COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 9, 2008

Appearances:

Bernard Coffey, Q.C. . . . . Commission Co-counsel
Sandra Chaytor, Q.C. . . . . Commission Co-counsel

Jackie Brazil . . . . . Her Majesty in Right of NL

Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al

Daniel Simmons . . . . . Eastern Regional Integrated
. . . . . Health Authority

Darlene Russell. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

LIST OF EXHIBITS

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THE COMMISSIONER:
Q. Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Good morning, Commissioner. The next witness is Kenneth Green.
MR. KENNETH GREEN, SWORN, EXAMINATION BY SANDRA CHAYTOR, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
MR. GREEN:
A. Ken Green, K-E-N G-R-E-E-N.
REGISTRAR:
Q. Thank you.
CHAYTOR, Q.C.:
Q. Good morning, Mr. Green.
MR. GREEN:
A. Good morning.
CHAYTOR, Q.C.:
Q. Commissioner, there are a number of new exhibits which I would ask, please, to have entered this morning. They are numbered P-2158 through to P-2173 inclusive.
THE COMMISSIONER:
Q. Entered.

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CHAYTOR, Q.C.:
Q. Thank you.
EXHIBITS ENTERED AND MARKED EXHIBITS P-2158 THROUGH P-2173
CHAYTOR, Q.C.:
Q. Mr. Green, perhaps you could begin by telling us about your educational and professional background?
MR. GREEN:
A. I was born in Carbonear and finished my high school education at St. Francis in Harbour Grace. Attended Memorial University for a year, went to College of Trades and Technology and did the three-year program for general laboratory, graduated in 1979. I wrote national certification exams for the Canadian Society of Laboratory Technologists and became a registered technologist in laboratory medicine. Currently registered member of the Canadian Society of Medical Laboratory Science, current member of the Newfoundland and Labrador Society of Laboratory Technologists, past president of Newfoundland Society of Laboratory Technologists, committee member for CSLT National Congress 1986 and a

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committee member for the CSMLS National Congress 2009.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. After graduating from the medical lab program, I went to work at St. Clare's Mercy Hospital in June of 1979, stayed there for 23 years and applied for a job at the Health Sciences in April 2002, where I presently work.
CHAYTOR, Q.C.:
Q. Okay. The general laboratory technologist program that you did in the--I guess it would have been the late 1979?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. You graduated in 1979?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. So the late 1970s.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:

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Q. Was there any particular focus or any particular area of laboratory technology that you've personally focused on?
MR. GREEN:
A. Well, it's a general lab program and covered all disciplines.
CHAYTOR, Q.C.:
Q. Okay, and I assume that included pathology?
MR. GREEN:
A. Pathology, yes.
CHAYTOR, Q.C.:
Q. Okay, and at that time, of course, there would not have been any study for immunohistochemistry?
MR. GREEN:
A. No, it was not included in the syllabus of studies.
CHAYTOR, Q.C.:
Q. And the societies that you said you belong to, could you just repeat that for us, please?
MR. GREEN:
A. The Canadian Society of Laboratory Technology, which is now known as the Canadian Society of Medical Labrador Science. That's the national certification society. And the provincial

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branch of the CSLT is also a professional society.
CHAYTOR, Q.C.:
Q. And is that the one that you are past president of?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and when was that? When were you the president?
MR. GREEN:
A. That would be in the 80s.
CHAYTOR, Q.C.:
Q. 1980s.
MR. GREEN:
A. 80s, the whole decade of the 80s, I served as past president--vice president, president and past president.
CHAYTOR, Q.C.:
Q. Okay, and what's the purpose of the provincial society?
MR. GREEN:
A. Provincial society is to promote professional development and education.
CHAYTOR, Q.C.:

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Q. And is there anything you have to do to maintain your national certification?
MR. GREEN:
A. At present, no, it's not mandatory.
CHAYTOR, Q.C.:
Q. And I take it then the provincial organization or provincial branch of the society concentrates on continuing education for its members?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And is it a voluntary membership or is it mandatory?
MR. GREEN:
A. It's voluntary.
CHAYTOR, Q.C.:
Q. Voluntary, and do you know how many current members there are in Newfoundland?
MR. GREEN:
A. I would estimate between five and six hundred.
CHAYTOR, Q.C.:
Q. And how would that compare in terms of percentage to the overall number of laboratory technologists in the province?

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MR. GREEN:
A. I would say it would be approximately 90 percent.
CHAYTOR, Q.C.:
Q. Okay. So most laboratory technologists would be part of the society?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. When you began your position at St. Clare's in June of 1979, were you assigned to a particular area of the lab?
MR. GREEN:
A. Pathology. I worked in pathology--I finished at the College on Friday and started on Monday at St. Clare's in pathology.
CHAYTOR, Q.C.:
Q. So you were 23 years at St. Clare's in the pathology lab?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And your position then in coming to the Health Sciences Centre in 2002, you continued on in the pathology lab?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And was there any section then or any particular area that you concentrated on at the Health Sciences?
MR. GREEN:
A. The position I applied for at the Health Sciences was a laboratory technologist two position, and the duties included one week rotation in immunohistochemistry, one week rotation in gross pathology, one week rotation in general lab. Other duties included pediatric pathology gross assisting, muscle histochemistry, frozen sections when required, kidney biopsy collection, cryostat cutting, immuno fluorescence, and finally aspiration collection and preparation at the Janeway.
CHAYTOR, Q.C.:
Q. Okay. So it was full gamut of pathology services with a one-week rotation in the IHC portion of the lab?
MR. GREEN:
A. Yeah. Well, when I moved over to the Health Science, there was no IHC lab. IHC was part

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of anatomic pathology.
CHAYTOR, Q.C.:
Q. So IHC services is probably a better way for me to state it?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. So you would concentrate one week--you were on a rotation. I understand at the time there were two other technologists there, Peggy Welsh and Mary Butler?
MR. GREEN:
A. That's correct.
CHAYTOR, Q.C.:
Q. So you would, every three weeks, rotate through IHC services?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. When you were at St. Clare's, in the pathology lab there, how much interaction would you have with the pathologists?
MR. GREEN:
A. We interacted hourly and daily. It was a constant interaction.

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CHAYTOR, Q.C.:
Q. And how did that compare to the amount, frequency of contact with the pathologists then at the Health Sciences?
MR. GREEN:
A. Pathologists at the Health Sciences, it wasn't as--there was a different atmosphere at the Health Science than it was at St. Clare's. During that time, there was an amalgamation in progress and earlier you would have the Grace Hospital, the St. Clare's Hospital, the Janeway and the Health Science. All of them had their own identity, and during the amalgamation, all these people came together to form a new culture and it was a mix of different cultures which were now coming together. It wasn't until I became familiar with the pathologists at the Health Science that I had more interaction with them.
CHAYTOR, Q.C.:
Q. Okay, and that was 2002 that you went there?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So the merger would have taken place back in

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1995/96 of the Health Care Corporation?
MR. GREEN:
A. Yeah, and then after the Grace Hospital closed, some employees from the Grace moved over to the Health Science. The Janeway new building was created, but the lab was incorporated into the General Hospital lab and the full merger was scheduled to take place where St. Clare's would eventually move to the Health Science.
CHAYTOR, Q.C.:
Q. Yes, and then in 2005, of course, there's the further amalgamation or the creation of Eastern Health and did you notice any change at that point in time, in terms of the culture and environment that you're referring to?
MR. GREEN:
A. Those were rough times for people within the laboratory and within the hospital in general. Finances were limited and people who were used to having defined roles in their own hospitals now were put into situations where the roles weren't quite as clear any more. So it took time for people to mesh and to come together as a single unit.

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CHAYTOR, Q.C.:
Q. In your position at St. Clare's, was there a period of time when St. Clare's embarked upon immunohistochemistry?
MR. GREEN:
A. At one brief period, we tried some kit methods.
CHAYTOR, Q.C.:
Q. I'm sorry?
MR. GREEN:
A. Some kits.
CHAYTOR, Q.C.:
Q. Kits, yes.
MR. GREEN:
A. We tried some kits on an experimental basis, but we found that it was too time consuming and costly and eventually the General Hospital took over all immunohistochemistry. We never did any diagnostic work with IHC.
CHAYTOR, Q.C.:
Q. So did you ever--so you never did ER/PR testing?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:

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Q. Okay, and do you recall what time period it was that St. Clare's had that brief stint in IHC?
MR. GREEN:
A. I can't recall right now.
CHAYTOR, Q.C.:
Q. Would it have been the 80s, 90s?
MR. GREEN:
A. Probably late 80s.
CHAYTOR, Q.C.:
Q. Okay, and at that point in time, who trained you or how were you trained to do IHC testing?
MR. GREEN:
A. We basically trained ourselves to do it. We got the instructions from the manufacturer and we followed the instructions that we had.
CHAYTOR, Q.C.:
Q. And I take it the test was done--or those tests, at that point in time, were done manually, were they?
MR. GREEN:
A. Yes, they were manual.
CHAYTOR, Q.C.:
Q. There was no machine such as the DAKO machine when you went to the Health Science?

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MR. GREEN:
A. No, all manual.
CHAYTOR, Q.C.:
Q. All manual, and do you recall how long did-- how long were you involved in carrying out IHC testing at that point in time?
MR. GREEN:
A. No longer than maybe a month, and the kits were so expensive and the time so consuming that it was not feasible.
CHAYTOR, Q.C.:
Q. And did you--I take it then any IHC testing that was required by the pathologists in St. Clare's from that point in time was then carried out at the Health Sciences Centre?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and would you have been involved then in arranging that testing?
MR. GREEN:
A. The request would come from the pathologist for IHC and we would forward the wax blocks to the General Hospital for cutting and staining.
CHAYTOR, Q.C.:

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Q. So the requisition would come through your lab, through you or whichever technologist?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And you would be involved in the preparation of the block? Is that correct?
MR. GREEN:
A. At first, we would prepare--cut slides and send them to the General Hospital. Later on in the process, the General Hospital took over completely and just requested the wax blocks, which we would send to the General Hospital.
CHAYTOR, Q.C.:
Q. So at one point in time, you were involved in actually doing it to the stage of the slides?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And then ultimately just blocks and they'd prepare the slides and sent them back?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. So do you recall that in terms of time

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periods? When were you actually sending your own slides?
MR. GREEN:
A. Most of the requests for IHC for St. Clare's would be for ER/PRs because St. Clare's was the breast centre and they would have the bigger number of breast cases. I don't recall the time frame, but it was a continuous process.
CHAYTOR, Q.C.:
Q. Okay, and so you don't know when--what period of time you stopped sending slides and began sending blocks?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. Knowing what I know now, I would assume that they were using specialized slides at the Health Science for IHC and they would have those slides. Those slides were treated with an adhesive to secure the tissue to the slides, which would end up in a better product. So knowing what I know now, I would

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assume that's why they were brought over to the Health Science for cutting.
CHAYTOR, Q.C.:
Q. So I take it that at St. Clare's you weren't using those special slides?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. But at the time, nobody explained that to you that there were a certain type of slide that were preferable to use, that wasn't explained or the reasons for stopping St. Clare's preparing their own slides and having them prepared at Health Sciences?
MR. GREEN:
A. No, the reason was never told. At St. Clare's, we would use an adhesive on all slides, an albumin adhesive, to adhere the sections to the slide. Knowing what I know now, I know that those slides would have resulted in a background staining on immunohistochemistry. So that could have been a factor also.
CHAYTOR, Q.C.:
Q. Okay. So the adhesive that was being used in

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the creation of your slides may not have been the best for the IHC testing?

MR. GREEN:

A. True.

CHAYTOR, Q.C.:

Q. And how have you come to learn that since?

MR. GREEN:

A. Since I've moved over to Health Science, I've had the opportunity to receive continuing education and go to conferences. It's been an ongoing learning experience.

CHAYTOR, Q.C.:

Q. And is there anything else, in terms of when the slides were being prepared in house at St. Clare's and shipped over to the Health Sciences Centre for staining, is there anything else about the preparation of the slides at St. Clare's, with the knowledge you have today, you think may have been a concern or a factor?

MR. GREEN:

A. Breast tissue has always been an issue, as far as I know, with all pathology labs, the nature of the specimen itself. You've got a tissue which has tumour which is hard, fatty tissue,

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soft fatty tissue which surrounds it. It is technically difficult to cut.

CHAYTOR, Q.C.:

Q. So after you get to the stage that you're sending the blocks over and the slides are being prepared and sent back to St. Clare's, prepared at Health Science and sent back to St. Clare's, was there--would you have interaction with the laboratory technologist at the Health Science, would you be in contact with them? How would you actually, I guess, get the requisition over to them and would you sometimes be on the phone speaking to them about the test?

MR. GREEN:

A. Pathologists would request that the slides be sent. We would gather blocks and they would go over by--we had an in-house driver whose job was to go back and forth between Health Science and St. Clare's. They would drop them off to the laboratory over there. If there was a problem with blocks, Peggy or Mary would pick up the phone and call over and ask us about it.

CHAYTOR, Q.C.:

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Q. And were there ever concerns expressed by the pathologist or did you yourself notice anything about the slides that were coming back from the Health Sciences? Over the years, did you hear any concerns expressed about the quality of the slides?

MR. GREEN:

A. As technologists, we would not see the slides that returned from the Health Science. They would go directly to the pathologist for interpretation.

CHAYTOR, Q.C.:

Q. And did you ever hear any discussion or hear any comments or feedback from the pathologist as to the quality of the slides? For example, would they come back and ever ask that things be repeated?

MR. GREEN:

A. I would imagine from time to time they would ask for repeats, but it wouldn't be uncommon for a pathologist to ask for re-cuts on normal breast tissue because in order to request an ER/PR on the tissue, pathologists would need the routine stain, which is a hematoxylin and eosin stain. They would need to look at those

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slides to assess the quality before they would order the ER/PR.

CHAYTOR, Q.C.:

Q. Okay, and perhaps you can just explain that then a bit more for us?

MR. GREEN:

A. In pathology, every specimen receives a routine stain which is hematoxylin and eosin. It's the work horse stain of the lab. It is the stain that the pathologist would look at to make a diagnosis. It is the slide that the pathologist will review to order specialized tests. Usually the pathologist will know by looking at the H & E slide, they will have a fair idea what the diagnosis would be. They will request these other tests to confirm what they suspect. In the case of ER/PR, a pathologist would look at the slides that we had prepared, the H & E slides. They would determine the appropriate -- most appropriate slide to send for IHC, and in ER/PR, in particular, they would want to send a slide which had normal tissue and tumour tissue.

CHAYTOR, Q.C.:

Q. And did you know that at the time?

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MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And was that something -- when did you come to realize that, that they would try to pick a slide that had normal tissue and tumour tissue?
MR. GREEN:
A. When I moved to Health Science and became involved in IHC.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. I knew from sitting with the pathologists at the gross bench that they wanted to identify the tumour and they wanted to identify how far the tumour moved out into the tissue so they could find margins to see how far it had advanced.
CHAYTOR, Q.C.:
Q. So this idea we've heard talked about here at the Commission regarding internal controls, is that something that you were aware of during your time at St. Clare's?
MR. GREEN:

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A. No.
CHAYTOR, Q.C.:
Q. Is that something you ever heard pathologists discuss or mention?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So the idea of picking a block or a slide that had both the normal and tumour tissue, that's something that came to your knowledge after you moved in 2002?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. Okay. I understand then that the slides would be sent back and you would not see them, but there may be times when pathologists would request a repeat?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Was there ever anything brought to your attention that they had any particular concerns about the quality of the slide other than, you know, yes, there's a repeat

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

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

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CHAYTOR, Q.C.:
Q. And when was that suggestion made by that pathologist?
MR. GREEN:
A. I'm not exactly sure of the year Dr. Tadross was there but it had to be late 80s.
CHAYTOR, Q.C.:
Q. How long then did reprocessing remain a procedure carried out at St. Clare's?
MR. GREEN:
A. From that point onward, reprocessing was routinely carried out on blocks that we considered sub-optimal until the time I left St. Clare's to move to the Health Science.
CHAYTOR, Q.C.:
Q. Are you able to give us any indication as to the percentage of blocks that would have been considered sub-optimal?
MR. GREEN:
A. No, I can't give a percentage. It would vary by case, case to case. Some breast specimens would be processed and they would be cut routinely with no problems. Another specimen may be cut and it would have problems.
CHAYTOR, Q.C.:

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Q. And was there -- well, I guess, then a different way to ask the same question would be, was it a common thing to reprocess blocks or was it fairly infrequent?
MR. GREEN:
A. Depending on the surgeries that happened that week, if there were a lot of breast specimens that went through that week, sometimes there would be a fair amount of breast tissue reprocessed.
CHAYTOR, Q.C.:
Q. So do I take it from what you're telling us that it was more common to reprocess for breast tissue?
MR. GREEN:
A. Breast tissue is the only tissue that I can recall reprocessing.
CHAYTOR, Q.C.:
Q. And in terms of the amount of those that would have been reprocessed, was it a common thing to reprocess breast tissue blocks?
MR. GREEN:
A. After we started reprocessing, we would reprocess blocks every week.
CHAYTOR, Q.C.:

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Q. Every week?
MR. GREEN:
A. Yes.
COMMISSIONER:
Q. Excuse me, Mr. Green, but the question of whether there would be a reprocessing, was that something you as a technologist assessed or was that something that a pathologist might direct you to do?
MR. GREEN:
A. At first the pathologist -- we would mention to the pathologist and they had no problem with it, and after it became common practice to reprocess, we would know when specimens came off the processor in the morning if they had to be reprocessed because some of them you could tell -- we would not even try to cut those blocks because we knew we would not be able to get a technically good section from those blocks. So we would just take those blocks and reprocess them ourselves.
COMMISSIONER:
Q. So you -- when they came off the processor, is it?
MR. GREEN:

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A. Yes.
COMMISSIONER:
Q. You would assess whether or not it was a block from which in your view you could get a good slide effectively?
MR. GREEN:
A. Yes.
COMMISSIONER:
Q. Make a good cut.
MR. GREEN:
A. Yeah.
COMMISSIONER:
Q. Okay, thank you.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. What was it then, Mr. Green, about the processing, the tissue processor, what was causing this issue?
MR. GREEN:
A. It's a combination of factors. The tissue itself, most tissues that went through on the processor were fine. The majority of specimens that we did on a daily basis, we had no problems with. It would only be the breast tissue and those were the ones that we had to reprocess.

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CHAYTOR, Q.C.:
Q. Did anyone make any inquiries as to why that would be, why there were problems with the breast tissue?
MR. GREEN:
A. It seemed to be the school of thought that it was the nature of the specimen, a lot of fatty tissue, which doesn't process well at any time, plus a lot of -- since St. Clare's had the distinction of doing most of the breast surgery, we would have a larger volume of breast blocks. So it probably would not even be apparent at the Health Science who processed very little breast. So we processed -- it was a combination of processing a lot of specimens that were of this nature. So when they were processed a second time, it means that the alcohols had a chance to go in and dehydrate the specimen for to process them.
CHAYTOR, Q.C.:
Q. And when you say it seemed to be the school of thought, whose school of thought? Was that just discussed amongst the technologist, or was that something that was brought to the attention of the pathologist?

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MR. GREEN:
A. Both pathologists and the technologists were aware of the problems with breast tissue, and after we started the practice of reprocessing, it was policy.
CHAYTOR, Q.C.:
Q. It was policy?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And was anyone aware or was it brought to your attention as a technologist of any particular pitfalls or dangers in reprocessing the tissue?
MR. GREEN:
A. No, because the -- knowing now what I know, I know that looking down the road for future test for IHC, it could have been a problem, but our goal was to produce the best H & E sections for the pathologist to make a diagnosis. So that was our job. We didn't look at the secondary testing of the block because if the pathologist couldn't make the primary diagnosis, had no H & E slides to work with, he wouldn't be able to order IHC stains.

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CHAYTOR, Q.C.:
Q. And what do you now understand to be some of the shortcomings of reprocessing for IHC testing?
MR. GREEN:
A. I don't know if anybody knows what the results of reprocessing are. Knowing what I know now with my training in IHC, I know that in order to demonstrate the antigen antibody reaction we need to expose the antigen sites. What damage the reprocessing did to these sites, I couldn't -- I don't want to guess, but it may or may not affect it. I don't know if there's any -- if there's any research to show that it can or cannot affect it.
CHAYTOR, Q.C.:
Q. Dr. Tadross, was it, from Kingston?
MR. GREEN:
A. Yes, Tadross.
CHAYTOR, Q.C.:
Q. And he's the person who suggested to you reprocessing?
MR. GREEN:
A. Reprocess.

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CHAYTOR, Q.C.:
Q. Did he have any particular area of expertise?
MR. GREEN:
A. As far as I know, it was general pathology.
CHAYTOR, Q.C.:
Q. Was he -- how much experience had he had? Was he a fairly senior pathologist or fairly new?
MR. GREEN:
A. I'm not sure. I didn't think he had a -- he wasn't a senior pathologist, but he had some experience, and from talking with him, he told us that this was accepted practice in a hospital he had been in before.
CHAYTOR, Q.C.:
Q. And that was back again in the 1980s?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And whether or not that hospital had been engaged in IHC, would you know that?
MR. GREEN:
A. I have no way of knowing.
CHAYTOR, Q.C.:
Q. Or whether he had any experience with IHC?
MR. GREEN:

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A. No, I don't.
CHAYTOR, Q.C.:
Q. But this was accepted then and known by the other pathologists at St. Clare's that reprocessing was taking place?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. In terms of the fact that certain blocks had to be reprocessed or it was felt necessary to reprocess them to get adequate H & E slides as you're describing, was there any investigation or inquiries made as to how better the processing -- initial processing could be carried out to avoid having to reprocess?
MR. GREEN:
A. The processor that we used, it was changed -- regularly changed. I'm not sure of the schedule now. I think it was changed every second day, fully changed, and each day in between the solutions would be topped up.
CHAYTOR, Q.C.:
Q. So it was undergoing regular cleaning and maintenance?
MR. GREEN:

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A. Yes, and we weren't -- we were not having a problem with all the other specimens. So if there was only one specimen that's causing a problem with fixation and processing, you would attribute it to that specimen and not to the processor which processed hundreds of other specimens from all organs which we didn't -- as a rule, we did not have a problem with.
CHAYTOR, Q.C.:
Q. Okay. When the reprocessing took place on various blocks, was there any record kept as to which blocks had been reprocessed?
MR. GREEN:
A. We would have a book which we used to record the gross specimens every day, and we would have a total number of blocks so we know how many to put on the processor, and I think the processor took 150 blocks. So if we had, say, 140 blocks that day and we had ten reprocessed blocks, we would write on the sheet for that day, "ten reprocessed blocks". Sometimes we would put the surgical number and other times we would just put "ten reprocessed blocks".
CHAYTOR, Q.C.:

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Q. And would that record still exist?
MR. GREEN:
A. I'm not sure how long the yearly -- we would probably generate maybe one of those books per month. I'm not sure how long those books were kept.
CHAYTOR, Q.C.:
Q. And where were those books generally kept?
MR. GREEN:
A. It would be kept at -- the ones at St. Clare's were kept in the gross room at St. Clare's, and the gross room would have a set of drawers in there and they would be put in there.
CHAYTOR, Q.C.:
Q. And in your 23 years there, did it seem to you that all those books were still in existence and kept in those drawers?
MR. GREEN:
A. I don't think so. We would have generated probably twelve books a year, and I can't see keeping those books for an extended period of time.
CHAYTOR, Q.C.:
Q. Okay. Would there have been -- I take it, other than those books, no other record or

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means of identifying which blocks may have been reprocessed?
MR. GREEN:
A. No, you can't physically tell by looking at the blocks once they've been reprocessed.
CHAYTOR, Q.C.:
Q. I'm going to take you to -- eventually today we'll get to the current processes, and whether or not reprocessing is still continuing. So we'll pick up that theme again later with you. In keeping then with your time at St. Clare's, were there ever any other concerns expressed about the quality then of the work product coming back from the Health Sciences Centre?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So you move over then to the Health Sciences in 2002?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And when you go there, you told us that you weren't dedicated as such to IHC, that was

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once every three weeks you would be doing the IHC testing?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And the other two weeks doing all of your other duties?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Was there a pathologist in charge of the IHC portion of services?
MR. GREEN:
A. Not a dedicated pathologist. Dr. Robb had experience in IHC. You could go to him if you had problems. Dr. Chittal seemed to be quite knowledgeable in IHC, and I gathered talking to Peggy and Mary that he had initiated a lot of the protocols that were there and set it up initially.
CHAYTOR, Q.C.:
Q. I'm sorry, that was Doctor?
MR. GREEN:
A. Dr. Chittal.
CHAYTOR, Q.C.:

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Q. Dr. Chittal, yes. Okay. So when you went to the Health Sciences in 2002, what initiation or training did you receive in IHC?
MR. GREEN:
A. For the first two weeks, I kind of shadowed Peggy Welsh. She was the lead person in the IHC department, and for the next two weeks after that, I would do the IHC and Peggy would observe me, and that was the on the job training that we received.
CHAYTOR, Q.C.:
Q. Okay. So I take it your other job duties, you were quite familiar with, the other things that you had to do weren't for the most part new to you over the past 23 years?
MR. GREEN:
A. On the contrary, most of the duties were new to me.
CHAYTOR, Q.C.:
Q. Okay, so what training did you receive? So how was it different, tell us how was your job then different when you arrived at the Health Sciences?
MR. GREEN:
A. At St. Clare's, we assisted the pathologist on

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the gross, but we did not do any of the gross specimens ourselves. So at the Health Science, we were trained to process small specimens, which means that we would describe and dictate the specimens and put those in -- make sure they were numbered, and put in cassettes for whatever pathologist was on the gross that day.
CHAYTOR, Q.C.:
Q. So you had to learn that too?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And actually did it. I take it when you say "small specimens", you weren't involved, however, in grossing breast tissue?
MR. GREEN:
A. No, they were done by the pathologists or the pathologist residents at the time.
CHAYTOR, Q.C.:
Q. Okay, all right. So not only did you have to learn IHC and everything that I'll take you through that that entailed, you also had to learn to do this grossing?
MR. GREEN:

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A. Yeah.
CHAYTOR, Q.C.:
Q. What else was new for you?
MR. GREEN:
A. Muscle histochemistry. Muscle histochemistry at that time was far more challenging than the IHC for me to learn.
CHAYTOR, Q.C.:
Q. And why was that?
MR. GREEN:
A. Muscle histochemistry is approximately a two day process where the first day you have to cut fresh muscle biopsies, and the muscle biopsies had to be cut in sequence. They had to be cut into five tier (phonetic) fresh tissue, if it had to be a cut in the cryostat and they had to be consecutive, and they have to be technically perfect when doing those specimens. The stains that you would do the following day, there were 14 stains. They were pH sensitive, temperature sensitive, weight sensitive and time sensitive, and they were quite demanding. So those were -- that was a bigger challenge to me at that time than IHC, running the IHC system.

