. Get advice from her, okay, and you note that

16 "they don't run controls with every run, but

17 the following will always run with controls"

18 and that list includes ER/PR.

19 MR. GREEN:

20 A. These are what they consider class two

21 antibodies. So those antibodies will be used

22 for--the patient's diagnosis will be directly

23 affected or treatment will be directly

24 affected by these antibodies.

25 CHAYTOR, Q.C.:



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1 Q. Okay, and the technologist, you note, "will  
2 read the controls to validate the system."  
3 MR. GREEN:  
4 A. Yeah.  
5 CHAYTOR, Q.C.:  
6 Q. Okay, and that was happening in any event in  
7 St. John's. You were also reading the  
8 controls?  
9 MR. GREEN:  
10 A. Yes.  
11 CHAYTOR, Q.C.:  
12 Q. At the time?  
13 MR. GREEN:  
14 A. We were checking the controls for positivity.  
15 CHAYTOR, Q.C.:  
16 Q. You were checking them, okay. But you weren't  
17 actually reading them?  
18 MR. GREEN:  
19 A. No, now the--but they did not--the  
20 technologists there would not read the patient  
21 tissue. They would just check the controls.  
22 CHAYTOR, Q.C.:  
23 Q. Just the controls, yes. And currently in St.  
24 John's, do you--and I know, when I say  
25 currently, I mean, after the testing resumed

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1 in February 2007, was there any change in  
2 whether or not the technologists would read  
3 the controls?  
4 MR. GREEN:  
5 A. The responsibility of the technologist at the  
6 Health Care Corporation still is to check the  
7 positive control to make sure that our system  
8 is working.  
9 CHAYTOR, Q.C.:  
10 Q. Okay. So there's no change really in what you  
11 were doing before?  
12 MR. GREEN:  
13 A. No.  
14 CHAYTOR, Q.C.:  
15 Q. Okay. You were given full access to their lab  
16 protocol and protocol manuals with permission  
17 to copy and given full access to the immuno  
18 protocols. Considerable time was spent on  
19 review of the benchmark system maintenance  
20 protocols and configuration. We reviewed  
21 ER/PR and HER2/neu protocols, results and  
22 controls. We ran a panel of your slides  
23 using--for ER/PR using their protocols to  
24 compare the same to the panel already at  
25 Health Care Corporation, you say. Discussed

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1 the merits of antibodies, titrations, pitfalls  
2 and troubleshooting, as well as recommended  
3 protocols to follow when introducing new  
4 antibodies into the immuno lab. On that  
5 point, in terms of recommended protocols to  
6 follow when introducing new antibodies, had  
7 you had any such protocols at your disposal  
8 prior to this?  
9 MR. GREEN:  
10 A. We didn't have a written protocol, no. We  
11 would use the manufacturers -  
12 CHAYTOR, Q.C.:  
13 Q. Specifications.  
14 MR. GREEN:  
15 A. - instructions that came on the data sheets.  
16 THE COMMISSIONER:  
17 Q. Ms. Chaytor, wherever you can find a  
18 convenient spot, we'll break for the day.  
19 CHAYTOR, Q.C.:  
20 Q. Thank you. And then your summary is, you say  
21 "it's an opportunity to bring back to our  
22 immuno lab, some valuable practical,  
23 theoretical knowledge and skills. And most  
24 importantly, it reenforces our belief that we  
25 are performing the protocols and procedures

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1 with the Ventana system, using the same checks  
2 and balances used anywhere in North America.  
3 And what did you mean by that, Mr. Green?  
4 MR. GREEN:  
5 A. I meant that we were using positive controls  
6 on the antibodies that we ran.  
7 CHAYTOR, Q.C.:  
8 Q. I'm sorry.  
9 MR. GREEN:  
10 A. I meant that we were running positive controls  
11 on the antibodies that we performed.  
12 CHAYTOR, Q.C.:  
13 Q. The positive controls?  
14 MR. GREEN:  
15 A. Yeah.  
16 CHAYTOR, Q.C.:  
17 Q. So in that respect that your procedure was  
18 very similar to theirs?  
19 MR. GREEN:  
20 A. Our protocols were doing what they were  
21 supposed to do and demonstrating what they  
22 were supposed to demonstrate.  
23 CHAYTOR, Q.C.:  
24 Q. Okay, and this is in January of 2006 that  
25 you're there?