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CHAYTOR, Q.C.:
Q. Okay. So you had to learn all that as well, and so in terms of the two week job shadowing Ms. Welsh, was that just for IHC or was that for all of your duties?
MR. GREEN:
A. That was for IHC, and Barry Dyer taught me the muscle histochemistry. He had done that procedure at the Janeway. He was quite familiar with that.
CHAYTOR, Q.C.:
Q. How much time did you spend learning that aspect?
MR. GREEN:
A. It was probably about a month learning that procedure, and then you would have to do the procedure several times to become proficient in it.
CHAYTOR, Q.C.:
Q. Okay. So then in terms of IHC, you spent two weeks watching Peggy Welsh do what needed to be done in the IHC portion of the services, and then you said you spent two weeks doing it while she watched you?
MR. GREEN:

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A. That's correct.
CHAYTOR, Q.C.:
Q. And then I take it the next time you were in the IHC lab, you were in there alone?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Or in the IHC portion of the lab, I should say?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And then you ran your own tests?
MR. GREEN:
A. Yes. Now like I said earlier, the IHC portion of the lab at the Health Science was the next bench, so if you had a problem, Peggy was probably about the same distance you are from me, or Mary, so there would be no problem contacting them.
CHAYTOR, Q.C.:
Q. And they were available then for you to be able to consult with?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. And did you find in those early days that you frequently had to ask them questions?
MR. GREEN:
A. There were many times when questions would arise, yeah.
CHAYTOR, Q.C.:
Q. And what kinds of questions? What was it that you would have to seek further advice or instruction on?
MR. GREEN:
A. It would depend on the antibodies that were requested, the controls that were used, which control to use. We had a list of controls, plus a list of the antibodies which required antigen retrieval, and a list of ones which didn't require antigen retrieval. So if you were in doubt about an antibody that required antigen retrieval, you'd check with Peggy or Mary.
CHAYTOR, Q.C.:
Q. Okay, and other than job shadowing Peggy, were you given anything to read to familiarize yourself with how to do IHC?
MR. GREEN:

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A. There were no formal textbooks except there was a textbook there by Leon & Leon (phonetic) on all the antibodies with the characteristics of the antibodies.
CHAYTOR, Q.C.:
Q. And the purpose, I hear, of the antibodies?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But no actual textbooks, for example, as to the theory of IHC, anything like that?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And were there other resources available to you, such as the internet, journals, articles, anything like that?
MR. GREEN:
A. The internet was not down in our part of the lab, but it was available in the main lab.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And like I said earlier, the main lab is not a long distance away.

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CHAYTOR, Q.C.:
Q. So that was one computer, I take it, for everybody to be able to access?
MR. GREEN:
A. Yeah, and the Health Science had the library over in the next corridor, so if you're inclined, you could go over to the library and check out information there, plus we had the data sheets that came from the manufacturer.
CHAYTOR, Q.C.:
Q. Okay. So did you take it upon yourself to do any of those things, to go on the internet and study, or go to the library, or obtain other reading material?
MR. GREEN:
A. At St. Clare's, I would go in at 7 o'clock and I would leave at 2. I would work through lunch. So when I went to the Health Science, I would take a lunch period and in the beginning I would go over to the library at the Health Science here and look up various information.
CHAYTOR, Q.C.:
Q. And, in particular, I'm wondering what information would have been available or did

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you avail of regarding IHC?
MR. GREEN:
A. It would be articles mostly, but the DABB's book was at the library over there. I didn't use that, but then Maurice Larkin told me that she had told Dr. Ejeckam about the DABBs, which he got for us after.
CHAYTOR, Q.C.:
Q. And when was that conversation with Dr. Maurice Larkin?
MR. GREEN:
A. It was probably recently after we had been discussing the ER/PR episode, and Dr. Ejeckam had referred to DABBs as his Bible, and she said -- well, she said I had told him about that. So I was familiar with it before.
CHAYTOR, Q.C.:
Q. So in terms of what you had available to you or what knowledge, that's what I'm trying to ascertain, what knowledge you had in 2002 when you started doing IHC testing, and you've told us about job shadowing Peggy and Peggy observing you do the work, and you had the data spec sheets from the manufacturers?
MR. GREEN:

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A. Yes.
CHAYTOR, Q.C.:
Q. And I guess you would refer to them as need be?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. When you were doing particular antibodies.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. There were no other standard operating procedures, I understand, available?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And in terms of anything else then in terms of you familiarizing yourself through any articles at that point in time or reading on the internet, or referencing textbooks, do you recall whether or not you did that in 2002/2003 time frame?
MR. GREEN:
A. We would check out the PubMed site. That was a site for immunohistochemistry.

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CHAYTOR, Q.C.:
Q. So from time to time if you had any questions, you would go on that site?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And sometimes the pathologists would bring us articles from that site that they had looked up.
CHAYTOR, Q.C.:
Q. And, Mr Green, by the time you finished your four weeks of training with Peggy in the IHC portion, how comfortable did you feel about then being able to run that testing on your own with having them available to consult if necessary?
MR. GREEN:
A. The comfort level increased as I obtained more experience. It was kind of a daunting task at first, but it was a challenge, and after a few month there, I was quite confident in running the procedure itself.
CHAYTOR, Q.C.:

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Q. How many antibodies would have been in use at that time?
MR. GREEN:
A. Probably in excess of 100.
CHAYTOR, Q.C.:
Q. And I take it they all had separate spec sheets?
MR. GREEN:
A. They did.
CHAYTOR, Q.C.:
Q. And those -- were those at that time already programmed into the computer?
MR. GREEN:
A. When I had arrived at the Health Science, all the programs were programmed into the computer, all the protocols were developed, and all the validations had been done.
CHAYTOR, Q.C.:
Q. Had already been done on those antibodies, and did you have the experience then of having to introduce a new antibody?
MR. GREEN:
A. No, in my time there in the first year if there was a new antibody, Peggy would take care of that because even though I had 23

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years experience in pathology, I still only had one year in IHC, and they would be the senior people to put new antibodies into the system.
CHAYTOR, Q.C.:
Q. How about a situation where a current antibody in your inventory ran out or became low and a new batch of that antibody had to be ordered, were you involved in that?
MR. GREEN:
A. Not at first, but later on as I gained more experienced, I would order the antibodies too.
CHAYTOR, Q.C.:
Q. Okay, and then what process of validation would be undertaken in receiving a new batch of a particular antibody?
MR. GREEN:
A. If there was a different clone, you had to revalidate the antibody. If it was the same clone, but of a different batch, it was not revalidated. There was no lot to lot validation.
CHAYTOR, Q.C.:
Q. No lot to lot validation?
MR. GREEN:

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

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usually took the most concentrated antibody and worked backwards. Those slides would be brought to the pathologist. They would tell us which one they like best and that one would be used.
CHAYTOR, Q.C.:
Q. Okay, and I take it what you're trying to do then is optimize the stain?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And the pathologist then ultimately would make that call based on what they're seeing?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And the dilution range then, was it always within the range provided by the manufacturer on the spec sheet?
MR. GREEN:
A. To the best of my knowledge, it would be, but each antibody has to be optimized for each laboratory. So if you had an antibody which did not work well with your fixation and process tissues, you would have to adapt that

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antibody to work in your laboratory because the guidelines that the manufacturer would give would be guidelines, and they would always specify that these should be optimized with your laboratory. There's not one size fits all philosophy, so each laboratory would be different.

CHAYTOR, Q.C.:

Q. So it could be outside the range provided or suggested by the manufacturer?

MR. GREEN:

A. Yes, because those were recommended dilutions.

CHAYTOR, Q.C.:

Q. If we could have, please, 2177, page seven. Actually, page five first, please. These are the specification sheets that we've been provided from Eastern Health, and this one has the date of June 13, 2001, written on it. Come down under -- I don't see anything written on that particular one in terms of -- anything handwritten in terms of what dilution may be used. So would I take it from that that it would have been somewhere within the range of what the manufacturer was suggesting. It's quite the large range, though. It's an

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optimal staining and dilution of 1 to 50 to 1 to 100. Do you remember when you -- in terms of ER/PR when you first arrived in 2002, what dilution was being used?

MR. GREEN:

A. I can't really specifically recall the dilution that we used. It was probably in the range of 150. 150 seems to ring a bell.

CHAYTOR, Q.C.:

Q. Okay. This talks about the LSAB methods?

MR. GREEN:

A. The Labelled Streptavidin Biotin Method.

CHAYTOR, Q.C.:

Q. And is that what was being used?

MR. GREEN:

A. They put the EnVision on the DAKO system, that was the EnVision which they used for that system, yes. It was the detection system that they used. On the Ventana system we also used the Streptavidin Biotin Method.

CHAYTOR, Q.C.:

Q. Okay. And then on the next page, the next specification sheet, at page seven, has the date of April 3, 2003 and it looks like one over fifty written here.

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MR. GREEN:

A. That looks familiar.

CHAYTOR, Q.C.:

Q. So, that looks familiar? Is this your handwriting?

MR. GREEN:

A. Looks a bit neat for my handwriting.

CHAYTOR, Q.C.:

Q. Okay. And again, in terms of the dilution suggested by the manufacturer, may be used at a dilution of 1 to 35 when performing IHC as in DAKO EnVision.

MR. GREEN:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And DADO EnVision double stain or DAKO LSAB2 detection system. So, I take it you were using which of those -

MR. GREEN:

A. They were using the EnVision at the time.

CHAYTOR, Q.C.:

Q. The EnVision at the time, okay. And at this point in time was suggesting 1 to 35. So, I take it there would have been a revalidation that took place at this point in time?

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MR. GREEN:

A. Most likely, yeah.

CHAYTOR, Q.C.:

Q. And if we go forward then to page 11, later that month, April 28, 2003 we see a 1 to 20 or 1 in 20.

MR. GREEN:

A. Yeah, seems that the concentration is increasing.

CHAYTOR, Q.C.:

Q. Okay. Now, do you remember anything in that time period then in April of 2003 as to why it would have changed from 1 to 50 to 1 to 20?

MR. GREEN:

A. I wasn't involved in the revalidation of the antibody at that time because I would have been the junior employee in the IHC department. Peggy was probably gone or pretty close to going, could have bene Mary. It may be at time that Dr. Ejeckam had problems with some of the antibodies which I didn't realize until after.

CHAYTOR, Q.C.:

Q. Yes, and I'll take you through that as to when you became aware of Dr. Ejeckam and anything

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he was doing to tweak the system at this point in time. So, the fact that it had changed from 1 to 50 to 1 to 20 in that month, would you have been aware of that?

MR. GREEN:

A. If it was not my week on the machine, I'd probably be two weeks without being in that part of the lab. It's possible that other-- not only possible, it's factual that I was not aware that it was not happening.

CHAYTOR, Q.C.:

Q. You didn't know that the change had taken place in the dilutions?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. How then when you next ran the machine would you be aware that the dilution had changed?

MR. GREEN:

A. Because we went to re-dilute the antibody for that run, it would have been changed on the bottle, on the vial that the antibody would come in, it would have been changed to indicate 1 in 20. If it had not been changed to indicate 1 in 20, there would be no way of

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knowing.

CHAYTOR, Q.C.:

Q. And do you know whether or not it had been changed on the vial?

MR. GREEN:

A. I don't recall.

CHAYTOR, Q.C.:

Q. You don't recall?

MR. GREEN:

A. No. Because I had not been aware that there had been work done on the antibodies. So, I would have no way in knowing.

CHAYTOR, Q.C.:

Q. So, unless it was written on the vial and, unless it was written on the vial and you checked it, you would have no way in knowing?

MR. GREEN:

A. You would have to check in the vial in order to make the antibody because in the ER/PRs we would run most of them in batches. And on a DAKO system, the amount of antibody needed to run the tests would come up on the machine before we ran a test. We made up the antibody fresh. I think it took 250 microlitres per slide and so on millilitre, we would need--

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would cover four slides. We very seldom had a run of four slides on ER/PR, wouldn't be much more than that. So, you would have to make up approximately 10 mills of antibody for that run. So, you would have to look at the -

CHAYTOR, Q.C.:

Q. You'd have to check the vial.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And so no other form of communication of the information to you other than what may or may not have been written on the vial. So, no memo would go out, for example, or nothing posted int he lab to advise when there have been change in dilutions?

MR. GREEN:

A. No. And 1 in 20 dilution from a 1 in 50 dilution would suggest that you're trying to increase the primary antibody. So, you're trying to increase the expression of the antibody.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

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A. As opposed to going in the opposite direction which means it would be too strong. So, it would indicate that it was too weak.

CHAYTOR, Q.C.:

Q. It was too weak, yes, okay. And so the concern being that, I take it, that the antibody wasn't expressing, primary antibody wasn't expressing itself enough on the test.

MR. GREEN:

A. It wouldn't be as sensitive as you wanted it to Be.

THE COMMISSIONER:

Q. Mr. Green, I just want to make sure that I understand precisely what occurred here when there was a change made. So, am I understanding you to say that you realized a change had been made because when you actually went to take the solution, there was a changed marked on the bottle of the solution or the container in which the solution was kept.

MR. GREEN:

A. Yes, the practice at the Health Science IHC paraffin lab was to write the dilutions on the bottle which came from the manufacturer, write it on the specification sheet that went in the

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file and to write it on the working dilution bottle which you would put on the machine.

THE COMMISSIONER:

Q. Okay, but do I--now, I'm making an assumption here which is maybe incorrect, so you should tell me--I'm assuming that once you were comfortable with doing this test, you probably didn't look at the specification sheet every day?

MR. GREEN:

A. Well, you wouldn't have to go back to the specification sheet unless you had a problem.

THE COMMISSIONER:

Q. All right.

MR. GREEN:

A. Because their protocol would have been written and the protocol is--and you would not change a protocol. Once a protocol is set, it wouldn't be changed and shouldn't be changed unless you got a problem.

THE COMMISSIONER:

Q. Okay. Coming back to the dilution, when you went to get the solution from the refrigerator as -

MR. GREEN:

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A. Yes, it was kept in the refrigerator.

THE COMMISSIONER:

Q. - then the way you knew that there was a change was because the numbers on the side -

MR. GREEN:

A. Would have Changed.

THE COMMISSIONER:

Q. - would have changed.

MR. GREEN:

A. Yes.

THE COMMISSIONER:

Q. Now, would somebody take out all the old solution, perhaps I'm incorrect, would there have been around a container with the same solution with a different number on it?

MR. GREEN:

A. No.

THE COMMISSIONER:

Q. Would they, sort of, cross it out on the vial and put on another number?

MR. GREEN:

A. The manufacturer would send a concentrated solution. From that concentrated solution we would make up a working dilution to use.

THE COMMISSIONER:

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Q. Would you make it up each occasion that you used it as opposed to -

MR. GREEN:

A. Each time you ran the machine.

THE COMMISSIONER:

Q. All right.

MR. GREEN:

A. So, depending on the number of slides that you ran, if you had to run two slides and you went and you got your antibody to put on the machine and you looked and you had two loads of antibody, you will have no reason to add antibody to that solution, but if you had a run of 10, 20, 30, 40 which wasn't unusual, you would have to make sure you had sufficient antibody to cover all--you would have to make up your antibody. And in the case with ER/PR, they were batched. So you would have to make up your antibody.

THE COMMISSIONER:

Q. Okay. So, somebody in the system did the tweaking, determined that that dilution should be at a different rate than it had been prior to this and that was recorded by changing what was on the side of the bottle.

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MR. GREEN:

A. Yes.

THE COMMISSIONER:

Q. Okay. I'm saying bottle, it may not be a bottle, but the container.

MR. GREEN:

A. Yeah, container.

THE COMMISSIONER:

Q. Which was kept in the fridge.

MR. GREEN:

A. Yes.

THE COMMISSIONER:

Q. All right, thank you.

CHAYTOR, Q.C.:

Q. Okay. And if that change, Mr. Green, had not been made on the side of the vial, what would you do? What would happen?

MR. GREEN:

A. If the change had not been made on the (inaudible - coughing).

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. We would--if it was my turn to run the machine I would take the vial from the refrigerator,

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check whatever was on the label and whatever dilution is indicated would be the dilution that would go on. There would be no reason to change the dilution, if you weren't instructed to do so. And I take it that the tests would proceed as normal?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And there'd be no way of you knowing that that was not the -

MR. GREEN:

A. Change had been made.

CHAYTOR, Q.C.:

Q. Right.

MR. GREEN:

A. There would be no way of knowing.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. The slide would go to the pathologist to read.

CHAYTOR, Q.C.:

Q. Okay. Now, you mentioned in terms of your training and learning about the different antibodies and there were about a hundred at

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the beginning, some of them required antigen retrieval. What were you taught in terms of why you needed to do antigen retrieval and how you, in fact, went around doing antigen retrieval?

MR. GREEN:

A. There was some information in the lab on antigen retrieval. I remember it because in the literature back then they referred to it as unmasking and we don't refer to that nomenclature. It's called antigen retrieval. And we would have a list and the antigen retrieval, ones that required antigen retrieval were highlighted and the ones that didn't, were not. They were already pre-determined, which ones needed antigen retrieval. If you had any doubts about that, you would check the specification sheets and all the protocols were already programmed into the computer. So, unless there was a new antibody, there would be--you would know it.

CHAYTOR, Q.C.:

Q. And was there anything then in particular told to you in terms of caution to be taken with respect to those antibodies?

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MR. GREEN:

A. I knew from the reading that was there that antigen retrieval was needed because of formalin fixation. I had read that the IHC had been developed on fresh human tissue which were done on frozen sections and they had great success with the frozen sections and somewhere along the process scientists had discovered that they could use paraffin sections. Paraffin sections, it was breakthrough in IHC because when you used frozen tissue, you had a limited amount of frozen tissue and when the tissue was gone, you had nothing to go back to. When they discovered that you could use antigen retrieval to, kind of, reverse the effects of formalin fixation, it was a breakthrough in IHC and a number of IHC antibodies expanded that exponentially. And so they figured that that--it's kind of a paradox that with the antigen antibody reaction, you kind of got to watch the temperatures. You don't want to have your oven at a higher temperature because the literature says that it can affect the antigen antibody reaction. But with antigen

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retrieval, you would subject the tissue to a citrate buffer between 95 and 100 degrees for 20 minutes. Take it from the water bath, let it sit for another 30 minutes and then go and perform the same peroxidase, anti-peroxidase method that you used on tissues that didn't require antigen retrieval. Not al antibodies require antigen retrieval. Some antibodies will work with the Labeled Streptavidin Method quite well with no antigen retrieval. Some of the antibodies that we ran worked better with our proteolytic enzyme which was used in the digestion process to do antigen retrieval. But the ones like ER/PR, they require a heat induced antigen retrieval which was needed to be heated in a water bath. One of the reasons for the ER/PR, heat induced antigen retrieval was because it was a nuclear antibody and the nuclear antibody being far deeper in the cell, it required more unmasking to expose an antibody, find primary antibody.

CHAYTOR, Q.C.:

Q. And Mr. Green, is that something you knew at the time when you started doing the test in 2002 or is that knowledge you have gained over

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time?
MR. GREEN:
A. I've gained it over time.
CHAYTOR, Q.C.:
Q. Yes, okay. So, the importance of antigen retrieval and the detail that you've just told us, that's something you've learned, I take it, since 2005?
MR. GREEN:
A. Sure.
CHAYTOR, Q.C.:
Q. And in terms of the importance of it, specifically for ER/PR in that being a nuclear antibody, is that something that you've also learned since 2005?
MR. GREEN:
A. I knew that the ER/PR was a nuclear antibody very soon after I moved over to the Health Science because when you read the specification sheet that it will clearly tell you which elements are supposed to be demonstrated and the purpose of the stain. By reading the sheet you would know that it was nuclear antibody and by my general lab knowledge, I knew that nuclear antibodies were

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deeper in the cell than the cytoplasmic antibodies.
CHAYTOR, Q.C.:
Q. Okay. And in terms of then anything, any special precautions for ER/PR, were you aware of those at the time?
MR. GREEN:
A. I learned when I went to Health Science that since every antibody that needed antigen retrieval had to be put on a special slide which used the histogrip adhesive because breast tissue was known to come off the slides in normal pathology. And being exposed to antigen retrieval complicated the matter. So, it was even--you needed to take more precautions. You wanted every help that you could get to get that piece of tissue to stay on the slide during the process.
CHAYTOR, Q.C.:
Q. Okay. And in doing antigen retrieval then, and were all the antibodies that required antigen retrieval subjected to the same process, the sam temperature, the same amount of time?
MR. GREEN:

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A. Yes. There were two--on the DAKO system, there were two antigen retrieval solutions. The one we used for the ER/PR was a citrate buffer which was pH 6. There was a higher antigen retrieval solution of pH 8 which was used very infrequently. Most of the antibodies used the citrate buffer.
CHAYTOR, Q.C.:
Q. I'm sorry, so was it a different pH?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. For ER.
MR. GREEN:
A. Citrate bugger of pH 6 we used for ER.
CHAYTOR, Q.C.:
Q. Okay. And who would have told you that so that you would know that?
MR. GREEN:
A. It would have some on the manufacturer's -
CHAYTOR, Q.C.:
Q. On the spec sheet?
MR. GREEN:
A. On the spec sheet.
CHAYTOR, Q.C.:

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

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2005 in IHC, is there anything then that's come to your attention regarding the antigen retrieval process you were using with the DAKO system that now causes you to look back and question or concern?

MR. GREEN:

A. Hindsight is 20/20.

CHAYTOR, Q.C.:

Q. Yes, fair enough.

MR. GREEN:

A. And looking back now, when we set up the--I worked for a little over a year on the DAKO system, so I had the advantages of working on both the DAKO system and the Ventana system. When we introduced the Ventana system, we transferred the protocols from the DAKO over to the Ventana and we had protocols from other institutions which we checked at the same time. And the specs from Ventana suggested that we use antigen retrieval standard which was on--there a quite a few differences between the DAKO system and the Ventana system. On the DAKO system, the antigen retrieval was done as a manual method and on the Ventana system it was what we call

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onboard. And on the Ventana system, we could choose an antigen retrieval of short which was eight minutes. And if you pick the short, it was eight minutes each time and every time. We could pick mild which was 30 minutes and if you picked 30 minutes, it was 30 minutes every time with no variation. If you picked standard, it was 60 minutes with no variation. And if you pick extended, it was 90 minutes with no variation. The protocol that we decided to run on the Ventana was called CC1 mild. CC1 is the manufacturer's name for antigen retrieval. The solution is an EDTA borate solution with a pH of 8. That one we used on the Ventana system and I think the primary antibody time was probably 24 minutes, 24, 28, one or the other for ER and one for PR. We ran those protocols on our controls on the Ventana system and the results were exceptional.

CHAYTOR, Q.C.:

Q. So, that's when you were doing--brought in the Ventana and did the validation in terms of which would be the optimal time for antigen retrieval, I take it.

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MR. GREEN:

A. Yes. Compared to the DAKO system, the Ventana system had a higher pH antigen retrieval and a longer time and is controlled precisely by a machine. The other differences in the Ventana system, the antigen retrieval was done onboard. We brought in what we called pre-dilute antibodies which means that the antibodies were optimized by the manufacturer and they weren't meant to be tampered with. You could control your antigen retrieval and you could control your antibody incubation time, but you could not control your antibody dilution.

CHAYTOR, Q.C.:

Q. So, your understanding was the pre-diluted antibodies, that's it, there's no validation or optimization of those.

MR. GREEN:

A. No, by pre-diluted antibody it means that you do not change dilution of the antibody.

CHAYTOR, Q.C.:

Q. You don't change the dilution under any circumstances.

MR. GREEN:

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A. Or as far as the validation goes with the antibody, validation is a different concept. Validation is where you take your antibody and adapt it to work in your lab. What you want to achieve is optimal demonstration of the antibody which you want to observe with minimal background staining which is referred to it as signal to noise ratio. You want it optimized so that you demonstrate what you want to demonstrate with the least amount of antigen retrieval because antigen retrieval is harsh on the tissue, but optimal results demonstrating the elements that you want to demonstrate and keeping at a minimum, the elements that you don't want to demonstrate.

CHAYTOR, Q.C.:

Q. Okay. So, but in adapting it as you say to your particular lab, you don't tamper at all with the dilution of a pre-diluted antibody?

MR. GREEN:

A. On a pre-diluted antibody you do not touch the dilution. It is optimized by the manufacturer.

CHAYTOR, Q.C.:

Q. Okay. So, back to the issue of my question

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regarding antigen retrieval and how it was done with the DAKO system. And I appreciate how it's now change and what happened with Ventana. So, with that knowledge and any other knowledge that you've acquired, looking back, is there anything about the antigen retrieval system in the DAKO days that causes you concern?

MR. GREEN:

A. It seemed to be working fine in the earlier stage of the DAKO system, but the checks and the balances that should have picked up low expressors which would be the internal controls which means that if the pathologist read the slide, we run external batch controls. And a batch control tells us that the system worked and that the antibody was applied when it was supposed to be applied and the detection system was applied when it was supposed to be applied. But an internal control will tell you if the patient's tissue, if the antibody in the patient's tissue, if it was applied in the patient's tissue and had worked--what I'm trying to say is that if the proper piece of tissue had been submitted and

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the process had happened as it was supposed to have happened, if the internal control was positive, you would know that the system worked. If there was no internal control and the system didn't work, you would have no way of knowing that the tissue itself was treated properly.

CHAYTOR, Q.C.:

Q. So when you say a batch control, you're referring, I take it, to the external controls?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. We've heard them called external controls.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So your external control would tell you that the test itself had worked, the system had worked?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. But you see the internal control as being

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crucial to determining whether or not the test worked for that particular patient?

MR. GREEN:

A. That patient.

CHAYTOR, Q.C.:

Q. Yes, okay. So if internal controls had not worked or were absent, whether or not -- whether or not the test had been effective for that particular patient, that would be the key?

MR. GREEN:

A. That would be the key because if your internal control works, which is normal ductal epithelium which would -- if that was present and had stained, you would know that that patient's tissue had been treated.

CHAYTOR, Q.C.:

Q. And do you connect then -- my question had been about the antigen retrieval. Do you connect the antigen retrieval process to the internal control, and whether or not the internal control worked or not?

MR. GREEN:

A. No, not -- no.

CHAYTOR, Q.C.:

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Q. Okay.

MR. GREEN:

A. When I connected the antigen retrieval was when the ER/PR episode unfolded, and I started to ask questions and one of my first questions was the specimens that were converting from Mount Sinai, I said what protocol are they using because from a technical point of view, if we were running tests and we were getting a negative result, and they were being retested and getting a positive result, I would think of -- I would want to know what was going on because it would be -- that was my area. So I wanted to know what protocols they were using, what antibody they were using, the clone and the dilution, and the antigen retrieval. I found out subsequently that the antigen retrieval that they were using was a pressure cooker at 121 degrees. So our antigen retrieval was at a water bath at 95 to 100 degrees, and I had experience with the Ventana System, knowing that we were getting good results with the Ventana, and the differences between the DAKO, our DAKO and the Ventana, was the antigen retrieval.