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1 MR. GREEN:  
 2 A. Yes.  
 3 CHAYTOR, Q.C.:  
 4 Q. The protocols then that you brought back, you  
 5 use those--did you make any use of those on a  
 6 go-forward basis?  
 7 MR. GREEN:  
 8 A. I would refer to them when we had problems  
 9 with our antibodies. I would look at my notes  
 10 from the Jewish General and see that clones  
 11 they were using, what dilutions they were  
 12 using, what antibodies, what manufacturer,  
 13 because those--because they had similar  
 14 machines to ours, the antigen retrieval, that  
 15 would be the same.  
 16 CHAYTOR, Q.C.:  
 17 Q. Okay, thank you. Okay, I think this is a  
 18 convenient place, Commissioner, although I  
 19 have two new exhibits that -  
 20 THE COMMISSIONER:  
 21 Q. Do you want to put them in now?  
 22 CHAYTOR, Q.C.:  
 23 Q. Yes, I think we should put them in now. It's  
 24 2174 and 2224, and those are protocols 46 and  
 25 48, which I believe the witness referred to.

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1 So perhaps next day we'll have a chance to  
 2 look at those.  
 3 THE COMMISSIONER:  
 4 Q. So that's 2174 and 2224?  
 5 CHAYTOR, Q.C.:  
 6 Q. That's correct.  
 7 THE COMMISSIONER:  
 8 Q. All right. Entered.  
 9 EXHIBIT ENTERED AND MARKED P- 2174  
 10 EXHIBIT ENTERED AND MARKED P- 2224  
 11 THE COMMISSIONER:  
 12 Q. Now does life get complicated tomorrow?  
 13 CHAYTOR, Q.C.:  
 14 Q. Yes, life gets complicated tomorrow. We have  
 15 two--the next two witnesses are coming from  
 16 outside St. John's, so what we--I've discussed  
 17 with Mr. Green and his solicitor is that we  
 18 may not use all day Friday with one of the  
 19 witnesses, so if Mr. Green, and he's agreeable  
 20 to be available Friday afternoon, if we are  
 21 freed up, we could continue then.  
 22 THE COMMISSIONER:  
 23 Q. So tentatively continue with Mr. Green on  
 24 Friday afternoon?  
 25 CHAYTOR, Q.C.:

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1 Q. Friday afternoon tentatively, and if not, then  
 2 into Tuesday of next week.  
 3 THE COMMISSIONER:  
 4 Q. All right. Well, yes, if not--and we'll rely  
 5 on the good offices of Mr. Simmons to  
 6 communicate with Mr. Green as the day  
 7 progresses on Friday, if you would, Mr.  
 8 Simmons. Thank you all. I know it's been a  
 9 very long, very hot day, and everybody  
 10 deserves to get out and find cool air some  
 11 place, maybe that means going in. I'm not  
 12 sure. 9:30 in the morning. Thank you.  
 13

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1  
 2 CERTIFICATE  
 3  
 4  
 5 I, Judy Moss, hereby certify that the foregoing is  
 6 a true and correct transcript in the matter of the  
 7 Commission of Inquiry on Hormone Receptor Testing,  
 8 heard on the 9th day of July, A.D., 2008 before the  
 9 Honourable Justice Margaret A. Cameron,  
 10 Commissioner, at the Commission of Inquiry, St.  
 11 John's, Newfoundland and Labrador and was  
 12 transcribed by me to the best of my ability by  
 13 means of a sound apparatus.  
 14  
 15 Dated at St. John's, Newfoundland and Labrador  
 16 this 9th day of July, A.D., 2008  
 17  
 18  
 19  
 20 Judy Moss

<p style="text-align: center;"><b>-&amp;-</b></p> <p><b>&amp;</b> [7] 24:14,19 27:10 34:19,24 37:11 48:2</p> <hr/> <p style="text-align: center;"><b>-'-</b></p> <p><b>'02</b> [2] 120:6 194:14 <b>'03</b> [1] 224:24 <b>'04</b> [1] 340:2 <b>'05</b> [4] 312:10,12 320:16 340:4 <b>'08</b> [1] 194:13</p> <hr/> <p style="text-align: center;">---</p> <p><b>-he</b> [1] 124:9 <b>-your</b> [1] 272:2</p> <hr/> <p style="text-align: center;"><b>-.-</b></p> <p><b>.5</b> [1] 143:7</p> <hr/> <p style="text-align: center;"><b>-0-</b></p> <p><b>03/11/17B</b> [1] 185:8</p> <hr/> <p style="text-align: center;"><b>-1-</b></p> <p><b>1</b> [28] 55:24,25,25,25 58:1 58:1 59:11,23 60:5,6,13 60:13 61:3,3,24,25 63:18 63:18 90:25 99:1,2 153:16 154:2,3 265:13 265:13 267:6,6 <b>1-2-3</b> [1] 185:23 <b>1-2-3-4-5</b> [1] 185:21 <b>1.5</b> [2] 335:22,24 <b>1/02</b> [2] 119:12,25 <b>10</b> [5] 55:25 63:4 67:14 130:12 264:7 <b>100</b> [12] 53:4 55:25 58:2 72:2 76:6 84:20 85:13 179:25 192:24 217:18 231:16 248:18 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