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CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. So I connected the dots and the antigen retrieval they were using to optimize our specimens there was a factor.
CHAYTOR, Q.C.:
Q. So while Mount Sinai was using the DAKO System, and for the vast majority of years involved in the retrospective review St. John's had been using the DAKO System, the difference that you were able to determine was that you were using water bath hash 95 to 100 degrees whereas the antigen retrieval process at Mount Sinai involved the pressure cooker at 125 degrees?
MR. GREEN:
A. And the very chemistry behind it, you know, if you increase the temperature, you're going to increase the reaction rate.
CHAYTOR, Q.C.:
Q. Were the other -- when you made those inquiries, Mr. Green, as to, for example, the protocol and the antibodies they were using, the clone and the dilution as you say, were

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all of those variables consistent?
MR. GREEN:
A. I didn't get that information.
CHAYTOR, Q.C.:
Q. Okay. The one thing that you were able to determine was different was the antigen retrieval process?
MR. GREEN:
A. Antigen retrieval.
CHAYTOR, Q.C.:
Q. I had asked you about difference in ER/PR in terms of the antigen retrieval, or your understanding of how ER/PR may be different, and you did understand, of course, that it was a nuclear antibody early on. Did you understand when you first began doing ER/PR tests the importance or significance of the test?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So you knew what it was for, what the purpose of the test --
MR. GREEN:
A. I knew what it was, a test that -- that was a

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subjective test, and that the results of that test were used for patient treatment.
CHAYTOR, Q.C.:
Q. And if we just look back for a moment at 2177, these specification sheets, where were those kept within the lab?
MR. GREEN:
A. Those were kept in an accordion type folder underneath the bench because the folder was too big to -- we didn't have bench space, so it was underneath the bench.
CHAYTOR, Q.C.:
Q. So it was underneath the bench in an accordion folder?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And were they in any particular order, if you needed to consult and go back?
MR. GREEN:
A. Alphabetical order.
CHAYTOR, Q.C.:
Q. They were in alphabetical order in the accordion folder?
MR. GREEN:

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A. Yeah.
CHAYTOR, Q.C.:
Q. So if you had taken out a specification sheet, two or three out that day for whatever reason and had to put them back, what order would they go back in?
MR. GREEN:
A. The most recent would be put close to the front.
CHAYTOR, Q.C.:
Q. Uh-hm.
MR. GREEN:
A. But we didn't necessarily throw out all the old sheets. We kind of just added the newer ones to the front.
CHAYTOR, Q.C.:
Q. And it's alphabetical according to -- for example, we have monoclonal mouse, so this is alphabetical and --
MR. GREEN:
A. Estrogen receptor would be under "E".
CHAYTOR, Q.C.:
Q. Okay, so it's under "E".
MR. GREEN:
A. Progesterone would be under "P".

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CHAYTOR, Q.C.:
Q. Okay, and when -- I'm going to ask you some detail about your knowledge of when Ms. Wegrynowski attended upon the lab and her investigation there. We did hear her indicate one of her findings that the specification sheets and documentation being left somewhat in random order in a drawer in the lab. What do you say about that observation?
MR. GREEN:
A. They were not compiled in a binder in alphabetical order but they were in the accordion type folder.
CHAYTOR, Q.C.:
Q. So they weren't in a binder, they were in like file folder?
MR. GREEN:
A. File folder, yes.
CHAYTOR, Q.C.:
Q. And they were in this drawer?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And were they always then in the file folder or were some of these sheets in the drawer and

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outside of the folder?
MR. GREEN:
A. Periodically somebody would take it upon themselves to take out some of the older ones because the binder would start to get bigger and bigger. So those would probably end up in the drawer, they would not be thrown out, they would be probably put in the drawer.
CHAYTOR, Q.C.:
Q. So I take it you could understand where that particular observation may have come from?
MR. GREEN:
A. Yes, I can see where somebody could make that observation.
CHAYTOR, Q.C.:
Q. Overall in terms of other record keeping then within the lab, and again this is up until this issue arises in 2005 -- so from when you get there in 2002 up until that point in time in 2005, what was happening in terms of keeping track of what you were doing on any ER/PR test or on any IHC testing?
MR. GREEN:
A. You would create a daily run sheet which would be numbered 1 to 48. So the patient's surgical

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number would be on that sheet, plus the antibody that we were going to run, and that sheet would be entered into the computer and it would generate a -- the computer would generate a grid and we would match our slides to the grid and the run sheet was the sheet that we kept the -- that was our documentation.
CHAYTOR, Q.C.:
Q. And what would happen to your run sheet at the end of the day?
MR. GREEN:
A. At the end of the day, we would enter into the computer the number of slides that we ran, and that sheet would be filed.
CHAYTOR, Q.C.:
Q. And would you keep them, would your run sheets be kept for a period of time?
MR. GREEN:
A. They were probably kept for maybe a year. I don't think we had a specified time they were supposed to be kept, not that I was aware of.
CHAYTOR, Q.C.:
Q. And in going back and looking for run sheets for the period of time, for example, that the

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commission is involved with, I take it those run sheets would not exist any longer?
MR. GREEN:
A. I doubt very much if those sheets would be kept.
CHAYTOR, Q.C.:
Q. So what about in terms of then any documentation about quality control that may have been happening in the lab, documentation as to, for example, maintenance or cleaning of equipment, was there anything happening?
MR. GREEN:
A. The equipment -- the DAKO machine was set up so that after you ran 200 slides, the machine would shut down and you would have to clean it before it -- before you could run it again, but we didn't keep a record of that maintenance.
CHAYTOR, Q.C.:
Q. So what then, broadly speaking in terms of quality control, was happening with respect to the IHC tests?
MR. GREEN:
A. We would run an external control which would be checked by the pathologist, and -- our

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biggest quality control in IHC, and the pathology lab in general, is the fact that every slide that we sent out would be checked by the pathologist.

CHAYTOR, Q.C.:

Q. Okay, and in terms of quality assurance, ongoing quality assurance measures, and the equipment maintenance, what you're telling me is that after 200 slides, that the machine would have to be -- there would be a maintenance procedure then for the machine?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Was there anything happening in terms of daily check of the machine?

MR. GREEN:

A. No. The only check would be the pre-run check, so that before you ran a batch of slides, you would generate what we call a map. A map would show the relationship of the patient's slides to the grid on the machine, and we would generate a map of the reagents that we're going to use, the detection system, plus the antibodies that we would run. On

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that grid, it would show you the volume of antibody that you needed to put in each container.

CHAYTOR, Q.C.:

Q. Now I know we have the reagent map. I don't know if we have a copy of the patient's slides, the grid that you're referring to. I don't know if we have a sample of that or not, but if not, that might be helpful for us when I go through your questions on that aspect. So perhaps we can look into that. I take it then in terms of anything else that was happening in terms of quality assurance or quality control, is there anything else that you can think of that was taking place?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And we've heard that there was no external quality assurance as such for the IHC portion of the lab in that time period?

MR. GREEN:

A. Not in that time period. That would come later.

CHAYTOR, Q.C.:

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Q. That comes after 2005, and I believe you've been involved in that yourself?

MR. GREEN:

A. Yeah, that was initiated by Dr. Ejeckam.

CHAYTOR, Q.C.:

Q. And I'll take you through that when we talk about the present situation.

MR. GREEN:

A. Okay.

CHAYTOR, Q.C.:

Q. You indicated the location of the lab, which we understand there's also been some changes in terms of the physical setup now of the IHC portion, that it was part of the main pathology lab. Was there ever any discussion prior to 2005 that you're aware of as to concerns about the IHC lab being part of the overall general lab or the location of it?

MR. GREEN:

A. I was not aware -- I assumed that all IHC labs were part of the general anatomic pathology lab.

CHAYTOR, Q.C.:

Q. And you didn't hear anyone voice any concern or any issue regarding its location?

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MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. The refrigerator that you kept your antibodies in, you would go to the fridge to get the antibodies and you've described that to us. Was the refrigerator at that period of time equipped with an alarm?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And is it currently equipped with an alarm?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Do you know when that change came about?

MR. GREEN:

A. That change came about when we moved the IHC lab to its -- we now have a separate section for the IHC lab. We got a -- we purchased a refrigerator which was dedicated to IHC only, and then it was set up with an external alarm.

CHAYTOR, Q.C.:

Q. And in looking at the label on a given vial, a given antibody for the dilution, you'd have to

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do that you've explained to us. Would there be anything else on the label that you would check?

MR. GREEN:

A. The expiry date and the clone.

CHAYTOR, Q.C.:

Q. The expiry date and the clone, okay. How in the days of DAKO when you're diluting your own antibodies, how would you come up with an expiration date?

MR. GREEN:

A. The expiration date was supplied by the manufacturer.

CHAYTOR, Q.C.:

Q. And in terms of making up a quantity of the antibody, would you tend to make enough for a given period of time?

MR. GREEN:

A. You would make enough for that particular run.

CHAYTOR, Q.C.:

Q. Just per run?

MR. GREEN:

A. Per run.

CHAYTOR, Q.C.:

Q. And so why would there be any then -- so you would take -- what you would take and dilute for that day would just be for that run?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. And then you'd put the vial back with whatever was remaining?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. Did you ever have experience of noting that antibodies had been expired?

MR. GREEN:

A. An antibody like ER/PR or all the antibodies which we used on a regular basis, it would never expire because we did so many tests that -- the bigger problem was making sure that you had sufficient antibody on hand and you didn't run out.

CHAYTOR, Q.C.:

Q. So you never had the experience particularly with ER/PR that an expired antibody would be on hand?

MR. GREEN:

A. No, because like -- the dilution that I remember, in particular, was 1 in 50. The vials that we would order would come in 1 mil or 2 mil size. So they wouldn't last very long.

CHAYTOR, Q.C.:

Q. And the -- do you ever remember any comment or discussion about using up an antibody because of the cost of the antibody?

MR. GREEN:

A. I have never had a problem with cost of procuring antibody.

CHAYTOR, Q.C.:

Q. So that's not anything that's ever said within your earshot?

MR. GREEN:

A. We were aware that antibodies were expensive, but it was never a factor in our using antibodies, the cost.

CHAYTOR, Q.C.:

Q. So you were cognizant of the cost, but it was never an issue in term of -- if it had to be thrown out, for example, at the end of its expiry date, that was never an issue?

MR. GREEN:

A. Never.

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CHAYTOR, Q.C.:

Q. Okay. I want to turn now then and concentrate a little more on external controls, and how external controls were first of all created. What did you understand would be used to create a bank of external controls?

MR. GREEN:

A. We would use in-house tissues which were -- patients which were known positive.

CHAYTOR, Q.C.:

Q. And --

MR. GREEN:

A. Pathologists would supply those tissues.

CHAYTOR, Q.C.:

Q. So the pathologists would be involved in supplying the tissue.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Would there be any particular tissue for ER/PR tests for an external control?

MR. GREEN:

A. It would be known positive breast tissue.

CHAYTOR, Q.C.:

Q. Known positive breast tissue, okay, and for

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other IHC tests, are other things sometimes used, like, for example, tonsils, things like that, sometimes used for your external controls?

MR. GREEN:

A. Most of the other IHC tests have their own individual controls. Al the CD markers, the CD3s, the CD5s, all the lymphoma markers would be tonsils.

CHAYTOR, Q.C.:

Q. And for -- however, for ER/PR test, the external control is always breast tissue?

MR. GREEN:

A. Always breast tissue and progesterone. A lot of them were breast tissues.

CHAYTOR, Q.C.:

Q. And in terms of identifying then the need for more controls, for example, if your control bank is getting low, whose responsibility would that be to ensure you have a healthy supply?

MR. GREEN:

A. When the supply would start to run low, we would check with the pathologists and they would suggest blocks to use.

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CHAYTOR, Q.C.:

Q. And did you ever have any difficulty in receiving assistance from the pathologists in that regard?

MR. GREEN:

A. No, most of the pathologists were very approachable.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. Now controls were always a challenge because you ran so many tests, that we always needed controls, but when we asked, there was never a problem getting controls.

CHAYTOR, Q.C.:

Q. And when you brought on the Ventana System in terms of setting up control banks then -- I take it first of all for DAKO, there was already a supply of control slides in use.

MR. GREEN:

A. We used the same controls.

CHAYTOR, Q.C.:

Q. There was already control blocks already created, and then on the Ventana, did you use the same blocks that had been used on the DAKO

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machine?

MR. GREEN:

A. Yeah. When we started in the switch over, we ran parallel runs on the DAKO and on the Ventana System. We would use the same controls.

CHAYTOR, Q.C.:

Q. Okay.

CHAYTOR, Q.C.:

Q. And in doing then ER/PR tests, for example, if you had a request for an ER/PR test from St. Clare's, some for other outside hospitals, some for within, how many external controls would you run?

MR. GREEN:

A. Depending on how your run is set up for that day, if three pathologists at St. Clare's-- three different pathologists at St. Clare's requested an ER/PR, most times they would get one control and they would have to share that control at St. Clare's. If three pathologists at the Health Science requested an ER/PR, they got one control and they had to share that control. If we had one going to Carbonear, Grand Falls, Gander, Corner Brook, they each

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would get their control, which would be sent, an external control which would be sent to those. They would have to interpret the control and their own slides.

CHAYTOR, Q.C.:

Q. So from the time that you arrived in 2002, the practice was one external control per institution?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and the in house, what would happen to the external control in house? Where would that go, within the Health Science I mean?

MR. GREEN:

A. Pathologists at the Health Science would read their slides in what we call the reading room, which was a slide which was equipped with several microscopes, plus a multi-headed microscope, and there was a shelf marked controls. We would bring the controls for that day, we would mark if it was June 15th, we would write June 15th, bring the controls for that day, put them on a shelf in the reading room.

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CHAYTOR, Q.C.:
Q. So I take it they would be marked with a particular antibody, as well as the date?
MR. GREEN:
A. Yes, each antibody, the ER control would be written ER control and the date. PR, PR control and the date.
CHAYTOR, Q.C.:
Q. And they'd be put on a particular--in a particular spot within the reading room?
MR. GREEN:
A. Yeah, in the same spot.
CHAYTOR, Q.C.:
Q. And what then would happen in terms of once the pathologists are finished with the control slides, how would they end back into the system or being filed?
MR. GREEN:
A. We would not necessarily get those slides back in the IHC lab. They would be filed when all the slides were filed in the general pathology lab. They may or may not be filed with that specific case.
CHAYTOR, Q.C.:
Q. Okay, and would you do anything with the

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external controls prior to putting them out in the reading room or sending them out to the other hospitals?
MR. GREEN:
A. Sometimes we would look at the external controls to make sure that the antibody had been applied.
CHAYTOR, Q.C.:
Q. And what in particular were you looking for?
MR. GREEN:
A. We were looking for--in my particular case, I would be looking for brown diaminobenzadine staining in the tissue.
CHAYTOR, Q.C.:
Q. And was it any particular area of the tissue that you would be looking to see had stained?
MR. GREEN:
A. No, it wasn't until later that Dr. Ejeckam took the time to teach us, in detail, the controls.
CHAYTOR, Q.C.:
Q. Okay, and so Dr. Ejeckam some time--was that after 2005 that that happened or before that?
MR. GREEN:
A. Around 2005 when he took control of the IHC

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lab.
CHAYTOR, Q.C.:
Q. Okay. I take it when he more formally took -
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Yes, okay, and did you ever have occasion--does anything stick out in your mind as to the external controls not having worked, you, yourself, in looking at them?
MR. GREEN:
A. No, I never had occasion and if the controls didn't work, the pathologists would come back and if they had a problem, they would say.
CHAYTOR, Q.C.:
Q. Okay, and I take it you do have recollections of that happening, where the pathologist would come out and come back to you and say an external control hadn't worked?
MR. GREEN:
A. From time to time with any particular antibody, if there was a problem with the control, pathologist would come back and say that the controls is not working the way we would like. He'll ask for a repeat and we

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would do a repeat.
CHAYTOR, Q.C.:
Q. And what would happen? Would you just repeat that particular test?
MR. GREEN:
A. Yeah, we would repeat the test, using the same protocol we used before. If there was a problem at this point, then we would go back and troubleshoot and find out what the problem was.
CHAYTOR, Q.C.:
Q. So if you repeated the test, then it still wasn't satisfactory, then you would make further investigation?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But in terms of the other, for example, ER/PR test that had also run that day, if a pathologist comes back and has noticed that the external control hadn't worked, would there be any efforts undertaken to ascertain all other tests which had ER/PR carried out, all other patients which had ER/PR tests that day so that their tests could be rerun?

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MR. GREEN:
A. No, because it would be the pathologists responsibility to check their patient's tissue and it would be their responsibility to pick the appropriate--to submit the appropriate block with the appropriate internal control.
CHAYTOR, Q.C.:
Q. Okay. So there was no policy to automatically rerun all ER/PR tests with that batch -
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. - in the event that an external--it had been brought to your attention the external control hadn't worked?
MR. GREEN:
A. No.
THE COMMISSIONER:
Q. Ms. Chaytor, wherever you can find a spot, we'll break for the morning break.
CHAYTOR, Q.C.:
Q. Actually, this would be a good place, Commissioner.
THE COMMISSIONER:
Q. 15 minutes.

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CHAYTOR, Q.C.:
Q. Thank you.
(RECESS)
THE COMMISSIONER:
Q. Please be seated. Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. Commissioner, there are four other exhibits that I believe Mr. Green will be referring to. We had intended to put them in under another witness later, but if we could instead have them entered through Mr. Green.
THE COMMISSIONER:
Q. And they are?
CHAYTOR, Q.C.:
Q. They are P-2178 through P-2182 inclusive.
REGISTRAR:
Q. Excuse me, Ms. Chaytor, 2180 is (inaudible).
CHAYTOR, Q.C.:
Q. 21--oh, I'm sorry, yes, thank you, Registrar. It's 2178, 2179, 2181 and 2182.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED EXHIBITS P-2178 AND P- 2179
EXHIBITS ENTERED AND MARKED EXHIBITS P-2181 AND P- 2182

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CHAYTOR, Q.C.:
Q. And all counsel would already have received those.
THE COMMISSIONER:
Q. Thank you.
CHAYTOR, Q.C.:
Q. Thank you. Mr. Green, just sticking with external controls for a moment, external controls in particular for ER/PR slides, would those controls have been subjected to the same antigen retrieval process as the patient tissues?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So in terms of using though the DAKO or slides which would--or blocks which would have been--slides, sorry, which would have been prepared through the DAKO system for the Ventana system?
MR. GREEN:
A. It would go through the same fixation and processing.
CHAYTOR, Q.C.:
Q. Would it go through the same antigen retrieval

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process? Would those slides have--those external slides under the DAKO system, which were used for controls under the Ventana system, have been put through the same antigen retrieval process?
MR. GREEN:
A. No, the antigen retrieval process on the Ventana was different than the antigen retrieval on the DAKO.
CHAYTOR, Q.C.:
Q. And were there ever any concerns or issues raised in relation to that, that the slides-- the control slides may not have been put through the same process as the patient slide?
MR. GREEN:
A. I don't know if I'm misunderstanding you. The slides that were run on the DAKO system, they were put through the same system as the DAKO slides.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. The ones that were run on the Ventana, were run through the same as the ones on the Ventana slides.

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CHAYTOR, Q.C.:
Q. Yes, now my question is geared more towards then when the Ventana system came on, the control slides were controls slides--sorry, blocks, not--blocks which had been used through the old system versus the new?
MR. GREEN:
A. They would be the same blocks.
CHAYTOR, Q.C.:
Q. Okay, all right. That's it. Thank you. When you would look at external controls, when you would look at--look through and I understand what you said this morning that you learned a little more about that through Dr. Ejeckam later on in the process.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But when you would look at the external controls, would you be looking for any particular intensity in staining?
MR. GREEN:
A. No, not particularly, as long as it was positive.
CHAYTOR, Q.C.:

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Q. Okay. In terms of just sticking again with the external controls for a moment, if there were any request for a slide to be redone, would there be any record kept of that?
MR. GREEN:
A. The only way that you could tell is when we went into the computer to put in what we call units, you would go in and if you went in on Tuesday and put in the surgical number, surgical number 1000-2003, you would put in ER, if there's one block ER1 or ER2, PR1. If you went back the following day and you repeated that test, you would go back under the same surgical number and you would now go in and change the one to a two. So that you would know that there were two ERs done on that one and two PRs.
CHAYTOR, Q.C.:
Q. Okay. So in terms of keeping a log of any particular problems, that wasn't happening in that time, I take it?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Okay. So for example, if you kept track and

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then you would know, over a given period of time, how many repeats and whether or not that would cause you then to make any adjustments in your procedure, nothing like that was happening?
MR. GREEN:
A. We didn't keep any statistics on repeats.
CHAYTOR, Q.C.:
Q. And no log whatsoever in terms of any problems encountered with the testing?
MR. GREEN:
A. No, we didn't have a corrective action log.
CHAYTOR, Q.C.:
Q. Okay, and that's something, I understand, that you do currently have?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. And that's something that's come in recently?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Into use, okay. If we could look, please, at P-2149, and I believe it's page 24, please, Registrar? This is a--this Exhibit 2149 is a

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series of these special procedure request forms and this one in particular has your name as the histotech, and the date completed, it's a little difficult to see, but I think it's June 26th, 2002. If we look at the date up here, it's June 21st, 2002, in which Dr. Dalton would have ordered the test, and Dr. Dalton, we understand, is from outside Eastern Health region. Perhaps you could tell us, on the side here, it's written "controls checked KG." Is this your handwriting?
MR. GREEN:
A. That would be mine.
CHAYTOR, Q.C.:
Q. It's your handwriting, and this here as well, "slides and block returned"?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And what's this here?
MR. GREEN:
A. That says "diagnosis and sign out." That means that when we send a slide out of town to a out-of-town site, we'd go into the computer and we would go under diagnosis and we would

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says "slides returned to"--in this case, it would be "slides returned to Gander for reporting" and then you would go down and bring up the next screen and you would sign it out saying that we had finished with it here and it was gone.

CHAYTOR, Q.C.:

Q. Okay. So this indicates that it's gone back to Dr. Dalton?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. And does a copy of the form go back to Dr. Dalton?

MR. GREEN:

A. Yes, we would photocopy the form. We would keep a sheet in our files and one would go out with the slides.

CHAYTOR, Q.C.:

Q. Okay, and the slides would go out, okay. And again, it says "controls checked KG." What does that mean? Did you -

MR. GREEN:

A. That means I would have physically checked the control under the microscope to see that it

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was indeed positive.

CHAYTOR, Q.C.:

Q. Okay, and so that would--so was that your practice, to always note that on the form?

MR. GREEN:

A. Probably for out of town, it may have been a practice. I really can't say for sure.

CHAYTOR, Q.C.:

Q. Okay, and if I could have then, the same exhibit, page 49 please? And this is also one that goes out to Dr. Dalton and it's a little further along in 2002. September 16th, 2002 he ordered the test and on the bottom we see date completed, your signature as the histotech and September 18th 2002, and then there's another date underneath there which is a little difficult. I think it does say though October 4th, 2002? Would you agree with that?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And there's some writing along the side. Is this your writing?

MR. GREEN:

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A. No.

CHAYTOR, Q.C.:

Q. And it appears to be neat, neater.

MR. GREEN:

A. Yes, too neat for mine.

CHAYTOR, Q.C.:

Q. And it says here, "received" and then unfortunately cut off, but then "return to Health Science Centre, ER" looks like "control" and it says--little bit of the word missing, but I think it's "control unsatisfactory. October 1/02" and then there's--do you recognize those initials?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. No? It looks like an ES maybe, can you think who that might--or is it an EJ? Don't know, okay. So you didn't write this on the side?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. "Test was run September 18th" and it's indicated here that it appears the ER control was unsatisfactory and October 1/02, so

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perhaps that came back from Dr. Dalton's -

MR. GREEN:

A. I would say. That's what it looks like, yes.

CHAYTOR, Q.C.:

Q. Yes, okay, perhaps that came from Gander, and then October 4th '02, it appears that the test was rerun. Is that what that would mean?

MR. GREEN:

A. Repeated and sent again, yes.

CHAYTOR, Q.C.:

Q. Okay. So on this particular occasion, it appears that the controls and the--control slide and the test were sent out to Dr. Dalton, but he determined that the control was unsatisfactory. Do you recall--I take it you don't recall this specific incident, or does it stand out in your mind in any way?

MR. GREEN:

A. It doesn't, no.

CHAYTOR, Q.C.:

Q. And what would happen then in terms of that? The test would just be rerun and sent back out or would there be any investigation into the cause of why the first control was unsatisfactory or what Dr. Dalton may have

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been looking for in the control?
MR. GREEN:
A. We would just repeat it and most likely we would check with a pathologist before we sent it out again?
CHAYTOR, Q.C.:
Q. So check with a pathologist in terms of having a pathologist look then -
MR. GREEN:
A. Look at the control, yes.
CHAYTOR, Q.C.:
Q. At the control, so a pathologist within the Health Sciences to make sure that it was satisfactory?
MR. GREEN:
A. When Dr. Ejeckam took over running the IHC lab, all out-of-town IHC would have to go through him first.
CHAYTOR, Q.C.:
Q. So Dr. Ejeckam, once he took over, would check all of the controls before they went back out to -
MR. GREEN:
A. Yeah, we would check them together.
CHAYTOR, Q.C.:

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Q. You would look at them with him, and I take it that's the time period when you learned more about what to look for?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So was that some time then after this time period, this September -
MR. GREEN:
A. It would be after that time, yes.
CHAYTOR, Q.C.:
Q. So some time into 2003, I take it?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So in terms of any investigation as to what Dr. Dalton would have been looking for or what concern he may have had, there would have been no inquiry made?
MR. GREEN:
A. No. Sometimes they will submit an alternate block, but that says block number four there and it's probably the same block as previous.
CHAYTOR, Q.C.:
Q. Yes, probably, okay, and I assume if he wanted

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a different block chosen, then he would indicate it up here?
MR. GREEN:
A. Yes, because we usually return the blocks when we send the slides.
CHAYTOR, Q.C.:
Q. So the blocks and the slides would go out to the regions?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And again, I take it with respect to this type of an issue, this is something that currently, in the current system, a corrective action would be noted?
MR. GREEN:
A. A corrective action would be noted and no slide would leave the lab unless we knew that the control was working.
CHAYTOR, Q.C.:
Q. Okay. So if a similar situation were to happen, you know, today or next week, you would note that a repeat had been run?
MR. GREEN:
A. Yeah.

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CHAYTOR, Q.C.:
Q. And would then--now, would any inquiry be made of the pathologist requesting the repeat as to what the issue was?
MR. GREEN:
A. If we were asked for a repeat like that now, we would go ahead and do the repeat. We would show it to Dr. Ford Elms, who would come over--he comes over every day from St. Clare's and we go over all the controls and he would be made aware of it.
CHAYTOR, Q.C.:
Q. Okay, so -
MR. GREEN:
A. And he may take it upon himself, most likely he would call out and ask what the situation was.
CHAYTOR, Q.C.:
Q. Okay. So that would be up to Dr. Elms to make any inquiry he deemed appropriate?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And I will take you to that policy a little later. In terms of then repeating any other

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ER/PR tests which were run on September 18th, 2002, would that have happened?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Today would it happen?
MR. GREEN:
A. Today, we would not run a batch control. Each would have its own control.
CHAYTOR, Q.C.:
Q. On the slide?
MR. GREEN:
A. On each slide. We would have a negative control with each patient and we would have a triple batch control with each run to show that--the triple batch control will have a negative expresser, a low expresser and an intermediate expresser and a high expresser for the whole run.
CHAYTOR, Q.C.:
Q. And that, I understand, is on the patient slide now, your controls?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:

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

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negative"?
MR. GREEN:
A. I don't recognize it.
CHAYTOR, Q.C.:
Q. You don't know that? That's not your handwriting, is it?
MR. GREEN:
A. It's bad, it could be.
CHAYTOR, Q.C.:
Q. Okay, fair enough. Up in the corner here, there's some other things written. Do you know what that is or what that indicates?
MR. GREEN:
A. That means, UT means units taken and 18, that would be the code in the computer which says that they would go in the computer and I would say slides returned to St. Clare's and a certain date.
MR. BROWNE:
Q. Commissioner, sorry, is it possible if he could lean into the mike, we're having difficulty hearing back here.
CHAYTOR, Q.C.:
Q. Me or the witness?
MR. BROWNE:

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

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Dr. Chittal and he would have checked them and said the controls are fine.

CHAYTOR, Q.C.:

Q. And so Dr. Chittal at this point in time is at the Health Sciences, is he?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And why would that be written on this when it's going to Dr. Cook?

MR. GREEN:

A. We probably would not have had a control to send over with his slides.

CHAYTOR, Q.C.:

Q. So there were times when there may not have been a control available to send out to all of the other hospitals?

MR. GREEN:

A. That's true and there was a time when Dr. Parai was assigned to read the controls, so that if a control was not sent to St. Clare's, one of the pathologists at St. Clare's would have to call over and ask who checked the controls.

CHAYTOR, Q.C.:

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Q. Okay, so--and we heard a bit of that from Ms. Welsh yesterday, I believe you were here for her evidence in terms of them being checked, if you didn't have enough or sufficient controls to go around, then a pathologist in-house would do it.

MR. GREEN:

A. One of the major reasons you would not run a lot of controls would be space. We would probably have a hundred antibodies to run, you could run 48 antibodies per machine. We ran a control with every antibody, but if you had 10 ERs to run, you would run one--if they were confined, say to the Health Science and St. Clare's, no out of town ER/PRs, we would probably put one or two controls on there. In this case, we probably put one control on for the whole batch. So that control would have to be shared. If we had to put ten controls on for the ten ERs that were there, that would mean that ten other patients would be dropped from the list and they could not be done that day.

CHAYTOR, Q.C.:

Q. Okay, and in terms of Dr. Parai reading the

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controls, do you recall what time period that was?

MR. GREEN:

A. I don't, no.

CHAYTOR, Q.C.:

Q. At this point in time it appears Dr. Chittal, did he have any responsibility or was he just the pathologist you happened to contact that day?

MR. GREEN:

A. He, I probably had slides for Dr. Chittal that day and if I went out with his slides in the reading room and he was there, I figure it was a good time to get him to check my controls.

CHAYTOR, Q.C.:

Q. And so it was always one control, though, per antibody?

MR. GREEN:

A. Yes, one ER; one PR.

CHAYTOR, Q.C.:

Q. And those, of course, were positive controls.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Were negative controls being used at that

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point in time?

MR. GREEN:

A. They weren't, they were not.

CHAYTOR, Q.C.:

Q. And today are negative controls used?

MR. GREEN:

A. They are.

CHAYTOR, Q.C.:

Q. And when did that come in?

MR. GREEN:

A. That came in after we revalidated the, after we started sending slides to Mount Sinai for ER/PR testing and revalidated our whole ER/PR system, we decided to run negative controls with each patient.

CHAYTOR, Q.C.:

Q. Okay, so I take it once testing resumed in February of 2007, that was the first time that Health Sciences started using negative controls?

MR. GREEN:

A. Yes. A negative control is treated in--uses the same protocol as we used with the patient, all the steps are identical, except when it comes time to put the primary antibody, we

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take the--in place of the primary antibody, there's a buffer applied, antibody diluting buffer and so that we stain that patient with the same protocol with no antibody, and if we get any staining in the patient's tissue, we know that there's no antibody applied, so it's non-specific staining and the test would be invalid.

CHAYTOR, Q.C.:

Q. Okay. And within the Health Sciences when the controls went to the reading room to be shared by whatever pathologist may have had ER/PR test that day, did you ever observe any build up of control slides over a period of time?

MR. GREEN:

A. Control slides, each day they would build up until they got to the point where there was no space left, then we would take those out for filing and start again.

CHAYTOR, Q.C.:

Q. So there could be a period of time where ER/PR control slides for a couple of weeks, two or three weeks, could be in the reading room altogether?

MR. GREEN:

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A. That's possible.

CHAYTOR, Q.C.:

Q. And in that situation, the pathologist would have to look through or dig through the slides and figure out the correct dates for their tests?

MR. GREEN:

A. He would have to check the date on the slide.

CHAYTOR, Q.C.:

Q. And you said then you would take the control slides out of there. How would you know when it was okay to remove the control slides that they had been read or referred to by the pathologist?

MR. GREEN:

A. We had no way of knowing, when we would notice it when we went out to bring more control slides out and we were starting to run out of space.

CHAYTOR, Q.C.:

Q. Would there be an area where they would actually then physically move the control slides, when they were done, was there a tick off sheet or anything which would indicate for various pathologists to mark off that they had

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read anything to keep track of it?

MR. GREEN:

A. Not that I was aware of.

CHAYTOR, Q.C.:

Q. And in terms of then where the control slides ended up, and I appreciate earlier you said that you didn't file away the control slides, do you know if there was any record keeping, any central registry as to what patients had tests done together on a particular batch?

MR. GREEN:

A. I'm not aware of any way to link a particular patient to a batch. The only way you could link that would be to have the run sheet and the date of the run sheet.

CHAYTOR, Q.C.:

Q. So to be able to figure out, for example, who else on this particular date, January 30th, 2003, also had an ER/PR test run that day, there'd be no way of doing it, except to pull these and figure out who else and then go looking for the control slide, should be filed with one or the other patients.

MR. GREEN:

A. Yeah, that's the only way.

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CHAYTOR, Q.C.:

Q. With their slides.

MR. GREEN:

A. It's not the system we have now because each patient has its own control on the slide, so it's filed with the patient.

CHAYTOR, Q.C.:

Q. Yes, so it's not an issue today with the current -

MR. GREEN:

A. Not an issue.

THE COMMISSIONER:

Q. Mr. Green, do I take it there was only one batch run per day then?

MR. GREEN:

A. Usually only one batch run per day because a run would take approximately three and a half hours.

THE COMMISSIONER:

Q. Uh-hm.

MR. GREEN:

A. And we would have probably--it would be possible to have two runs per day, but what you would try to do, you would try to group all of your antibodies together, like you

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

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

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control?
MR. GREEN:
A. It's possible.
CHAYTOR, Q.C.:
Q. And on the form that I showed you earlier where it said that you had checked the control, remember that one, KG, would there-- in that particular circumstance, would there also have been a check done by the pathologist?
MR. GREEN:
A. Most likely at that stage, I was fairly new there, so I would have checked with a pathologist.
CHAYTOR, Q.C.:
Q. Was there ever an occasion where it was the technologist checking the controls to see if they had worked, as opposed to pathologists?
MR. GREEN:
A. It's possible.
CHAYTOR, Q.C.:
Q. Okay. And if we could just go back to that exhibit, please, I think it was P-2149, page 24? And this is going back to Dr. Dalton, controls check, KG?

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MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Would Dr. Dalton understand that it's you who checked--KG is you, you're the person who checked the control, as opposed to a pathologist?
MR. GREEN:
A. I have no way of knowing if he would have known, unless he probably knew the pathologist at the Health Sciences and knew there wasn't a KG, but I would have no way of knowing if he knew.
CHAYTOR, Q.C.:
Q. And then this particular case, perhaps you were the person who checked the control, as opposed to a pathologist?
MR. GREEN:
A. Most likely.
CHAYTOR, Q.C.:
Q. Most likely, okay. Did that happen very often? And why would that happen, why would it be you and not a pathologist?
MR. GREEN:
A. Probably if there was no pathologist available

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at that time.
CHAYTOR, Q.C.:
Q. And at this point in time, Mr. Green, in terms of your knowledge, this June of 2002, does this predate the additional knowledge you acquired from Dr. Ejeckam in terms of how to interpret external controls?
MR. GREEN:
A. My knowledge would be minimal.
CHAYTOR, Q.C.:
Q. Minimal at this point in time.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So you would not have understood looking at nuclear staining verses any other staining at this particular point in time?
MR. GREEN:
A. Probably not.
CHAYTOR, Q.C.:
Q. If we could have, please, P-1853, page 13? And this is called a reagent layout map and the date up in the corner, I'm not sure if that's July or September, would you know which this is?

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

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

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

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A. All these spaces here are blanks.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. We could put additional antibodies into those spaces. So if you want to run an ER, you could put an ER in B6. If you wanted to run a PR, you could put a PR in B7, and any other antibody you wanted to run, you could put it in those. It wouldn't - that is a very small run that was run that day. That was an easy day. Usually this grid would be pretty well filled.
CHAYTOR, Q.C.:
Q. So, for example, why do we have A4 filled in and not A3? Any reason?
MR. GREEN:
A. Whoever set up the grid, it looks like Mary, you would choose to put your antibodies to the right, far away from your other solutions.
CHAYTOR, Q.C.:
Q. Why would that be?
MR. GREEN:
A. Less chance of mixing the anti--the solutions.
CHAYTOR, Q.C.:

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Q. Okay.
MR. GREEN:
A. Inadvertently putting one next to the other.
CHAYTOR, Q.C.:
Q. And your--so then if we could, this would then we used, this is your layout map. You would use this to know where to place things on the machine?
MR. GREEN:
A. This layout map is a representation of the slide of the reagent holder that you use on the machine. The reagent holder had the same number of slots as the map. So you would physically put these reagents that you see here in their respective slots on the holder.
CHAYTOR, Q.C.:
Q. Okay, and was there any--we spoke, and I think you were here yesterday when this was asked of Ms Welsh about the potential for human error if the wrong reagent--or the reagent is put on the wrong spot, and that being a potential error. Was there any way of double checking? I understand that you would have been working yourself in the lab, but the other technologist would be nearby. So was there

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any system, for example, to have someone come over and double check or check off with you, or was there any requirement for you to do that, to actually --
MR. GREEN:
A. That would be your responsibility to check and to double check to make sure that you put the correct reagent in the correct slot on the machine.
CHAYTOR, Q.C.:
Q. And was there any requirement for you to document that you, in fact, had checked and indeed double checked?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So no--was there a practice that you would, in fact, do that, that you would not only check it, you would double check it?
MR. GREEN:
A. If you're on the machine, it would be your responsibility to check and double check, and triple check if you had to, to make sure that you put the right reagent in the right slot. The problem is that if you put the wrong

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reagent in one slot, you would also have to put the wrong reagent in another slot, so you would have to make two mistakes because -
CHAYTOR, Q.C.:
Q. You mix a couple up.
MR. GREEN:
A. Yeah, you just can't mix one up, you had to mix up at least two.
CHAYTOR, Q.C.:
Q. Right, okay, or I guess if your slots aren't filled, like this day, you could just put one in the wrong place.
MR. GREEN:
A. That's possible, but I think if you put one in the wrong, like this grid is also programmed into the computer and the robotic arm would come over and go down and dispense it, would aspirate the volume that it needed and then it would dispense it on the slide. And I wasn't aware of it until recently that there was an alarm on the DAKO system which said that if the volume wasn't there, it will alarm.
CHAYTOR, Q.C.:
Q. Yes, because I believe when we spoke initially, you didn't know that there was such

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

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in one position and stay there and you couldn't run the machine.
CHAYTOR, Q.C.:
Q. And when that happened, no alarm triggered?
MR. GREEN:
A. It wouldn't alarm because the--and not only if you were there, it just would not start up or if it started and stopped, it would alarm.
CHAYTOR, Q.C.:
Q. I just wanted to, I had understood you said that the entire time you never heard the alarm go off.
MR. GREEN:
A. I never heard the alarm for a reagent volume.
CHAYTOR, Q.C.:
Q. Okay, for reagent volume.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So there may not be an alarm triggered if the robotic arm failed?
MR. GREEN:
A. It's possible.
CHAYTOR, Q.C.:
Q. There may not have been?

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MR. GREEN:
A. There may not have been
CHAYTOR, Q.C.:
Q. Okay, so there was an alarm for reagent volume if the volumes were wrong or insufficient amount of reagent was applied.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But there may not have been an alarm for any difficulties with the robotic arm and I understand the robotic arm is dispensing the reagent, was that correct?
MR. GREEN:
A. Yes, that's true.
CHAYTOR, Q.C.:
Q. But if that's the case and there's a problem with the robotic arm and such that no reagent is applied, you would expect the alarm to be triggered?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So when you became aware that there was some issue with the robotic arm going so far and

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stopping, did you actually observe that or how did it come to your attention?
MR. GREEN:
A. You would observe that it would either try to move and couldn't move, that would be what you would observe, it was actually trying to do what it's supposed to do, but it wouldn't move.
CHAYTOR, Q.C.:
Q. And if the robotic arm went a certain distance, I understand it took two or three hours to run the test?
MR. GREEN:
A. Approximately three and a half hours per run.
CHAYTOR, Q.C.:
Q. Three and a half? Okay, depending, I guess, how many -
MR. GREEN:
A. How many antibodies.
CHAYTOR, Q.C.:
Q. That particular day or that particular run. So if the robotic arm were to go a certain distance, correct itself and continue on, would you have any way of knowing that?
MR. GREEN:

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

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there and it was your responsibility to ensure that the patient that was listed on No. 1 on your list was put in slide No. 1 on the machine and the same way down.
CHAYTOR, Q.C.:
Q. And again, in terms of rechecking or double checking that that happened, was there any record of that kept?
MR. GREEN:
A. No, the only record would be the run sheet that you had which indicated the order that you had there.
CHAYTOR, Q.C.:
Q. Would you have to sign off or initial that to indicate that you had in fact verified that the slides were placed in the right slots?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And no policy - sorry, go ahead.
MR. GREEN:
A. I was going to say and you would also have to mix up two slides, so that if you misplace slide one in slot one, that means that the slid that you were supposed to put there had

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to go somewhere else, so you would have to make the same mistake twice.
CHAYTOR, Q.C.:
Q. You'd have to mix a couple - right. And would you then, say for example in this case, I don't know, you only have like a dozen or less than a dozen, would you always go from one to ten, one to twelve or would you skip slots on the machine as well?
MR. GREEN:
A. Not usually, usually you went in order, numerical order, one -
CHAYTOR, Q.C.:
Q. And if, in terms of your control slides, were they always placed in a certain place on the machine?
MR. GREEN:
A. We usually put the controls at the end.
CHAYTOR, Q.C.:
Q. And was that a policy or a procedure that required that they always be put at the end?
MR. GREEN:
A. No, it was just that's the way that Peggy taught me to do it, so -
CHAYTOR, Q.C.:

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

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

THE COMMISSIONER:

Q. And they're grouped by antibody, not by patient?

MR. GREEN:

A. You could do either, but like in the case of ER/PR, we would usually group all the ERs together and all the PRs together, because you got a larger volume.

THE COMMISSIONER:

Q. Okay.

CHAYTOR, Q.C.:

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

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before for that matter?

MR. GREEN:

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

CHAYTOR, Q.C.:

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

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. That could happen?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. And do you know whether or not any maintenance was ever carried out on the alarm system for the DAKO machine?

MR. GREEN:

A. Not that I'm aware of.

CHAYTOR, Q.C.:

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

MR. GREEN:

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

CHAYTOR, Q.C.:

Q. And on the occasions when you noticed that the robotic arm hadn't completed the run, would the entire run be repeated or just the -

MR. GREEN:

A. If the run had started, the entire run would have to be repeated. If the run didn't start, then they would--the slides would only be covered in buffers, so that would be fine, but if there was a malfunction midway through a run, they would have to be repeated.

CHAYTOR, Q.C.:

Q. So that would mean taking all of your slides off, even though some of them may have worked, they would all be taken off and redone?

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MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And in the situation that the hypothetical that I was giving you about your controls coming before your patients tests and if the robotic arm worked up to a certain point, such that your control slides stained but not before--but then it stopped before it got to the patient slides, but somehow it fixed itself or continued on after that, you could have a situation where your controls, external controls worked, your patient slides had not been exposed to the antibody and you wouldn't know it?

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. Okay, and -

MR. GREEN:

A. That's why a positive external control on every patient is the optimal -

CHAYTOR, Q.C.:

Q. Having the control on the patient slide?

MR. GREEN:

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

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

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

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Q. Okay. So whether that's because the alarm system wasn't working or because there was no reason for the alarm to go off, you don't know?
MR. GREEN:
A. I would hope that there was no reason for the alarm to go off.
CHAYTOR, Q.C.:
Q. I hope too. But in terms of even if the alarm went off and the person running the machine is not within earshot, the machine would continue on?
MR. GREEN:
A. That's my understanding.
CHAYTOR, Q.C.:
Q. Okay, and the result then, in terms if that were to happen, and inadequate amount of reagent having been applied, what would be the result with respect to an ER/PR test?
MR. GREEN:
A. Well, we're talking--these reagents, we're talking primary antibody, is an antigen antibody reaction. If no primary antibodies are applied, there will be no reaction.
CHAYTOR, Q.C.:

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Q. So I take it the test would be negative?
MR. GREEN:
A. It would be negative. It would be a false negative.
CHAYTOR, Q.C.:
Q. It would be a false negative.
MR. GREEN:
A. Oh, assuming that it was -
CHAYTOR, Q.C.:
Q. Meant to be a positive.
MR. GREEN:
A. - positive to begin with.
CHAYTOR, Q.C.:
Q. Yes, right.
THE COMMISSIONER:
Q. Do you know whether if that occurred your computer would tell you that there had been an alarm?
MR. GREEN:
A. I'm not aware of it. I can't tell you for sure.
CHAYTOR, Q.C.:
Q. And that particular issue or the potential for that as being a pitfall, does that exist with the Ventana machine?

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

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

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oven, put on the machine. It is not touched any more until the process is complete and ready to be cover slipped.
CHAYTOR, Q.C.:
Q. Okay, and with respect to any of those, so the slide placement, reagent placement, the volume of your reagent and the antigen retrieval, there was no procedure or policy in place which required documentation of what was happening and/or any requirement to document or have someone else do a second check as to what you were doing?
MR. GREEN:
A. There was no second check, no.
CHAYTOR, Q.C.:
Q. No second check, and no requirement for the technologist doing those procedures to document what in fact they had done?
MR. GREEN:
A. No, the only requirement was the due diligence on the part of the person who ran the procedure.
CHAYTOR, Q.C.:
Q. Okay, and if I could look at, please, 2190? That's not entered yet, is it?

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

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A. No, I didn't have a lot of opportunity to load slides on the processor at the Health Science because my duties had changed since I went over to the Health Science and other people took care of that.
CHAYTOR, Q.C.:
Q. So in the two weeks that you weren't in the IHC portion of services, you wouldn't be involved in the tissue processing aspect?
MR. GREEN:
A. I wouldn't be involved in the changing of the solutions or with the processor, no.
CHAYTOR, Q.C.:
Q. Okay, and do you know whether or not, other than personal firsthand knowledge, whether or not there were any issues identified with the tissue processor at the Health Sciences?
MR. GREEN:
A. It wasn't a common practice to reprocess blocks at the Health Science.
CHAYTOR, Q.C.:
Q. Okay, so that wasn't a common practice?
MR. GREEN:
A. No, I don't know if they have ever reprocessed blocks at the Health Science.

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CHAYTOR, Q.C.:
Q. When did that come to your attention, and did you make any inquiries as to why that would be the case?
MR. GREEN:
A. No, I knew we reprocessed blocks at St. Clare's. I knew that we had a lot of breast specimens at St. Clare's. I knew that the Health Science didn't have a lot of breast specimens. I probably made the assumption because they didn't have a lot of breast specimens, they didn't need to reprocess blocks.
CHAYTOR, Q.C.:
Q. But they were doing breast specimens as well?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. But perhaps not the same quantity?
MR. GREEN:
A. Not the volume that -
CHAYTOR, Q.C.:
Q. Not the same volume as St. Clare's?
MR. GREEN:
A. No.

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CHAYTOR, Q.C.:
Q. But was it your understanding that they weren't doing much, if any, reprocessing in any event, regardless of the type of specimen?
MR. GREEN:
A. Reprocessing didn't seem to be an issue at the Health Science.
CHAYTOR, Q.C.:
Q. Okay, all right. And when did you learn that?
MR. GREEN:
A. Probably--I was probably over there a while and I'm not sure when I--I would have--because it wasn't an issue over there, so -
CHAYTOR, Q.C.:
Q. But did it--were you curious about that, "well, why isn't that an issue here? Why don't they do reprocessing?"
MR. GREEN:
A. Not really because I was so concerned with learning all the new techniques and that that I had to learn that I just didn't give it any thought.
CHAYTOR, Q.C.:
Q. Okay. What would happen to the DAKO machine if there were a power outage?

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MR. GREEN:
A. The DAKO machine would just stop.
CHAYTOR, Q.C.:
Q. And what would have to happen to your run?
MR. GREEN:
A. You would have to repeat the whole run.
CHAYTOR, Q.C.:
Q. And what would happen to your tissue processor if there were a power outage? Tissue processing, I understand, was run overnight, is that right?
MR. GREEN:
A. Yeah, it usually takes approximately 11 and a half hours, somewhere between 11 hours 15 minutes, 11 hours and 30, depending, approximately 11 hours.
CHAYTOR, Q.C.:
Q. And what would happen if you had a power outage which interfered with your tissue processing?
MR. GREEN:
A. If you had a power outage, as far as I know, right now, the processors are under back up power and they're hooked up to an alarm, and I don't know how long they've been like that.

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

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

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happen, your sections would be high and dry.
CHAYTOR, Q.C.:
Q. Okay. So would you have to then start the whole process over, that -
MR. GREEN:
A. You would start the process where it stopped. Now if it happened at any time after the fixation, there would be no damage to the tissue. Fixation is the critical stage in the tissue processing. Fixation is the only stage that cannot be reversed.
CHAYTOR, Q.C.:
Q. Okay, and so what would happen if it happened after the fixation stage?
MR. GREEN:
A. If it happened after the fixation, you would just resume the processing schedule and the only ill effects would be that your blocks would be delayed.
CHAYTOR, Q.C.:
Q. And what if it happened before the fixation stage?
MR. GREEN:
A. Well, fixation starts from the time the specimen is taken at surgery and goes through

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the whole process. The last fixation stage takes place on the processor. I think there are two one-hour fixation stages before the alcohols. If it happened when a processor starts up, it starts up in formalin. So fixation is already started. The only danger would be if it happened before the next formalin.

CHAYTOR, Q.C.:

Q. Okay, and what would the result be in that case?

MR. GREEN:

A. For a tissue processor, enclosed system, there would be no problem because the solutions are still confined inside the machine. Had it been one of the older machines, all the tissues could dry out.

CHAYTOR, Q.C.:

Q. And again, in terms of documenting any issues in that regard, was there any corrective action log taken for any issues around the tissue processor?

MR. GREEN:

A. At that time, there was not.

CHAYTOR, Q.C.:

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Q. I'm being told that we can now, please, enter 2190, Commissioner.

THE COMMISSIONER:

Q. Okay.

REGISTRAR:

Q. 2190.

THE COMMISSIONER:

Q. Entered.

CHAYTOR, Q.C.:

Q. Thank you.

EXHIBIT ENTERED AND MARKED EXHIBIT P-2190

CHAYTOR, Q.C.:

Q. And if we could bring up--I'm sorry, if we could bring up 2190, please? And do you recognize what type of form this is?

MR. GREEN:

A. That looks like the sheet I was referring to earlier, the run log with the 48.

CHAYTOR, Q.C.:

Q. Okay, so this is a run log, and we see the 48 here.

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. Okay, and so, for example, in--we have a

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number, antibody, comments?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. Three columns, and so the numbers coming down the side, I take it that's the slide position on the machine? Is that correct?

MR. GREEN:

A. It is, yes.

CHAYTOR, Q.C.:

Q. Okay, and then your antibody, of course, speaks for itself, and what's the comment section?

MR. GREEN:

A. This one here, in particular, looks like somebody was doing a validation on the antibodies and because they don't have a surgical number in there, what they have in there is a dilution, and it got like tonsils, skin lesion, thymus, and one in ten, one in 20. It looks like somebody was running a run and they were checking control.

CHAYTOR, Q.C.:

Q. Okay. So in this one, we see one in 50, these dilutions, one in 100. So that's someone

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running a validation?

MR. GREEN:

A. It looks like number one, two and three. It looks like they were using one in 50 dilution on a L26 antibody and they probably used three different blocks and they were trying to determine which block would be the best for the control, or if they could use all three for a control. Next one is the--they're using a skin lesion to do--try on the L26 antibody and the next one, they're using a tonsil for control, looks like.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. And CD79A, which is another lymphoma marker, probably doing different -

CHAYTOR, Q.C.:

Q. So they're trying different dilutions as well as different control tissues?

MR. GREEN:

A. Controls.

CHAYTOR, Q.C.:

Q. Okay, and if we could -

MR. GREEN:

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A. Probably trying to--it looks like they're trying to get a control bank.
CHAYTOR, Q.C.:
Q. Okay, and that, I take it, that's not your handwriting?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Okay. If we could have page 24, please? Now on this particular one, we'll see under the comments sections, we have what appears to be surgical numbers?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. So I take it normally the comments section -
MR. GREEN:
A. Yeah, normally it would be a surgical number in that area.
CHAYTOR, Q.C.:
Q. Okay, and so on this particular one then, it appears that you had up to 44 for that day?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:

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Q. 44 of your slide slots used or whoever, who's doing this run, and again, I take it it's not your handwriting, or it might be? Do you know?
MR. GREEN:
A. Looks a little too neat for mine.
CHAYTOR, Q.C.:
Q. Little bit too neat, okay. And this one here, if we come down to 24, we see ER and a surgical number. So I take it that on slide slot 24, we would expect -
MR. GREEN:
A. Yes, it would be -
CHAYTOR, Q.C.:
Q. - this patient's slide and that ER will be the antibody?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. And then 25 PR?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And nothing written in, so what does that tell me in terms of the surgical number?

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MR. GREEN:
A. That would be the same patient carried over from the previous. This would be ER and that would be the PR on that patient.
CHAYTOR, Q.C.:
Q. So this is the PR now on that same patient?
MR. GREEN:
A. Yeah, and like -
CHAYTOR, Q.C.:
Q. And 26?
MR. GREEN:
A. Yeah, and number 26, 27 would be the ER and PR on that surgical number. 28, 29 would be the surgical number, that patient. Looks like cases one to nine would be--would be all 94-21.
CHAYTOR, Q.C.:
Q. All on the same patient, from one to nine, inclusive?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and then starting at 30, we have MN-F116, is that right, and control?
MR. GREEN:

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A. Controls, yeah.
CHAYTOR, Q.C.:
Q. And then do I understand from this that from 30 through to 44 are all control slides.
MR. GREEN:
A. Controls.
CHAYTOR, Q.C.:
Q. Okay, and so in this particular case, your ER/PR controls are 41 through 44 inclusive?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And so there were two ERs and two PRs run that day?
MR. GREEN:
A. Controls, yes.
CHAYTOR, Q.C.:
Q. Controls, I'm sorry, yes, controls, and there were three patients -
MR. GREEN:
A. Three patients.
CHAYTOR, Q.C.:
Q. - who had ER/PR tests?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. And then these are more pages of the same, and on this particular day then, page 26, and there's no date on this particular--is this is the date--no, is this a date, do you know, and it's got a B after it, so perhaps it's a date and a separate batch? Do you know any significance to 03/11/17B? Would you use a letter, for example, if you ran more than one batch on the same day?
MR. GREEN:
A. It's possible.
CHAYTOR, Q.C.:
Q. Okay. You don't recall that being your practice?
MR. GREEN:
A. I don't recall, no.
CHAYTOR, Q.C.:
Q. Okay. All right. Then on this particular day then, we see a number of ER/PR tests from slot nine. So there appears to be 1-2-3-4-5 patients who had ER/PR tests and then we had 1-2-3, three controls.
MR. GREEN:
A. Three sets of controls.

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CHAYTOR, Q.C.:
Q. Okay, and they appeared to be have been placed at the end of your run?
MR. GREEN:
A. At the end of the run.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And most likely in a situation like this, you would have--you wouldn't have a control for each case because maybe two cases were Health Science and that control would be shared.
CHAYTOR, Q.C.:
Q. Right, okay. Now we spoke briefly about a situation if a pathologist wasn't satisfied with a slide or a particular test and asking to have a repeat done. Did it--was it ever brought to your attention that a pathologist wasn't satisfied and looking for a retest because the result wasn't what the pathologist was expecting?
MR. GREEN:
A. We would have no way of knowing, you know. Lots of times you would--they would ask for a repeat and just say repeat, you know, and they

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would not necessarily specify what the problem was. It could be that they wanted a better section. Maybe when they looked at the slide, it wasn't what they needed, so they would ask for a--maybe it was because that it didn't work. But they would not always--but usually, if it didn't work, you would know because they would tell you it didn't work.
CHAYTOR, Q.C.:
Q. Okay, so would tell you that the control hadn't worked.
MR. GREEN:
A. The control hadn't worked or they were expecting a different result.
CHAYTOR, Q.C.:
Q. Yes, and that's what I was wondering, was that ever articulated to you that they were expecting a different result, the control may have worked, but they were expecting a different result, so they were requesting a repeat?
MR. GREEN:
A. That has happened, yes.
CHAYTOR, Q.C.:
Q. That happened?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and in those particular instances, do you know if, when the repeat then happened, was there ever any communication as to whether a different result had been obtained the second time around?
MR. GREEN:
A. Usually there wouldn't be any follow up, you would have no way of knowing the second time around if the result had changed or not. And as with all these antibodies and you're dealing with human tissue, although there's always the chance that, for some reason a particular biological specimen will not react, as you think it will react.
CHAYTOR, Q.C.:
Q. So there were occasions, though, that you recall a pathologist looking for a repeat because he or she didn't get the result they had anticipated.
MR. GREEN:
A. They had anticipated, yes.
CHAYTOR, Q.C.:

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Q. Okay, and then the test was repeated, I take it?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And was there ever any, in that situation, any follow up as to why the test needed to be repeated?
MR. GREEN:
A. I would assume that after the repeat if the problem wasn't resolved, you would know about it and we would have to do work in a particular antibody.
CHAYTOR, Q.C.:
Q. What do you mean, though, with the problem resolved, because perhaps the second time round the pathologist got the answer he or she was expecting.
MR. GREEN:
A. Then the problem would be solved.
CHAYTOR, Q.C.:
Q. And the problem was solved.
MR. GREEN:
A. Because then you would have to put it down to that particular antibody and that particular

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specimen.
CHAYTOR, Q.C.:
Q. Or perhaps in getting a second or different result the second time around, the problem is identified, as opposed to resolved?
MR. GREEN:
A. Yes, and maybe the second time around the pathologist, it wouldn't be uncommon to ask for a testing on a different block on the same patient.
CHAYTOR, Q.C.:
Q. But you're not aware then of in those situations anyone coming to make further inquiry of your processes as to if a changed result had occurred, coming to make further inquiries of your processes?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And it wasn't brought to your attention whether or not changed results had occurred?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. For example, and I'm sure you're aware, you've

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

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

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

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

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MR. GREEN:
A. 4th, yes.
CHAYTOR, Q.C.:
Q. And written here is "tissue washed off slides"? Is that your handwriting?
MR. GREEN:
A. That is.
CHAYTOR, Q.C.:
Q. And so what would the problem have been on that particular day?
MR. GREEN:
A. That would mean that the block that we had to work with was probably suboptimal, which means that we had--there was probably a problem with fixation and/or processing and we had to, we had to work with the block that you had and it probably didn't have a lot of tissue on it, and then it had to be subjected to the antigen retrieval solution in the ER process and it's possible that some of the tissue would have washed off.
CHAYTOR, Q.C.:
Q. So are you indicating tissue washed off the slides with respect to the repeat test or a reason for why the test may have had to be

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

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CHAYTOR, Q.C.:
Q. Thank you, Commissioner, good afternoon Mr. Green.
MR. GREEN:
A. Good afternoon.
CHAYTOR, Q.C.:
Q. Mr. Green, did any pathologist up until 2005 ever suggest any change in your protocols or your way of doing IHC testing?
MR. GREEN:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. Was there ever any discussion, for example, as to changing or altering antigen retrieval times?
MR. GREEN:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. Did you, yourself, ever prior to 2005, ever express any concerns to anyone about the testing procedures?
MR. GREEN:
A. No, I had no way of knowing that there was a problem.
CHAYTOR, Q.C.:

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Q. And were you aware of whether or not anyone else may have expressed any concerns?
MR. GREEN:
A. I wasn't, no.
CHAYTOR, Q.C.:
Q. So from your perspective, everything seemed to be going along fine and if there was a problem, you were unaware of it?
MR. GREEN:
A. That's true.
CHAYTOR, Q.C.:
Q. So I take it other than things we've talked about that sometimes there'd be requests for retests, sometimes there were problems with the DAKO machine, as it aged, I take it. Other than those types of issues that we discussed this morning, were you aware of any other difficulties with the IHC testing?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Now we understand that the DAKO machine was replaced with the Ventana machine in early 2004?
MR. GREEN:

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A. That's correct.
CHAYTOR, Q.C.:
Q. Were you involved in that? Were you involved in the change over between the two machines?
MR. GREEN:
A. Yes, I was.
CHAYTOR, Q.C.:
Q. Perhaps you could tell us then about that? What was your involvement?
MR. GREEN:
A. I worked with Barry Dyer in setting up the Ventana system and we ran parallel runs on patient's tissue and on controls with the various protocols until the Ventana system was able to take over and run on its own.
CHAYTOR, Q.C.:
Q. And do you know how many--so you ran parallel tests on both DAKO and Ventana for both controls and -
MR. GREEN:
A. And patients.
CHAYTOR, Q.C.:
Q. And actual patients. And do you know how many tests you ran?
MR. GREEN:

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A. I don't recall exactly but we were, we worked on the machine for close to maybe a month, so on a daily basis we would run the machine, so quite a number, and we would take the slides to the pathologists to critique.
CHAYTOR, Q.C.:
Q. And so was there any particular pathologist involved in that?
MR. GREEN:
A. All the pathologists at the Health Science would be involved.
CHAYTOR, Q.C.:
Q. So it wasn't one particular pathologist, it was whoever was available at the time?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And so you would bring then, I would take it you would run the test, for example, on the DAKO and on the Ventana, would you bring both lots of slides then to the pathologist?
MR. GREEN:
A. Yes, usually if whatever pathologist requested the stains, would request the stains, the IHC stains, that would be the pathologist that we

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would show the slides to.
CHAYTOR, Q.C.:
Q. Okay, so it would be the current tests which were being requested and you would run the test on both DAKO and Ventana?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And you would bring it to--okay, now were there any differences between the two? Were there times when the tests weren't coming out comparable?
MR. GREEN:
A. I can't recall any differences between patients, but the stain itself seemed to be crisper and of better quality.
CHAYTOR, Q.C.:
Q. So the stain on which machine?
MR. GREEN:
A. On the Ventana machine.
CHAYTOR, Q.C.:
Q. Okay, so the staining itself appeared to be crisper and you observed that yourself by looking at the external controls?
MR. GREEN:

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A. Yes.
CHAYTOR, Q.C.:
Q. And but you don't recall any discussion or issue as to one test result being different from another, one patient being positive and one negative?
MR. GREEN:
A. No major discrepancies in testing, no.
CHAYTOR, Q.C.:
Q. No major discrepancies brought to your attention?
MR. GREEN:
A. No, not that I was aware of.
CHAYTOR, Q.C.:
Q. Okay, and would you and Mr. Dyer keep track of that then? Would you keep track of, not only that you had run these tests, but the outcomes after bringing it to the pathologist?
MR. GREEN:
A. I'm not sure if Barry kept a spreadsheet or not, he may have.
CHAYTOR, Q.C.:
Q. And do you know what time period this took place? I guess this is a concordance study, is it?

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MR. GREEN:
A. Yeah, it would be probably January, February, March of 2003.
CHAYTOR, Q.C.:
Q. 2004 perhaps?
MR. GREEN:
A. 2004, yes.
CHAYTOR, Q.C.:
Q. And if we could look, please, at P-2178? Mr. Green, do you recognize this document?
MR. GREEN:
A. Yes, I do.
CHAYTOR, Q.C.:
Q. And perhaps you could tell us then what this is? This a four-page document.
MR. GREEN:
A. These are protocols used by other hospitals across Canada who are using the Ventana system and these are their protocols, their antibody dilutions, the antigen retrieval required and the type of antibody, the antibody supplier.
CHAYTOR, Q.C.:
Q. Okay, so for example, on P-2178 we see Toronto General written at the top here?
MR. GREEN:

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A. That's true.
CHAYTOR, Q.C.:
Q. Now when would this information be acquired?
MR. GREEN:
A. This information was given to us when we set up the Ventana system by the company representative, the Canadian representative who came in to help us install the equipment.
CHAYTOR, Q.C.:
Q. So is this your writing on the document?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. That's the writing of the representative, is it?
MR. GREEN:
A. It could be the writing of the representative, it could be the writing of the technologist at that institution.
CHAYTOR, Q.C.:
Q. Oh, okay. So this was given to you so that you could use the same protocols from Toronto General, is that right?
MR. GREEN:
A. So that we could have a reference point to

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

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MR. GREEN:
A. It says "CC1/mild/32, one in fifty, nova 6F11", that means that it's the estrogen receptor antibody. CC1 mild refers to the antigen retrieval. CC1 is the Ventana company trademark name for antigen retrieval, that is the EDTA citrate for a buffer pH 8. Mild refers to the time in antigen retrieval, mild would equate to 30 minutes. And 32 minutes right here would be the time in primary antibody, the incubation time in primary antibody. Let's see, it's from Novacastra, that would be the company and the clone would be 6F11.
CHAYTOR, Q.C.:
Q. And what's the one over fifty.
MR. GREEN:
A. That would be the dilution, this antibody would not be a pre-dilute, it would come in concentrated from Novacastra and diluted one in fifty.
CHAYTOR, Q.C.:
Q. So for the Ventana system, you can have an ER antibody that's not pre-diluted?
MR. GREEN:

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

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

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you make any adjustments?
MR. GREEN:
A. We looked at these here and we found a common denominator to those and that's the way we decided the protocols to run, to try our controls and if I remember correctly, I think the ER was probably CC1 standard, 24 or 28 minutes.
CHAYTOR, Q.C.:
Q. Sorry, it was, if we just look at the ER here, so it was CC1, was it mild or -
MR. GREEN:
A. That one there is mild, yes.
CHAYTOR, Q.C.:
Q. But yours, the protocol you came up with was which?
MR. GREEN:
A. We used standard.
CHAYTOR, Q.C.:
Q. Standard.
CHAYTOR, Q.C.:
Q. Which would be, a standard would be 60 minutes in antigen retrieval as opposed to mild, which would be 30.
CHAYTOR, Q.C.:

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Q. Okay.
MR. GREEN:
A. We use these protocols as a guideline and different hospitals will use different protocols, which ever works better in their laboratory.
CHAYTOR, Q.C.:
Q. Okay. And if I could go back then, please, to P-2179? And do you recognize this document?
MR. GREEN:
A. I do.
CHAYTOR, Q.C.:
Q. Okay, and is this your handwriting?
MR. GREEN:
A. Probably, yeah.
CHAYTOR, Q.C.:
Q. All of this, three page document.
MR. GREEN:
A. Well this handwriting here is not, this sloppy handwriting on the left is mine.
CHAYTOR, Q.C.:
Q. This is yours, right, okay.
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:

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Q. And do you know who wrote the rest of this?
MR. GREEN:
A. No, I would imagine it's probably this person on the top which is probably the technologist at this hospital.
CHAYTOR, Q.C.:
Q. Okay, and do we know which hospital is this?
MR. GREEN:
A. I'm pretty sure it's in Quebec.
CHAYTOR, Q.C.:
Q. Okay, that's the name here, Protocole, I guess.
CHAYTOR, Q.C.:
Q. Protocole, I think that's French for protocol.
CHAYTOR, Q.C.:
Q. Protocol, oh, okay, so do you know the name for the hospital? This is a French hospital, though, is it?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And again this was provided to you by the Ventana rep?
MR. GREEN:
A. It was, yes, and it gives basically the same

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information, it tells the antibody, the dilution and the clone and company where it was purchased. It can also give the antigen retrieval and the primary antibody incubation time.
CHAYTOR, Q.C.:
Q. Okay, and so then you use this as well as a guide, I take it?
MR. GREEN:
A. Yes. And you would also, along with these, you would also use the package inserts from the antibodies that you were putting in there too.
CHAYTOR, Q.C.:
Q. I'm sorry?
MR. GREEN:
A. We would also--in addition to these here we would also cross check against the package inserts or the datasheets from the antibody to see what the manufacturer recommended.
CHAYTOR, Q.C.:
Q. Okay, and so you used the spec sheets and you used those two hospitals, their protocols?
MR. GREEN:
A. Yes.

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CHAYTOR, Q.C.:
Q. Did you have any others or is that it?
MR. GREEN:
A. There's one more that seems to be missing from that list.
CHAYTOR, Q.C.:
Q. Okay, maybe we have it, 2181?
MR. GREEN:
A. From Vancouver probably.
CHAYTOR, Q.C.:
Q. Let's just see, is this it?
MR. GREEN:
A. No, that's not it. That's a sheet from Cell Marque company which gives some of their suggested protocols or new Cell Marque antibodies.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And it gives the same type of information, except that would be limited to the Cell Marque antibodies only.
CHAYTOR, Q.C.:
Q. Yes, I don't see ER on this list.
MR. GREEN:

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A. No, Cell Marque has some kind of agreement with Ventana, they supply a lot of their antibodies.
CHAYTOR, Q.C.:
Q. Okay, I think maybe then it's 2182, that might be the Vancouver St. Paul's Hospital? This one?
MR. GREEN:
A. Yes, that's it.
CHAYTOR, Q.C.:
Q. And so again, this is the same thing you would have received this from the Ventana rep as a -
MR. GREEN:
A. Those were all protocols which they had in use at that time.
CHAYTOR, Q.C.:
Q. Okay, and for example under ER at St. Paul's Hospital, the clone is CF11 and the antigen retrieval is CC1 mild.
MR. GREEN:
A. Mild 16.
CHAYTOR, Q.C.:
Q. And 16, what does the 16 mean?
MR. GREEN:
A. CC1 mild is the same thing again, CC1 is

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antigen retrieval solution, mild means 30 minutes and 16 is the primary antibody incubation time.
CHAYTOR, Q.C.:
Q. Okay, and BF110, what's that?
MR. GREEN:
A. These are the fixatives that this column right here, BF is buffer formalin, the others Bouins B5 are carnoys, so if any of the tissues were fixed in those, those are codes they would have for those.
CHAYTOR, Q.C.:
Q. Okay, and then we have progesterone down here and -
MR. GREEN:
A. CC1 mild, 32, so that progesterone, 16 is the clone on that one in the first column on the left and then the other one is the antigen retrieval, mild, which is 30 minutes. 32 minutes is primary antibody incubation time. Primary antibody incubation time is the time that the tissue would be exposed to the primary antibody.
CHAYTOR, Q.C.:
Q. And I take it you used those three hospitals,

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their protocols as a guide, along with the spec sheets, but you and Mr. Dyer did your own -
MR. GREEN:
A. We did -- we ran our own variations of these until we came to a protocol that the pathologists were happy with.

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protocols that you had used in your DAKO system and input those into your Ventana System?

MR. GREEN:

A. We didn't go verbatim, no.

CHAYTOR, Q.C.:

Q. So you know with respect to the ER antibody, any change that took place to the protocol from the DAKO System to the Ventana?

MR. GREEN:

A. The biggest change would have been the antigen retrieval. We would have worked with a standard antigen retrieval. On the CCI, which would be EETA 48 solution, which was Ph8 as opposed to the one which was used on the DAKO which was pH -- which was citrate buffer Ph6, and that one went for 20 minutes between 95 and 100 degrees, an extra 30 minutes on the bench. It's still an antigen retrieval, but the temperature was cooling down. That would be the biggest change.

CHAYTOR, Q.C.:

Q. So even for the time period when you were continuing to use the antibodies that you had in your supply or in your inventory, you still

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-- this tweaking of protocols took place in any event, you didn't just use up those antibodies and then do the tweaking, the tweaking took place before the Ventana was brought on stream?

MR. GREEN:

A. It would have -- it would have been done while the DAKO was still there, and once we used up all the antibodies, then we brought in the predilutes from Ventana.

CHAYTOR, Q.C.:

Q. So this -- that's what I'm wondering. This process of what you went through here and comparing to other hospitals, did that happen before Ventana was brought on stream or was this used, the protocols changed, or any tweaking to the protocols after?

MR. GREEN:

A. No, this was in the initial setup.

CHAYTOR, Q.C.:

Q. This was the initial setup, okay. Did you receive any additional training on the Ventana machine prior to it being operationalized?

MR. GREEN:

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

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2004, I went to Tucson, Arizona, to Ventana's data training and a production area there. We went there for -- myself and Barry Dyer went there for a week to get hands-on training as well as classroom training.

CHAYTOR, Q.C.:

Q. And what was involved in the classroom training?

MR. GREEN:

A. The classroom training would be theory, immunoperoxidase basics, and theory, how to set up a protocol, which antigen retrievals to use, the significance of antigen retrieval, significance of antibody incubation time.

CHAYTOR, Q.C.:

Q. And this is February, 2004?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And were there things that you learned in that process that you didn't know before?

MR. GREEN:

A. Every day was a learning process for me at this point because this whole IHC area was fairly new, so my knowledge increased greatly

CHAYTOR, Q.C.:

Q. Okay, and do you recall was Dr. Ejeckam involved at all in the process?

MR. GREEN:

A. Dr. Ejeckam was there when the process was going on. I'm sure he would have seen some of the slides.

CHAYTOR, Q.C.:

Q. Was there any one pathologist at that point in time who was considered to be overseeing IHC?

MR. GREEN:

A. I think Dr. Ejeckam was probably the man to go to. I don't know if he had an official title at that time, but if he was there, we would have certainly went to him.

CHAYTOR, Q.C.:

Q. Okay. So it wasn't a situation based on this information. You didn't just take the

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starting with the Ventana training.

CHAYTOR, Q.C.:

Q. So I take it that was an helpful process for you, not only just in terms of how to operationalize the machine, but how to understand the theory behind IHC?

MR. GREEN:

A. It's invaluable background into not just how to do something, but why to do it, how to troubleshoot, what to go wrong -- when something goes wrong, how to trace back and find the problem.

CHAYTOR, Q.C.:

Q. And you say Mr. Dyer also went on that training exercise with you?

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. You spent some time in the classroom and the rest you spent actually learning how to use the machine?

MR. GREEN:

A. They had several machines set up there, maybe 12/14 machines, and they had classroom sessions set up, week sessions, for all over

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the country. So you would interact with people. There were people there from Florida, people from Texas, mostly from different parts of the US, so -- who were buying their equipment and they were getting training, and you would also get to interact with these people and learn how their hospitals work, how their laboratories work. So that was a good aspect too.

CHAYTOR, Q.C.:

Q. Did you actually bring down slides from the Health Sciences Centre?

MR. GREEN:

A. We did.

CHAYTOR, Q.C.:

Q. You did?

MR. GREEN:

A. We brought down slides so that we could stain our slides on their equipment down there.

CHAYTOR, Q.C.:

Q. And do you know how many slides you brought down?

MR. GREEN:

A. Not specifically. I know Barry carried the slides himself, and they were probably in one

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of our plastic slide containers, probably 40 or 50 slides.

CHAYTOR, Q.C.:

Q. Forty or fifty slides?

MR. GREEN:

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

CHAYTOR, Q.C.:

Q. Yes, okay, and -- so then you used your own slides that you had processed in-house back in St. John's and used those for staining while you were in Arizona?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And was there any feedback given -- was anyone interacting with you on that from Ventana in terms of the quality of the staining of those slides?

MR. GREEN:

A. The quality of our stains were just as good or better than the quality of the other people who were there who had brought slides.

CHAYTOR, Q.C.:

Q. Okay, and would pathologists be involved in this training exercise?

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MR. GREEN:

A. They -- not to my knowledge, not that I know. They had a person who was -- that was her job.

CHAYTOR, Q.C.:

Q. So she wasn't a pathologist?

MR. GREEN:

A. I don't think so.

CHAYTOR, Q.C.:

Q. So in terms of looking at the quality of the slides, was there any feedback given to you regarding any issues about the quality of the slides that you brought down?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Were you taught how to maintain the Ventana machine, how to clean it and what would be necessary?

MR. GREEN:

A. That would be part of the training.

CHAYTOR, Q.C.:

Q. And what did you understand in terms of how frequently cleaning and maintenance were supposed to take place?

MR. GREEN:

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A. There's daily maintenance on the Ventana machine, and there's monthly maintenance, and quarterly maintenance, and the company will do the annual preventive maintenance.

CHAYTOR, Q.C.:

Q. And you came back to St. John's. How did you feel in terms of your comfort level after that week in being able to operate the Ventana machine?

MR. GREEN:

A. It was -- the comfort level had increased greatly because by that time we had been learning the machine for a couple of months, so we knew some parts of running it, but this gave us a much greater comfort level in operating the machine.

CHAYTOR, Q.C.:

Q. And in terms of the other technologists then, I guess, Mary and Peggy, how did they then learn how to use the Ventana machine?

MR. GREEN:

A. Peggy was left by this time.

CHAYTOR, Q.C.:

Q. Peggy was -- right, yes, Peggy is gone in '03, that's right.

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MR. GREEN:

A. Yeah, the Ventana system --

CHAYTOR, Q.C.:

Q. So it's Les and Mary.

MR. GREEN:

A. It would be Les and Mary, and so -- basically I trained Mary and Les how to operate the machine, brought back the training manual that I had there and discussed with them the procedures and the knowledge that I had brought back.

CHAYTOR, Q.C.:

Q. Okay, and how long did that take for you to train them?

MR. GREEN:

A. It was ongoing. It probably took place over the following month after I returned because we were still taking turns on the machine. So when it was Mary's turn on the machine, I would tell -- pass on the information to her, and when it was Les' turn, I would pass on the information to him.

CHAYTOR, Q.C.:

Q. So when it was Mary's week to operate --

MR. GREEN:

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A. Operate the machine.

CHAYTOR, Q.C.:

Q. The IHC, the DAKO, I guess, was still in operation?

MR. GREEN:

A. By this point the DAKO was probably winding down, but when myself and Barry were working on the Ventana system, Mary and Les concentrated on running the DAKO.

CHAYTOR, Q.C.:

Q. Okay. So while you and Barry were using the Ventana to do the concordant study, they would be doing the tests on the DAKO?

MR. GREEN:

A. On the DAKO.

CHAYTOR, Q.C.:

Q. So at some period then, I take it, it would be Mary, though --

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. Or Les. So both of you then would have been in the IHC lab at the same -- a portion of the lab at the same time?

MR. GREEN:

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A. Yeah, and what we would do, I would set up runs and then Les or Mary would set up runs after, and if they had any questions, they would ask.

CHAYTOR, Q.C.:

Q. And I'm just thinking in terms of the amount of training then that they received and you came back and taught them how to do this, that was done, I take it, while the Ventana machine was up and running, you would work with them for a period of time?

MR. GREEN:

A. Yes, yeah, that's true.

CHAYTOR, Q.C.:

Q. And how long did that last? For example, if it was a week on -- you were still on your weekly rotations at that point, were you?

MR. GREEN:

A. It was shortly after that that once we moved down -- we had moved down to our new location by that time, and we had our separate area. So by that time we were starting to move away from the general lab and most of our time would be spent down in Immunohistochemistry.

CHAYTOR, Q.C.:

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Q. Now this would be April, 2004, I take it?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So that's when you started your training of Mary and Les. How many slides would fit on the Ventana machines? We heard that it's 48 on the DAKO. How many were on the new Ventana?
MR. GREEN:
A. We had two Ventana machines, two bench marks, and they would accommodate 20 slides each.
CHAYTOR, Q.C.:
Q. And did you have two from the beginning in April, 2004?
MR. GREEN:
A. Yes, we had two.
CHAYTOR, Q.C.:
Q. So you had two machines, so you were able to do 40?
MR. GREEN:
A. Forty slides.
CHAYTOR, Q.C.:
Q. And in terms of the validation exercises or concordance studies that you and Mr. Dyer

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carried out, that had to be done on two machines then?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So that period of time, there were two machines that actually had to be validated?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Do you know what happened to the DAKO machine?
MR. GREEN:
A. After the DAKO machine was taken out of service, it was stored in the back of the lab for a while, maybe five or six months, and as far as I know, it was sold to a person -- one of the people who does repairs on equipment in the hospital.
CHAYTOR, Q.C.:
Q. Do you know who that person is?
MR. GREEN:
A. Probably Joe White.
CHAYTOR, Q.C.:
Q. Joe White?
MR. GREEN:

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A. Yeah.
CHAYTOR, Q.C.:
Q. And do you know what he used the machine for or why he would have acquired it?
MR. GREEN:
A. He probably would have sold it.
CHAYTOR, Q.C.:
Q. Sold it again?
MR. GREEN:
A. Resold it.
CHAYTOR, Q.C.:
Q. Resold it, yes. You say it was about five or six months after. So by the time these issues arose in the spring of 2005, the ER/PR issues that we're dealing with, was the DAKO machine already gone out of the hospital by then?
MR. GREEN:
A. It was long gone by then.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. It was shortly after we had the two Ventana machines that we realized that we had a problem with running controls, and if we -- the Ventana machine with only 20 slides, if we

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ran a control for each patient, we would cut our volume by 50 percent. So Barry had been in Montreal, some part of Quebec, Montreal, I think, and he had visited a hospital there and they had used controls on their slides. So he proposed that we cut our controls and put them on individual slide. That way we could -- not only would be have a positive control on each slide, but we would increase our volume of slides. It would double the volume of slides that we could run. On the DAKO system, the slide was divided into three zones, three drop zones, and you had to pick a zone. If you picked all three zones, you would need three times as much antibody. On the Ventana system, it was designed to use 100 microlitres of antibody per slide, and the machine didn't care if there was one piece of tissue on a slide or two or three, it didn't matter. So we could have some quality control and some cost savings by running the control slide -- control on top of the slide.
CHAYTOR, Q.C.:
Q. And when that -- so that decision was made before any issue arose in 2005?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. That was already the practice by the time May/June of 2005 came around?
MR. GREEN:
A. Yeah, and shortly after we started doing that, then we would show the slides to Dr. Ejeckam and he kind of liked that idea too, put the control on top of the slide. Dr. Ejeckam was very knowledgeable in the DAKO System. The Ventana was new to him also. So he was starting to come around and take a liking to the machine by that time.
CHAYTOR, Q.C.:
Q. Okay, so I take it he didn't initially embrace it?
MR. GREEN:
A. He was comfortable with the DAKO machine because that's what he knew.
CHAYTOR, Q.C.:
Q. Yes.
MR. GREEN:
A. Even after we had the Ventana up and running, and we would run into a problem with an

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

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

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top, patient's tissue will be on the bottom. We will run an adjacent slide with the patient's tissue only, which will be a negative control, and for each patient gets treated like that, and for the batch, we will run a triple control, which is there will be ER negative on this one here. There'll be an ER intermediate and there'll be an ER positive, and the same will apply to the PR.
CHAYTOR, Q.C.:
Q. Okay, and when did that become your practice?
MR. GREEN:
A. That became the practice after we resumed ER/PR.
CHAYTOR, Q.C.:
Q. In February 2007?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and Mr. Dyer's initial idea to have the control tissue on the patient slide, I take it, was only one control placed at that time, was that?
MR. GREEN:
A. Yes, one positive control.

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CHAYTOR, Q.C.:
Q. One positive control.
MR. GREEN:
A. Because not only ER/PR. We run a positive control on all antibodies on all slides now.
CHAYTOR, Q.C.:
Q. Okay, and at the time when it was just one external control being used, who--what type of control--because I know now you're talking about, you know, a strongly positive or what -
MR. GREEN:
A. That would be -
CHAYTOR, Q.C.:
Q. So what was used?
MR. GREEN:
A. This is a positive control, strong positive.
CHAYTOR, Q.C.:
Q. A strong positive?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, so the tissue that was chosen for your controls, when it was only one, was a strong positive?
MR. GREEN:

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A. Yeah.
CHAYTOR, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. Okay, let me make sure I now understand what the current practice is. So that if you are doing an ER, for example, you will have a piece of patient tissue, which, as I understand it, will contain the internal control and the tumour?
MR. GREEN:
A. Yes.
THE COMMISSIONER:
Q. And in addition, on that same slide, there will be a strongly positive control which is know to you?
MR. GREEN:
A. That's correct.
THE COMMISSIONER:
Q. And in the next spot over, there will be a separate slide which will have--I'm not sure I've got the order right, but there will be another slide with three controls on it?
MR. GREEN:
A. Yes.

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THE COMMISSIONER:
Q. And there will be also the piece of--a separate slide with a piece of tissue which is the negative control?
MR. GREEN:
A. Yes, the negative will be the patient's tissue, which is subjected to the same protocol as the ER protocol, except a primary antibody will be omitted.
THE COMMISSIONER:
Q. All right.
MR. GREEN:
A. And the theory being that the antigen antibody reaction should not take place if you don't have the primary antibody there to begin with. So this will show any staining that's in the tissue.
THE COMMISSIONER:
Q. Okay. So effectively for each patient, there are two slides which are unique to that patient?
MR. GREEN:
A. Correct.
THE COMMISSIONER:
Q. And then there is the third one which is

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relevant which would--but is for the batch?
MR. GREEN:
A. Yes, that's correct.
THE COMMISSIONER:
Q. And that same thing--and if someone orders both ER and PR to be done, then you multiple that by two because the same process -
MR. GREEN:
A. Same process for the PR, yes, exactly.
THE COMMISSIONER:
Q. Okay, thank you.
MR. GREEN:
A. And then on the ER/PR, when these slides are run, those were--they were sent to the St. Clare's Hospital, to the Breast Group, and the Breast Group would read the slides and we would run a duplicate control, which we would keep in the lab and we would print from the Ventana machine the run reports which shows all the antigens used, the antibodies used, the reagents used, their expiry dates, their lot numbers, and the total run report with all the patients, that would go with the slides to the Breast Group to read.
CHAYTOR, Q.C.:

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

MR. GREEN:

A. For our records, yes.

CHAYTOR, Q.C.:

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

MR. GREEN:

A. No, those are real slides.

CHAYTOR, Q.C.:

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

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

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

MR. GREEN:

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

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

CHAYTOR, Q.C.:

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

THE COMMISSIONER:

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

CHAYTOR, Q.C.:

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

MR. GREEN:

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

CHAYTOR, Q.C.:

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

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MR. GREEN:

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

CHAYTOR, Q.C.:

Q. The Ventana was in operation?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So sometime after April 2004?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

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

MR. GREEN:

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

CHAYTOR, Q.C.:

Q. So Mr. Dyer ran for -

MR. GREEN:

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

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essential.

CHAYTOR, Q.C.:

Q. You were called back to work?

MR. GREEN:

A. We were called back as needed.

CHAYTOR, Q.C.:

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

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. When did that take place?

MR. GREEN:

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

CHAYTOR, Q.C.:

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

MR. GREEN:

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

CHAYTOR, Q.C.:

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

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the IHC portion of the lab?
MR. GREEN:
A. The only thing it probably would have affected would have been any paperwork that we had around.
CHAYTOR, Q.C.:
Q. Okay, so you lost some paperwork?
MR. GREEN:
A. Yeah. Antibodies wouldn't be affected. They would be in the fridge. I'm not aware of any ill effects from it.
CHAYTOR, Q.C.:
Q. Okay, and what about the machinery itself? Were they--was that affected? Was there any water -
MR. GREEN:
A. As far as I know, it wasn't affected.
CHAYTOR, Q.C.:
Q. Okay. Did the lab have to relocate for a period of time?
MR. GREEN:
A. We did. We moved over to the medical school.
CHAYTOR, Q.C.:
Q. So the entire pathology lab?
MR. GREEN:

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A. I'm pretty well sure the whole lab was closed down.
CHAYTOR, Q.C.:
Q. And how long did that last?
MR. GREEN:
A. Probably a couple of weeks.
CHAYTOR, Q.C.:
Q. So the DAKO machine would have been moved out and moved back?
MR. GREEN:
A. I'm not really clear on which machine was there and what time it was.
CHAYTOR, Q.C.:
Q. But whatever machine was there doing the IHC testing, the machinery was physically moved to the medical school?
MR. GREEN:
A. I don't recall the IHC equipment being moved.
CHAYTOR, Q.C.:
Q. Okay. So perhaps Mr. Dyer would have a better recollection of that?
MR. GREEN:
A. He probably would, yeah.
CHAYTOR, Q.C.:
Q. You indicated earlier this morning, in your

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time at St. Clare's, there was a fairly close working relationship between the technical staff and the pathologists and you had fairly frequent interaction and at Health Science, it wasn't quite the same amount of interaction.
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Was there any issues though of any tension between medical technologists and the medical staff?
MR. GREEN:
A. No, I've always had a good relationship with all the pathologists there, and as I spent more time at the Health Science and got to know the pathologists, the same kind of relationship developed that I've had at St. Clare's.
CHAYTOR, Q.C.:
Q. And are you aware whether or not there was, in general, any issues between the technical side of the staff and the medical side?
MR. GREEN:
A. From a technologist's point of view, I'm not aware of any. There may have been some issues

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between management and pathologists, but that's kind of -
CHAYTOR, Q.C.:
Q. Nothing at your level, nothing--all right.
MR. GREEN:
A. Nothing that I can speak to.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. But from a technologist's point of view, there's always been a great relationship between the pathologists at St. Clare's and at the Health Science. I've never had--personally, I've never had a problem with pathologists.
CHAYTOR, Q.C.:
Q. Okay, and if there were any issues or questions that you needed to ask regarding your processes, the pathologists were approachable to answer any questions you may have?
MR. GREEN:
A. More than willing to help at any time.
CHAYTOR, Q.C.:
Q. Okay, and with respect to Dr. Ejeckam, did he

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take a particular interest in trying to train the technologists?

MR. GREEN:

A. Yeah, he did. He would--after we had the Ventana system up and operating, we would go to him for controls and he developed a--he got us to set up a control bank where he would--so we would have controls to draw from. He would set up sessions on the multi-headed scope so that we could review the controls and the patient's tissue and that's where I first learned about internal controls, from Dr. Ejeckam, and we were particularly interested in the breast tissue at that time and that was the time that he would show us the internal controls, the ductal epithelium to explain that it should be--it should normally be positive, but not necessarily 100 percent of the time. There are times when it won't be, but as a general rule. So before that, we weren't aware of those.

CHAYTOR, Q.C.:

Q. Okay, and how knowledgeable did Dr. Ejeckam appear to you to be in IHC?

MR. GREEN:

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A. From my perspective, he was probably the most knowledgeable pathologist for IHC that I knew.

CHAYTOR, Q.C.:

Q. Was there a point in time where you sensed from Dr. Ejeckam that he was becoming frustrated?

MR. GREEN:

A. He didn't hide his feelings. When he was frustrated, you knew he was frustrated, and there were times when he was. He had a particular vision in mind for the laboratory. One was he wanted a separate space. He wanted dedicated technologists full time and when things didn't move fast enough for him, he would be upset.

CHAYTOR, Q.C.:

Q. Okay, and you -

MR. GREEN:

A. But he would be upset at us, but he would be upset at the system.

CHAYTOR, Q.C.:

Q. And he'd voice that to you?

MR. GREEN:

A. On many occasions, yes.

CHAYTOR, Q.C.:

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Q. Okay. So things weren't--the changes he wanted to see happening in IHC weren't taking place quickly enough for him?

MR. GREEN:

A. They weren't taking place quickly enough for him. He had been used to working, I think it was in Dohar.

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. And I think things moved a bit faster there, and he had--he brought a copy of the manual that they used in Dohar, so he wanted us to prepare a manual that was similar to that one.

CHAYTOR, Q.C.:

Q. So a manual like a standard operating procedure manual?

MR. GREEN:

A. Yeah, like a manual procedures for IHC. So he gave me that manual which we read over and I took that one and adapted it to--because that one had DAKO information and I adapted it to the Ventana system, and we used a lot of the information from that. I revised it and brought it back to him and he said "it's a

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good start," but that's the way he was, you know. He always wanted us to do better and he told us that we could be the best and he was on his way to teaching us to go that route.

CHAYTOR, Q.C.:

Q. So the manual that you did an initial draft for, would that contain things like--was that policies and procedures like we see in what you've prepared now?

MR. GREEN:

A. It was more of a technical manual.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. It's a step A, B and C to doing procedures and procedures, say, for immuno fluorescence, the procedures they ran with the DAKO system, dilutions and technical like that, not a standard operating procedures manual.

CHAYTOR, Q.C.:

Q. So did you ultimately get that technical manual developed?

MR. GREEN:

A. I believe, we did a clone of the one that he had, yeah.

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CHAYTOR, Q.C.:
Q. And when was that? When did you -
MR. GREEN:
A. That would have been around 2005, I would say, at the same time he started teaching us to read controls.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And he would--he'd set up lectures so that all the staff could be involved. He'd give lectures on formalin fixation and tissue processing, slide preparation, troubleshooting, defects in tissue, especially defects in lymph node tissues and stuff like that. So he was proactive in that sense.
CHAYTOR, Q.C.:
Q. And I take it you learned a lot through Dr. Ejeckam?
MR. GREEN:
A. That was when we started to take this IHC onto its own and make it a separate department.
CHAYTOR, Q.C.:
Q. And after Dr. Ejeckam left, did another pathologist take up his torch?

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MR. GREEN:
A. I think Dr. Makarla probably filled in for a while. Dr. Makarla had come from the U.S. He had spent time down in Arizona. Matter of fact, he had worked with one of the pathologists who designed the Ventana system and he knew him quite well. So I figured, great, we've got a person on the inside, and he was quite willing to make his contact there, but he didn't stay around long enough to--he started to work with it, but he didn't stay around that long.
CHAYTOR, Q.C.:
Q. And after Dr. Makarla, did somebody else step up?
MR. GREEN:
A. I think Dr. Dan Fontaine stepped in for a while. Dr. Fontaine would help us with any problems we have in antibodies or any questions that we had.
CHAYTOR, Q.C.:
Q. And was there anyone then after Dr. Fontaine? He's there's for a while assisting, I take it.
MR. GREEN:
A. There was probably a gap in between and then

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Dr. Ford Elms took over.
CHAYTOR, Q.C.:
Q. Okay, and I understand that's after the issues arise in 2005?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. That Dr. Elms steps up?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, and so in terms of another pathologist in that year or so after Dr. Ejeckam leaves filling the gap, was there the same type of interest shown to the staff, towards staff training, by any other pathologist that Dr. Ejeckam had displayed?
MR. GREEN:
A. Dr. Bev Carter took an interest in the training and education. She set up the academic pathology rounds, which would take place every Friday. She encouraged all the residents and the pathologists and the technologists to, if they went to a conference or went to a lecture, so they would come back,

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it was their responsibility to give that information to your colleagues. So she included us in that process.
CHAYTOR, Q.C.:
Q. And was that the first time technologists had been invited to academic rounds?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And does that practice still continue today?
MR. GREEN:
A. They still go on every Friday.
CHAYTOR, Q.C.:
Q. And I'm going to ask you a little bit later about some continuing education that you've had. Did you have an opportunity to present at those academic pathology rounds?
MR. GREEN:
A. Twice. The first time, after I came back from Phoenix, Arizona to the NSH conference. That's a conference where it's devoted solely to pathology, in the U.S., so you get a lot of exposure to pathology and IHC. So after I came back, she wanted me to give a report and kind of an overview of the lectures and that

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we went to. And later on, maybe in the same year, she wanted me to give a lecture on the basics of immunohistochemistry.

CHAYTOR, Q.C.:

Q. Okay, and if I could just go back then to Dr. Ejeckam's time, and I'll ask you some more about those conferences that you attended. Dr. Ejeckam, the Commissioner has heard that he did raise issues with certain stains in April 2003 initially. Two of those stains were ER and PR. Do you recall those issues at the time that were raised by Dr. Ejeckam?

MR. GREEN:

A. I was not aware that there was a problem with the stains and I was not involve in the collective actions that took place during that time. I'm pretty well sure that Dr. Ejeckam worked with Barry and Mary on those.

CHAYTOR, Q.C.:

Q. Okay. Now, you weren't aware of the corrective action that took place. Do you recall at all that there was corrective action taking place, that there was any testing happening or any adjustments happening?

MR. GREEN:

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A. I was not even aware that it happened.

CHAYTOR, Q.C.:

Q. When did you first become aware of that?

MR. GREEN:

A. When the Commission set up and all these documents started to appear; that's when I first saw it.

CHAYTOR, Q.C.:

Q. That's when you first learned about any adjustments that Dr. Ejeckam had made or any issues he brought forward.

MR. GREEN:

A. Because I was surprised that the assumption was made that the lab had shut down. As long as I've been there, I was never aware that the lab was shut down.

CHAYTOR, Q.C.:

Q. No.

MR. GREEN:

A. I'm sure somebody would have told me when I showed up for work.

CHAYTOR, Q.C.:

Q. And what about the suspension of any testing for those particular eight stains, were you aware that had happened?

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MR. GREEN:

A. I was not aware.

CHAYTOR, Q.C.:

Q. Okay. And I take it you learned that too then much later in 2007.

MR. GREEN:

A. So, obviously it happened on the two week stint that I had been out of the IHC area.

CHAYTOR, Q.C.:

Q. But you weren't in there?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. If we could look at, please, P-0113 and this is the first of Dr. Ejeckam's memos, April 4, 2003 and this where he writes that, "kindly note"--"this is sent to pathologists, Health Sciences, St. Clare's and out of town hospitals. Kindly note that immunohistochemical stains with the following antibodies" and there's a list which include ER and PR have remained unreliable, erratic and therefore unhelpful for diagnostic purposes. Consequent, on the above staining with these antibodies shall stop forthwith

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until we can solve the reliability, sensitivity and specificity problems. Efforts are underway and hopefully a solution will be found within the next four to six weeks. You'll be duly informed when such stains can resume". And it's indicated to be copied to Barry Dyer as well as all technical staff on immunohistochemistry.

Mr. Green, did you receive a copy of this memo?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. Do you know of if any of the technologists received a copy of this memo?

MR. GREEN:

A. Not that I'm aware of. I'm pretty sure if Mary or Les had received a copy, that would have shared that information with me.

CHAYTOR, Q.C.:

Q. You would have expected they would have -

MR. GREEN:

A. I would expect that they would.

CHAYTOR, Q.C.:

Q. Yes.

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MR. GREEN:
A. This is the second time I've seen it. The first time I seen it was when Dan Simmons showed it to me earlier the week.
CHAYTOR, Q.C.:
Q. Earlier this week?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. And do you have any recollection at all that there was any suspension of or any adjustments made to any antibodies in this time period?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. Nothing involving lymphoma markers?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. If we could have please, P-2173, page five. And these are again, the request forms that we were referring to earlier. And you are the tech on this one and it's completed March 21, 2003 and then it's indicated M. Butler, April

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28, 2003. So, it's over a month later. And on the bottom here we see written "checked by Dr. Ejeckam".
MR. GREEN:
A. That would be my handwriting.
CHAYTOR, Q.C.:
Q. This is probably your handwriting?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. And what would you mean by "checked by Dr. Ejeckam"?
MR. GREEN:
A. That means that I would have brought the slides over to him, the control slides along with the patient slides and he would have checked the controls and knowing Dr. Ejeckam, he would have looked at the patient slides too and probably knew what the diagnosis was before it left his office.
CHAYTOR, Q.C.:
Q. Okay. Now, this says on the top, "Dr. Elms has ER/PR control".
MR. GREEN:
A. That's probably the first--is this a repeat?

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

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

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

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Any of this information brought to your attention in April of 2003 or that this was -

MR. GREEN:

A. No, it wasn't.

CHAYTOR, Q.C.:

Q. Okay. And the suggestions here in terms of changes to how to conduct the ER/PR, was this information shared with you?

MR. GREEN:

A. No. I notice that the dilution has been changed.

CHAYTOR, Q.C.:

Q. Yes, from 1 to 50 to 1 to 20.

MR. GREEN:

A. But the second statement is interesting. "If the staining is still inadequate, you should try using the high pH target retrieval solution for antigen retrieval. The high pH buffer produces best results for all three of these antibodies. Although tissue damage or loss can occur". So, you probably fix -

CHAYTOR, Q.C.:

Q. Yes, and why is that of interest to you?

MR. GREEN:

A. It's interesting because when we set up the Ventana system, we had used a higher pH target retrieval system.

CHAYTOR, Q.C.:

Q. And this is April of 2003, so was this change not made at that point in time and not made until April 2004?

MR. GREEN:

A. I would seriously doubt if the higher pH antigen retrieval was ever used on the ER/PR on the DAKO system. I was not aware of it, if it was.

CHAYTOR, Q.C.:

Q. And you were running the test every three weeks.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So, you would expect to be aware if that had changed.

MR. GREEN:

A. From my recollection, we didn't change the antigen retrieval on the ER/PR on all the time that I worked on the DAKO system. I can't say what happened before I went there.

CHAYTOR, Q.C.:

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Q. Okay. And if we could look at P-2177, please. And these are the spec sheets again that I showed you earlier. And if we just come forward to page seven, we see--I believe I showed you this earlier, April 3rd, 2003, it's 1 in 50. And then April 28th, 2003, 1 in 20.

MR. GREEN:

A. One in twenty.

CHAYTOR, Q.C.:

Q. So, that's consistent with the memo I showed you from DAKO and the recommendation.

MR. GREEN:

A. Yeah, it is.

CHAYTOR, Q.C.:

Q. And do you recall this change yourself in the -

MR. GREEN:

A. I was never officially made aware of it, no. The only way I would have known is when my turn came to run the slides, that when I made up the antibody, it would have been changed on the antibody concentrate.

CHAYTOR, Q.C.:

Q. Okay. So, the memo that I showed you, April 22nd, 2003 from DAKO, that was never

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distributed to you?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. If I could have, please, P-1572 and this is a meeting of Surgical Pathology Review Committee, April 15th, 2003. So again, this is in the same time period, April 2003. And Dr. Ejeckam was the chair of that committee and he's in attendance with a number of other physicians, and Theresa Curtis, secretary. And under "New Business, 3.1, ER and PR receptors, Dr. G. Ejeckam stated that the ER and PR receptors are not being performed for the next six weeks due to a technical problem". And again, this is April 15th. You have no recollection of any suspension in ER and PR in that time period?

MR. GREEN:

A. No recollection for stopping that service at all.

CHAYTOR, Q.C.:

Q. Okay. And obviously if it went on for that long or for this period of time, it would have also been during your time in rotating -

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MR. GREEN:

A. In my general rotation -

MR. GREEN:

A. Because you would rotate through every third week. "If a solution cannot be found, these tests will be sent outside St. John's". I take it you weren't aware that that was being contemplated?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. He stated, "it's being considered to send one or two technologists to Halifax or Toronto for training". Now, in April of 2003 was that ever discussed with you, that there was consideration to have your or any of your colleagues sent outside the province for training?

MR. GREEN:

A. Dr. Ejeckam did talk to me about going outside the province for training, not sure of the time line, but I think--let's see--January 2006 was the time I went to the Jewish General. This is -

CHAYTOR, Q.C.:

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Q. This is 2003, January 2003.

MR. GREEN:

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

CHAYTOR, Q.C.:

Q. So, the first time you received training outside of the province other than the Ventana machine and learning to use that, the first time you received any training outside the province was January 2006?

MR. GREEN:

A. Ventana in 2004 in Tucson and Fort Lauderdale 2005.

CHAYTOR, Q.C.:

Q. Okay. When in 2005?

MR. GREEN:

A. Fort Lauderdale, September 2005.

CHAYTOR, Q.C.:

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

MR. GREEN:

A. Yes.

THE COMMISSIONER:

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

CHAYTOR, Q.C.:

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Q. Thank you. Mr. Green, the issue--we've been calling it the ER/PR issue, just our abbreviated way of referring to it--when did you first learn that there was such an issue?

MR. GREEN:

A. I first learned on, I think it was August 8, 2005, when I received a letter from Dr. Cook.

CHAYTOR, Q.C.:

Q. Okay. And I'm going to refer you to that memo. So, you heard nothing verbally before that?

MR. GREEN:

A. Nothing officially up until that time, I had no idea what was going on, but I knew something was going on because we were getting increased requests for ER/PR and tests for older cases for ER/PR.

CHAYTOR, Q.C.:

Q. I'm sorry, tests for?

MR. GREEN:

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

CHAYTOR, Q.C.:

Q. You could tell that from the surgical number, I take it.

MR. GREEN:

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A. You could tell from the surgical numbers that--your regular work load would come in and you would get the current workload. And then if you got numbers that were right back, you know, there's probably a reason for it. But officially, nobody ever mentioned it to me.

CHAYTOR, Q.C.:

Q. So, I believe that was June and July of 2005 that there were a number of retests taken place. So, those probably what you were seeing through in terms of volume.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. But nobody spoke to you to tell you why it was happening or what was going on?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. And was that the subject of discussion amongst you and your colleagues?

MR. GREEN:

A. You could tell that there was something going on, we just didn't know what was going on and there were a lot of meetings going on. So, we

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never knew exactly what was going on or the depth or the scope of it and in hindsight, maybe not a lot of people knew the depth or scope in the beginning.

CHAYTOR, Q.C.:

Q. And I take it then in that, you know, May/June/July, 2005, well until August 8, 2005 when you received a memo, and even in receiving the memo, you hadn't been told anything in person?

MR. GREEN:

A. No, even the memo itself, which I guess we'll get to read when you're ready, the memo suggests that we are sending ER/PR specimens outside the province, but we will continue to do ER/PR. So, ER/PR was never suspended, from my point of view, in the IHC lab. We continued to do our specimens as usual using the protocols we had in place.

CHAYTOR, Q.C.:

Q. Yes, and I'm going to take you to that. But in terms of even then, someone coming to you with the memo and sitting down and explaining what it meant, did anyone do that?

MR. GREEN:

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A. I think Barry dropped off the memo and that was the--knowing that background.

CHAYTOR, Q.C.:

Q. And throughout the spring, May/June and in the summer, July of 2005, I take it, nobody--did anyone come though and ask questions about your process or come and observe what was happening in the lab? Was there anything unusual happening like that?

MR. GREEN:

A. Not that I can recall. Somewhere along the way, I heard about a case that had been ER/PR negative and had been retested and it was ER/PR positive, but it was never officially told to me.

CHAYTOR, Q.C.:

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

MR. GREEN:

A. It would have been after.

CHAYTOR, Q.C.:

Q. After. If we could look, please, at P-0515 and I think the second page will be better to read. And this is a meeting of July 21st, 2005 between Drs. Carter, Cook and Williams.

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And it's just some bullets, we understand these are Dr. Williams' notes, a typed version of his notes of that meeting. And Dr. Carter, is written here, "feels there was a problem in 2002, some runs on retrospect were not normal. Inconsistency from one batch to another, current Ventana test is picking up too much. Dr. Carter also doing some work on quality control and use them as controls. Techs may need to be retrained on immunoperoxidase and need controlled access to the room. Training of techs in the immunohistochemistry needs separate service; need QA and proficiency testing; need to have an external consultant to come to the lab and do QA.

So, in terms of any training that you had in immunohistochemistry, did anyone make any inquiries as to that in this time period?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. In terms of whether or not controls were being run with all of your -- with all your tests, was there any discussion regarding that?

MR. GREEN:

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A. No.
CHAYTOR, Q.C.:
Q. So any suggestion that Dr. Carter may have expressed some concern as to whether or not controls were run with every batch, was there ever any discussion with that -- about that with you?
MR. GREEN:
A. Never brought to my attention.
CHAYTOR, Q.C.:
Q. And, Mr. Green, how confident are you that a control was run with every batch of ER/PR testing?
MR. GREEN:
A. Quite confident. It was -- it was the normal practice for us to run controls.
CHAYTOR, Q.C.:
Q. Okay. Thank you, Commissioner, this is a good place.
COMMISSIONER:
Q. All right, we'll take the afternoon break.
(RECESS)
COMMISSIONER:
Q. Ms. Chaytor.
CHAYTOR, Q.C.:

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

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Q. When did you see Dr. Banerjee's report?
MR. GREEN:
A. When it was released by the -- when the Commission released the report.
CHAYTOR, Q.C.:
Q. So this year?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. In February, 2008?
MR. GREEN:
A. Yeah, that was the first time I saw the report.
CHAYTOR, Q.C.:
Q. Okay. So you never learned that anyone had any suggestion about the Ventana machine being too sensitive in 2005?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. And who amongst the technologists would have been seen to be most knowledgeable about the Ventana machine?
MR. GREEN:
A. It would be me.

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CHAYTOR, Q.C.:
Q. So if there were a concern about the Ventana machine, would you have expected it to be brought to your attention?
MR. GREEN:
A. I would have, yes.
CHAYTOR, Q.C.:
Q. If we could look, please, at P-0552, and this is a report from Carole -- I believe -- how do you pronounce her name, Mr. Green?
MR. GREEN:
A. Quevillon.
CHAYTOR, Q.C.:
Q. Quevillon. We've been pronouncing that wrong. August 5th, 2005, written to Mr. Gulliver. Now do you recall -- I've forgotten already.
MR. GREEN:
A. Quevillon. Carole, yeah.
CHAYTOR, Q.C.:
Q. You recall her visiting the lab in the beginning of August, 2005?
MR. GREEN:
A. I do.
CHAYTOR, Q.C.:
Q. And did you - what were you told about the

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reason for her visit at that time?
MR. GREEN:
A. That there were problems with some antibodies and some of the pathologists were having -- were questioning the Ventana System.
CHAYTOR, Q.C.:
Q. So you were aware that there was some questioning about the Ventana System at that time?
MR. GREEN:
A. Yeah, I knew that's the reason Carole was down.
CHAYTOR, Q.C.:
Q. Okay, but whether or not it was an issue of it being too sensitive, you weren't aware of that kind of detail?
MR. GREEN:
A. No, I think they were questioning the whole Ventana platform.
CHAYTOR, Q.C.:
Q. Oh, is that right, the whole system?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and was it regarding certain antibodies

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or the whole system?
MR. GREEN:
A. From what I recall, it was the ER/PR.
CHAYTOR, Q.C.:
Q. ER/PR, okay. So by the beginning of August, 2005, you were aware of that. Now this predates -- her visit predates you actually receiving the memo from Dr. Cook on August 8th?
MR. GREEN:
A. I would have -- like I say, not officially, but I knew that Carole was down, that she had checked out our protocols.
CHAYTOR, Q.C.:
Q. And I guess around -- shortly before that, you would also seeing all the ER/PR retests from the old system?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Did you meet with her while she was down on this visit?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:

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Q. What did she discuss with you?
MR. GREEN:
A. I don't remember the specifics. She just went over the machine again, took protocols. I think she printed out copies of all our protocols when she was down so that we could put them in a binder where we would have hard copies.
CHAYTOR, Q.C.:
Q. So that's printed off from the computer on the Ventana machine?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And were you present when she did that then and whatever checks she carried out on the system?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And were you advised of the outcome of her assessment?
MR. GREEN:
A. I would assume that -- well, we didn't make any changes, so I would assume that she found

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no problems with the protocols.
CHAYTOR, Q.C.:
Q. And this letter that we see here drafted to Mr. Gulliver, did you ever receive a copy or were you ever told the contents of the letter?
MR. GREEN:
A. I've never received a copy.
CHAYTOR, Q.C.:
Q. So you assumed the fact there were no changes to the protocols after she was in, you assumed that she found no problem?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And when we enrolled in the external proficiency program for the ER/PR, I used identical protocols that we had been running. Those were the slides that I sent off for the external proficiency testing.
CHAYTOR, Q.C.:
Q. So you used the same protocols. Those were what -- did you actually send the protocols, though, or just your slides?

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MR. GREEN:

A. We send -- you would send the information from the protocol from NEQAS. They would ask you what antibody you used, what clone you used, what antigen retrieval you used, antibody incubation time. You would have to provide all this information.

CHAYTOR, Q.C.:

Q. And that information is the same as when you set the system up in April of 2004?

MR. GREEN:

A. Yes, we didn't change the -- if I remember, protocols 46 and 48 were the ones that we sent, and those were the same ones that we sent to NEQAS.

CHAYTOR, Q.C.:

Q. I don't know if we have copies of those protocols. We got those, okay. You don't know the number to put your hand on them?

MR. SIMMONS:

Q. It would be in Volume 14, I think.

CHAYTOR, Q.C.:

Q. That's okay. We'll come back to it. Thank you. In this letter then, Mr. Green, it indicates that as per your request, so

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presumably Mr. Gulliver's request, "I checked the Ventana bench mark instruments, the procedure and protocols used for the ER and PGR stains, the knowledge and the capacity of the technicians to troubleshoot and run the instruments". Now did you know that you were -- she was also making inquiries as to your knowledge and capacity to troubleshoot?

MR. GREEN:

A. Yeah, I was aware of that.

CHAYTOR, Q.C.:

Q. And she says, "I performed a level one on both instruments, level one being check instrument levels, slide volumes, rinsing volumes, bar code reader alignment. Both instruments are within specifications". So she checked both Ventana machines, I take it. "I ran a full coverage Vimentin --

MR. GREEN:

A. Vimentin.

CHAYTOR, Q.C.:

Q. "On both instruments to validate the staining of the instruments. Both gave good results. I checked the protocols that you are using for the ER and PGR antibodies, CC1 standard, and

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32 min primary incubation. These protocols are used in many accounts in Canada and recommended by Ventana Medical Systems Inc. I checked the pH of the solutions, pH within specifications. I asked questions to the different technicians using the instruments. They are properly trained and able to troubleshoot if a problem occurs. I found out that the recommended maintenance procedures monthly and quarterly were never done on the instruments. We did it monthly and quarterly on one bench mark yesterday and they are doing the second one today. A monthly and quarterly maintenance will be put in place". So this part here about the maintenance, she's indicating that the recommended maintenance, monthly and quarterly had never been done on the instruments. Is that correct?

MR. GREEN:

A. That's true.

CHAYTOR, Q.C.:

Q. So did anyone advise you of that in August of 2005 that this needed to be done, and that a monthly and quarterly maintenance schedule be put in place?

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MR. GREEN:

A. I haven't seen this.

CHAYTOR, Q.C.:

Q. You haven't seen this letter, but were you verbally told about this finding and that the maintenance should be carried out on a monthly and quarterly basis?

MR. GREEN:

A. We would have been aware of that after Carole had come there, yeah.

CHAYTOR, Q.C.:

Q. So she discussed that with you?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And did it change after her visit in August, 2005?

MR. GREEN:

A. Yes, we do that regularly now.

CHAYTOR, Q.C.:

Q. And was that true as of August, 2005, after her visit that you started doing monthly and quarterly maintenance on the machines?

MR. GREEN:

A. Yes.

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CHAYTOR, Q.C.:
Q. And she concludes by saying that she feels confident that the technicians know what they are doing, they know how to use the instruments, and that the bench mark instruments are staining as they should be, and I take it her conclusion that regard was not communicated to you at the time?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. But you were made aware of the issue regarding maintenance procedures?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. If we could look then, please, at P-0559. This, I believe, is Dr. Cook's memo of August 8, 2005. It's written to Mr. Gulliver, Mr. Dyer, Ms. Butler, Mr. Green, and -- yourself, sorry, and Mr. Simms, "re: estrogen receptors and progesterone receptors", and there's seven points written out here, "First there will be a hold on reporting of all ER and PRs by all pathologists. Secondly, immunohistochemical

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form will continue to be filled out by our pathologists. Thirdly, upon receipt of our immunohistochemical form, fax a copy to Dr. Carter at St. Clare's. Fourth, you will continue to proceed with requests and return stained ER and PR slides using the Ventana System to the ordering pathologist. Fifth, following this, the same paraffin block will be forwarded to Dr. Carter at St. Clare's. Sixth, Dr. Carter will forward the paraffin blocks to Mount Sinai with the standardized request, and seventh, the Mount Sinai report, with the slides and paraffin block, will be returned to the St. Clare's site", and it's signed by Dr. Cook, Clinical Chief. How usual was it for you to get a memo from the Clinical Chief?
MR. GREEN:
A. That is the only memo that I've ever received from the Clinical Chief.
CHAYTOR, Q.C.:
Q. And was this hand delivered to you?
MR. GREEN:
A. I think Barry probably would have delivered that.

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CHAYTOR, Q.C.:
Q. And did Mr. Dyer elaborate upon the contents of the memo or was there any discussion as to why this was happening?
MR. GREEN:
A. Not in great detail, no.
CHAYTOR, Q.C.:
Q. What did you understand from this point forward was to happen with respect to ER/PR testing?
MR. GREEN:
A. At this point, I would have figured out that there was a problem with previous ER/PRs, and that there had been some conversions. By this time, I probably would have been aware that there had been an index case, and that it was being investigated.
CHAYTOR, Q.C.:
Q. And what did you understand on a go forward basis was to happen with respect to ER/PR testing?
MR. GREEN:
A. I would -- I continued as usual doing the ER/PR testing.
CHAYTOR, Q.C.:

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Q. So while you're being told there's going to be a hold on the reporting of the ER/PRs by the pathologists, from a technical point of view, you continued on as per usual?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And did the tests?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And upon receipt of the form, did you fax a copy of the request form -- did you fax a copy to Dr. Carter at St. Clare's?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So I take it that was a change in your usual procedure?
MR. GREEN:
A. Yes. Actually we had two stamps made up, one with "ER/PR" written on it and the other "Attention Dr. Bev Carter". We would stamp the forms and faxed them over.
CHAYTOR, Q.C.:

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Q. And did you do this with respect to all ER/PR tests, whether they were from within Eastern Health or not?

MR. GREEN:

A. Yeah, they would all be faxed over to St. Clare's.

CHAYTOR, Q.C.:

Q. And so you continued then -- it says, "To proceed with the requests and return the stained ER/PR slides using Ventana System to the ordering pathologist". So you continued to do the tests as per normal and send the slides back to the ordering pathologist?

MR. GREEN:

A. That happened for maybe a month or two, and after a month or two, somebody told us to stop sending the slides to St. Clare's, they're all being sent to Mount Sinai and they're being read at Mount Sinai. So what we did, we just cut the slides in duplicate, sent them -- sent the blocks over to St. Clare's to be sent away, and we would file the slides in our refrigerator and when we had capacity on one of the machines, we would run the slides and just file it.

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CHAYTOR, Q.C.:

Q. Okay. So just let me understand that again then. So for about a month after receiving this memo, you continued to send the slides out to the reporting pathologist?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. And what was being sent? It says here in the memo you were to send the paraffin block, the same paraffin block to Dr. Carter?

MR. GREEN:

A. Yes, that's true.

CHAYTOR, Q.C.:

Q. And she was then going to send the block on to Mount Sinai, and then the Mount Sinai report, with the slides and paraffin block, were going to be returned to St. Clare's. So you continued on for about a month after receiving this memo, continued to send the slides out to the reporting pathologist and the blocks over to Dr. Carter?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

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Q. And after a month, do you recall who told you to stop doing that?

MR. GREEN:

A. I'm not sure who told us to stop sending them over to St Clare's, but it had to be one of the pathologists at St. Clare's because if they were waiting to get their slides, their ER/PR slides and they didn't show up, they never looked for them. So if they were waiting on ER/PR slides and ER/PR was the topic of conversation at the time, I would be very surprised if they didn't get ER/PR slides for a few months, that they would wonder where they went. So obviously the request to stop sending the slides must have come from the pathologist at St. Clare's.

CHAYTOR, Q.C.:

Q. Okay, and you said, though, that you then continued with the slides. Can you just explain that to us again?

MR. GREEN:

A. So when we get the request for an ER/PR, we would cut our duplicates -- we would cut a set of sections, ER/PR for ourselves, we would take the block and the requisition and we

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would fax a copy to St. Clare's, and then we would send it over by the courier system, and the slides that we had saved for ourselves, we stored in the same refrigerator that we stored our antibodies. When we had extra capacity on one of the machines, we would run the ER/PR slides and we just filed them in the lab.

CHAYTOR, Q.C.:

Q. Filed those in the lab?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So were these requests for patient tests on ER/PR?

MR. GREEN:

A. Yes. So and --

CHAYTOR, Q.C.:

Q. And they were still coming in from where?

MR. GREEN:

A. From the pathologists at St. Clare's mostly, just the regular ER/PR requests. So we kept -- - we stained these slides with the intention of comparing the results of those slides with the results from Mount Sinai when they were finished.

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CHAYTOR, Q.C.:
Q. Okay. So any requests that were coming in for ER/PR were still being sent to you and you continued to make the slides and stain the slides?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. When you got a chance?
MR. GREEN:
A. When we got a chance.
CHAYTOR, Q.C.:
Q. So when your workload permitted, you would then repeat the tests, knowing they were also taking place in Mount Sinai?
MR. GREEN:
A. Yeah, because we knew that the patients themselves, those tests were being taken care of, they were -- we know they were all going to Mount Sinai.
CHAYTOR, Q.C.:
Q. And were those only St. Clare's cases that you were doing that for?
MR. GREEN:
A. We were doing all requests that we would get.

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CHAYTOR, Q.C.:
Q. Uh-hm.
MR. GREEN:
A. And they all went to St. Clare's, to Dr. Bev Carter, to be sent to Mount Sinai.
CHAYTOR, Q.C.:
Q. And for how long did you continue to create slides on the same work that was going to Mount Sinai?
MR. GREEN:
A. We never ever stopped creating the slides right up until the time we revalidated the ER/PR again, and the system started up with the breast group in place. Then that system took over again.
CHAYTOR, Q.C.:
Q. So every -- this is go forward basis, obviously, not the ones which were part of the retrospective study. You didn't do any work on those, I take it?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So all the prospective cases, for all of those that were sent to Mount Sinai between August, 2005, and February, 2007, there were also slides created in St. John's?
MR. GREEN:
A. Duplicates, yes.
CHAYTOR, Q.C.:
Q. There were duplicates, okay, and to your knowledge, has anyone done any comparative work between the work from Mount Sinai and the work in St. John's?
MR. GREEN:
A. Not that I'm aware of.
CHAYTOR, Q.C.:
Q. And have you, yourself, had any occasion to look at the slides created through your work and those of Mount Sinai?
MR. GREEN:
A. I've never seen the Mount Sinai slides.
CHAYTOR, Q.C.:
Q. Have you looked at the slides that you created yourself?
MR. GREEN:
A. Some of them we've looked at.
CHAYTOR, Q.C.:
Q. And in what context did you do that?
MR. GREEN:

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A. Just to check on -- if we see some slides that are obviously positive, we will look at them just from a curiosity point of view.
CHAYTOR, Q.C.:
Q. Okay. So just looking at them to determine whether or not you were satisfied with the quality?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. And has any pathologist been involved in that process with you?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. So have all of those slides now been stained?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. So they're all completed, and where are those slides?
MR. GREEN:
A. Those slides are in the pathology lab in the IHC section at the General Hospital.
CHAYTOR, Q.C.:

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Q. You said at some point you became aware of the index case. Who told you that, who told you about the index case?

MR. GREEN:

A. I'm not really sure. Probably it might have been Barry, probably Barry.

CHAYTOR, Q.C.:

Q. And is there anything else that you recall being told about the index case?

MR. GREEN:

A. The information I was given was that it was a patient with lobular carcinoma, ER/PR reported as negative, patient had asked for a second opinion or a consult, and they were sent away to an outside laboratory and came back with a change result. Now the -- I think the -- it said that lobular carcinoma ER/PR should be positive in 80 percent or more of the cases, repeat ER/PR.

CHAYTOR, Q.C.:

Q. Okay. Before I leave this memo then, August 8th, 2005, the rerunning of or the continuation of the test, the ER/PR testing and the slides that were created, have you ever had an opportunity to compare any of your

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work to the results from Mount Sinai?

MR. GREEN:

A. I haven't, no.

CHAYTOR, Q.C.:

Q. Do you know if anyone else has done that?

MR. GREEN:

A. I'm not aware of it.

CHAYTOR, Q.C.:

Q. And when you received this memo, being the first time you ever -- and the only time you received a memo from the Clinical Chief, was that the subject of discussion amongst you and Ms. Butler and Mr. Simms?

MR. GREEN:

A. Yes, it was.

CHAYTOR, Q.C.:

Q. And what was discussed at that time?

MR. GREEN:

A. Well, it was the first time that I was aware of the suspension of the ER/PR antibodies. I knew the significance of the ER/PR antibodies, and I suspected that there was a problem.

CHAYTOR, Q.C.:

Q. And were there concerns expressed at that point in time?

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MR. GREEN:

A. Pardon me?

CHAYTOR, Q.C.:

Q. Were there concerns expressed at that point in time or was there anything in particular, for example, in your mind as to what may have caused this issue?

MR. GREEN:

A. Well, the first thing that would cross your mind is, is this a technical problem, and if this is a technical problem, how come nobody has spoken to me about it, because this is part of the work that I do.

CHAYTOR, Q.C.:

Q. Yes.

MR. GREEN:

A. So it would be a concern.

CHAYTOR, Q.C.:

Q. Okay, and did you bring that up with your managers?

MR. GREEN:

A. We had discussed it with Barry.

CHAYTOR, Q.C.:

Q. And did he provide you with any answers?

MR. GREEN:

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A. From the information, my conversation with Barry, I had the impression that the oncologists were blaming the pathologists and the pathologists were blaming technologists and nobody really knew the depth or the breadth of the problem.

CHAYTOR, Q.C.:

Q. Okay, and when did Mr. Dyer tell you that?

MR. GREEN:

A. It probably would have been after this became common knowledge, when the ER/PRs were stopped.

CHAYTOR, Q.C.:

Q. In August 2005, and so you continued on business as usual and continued on with the ER/PR testing. When did you next hear anything about the ER/PR issue?

MR. GREEN:

A. This was August in 2005. By this time, some of the information was starting to--I knew of the index case. I knew there had been--they were sending back cases out of province to be tested, and shortly after that, I learned that they were going back as far as 1997 and looking at cases.

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CHAYTOR, Q.C.:
Q. And how did you learn that?
MR. GREEN:
A. I probably learnt it from Barry.
CHAYTOR, Q.C.:
Q. Okay. Were you asked--in this memo, August 8th, the fact of what was going to be happening and then upon learning that there was also going to be a retrospective study, were you asked to keep any of that information confidential or would it just be assumed that that would be confidential?
MR. GREEN:
A. It would be assumed that it was confidential. Any discussion about patients would be assumed to be confidential.
CHAYTOR, Q.C.:
Q. So anything in terms of where testing is taking place would be confidential. If I could look, please, at P-2166? And this appears to be September 10th and 15th, through to the 15th, 2005, National Society for Histotechnology, 31st Annual Symposium, Fort Lauderdale, Florida, and I understand that you attended this symposium?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and there were workshops in immunohistochemistry, mathematics in the laboratory, introduction to immunohistochemistry, lymphomas, the control conundrum in histopathology, what can and should be controlled. So did you attend all of these workshops?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and how did it come about then, in September 2005, that you attended this symposium?
MR. GREEN:
A. Terry Gulliver asked me to go.
CHAYTOR, Q.C.:
Q. And do you know why you were chosen to go? Did anyone else go?
MR. GREEN:
A. Barry was there, Barry Dyer.
CHAYTOR, Q.C.:
Q. Okay, and do you know why you were chosen to go in terms of technologists?
MR. GREEN:
A. Probably because I had taken the lead using the Ventana system and immunoperoxidase.
CHAYTOR, Q.C.:
Q. And other than the training that you received on the Ventana machine back in the winter of 2004, this is the first, I take it -
MR. GREEN:
A. Yeah, the first formal -
CHAYTOR, Q.C.:
Q. - education that you've received in immunohistochemistry?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and did you find this helpful?
MR. GREEN:
A. It was very helpful, yes.
CHAYTOR, Q.C.:
Q. And when you came back, did you then disseminate the information to the other technologists or any learnings from the seminar?
MR. GREEN:

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A. I brought back the paper copies of the lectures, of the workshops, which we keep in the lab, and this was some of the information that I gave to the pathology academic meetings.
CHAYTOR, Q.C.:
Q. Was there anything in particular that stood out or that you learned, recall learning at this first formal symposium that you attended, something that you hadn't been aware of before?
MR. GREEN:
A. Nothing in particular.
CHAYTOR, Q.C.:
Q. Were there things though, in general, that you felt that -
MR. GREEN:
A. All the information that I got was very useful.
CHAYTOR, Q.C.:
Q. Okay. Mr. Green, there was then, we understand, Ms. Wegrynowski attended the lab in St. John's in September 2005. Did you meet with her when she came?
MR. GREEN:

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A. Briefly, yes.
CHAYTOR, Q.C.:
Q. Okay, and what did you discuss with her?
MR. GREEN:
A. She went on a tour of the lab and she gave a presentation of the immunohistochemistry and the basics.
CHAYTOR, Q.C.:
Q. And what did you understand was the purpose of her visit at the time?
MR. GREEN:
A. I assumed that she was checking out our laboratory, with the help--with the idea of finding any weaknesses that existed, so that we could use that on a go-forward basis to help us with any deficiencies that we had.
CHAYTOR, Q.C.:
Q. Okay, and we also understand that in the fall of 2005, Dr. Banerjee visited the lab as well, and St. Clare's lab. Did you have any meetings or discussions with him?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Okay. If we could look at, please, 2172? And

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I meant to bring this to your attention before, Mr. Green, because I think--do you recognize this or what this involves?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. Perhaps you could explain to us what this document is? And there's several pages here, so you can always click up here and go through it for us.
MR. GREEN:
A. This is a grid that myself and Barry set up to run ER/PRs on the Ventana system, checking out different patients, using our protocol.
CHAYTOR, Q.C.:
Q. So this is when you're bringing the Ventana online for the first time in 2004?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. That's what this is?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, and there's a note here, "Ken, a little

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bit rushed, but you get the idea. Bev, I'm on holiday Friday, vacation," and then is this your signature?
MR. GREEN:
A. That would be mine.
CHAYTOR, Q.C.:
Q. That's your signature, okay. So was Dr. Carter involved in the process? What's this about?
MR. GREEN:
A. Yes, she was.
CHAYTOR, Q.C.:
Q. Okay. So that was in, again, setting up the--this is setting up the Ventana in 2004?
MR. GREEN:
A. I think that was--I just think that was checking--we were checking our protocols against surgicals, the ER/PR cases that were there.
CHAYTOR, Q.C.:
Q. Do you know what time period this is?
MR. GREEN:
A. Not exactly, no. I know from the previous page there--see all these antibodies here?
CHAYTOR, Q.C.:

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Q. Yes.
MR. GREEN:
A. A, E, K would be my initial in front of it. I used those protocols so that I could separate those protocols from the ones that we--our normal protocols. So we were trying different -
CHAYTOR, Q.C.:
Q. So this page is definitely you and Mr. Dyer setting up the Ventana back in 2004? Is that right?
MR. GREEN:
A. I would assume that's the time.
CHAYTOR, Q.C.:
Q. And this note from Dr. Carter, you're not sure what this is?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Do you know -
MR. GREEN:
A. But I know Dr. Carter, she would be reviewing the slides that we produced, because we had set up a grid and she reviewed it.
CHAYTOR, Q.C.:

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Q. Okay, so that was still at the time that you're setting up the Ventana in 2004?
MR. GREEN:
A. I would assume that's -
MR. SIMMONS:
Q. Excuse me. Go ahead a few pages. There are some dates on some of the documents a little further along, on these (inaudible).
CHAYTOR, Q.C.:
Q. Okay, this one, this is in '05.
MR. GREEN:
A. Okay, this must be '05 then.
CHAYTOR, Q.C.:
Q. All right. So this is after the problem arose?
MR. GREEN:
A. Yeah, the Ventana would have been long set up by then.
CHAYTOR, Q.C.:
Q. Okay. So does that help then with your recollection as to what's going on here? And you can take the mouse and click on and go through the pages, if you wish. I just want you to be able to explain to us what these documents are about and what was happening in

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this process.
MR. GREEN:
A. We were running tissues using different protocols. All these are PRs. These are protocols. These are for a number of protocols and a different number in protocol -
CHAYTOR, Q.C.:
Q. Do you want to take the mouse and just point to what you're referring to, please?
MR. GREEN:
A. Okay.
CHAYTOR, Q.C.:
Q. So this has a date, a run started of August 25th.
MR. GREEN:
A. These numbers here on the protocol number.
CHAYTOR, Q.C.:
Q. Yes, try not to click on it. Just move it around for us, and you want to scroll down, we can do this. Okay, all right.
MR. GREEN:
A. These are protocol numbers, and the other one is the PR antibody and these letters, D, F, H, and J, those would be numbers which we would have assigned to different surgical numbers.

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So it looks like we were kind of doing a blind test, so that when the slides were read, you would not know which patients they belonged to.
CHAYTOR, Q.C.:
Q. Okay, and this was going on in August 2005?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. That would be the 25th of August, 2005. We got that memo from Don on -
CHAYTOR, Q.C.:
Q. August 8th.
MR. GREEN:
A. - August 8th, 2005. So I guess the question of the Ventana machine and the ER/PR protocols were probably being checked out.
CHAYTOR, Q.C.:
Q. And then if we just go back to this here, is this your document?
MR. GREEN:
A. That would be Barry's.
CHAYTOR, Q.C.:

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Q. That's Barry Dyer's?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, so perhaps we'll ask him then to explain what's happening. So I take it it was you and Barry Dyer and Dr. Carter involved in this process?
MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. And how long did that go on into -
MR. GREEN:
A. It was probably, by the look of that note there, "going on vacation" I'd say it was handled fairly swiftly, and this -
CHAYTOR, Q.C.:
Q. And page--sorry?
MR. GREEN:
A. - this one right here, this looks like mine.
CHAYTOR, Q.C.:
Q. Page ten, that's your writing?
MR. GREEN:
A. That's my writing.
CHAYTOR, Q.C.:

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Q. Okay, and can you explain what's going on there then? We've got block -

MR. GREEN:

A. We were running different protocols, some with blockers and some without blockers.

CHAYTOR, Q.C.:

Q. Blockers, okay.

MR. GREEN:

A. Blockers are used for endogenous peroxidase. Blockers are used to pick up staining activity which is not related to the antigen antibody reaction, so those would be--we'd block those so they wouldn't interfere with the reading of the slides.

CHAYTOR, Q.C.:

Q. And your understanding is that this is testing on the Ventana to see if the Ventana is operating properly?

MR. GREEN:

A. Yes, yeah.

CHAYTOR, Q.C.:

Q. That's what was happening here, okay. And then page 12, what's this document? And is this your handwriting?

MR. GREEN:

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A. It is.

CHAYTOR, Q.C.:

Q. And this is--is this antigen retrieval, mild and standard?

MR. GREEN:

A. Mild and standard, and this is primary antibody incubation times on the left, and we would have tried those, 28 minutes one with a mild antigen retrieval and 28 minutes with a standard, 24 mild and standard, 32 mild and standard. We would have tried all those protocols.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

A. And the clone we're using is 6F11. The clone, that clone would be a predilute clone, because it would be from the Ventana.

CHAYTOR, Q.C.:

Q. And again, this is part of what you were doing in August 2005 to -

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. - validate the Ventana system? And page 14,

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this is your writing?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. Is it Mr. Dyer's?

MR. GREEN:

A. Probably Bev's writing.

CHAYTOR, Q.C.:

Q. Okay, and this again, the same person?

MR. GREEN:

A. Probably.

CHAYTOR, Q.C.:

Q. None of this is yours, I take it? You recognize the document? Do you know--can you explain to us what's happening here?

MR. GREEN:

A. This document, those were--we would have run a blind test, sent them over to Bev with the protocols. Looks like she was reading the slides and commenting on the different protocols to see which way we were going, trying to reach a optimum protocol.

CHAYTOR, Q.C.:

Q. Okay, and this is just more of the same document, I take it?

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MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So is there anything else then about that that you recall? For example, if we look at the comments section, internal control weak, internal control weak, poor--not sure what -

MR. GREEN:

A. Poor cover slipping.

CHAYTOR, Q.C.:

Q. - cover slipping, those comments, are these being written in by--is that you or is that Dr. Carter?

MR. GREEN:

A. That would be a pathologist.

CHAYTOR, Q.C.:

Q. Pathologist, okay. Were any of those issues discussed with you at the time or did you see this document with these comments filled in?

MR. GREEN:

A. I can't remember seeing it after we done the work.

CHAYTOR, Q.C.:

Q. Okay, and was any issue of any problems with controls or any other problems with the

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testing brought to your attention?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. I just want to look at then, please, P-0637? This is a letter, Mr. Green, October 13, 2005, written by Dr. Cook and copied to Dr. Fontaine, Mr. Gulliver, Dr. Williams, written to Dr. Ejeckam. "As discussed, I appreciate your continuing role in overseeing the immunoperoxidase service. As you know, we are in the process of developing a specialized service with technologists solely dedicated in immunohistochemical technique." So I take it up to this point in time you weren't dedicated, October of '05.

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. "As agreed, you will oversee all aspects of the immunoperoxidase operation and have direct supervision over the technologists involved in the service." Mr. Green, was that told to you at the time or to the technologists at the time that Dr. Ejeckam would now have direct

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supervision over you?

MR. GREEN:

A. I thought he always had direct supervision over us, that was the impression that he gave us.

CHAYTOR, Q.C.:

Q. All right, so this would not have been seen as a change to you.

MR. GREEN:

A. It would not be a shock. It would be a shock if I saw it otherwise.

CHAYTOR, Q.C.:

Q. Okay, but in terms of--so in terms of him being able to directly supervise you with respect to IHC, did you see Dr. Ejeckam any different than any other pathologist in that regard?

MR. GREEN:

A. No, because when he was there, he was the man to go to for IHC, so I just assumed that he was always in that capacity.

CHAYTOR, Q.C.:

Q. If we could look, please, at P-0047? And, Mr. Green, this is Ms. Wegrynowski's first report on November 9th, 2005 and I understand you saw

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Dr. Banerjee's report after it was made public, is that also true of this report?

MR. GREEN:

A. Same time.

CHAYTOR, Q.C.:

Q. So the first time you received a copy or were able to read the report was in February of this year, 2008?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Were you otherwise any time prior to that advised of the content of the reports?

MR. GREEN:

A. About a year ago Dr. Denic had the report, had a spreadsheet with the report with a list of recommendations that we were to have put in place.

CHAYTOR, Q.C.:

Q. So a spreadsheet with recommendations and we've seen spreadsheets like that here in our process, so those spreadsheets were--a spreadsheet was shown to you at least about a year ago?

MR. GREEN:

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A. Yes, I never, after the report, I think there were only four copies of the report, but I wasn't aware of the content of the report before then.

CHAYTOR, Q.C.:

Q. Okay, and the spreadsheet, you saw that for the first time in the summer of 2007?

MR. GREEN:

A. I think that's about the time, the date I'm not exactly sure of.

CHAYTOR, Q.C.:

Q. Okay, and what was the purpose at that point in time of Dr. Denic showing you the spreadsheet?

MR. GREEN:

A. We were about to--there was a--we were supposed to get a visit from the QMPLS people in Ontario and they were going to do, I guess, they were doing a consult on our laboratory and Dr. Denic was checking to see what the progress of these recommendations were.

CHAYTOR, Q.C.:

Q. And prior to that, even if a general sense, were you made aware of what the recommendations were? Did you have any idea

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what the outcome was of Ms. Wegrynowski's report?

MR. GREEN:

A. Not in any real sense, no. I could read between the lines some of the stuff that we were doing, the external quality assurance, so we had started to do that and so I figured that would have been part of the report.

CHAYTOR, Q.C.:

Q. And we understand Ms. Wegrynowski had come back in the spring of 2006. Did you meet with her at that time as well?

MR. GREEN:

A. I cannot remember meeting with her when she made her return visit.

CHAYTOR, Q.C.:

Q. Okay, so you met with her when she was here in September 2005.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And you had some brief discussion with her then and when do you next hear anything about Ms. Wegrynowski or her assessment of the lab?

MR. GREEN:

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A. Well when this--it would have been before the QMPLS people came down, about a year ago, I guess.

CHAYTOR, Q.C.:

Q. In 2007.

MR. GREEN:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And in terms of any--and you have seen the report, I take it since and have had an opportunity to read it.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. I don't want to spend a whole lot of time taking you through it, but in terms of the recommendations in here, you did see a spreadsheet of recommendations sometime in 2007.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. But in terms of anything prior to that, you know, in the almost two years prior to that in terms of what needed to be done or done

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differently within IHC, did anyone have a meeting with you or explain anything to you?

MR. GREEN:

A. Dr. Ford Elms, I worked with Dr. Ford Elms probably before that, we were doing standard operating procedures and we were doing validation of antibodies, so I assume that all this stuff was part of the report.

CHAYTOR, Q.C.:

Q. You assumed anything new that was happening was part of a recommendation coming from -

MR. GREEN:

A. I figured that any improvements that were in place or anything new, was probably part of the report.

CHAYTOR, Q.C.:

Q. But in terms of anyone sitting down and asking you for your input into the recommendations or the changes that were taking place, did that ever happen?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. And you have had a chance to read through Ms. Wegrynowski's report?

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MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And in general, what do you think of the report?

MR. GREEN:

A. It's a good report, it has some valid concerns. I think we can take that report and, well a lot of the stuff that is there is already implemented or it's partially been implemented, it's all being worked on.

CHAYTOR, Q.C.:

Q. So it's all either implemented or currently being -

MR. GREEN:

A. Implemented, yeah.

CHAYTOR, Q.C.:

Q. Being implemented. So I take it you see it as having useful information in it?

MR. GREEN:

A. It's a positive approach and I take it as constructive criticism and it's a way for us to move on and to make, use this as a benefit to us so that we can make a better lab.

CHAYTOR, Q.C.:

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Q. And are there any parts of it that, and in fairness, but you know, take your time, is there any parts in it or when you read it, did you, was there anything in there you think is not a fair criticism or in fact might not be accurate?

MR. GREEN:

A. Criticism is never easy, you know, to take, but constructive criticism is fine. For the most part the recommendations that are there are not out of our capacity to do and they are things that should be done.

CHAYTOR, Q.C.:

Q. And again, now the first time you're seeing this is in February, 2008, so two and a half years after it's written and by that point in time, as you say, many changes have already been made.

MR. GREEN:

A. Uh-hm. And a lot of the changes in the report, like pathologist assistants, that would be out of my scope of work and like the standard operating procedures for fixation and grossing, although the results would affect me, those procedures there themselves would

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probably not be written by me. And a lot of the recommendations that would require resources would be handled by management.

CHAYTOR, Q.C.:

Q. Yes, okay. And in terms of the processing section, for example here, the points that she comes up with there and in terms of the immunohistochemistry laboratory, the recommendations for dedicated staff, of course, and that's something that I understand you had heard Dr. Ejeckam was looking for, before this?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And the idea of lines of authority or communication, was that any issue that was ever expressed? Did you hear that expressed before?

MR. GREEN:

A. It might have been a problem between the pathologists and the lab director.

CHAYTOR, Q.C.:

Q. Okay.

MR. GREEN:

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A. But it was never an issue for me.

CHAYTOR, Q.C.:

Q. Her recommendations regarding documentation.

MR. GREEN:

A. Yeah, we have no, we have our standard operating procedures either in place or in draft, manufacturer specification sheets are not catalogued and in a binder. All maintenance records are now done and posted on the wall, our pipettes are now calibrated.

CHAYTOR, Q.C.:

Q. So you continue to use pipettes in your work?

MR. GREEN:

A. Yeah, and we now run lot to lot validations on the antibodies, we have a requirement procedures for antibodies, we keep our records for two years. We have a correction action log in place.

CHAYTOR, Q.C.:

Q. And that's fairly new, I take it, that's in the past few months.

MR. GREEN:

A. Yes. So all these things are either in place or in the process of being handled.

CHAYTOR, Q.C.:

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Q. And Mr Green, in terms of having had this report or the contents of the report available to you back in 2005, would that have been helpful?

MR. GREEN:

A. It would have been helpful, it's pretty hard to implement changes if you don't know what they are.

CHAYTOR, Q.C.:

Q. I just want to continue, just quickly take you through, though, if there's anything--and the procedure manual outlining standard operating procedure is to be created and I'll talk to you about that probably next time we meet now, because you've done some substantial work on that.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. The issue regarding the antibody data specification sheet, I believe I've already spoke to you about that previously in your evidence and the equipment maintenance, I take it you don't take exception to any of this?

MR. GREEN:

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A. No, it's all good laboratory practice and it should be done in every laboratory.
CHAYTOR, Q.C.:
Q. Okay, and the guaranteed pipette and temperature accuracy and calibration, did you understand the importance of that before?
MR. GREEN:
A. The?
CHAYTOR, Q.C.:
Q. The importance of the accuracy of the volume of the pipette?
MR. GREEN:
A. Yes, I understood the concept of accuracy.
CHAYTOR, Q.C.:
Q. Particularly when you're -
MR. GREEN:
A. With the volumes that we use and the antibodies that we use, the one in fifty dilution, if we did get our pipette calibrated, I'm fairly sure that it came back with a 98.5 percent accuracy rate. So on the -
CHAYTOR, Q.C.:
Q. So it's since been calibrated, I take it?
MR. GREEN:

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

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

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system.
CHAYTOR, Q.C.:
Q. On the DAKO, that was still in existence.
MR. GREEN:
A. Well it's also important to point out, although it is the right thing to do and nobody can argue with that, but on the Ventana system and ER and PR antibodies which we used come pre-dilute from the manufacturer, so there is no pipetting of primary antibody.
CHAYTOR, Q.C.:
Q. Now, yes.
MR. GREEN:
A. Now.
CHAYTOR, Q.C.:
Q. And what if your dilution was one in twenty, how would that affect -
MR. GREEN:
A. One in twenty would be a stronger dilution, so if you're off by one percent -
CHAYTOR, Q.C.:
Q. 1.5 percent.
MR. GREEN:
A. 1.5 percent, depending if you were above or below. In my opinion, if you use that same

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antibody dilution on your patient and on your control, the same error would be carried forward on both and I don't know of anybody who runs antibody dilutions in one percent increments.

CHAYTOR, Q.C.:

Q. Okay, and--sorry, were you finished?

MR. GREEN:

A. No, carry on.

CHAYTOR, Q.C.:

Q. Okay, No. 18, "documented evaluation must be performed to ensure the sensitivity and specificity of the test results" and there's a number of things that she mentions along there about validation.

MR. GREEN:

A. I don't have any problem with any of those -

CHAYTOR, Q.C.:

Q. With any of the rest, okay.

CHAYTOR, Q.C.:

Q. - those recommendations.

CHAYTOR, Q.C.:

Q. And there's issue of the quality assurance and of course, recommending external proficiency testing and external quality assurance, I take

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it you have no issue with that?

MR. GREEN:

A. No, we're involved in external QA with NEQAS, United Kingdon, CAP, American Pathologists, we are involved in QMPLS and now we're currently looking at another place is Saskatoon in which we are going to be involved in.

CHAYTOR, Q.C.:

Q. Okay, and where is that? It's in Saskatoon, do you know which group?

MR. GREEN:

A. I'm not sure right now, but I know they're doing tissue arrays. Doctor Ford Elms is checking into it.

CHAYTOR, Q.C.:

Q. Okay, and on page 18, she refers to competency testing, staff to be assessed for competence to perform task following training, identify requirements of task performed, GAP analysis and develop action plans. Has that happened? Have you had any competency testing carried out?

MR. GREEN:

A. The only assessment I have done is from Barry Dyer.

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CHAYTOR, Q.C.:

Q. I'm sorry, from Barry Dyer?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And was that happening before 2005?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. Was that your regular performance evaluation?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And were you getting those regularly?

MR. GREEN:

A. I had one after I moved over to the Health Science, after I finished my probationary period and probably one a year after.

CHAYTOR, Q.C.:

Q. Okay, and did you have any while you were at St. Clare's?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. So you were having evaluations fairly

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routinely?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. And referenced to, she recommended internet be available at the work bench.

MR. GREEN:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And she didn't find any textbooks in the IHC.

MR. GREEN:

A. We have internet in our laboratory and we have reference manuals, DABB's is the one that Dr. Ejeckam recommended, so we have that one.

CHAYTOR, Q.C.:

Q. And the continuing education for the technologists and I understand that you've had substantial continuing education since?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. If we could look, please, at P-2160? And Mr. Green, I understand this is a list of the continuing education courses taken by you over the past three years and it's dated the first

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being your training on the Ventana in February '04 and continues on down to November, 2007. And in that time period is your trip to Florida in September of '05, which we talked about.

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. The Jewish General in January 2006, perhaps you could tell us about that?

MR. GREEN:

A. It was Dr. Ejeckam's idea to, he wanted to send us out for training at different hospitals. The Jewish General was chosen for me because it had the same equipment that we had, it had the benchmark equipment. Mary went to Mount Sinai to get training on documentation, standards of practice. I spent two weeks at the Jewish General, they took me through the whole laboratory. I was given free rein of all their protocols and procedures, got to run their equipment, got to stain our slides, got to look at their slides.

CHAYTOR, Q.C.:

Q. So you brought slides up from St. John's?

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MR. GREEN:

A. Yes, and they went through their protocols with me, they gave me copies of their protocols to take back, information on their antibodies, the pathologists would call me when they were grossing the breast specimens. They have PA's up there and they would gross the specimens, they would call me when they were grossing the specimens to show how the sections they took. So apparently they would know up there which section that they were going to submit for ER/PR from the gross bench. If Section B would be a section that they would take, they would know that it would have normal tissue. They would have tumour tissue and hopefully normal tissue. Of course, it would go to the pathologist first and the pathologist would specify which block, but majority that they had, the pathologist assistants would know in advance which block they would suspect would go for ER/PR, so they were very helpful, very accommodating, took time out of their busy schedules to help me, to answer all the questions that I had. It was a very worthwhile experience.

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CHAYTOR, Q.C.:

Q. And perhaps we could look at P-2170 please? And this is called a report on immunoperoxidase staining, Jewish General, Montreal, Quebec, January 16 through to 27, 2006. And it's prepared for the Immunopathology Department at Eastern Health, prepared by yourself. Who did you prepare this report for?

MR. GREEN:

A. When I came back from the Jewish General, I prepared it for Dr. Ejeckam.

CHAYTOR, Q.C.:

Q. And did you submit the report then to Dr. Ejeckam, is that who this went to?

MR. GREEN:

A. Yes, and I gave--there was a meeting called and I'm trying to remember who was at the meeting, probably Dr. Cook, Dr. Ejeckam, Barry, Mary, Les, myself.

CHAYTOR, Q.C.:

Q. And you brought back with you standard operating procedures from the Jewish General?

MR. GREEN:

A. Copy of their protocols.

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CHAYTOR, Q.C.:

Q. And what did you, sorry, it was the protocols?

MR. GREEN:

A. Protocols that they used for their antibodies, the dilutions that they use up there, the suppliers for their antibodies.

CHAYTOR, Q.C.:

Q. And overall what was your sense in terms of the lab at the Jewish General as compared to the lab here in St. John's? Was it comparable or -

MR. GREEN:

A. The Jewish General was a very well run organized hospital. They had a lot of the paperwork and the documentation which we didn't have, which I could learn from that, learn the documentation that they had. The basic protocols and the running of the Ventana system was very similar to ours.

CHAYTOR, Q.C.:

Q. Okay, and you say in your initial discussion, "Edward", is that Edward Depestry, is that his name?

MR. GREEN:

A. Yes.

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CHAYTOR, Q.C.:
Q. And that's Dr. Depestry, I guess, is it? "And I felt that even though my prime focus would be immunoperoxidase, some time devoted to routine pathology would be beneficial. And would you make notable differences from our laboratory, gross attendance, gross using the above classification and will call the pathologist only for clarification purposes." So I take it they had pathology assistants in place?
MR. GREEN:
A. Pathology assistants, yes.
CHAYTOR, Q.C.:
Q. "And the Jewish General tends to use a speciality system for specimen division. Jewish General sort and fill their processing baskets by colour code and classification and their embedded cut and stain are sorted accordingly. They generate a master gross list to check off blocks and help with embedding. There is no scraping of blocks, as the embedders do not use excess wax. They had 5 millilitres of alcohol" -
MR. GREEN:

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A. Alcoholic eosin.
CHAYTOR, Q.C.:
Q. - eosin to the second alcohol on the tissue processor to facilitate easier embedding and orientation. White tissue/white wax, white lens paper.
MR. GREEN:
A. The reason for that is that the eosin is a pinkish colour. So when they would stain their tissues, when you put them in a cassette, you got white tissue on a white background and white wax, so at least this would give the person embedding a better sense of the finding of tissue for orientation purposes.
CHAYTOR, Q.C.:
Q. Was there any reprocessing happening in the-- reprocessing of the blocks happening at Jewish General?
MR. GREEN:
A. I wasn't aware of any that they did there.
CHAYTOR, Q.C.:
Q. And then it says "the gross attendant and pathologist specializing in breast pathology spend considerable time explaining the breast

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dissection and the blocking sequence, in particular areas where the blocks would be used for ER/PR requests." So I take it they had pathologists specializing in breast pathology?
MR. GREEN:
A. They did. They had a pathologist that was her specialty.
CHAYTOR, Q.C.:
Q. Okay, and then day two was spent in the routine pathology lab where you observed a typical day. "Cutting was very similar," you note, "to our method. The next eight working days were spent in the immunoperoxidase lab. The immuno lab is a separate lab on its own." So that was different from your lab at that point in time?
MR. GREEN:
A. Yeah, they had a separate facility, yes.
CHAYTOR, Q.C.:
Q. Okay, and they used the Ventana system, using two benchmarks as well, and two Nexus IHC stainers. Is that the same as what you had?
MR. GREEN:
A. We used the Nexus IHC stainers for special

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stains. They had adapted two of those to use for IHC.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. But the benchmarks were identical to ours.
CHAYTOR, Q.C.:
Q. And the volume is obviously much more. They have about four immuno runs per day?
MR. GREEN:
A. Yeah.
CHAYTOR, Q.C.:
Q. So that would be higher. The antibodies are divided into two groups, one incubated at 37 degrees, the others at 56, and you've included a list for future reference. What was that about? That's okay. I'm sorry, you didn't hear me, did you?
MR. GREEN:
A. No, I didn't. No.
CHAYTOR, Q.C.:
Q. I'm sorry. I thought you were in deep thought.
MR. GREEN:
A. I was reading.

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CHAYTOR, Q.C.:
Q. What was this about the antibodies are divided into two groups, one incubated at 37 degrees and the other at 56 degrees?
MR. GREEN:
A. They had some antibodies which they would run at 37 and some at 56, so they would--they found that those temperatures, some antibodies would work better at those temperatures.
CHAYTOR, Q.C.:
Q. Okay.
MR. GREEN:
A. And I brought back a list of those.
CHAYTOR, Q.C.:
Q. For future reference, yes, and have you used that since?
MR. GREEN:
A. We haven't changed the temperature on the antibodies.
CHAYTOR, Q.C.:
Q. Okay, and "I brought a list of our antibodies and protocols to compare with those," and you also said that you brought slides along?
MR. GREEN:
A. I brought slides which we stained.

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CHAYTOR, Q.C.:
Q. And was there any concern expressed as to the quality of your slides at the Jewish General?
MR. GREEN:
A. No, they had no problem with the quality and the stains we did, I think were mostly ER/PR slides we stained.
CHAYTOR, Q.C.:
Q. Okay, and did you do a comparison? Did you stain your slides as well as stains from--or slides from the Jewish General?
MR. GREEN:
A. I would look at their slides up there that they stained daily.
CHAYTOR, Q.C.:
Q. And "the most noticeable difference being antibody supplier and dilution on some antibodies. They used very few protocols with block as they claim background staining blushes easily, different from positive staining. After each run, the technologist would check the slide and show me the controls, both internal and external." So in terms of the most notable difference, "most of the protocols being different, with the most

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notable difference being antibody supplier and dilution," was there notable difference with respect to the ER/PR antibody?
MR. GREEN:
A. No.
CHAYTOR, Q.C.:
Q. Antibodies, I should say.
MR. GREEN:
A. No, noticeable difference. They would use very few blockers because they say the blush that you would see in the background is blush and it should be discounted. So like some people run the immunoperoxidase stains and they like to have a clear crisp background, and it would give it this blush. But they'd say don't worry about that blush. It's non-specific, doesn't interfere. If it doesn't interfere with the reading of the slides, it's not a problem.
CHAYTOR, Q.C.:
Q. Okay, and the technologist there was looking at both the internal and external controls?
MR. GREEN:
A. They would show--she would show me the breast tissue. We looked at the internal controls.

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She would show S-100 stains and show the nerve fibres for internal controls, or look at factor eight stain and look at the blood vessels.
CHAYTOR, Q.C.:
Q. And how did the knowledge level seem to be of the technologist who was assisting you?
MR. GREEN:
A. The technologist there had approximately 30 years, most of it which was in IHC, and she knew her material inside out and backwards and forwards and a lot of times the pathologists would come to her with questions on the IHC.
CHAYTOR, Q.C.:
Q. Get advice from her, okay, and you note that "they don't run controls with every run, but the following will always run with controls" and that list includes ER/PR.
MR. GREEN:
A. These are what they consider class two antibodies. So those antibodies will be used for--the patient's diagnosis will be directly affected or treatment will be directly affected by these antibodies.
CHAYTOR, Q.C.:

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Q. Okay, and the technologist, you note, "will read the controls to validate the system."

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. Okay, and that was happening in any event in St. John's. You were also reading the controls?

MR. GREEN:

A. Yes.

CHAYTOR, Q.C.:

Q. At the time?

MR. GREEN:

A. We were checking the controls for positivity.

CHAYTOR, Q.C.:

Q. You were checking them, okay. But you weren't actually reading them?

MR. GREEN:

A. No, now the--but they did not--the technologists there would not read the patient tissue. They would just check the controls.

CHAYTOR, Q.C.:

Q. Just the controls, yes. And currently in St. John's, do you--and I know, when I say currently, I mean, after the testing resumed

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in February 2007, was there any change in whether or not the technologists would read the controls?

MR. GREEN:

A. The responsibility of the technologist at the Health Care Corporation still is to check the positive control to make sure that our system is working.

CHAYTOR, Q.C.:

Q. Okay. So there's no change really in what you were doing before?

MR. GREEN:

A. No.

CHAYTOR, Q.C.:

Q. Okay. You were given full access to their lab protocol and protocol manuals with permission to copy and given full access to the immuno protocols. Considerable time was spent on review of the benchmark system maintenance protocols and configuration. We reviewed ER/PR and HER2/neu protocols, results and controls. We ran a panel of your slides using--for ER/PR using their protocols to compare the same to the panel already at Health Care Corporation, you say. Discussed

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the merits of antibodies, titrations, pitfalls and troubleshootings, as well as recommended protocols to follow when introducing new antibodies into the immuno lab. On that point, in terms of recommended protocols to follow when introducing new antibodies, had you had any such protocols at your disposal prior to this?

MR. GREEN:

A. We didn't have a written protocol, no. We would use the manufacturers -

CHAYTOR, Q.C.:

Q. Specifications.

MR. GREEN:

A. - instructions that came on the data sheets.

THE COMMISSIONER:

Q. Ms. Chaytor, wherever you can find a convenient spot, we'll break for the day.

CHAYTOR, Q.C.:

Q. Thank you. And then your summary is, you say "it's an opportunity to bring back to our immuno lab, some valuable practical, theoretical knowledge and skills. And most importantly, it reenforces our belief that we are performing the protocols and procedures

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with the Ventana system, using the same checks and balances used anywhere in North America. And what did you mean by that, Mr. Green?

MR. GREEN:

A. I meant that we were using positive controls on the antibodies that we ran.

CHAYTOR, Q.C.:

Q. I'm sorry.

MR. GREEN:

A. I meant that we were running positive controls on the antibodies that we performed.

CHAYTOR, Q.C.:

Q. The positive controls?

MR. GREEN:

A. Yeah.

CHAYTOR, Q.C.:

Q. So in that respect that your procedure was very similar to theirs?

MR. GREEN:

A. Our protocols were doing what they were supposed to do and demonstrating what they were supposed to demonstrate.

CHAYTOR, Q.C.:

Q. Okay, and this is in January of 2006 that you're there?

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MR. GREEN:
A. Yes.
CHAYTOR, Q.C.:
Q. The protocols then that you brought back, you use those--did you make any use of those on a go-forward basis?
MR. GREEN:
A. I would refer to them when we had problems with our antibodies. I would look at my notes from the Jewish General and see that clones they were using, what dilutions they were using, what antibodies, what manufacturer, because those--because they had similar machines to ours, the antigen retrieval, that would be the same.
CHAYTOR, Q.C.:
Q. Okay, thank you. Okay, I think this is a convenient place, Commissioner, although I have two new exhibits that -
THE COMMISSIONER:
Q. Do you want to put them in now?
CHAYTOR, Q.C.:
Q. Yes, I think we should put them in now. It's 2174 and 2224, and those are protocols 46 and 48, which I believe the witness referred to.

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So perhaps next day we'll have a chance to look at those.
THE COMMISSIONER:
Q. So that's 2174 and 2224?
CHAYTOR, Q.C.:
Q. That's correct.
THE COMMISSIONER:
Q. All right. Entered.
EXHIBIT ENTERED AND MARKED P- 2174
EXHIBIT ENTERED AND MARKED P- 2224
THE COMMISSIONER:
Q. Now does life get complicated tomorrow?
CHAYTOR, Q.C.:
Q. Yes, life gets complicated tomorrow. We have two--the next two witnesses are coming from outside St. John's, so what we--I've discussed with Mr. Green and his solicitor is that we may not use all day Friday with one of the witnesses, so if Mr. Green, and he's agreeable to be available Friday afternoon, if we are freed up, we could continue then.
THE COMMISSIONER:
Q. So tentatively continue with Mr. Green on Friday afternoon?
CHAYTOR, Q.C.:

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Q. Friday afternoon tentatively, and if not, then into Tuesday of next week.
THE COMMISSIONER:
Q. All right. Well, yes, if not--and we'll rely on the good offices of Mr. Simmons to communicate with Mr. Green as the day progresses on Friday, if you would, Mr. Simmons. Thank you all. I know it's been a very long, very hot day, and everybody deserves to get out and find cool air some place, maybe that means going in. I'm not sure. 9:30 in the morning. Thank you.

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 9th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 9th day of July, A.D., 2008

Judy Moss

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