COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 8, 2008

Appearances:

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

Rolf Pritchard/Jackie Brazil . . . . Her Majesty in Right of NL

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

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

Ches Crosbie, Q.C. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

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Certificate

THE COMMISSIONER:
Q. Please be seated. Mr. Crosbie.
DR. DONALD COOK, EXAMINATION BY CHESLEY CROSBIE, Q.C.
(CONT'D)
CROSBIE, Q.C.:
Q. The issue came up yesterday, I asked Dr. Cook about his source for the 50 or 85 percent spread in positivity rate.
THE COMMISSIONER:
Q. Um-hm.
CROSBIE, Q.C.:
Q. And I said I thought there was--Dr. Cook had said he believed there was no literature current to the period for the late 1990s, and I said I thought there'd been an article put into your database which was relevant, and this is an article Rhodes and others, published in the Journal of Clinical Pathology for the year 2000 and involves an analysis of 7,016 breast carcinomas. I think if we--did you notice--did you have a chance to notice the period there?
DR. COOK:
A. No, just highlight that for me.
CROSBIE, Q.C.:

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Q. I'm just seeing this now myself, so -
DR. COOK:
A. I haven't had a chance -
THE COMMISSIONER:
Q. Dr. Cook, you have a mouse. So you're in--you can be in control, if you wish.
CROSBIE, Q.C.:
Q. In the headnote, I think I'm seeing here two to 26 months between June 1996--you're moving too fast for me--and September 1998, under methods there. Would you like a chance to read that headnote or abstract?
DR. COOK:
A. We have what, 77 percent?
CROSBIE, Q.C.:
Q. Yeah, they end up in around that range, don't they?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And that's a pretty big series from -
DR. COOK:
A. But is this a North American series?
CROSBIE, Q.C.:
Q. No, it's UK, as you can see.

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DR. COOK:
A. But the quote that I quoted yesterday from the textbook was North American series.
CROSBIE, Q.C.:
Q. Oh, I see, so North America could be as low as 50 percent?
DR. COOK:
A. Could be.
CROSBIE, Q.C.:
Q. Well, I'd say it's a good thing you've now linked up with them for external proficiency testing.
DR. COOK:
A. Well, they're a good outfit.
CROSBIE, Q.C.:
Q. Indeed they are. Registrar, could we have document 0783, page two, please? Scroll down a little bit. Thank you. Under important facts to the history and understanding the case include the following: "there are no mistakes or technical errors at the root of the problem." How did that come up?
DR. COOK:
A. Mr. Crosbie, I don't know how that came up in that particular meeting.

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CROSBIE, Q.C.:
Q. Did you hear that discussed?
DR. COOK:
A. No.
CROSBIE, Q.C.:
Q. Did you hear Dr. Denic attempt to read portions of the Banerjee report?
DR. COOK:
A. Yes, that came out in the discussion.
CROSBIE, Q.C.:
Q. And he was prevented -
DR. COOK:
A. Not the Banerjee report, the Gown report.
CROSBIE, Q.C.:
Q. The Gown report?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. Do you mean affidavit?
DR. COOK:
A. Well, he didn't have the affidavit there. I believe he included some statements or his interpretation of the affidavit.
CROSBIE, Q.C.:
Q. Okay, this is something I've not seen then.

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So you feel it was something written by Dr. Gown that he tried to read?
DR. COOK:
A. That's what I recollect, it was written by Dr. Gown.
CROSBIE, Q.C.:
Q. However, it's fair to say you knew there were mistakes and technical errors?
DR. COOK:
A. But I can't remember any recollection about that in that particular meeting.
CROSBIE, Q.C.:
Q. So if that conversation took place, it just passed you by?
DR. COOK:
A. I can't remember any significant discussion or any discussion surrounding that.
CROSBIE, Q.C.:
Q. So you can't tell me who informed Mr. Singleton that there are no mistakes or technical errors?
DR. COOK:
A. Well, I can't even remember it being brought up in that particular way.
CROSBIE, Q.C.:

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Q. If you had heard the statement made, would you have corrected it?
DR. COOK:
A. Well, I would have said there were system errors. We had system errors by--you know, by the way of system, how the tissue was handled, how it was tested, how it was interpreted.
CROSBIE, Q.C.:
Q. What's a system error, in your view?
DR. COOK:
A. System error means that we have problems on how the tissue was handled in the first place, how it was tested, how it was interpreted, and how it was acted upon by oncology in some areas.
CROSBIE, Q.C.:
Q. System error got to do with blame free culture?
DR. COOK:
A. I don't know. I can't answer that.
CROSBIE, Q.C.:
Q. Could we have 0626, please? And that's probably it. Now somewhere in here, there's a statement about a ten percent error rate. You may be more familiar than I am.

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MR. BROWNE:
Q. Sixth paragraph.
CROSBIE, Q.C.:
Q. Yes, "we are anticipating that less than ten percent of all breast cancer patients will convert from a negative to a positive."
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. That was put out for quite a while, wasn't it?
DR. COOK:
A. Well, that was our thinking at the time. We didn't have all the data in and I mean, that was our best estimate on what we had so far. I mean, we still had about five or six hundred cases coming in.
CROSBIE, Q.C.:
Q. What's the date of this? Seems to be around October, early October?
DR. COOK:
A. In early October, yeah.
CROSBIE, Q.C.:
Q. October 4, it seems to be dated at the bottom there. Sir, the earliest information you had was about was it 58 cases you had read by the

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end of the summer?
DR. COOK:
A. Those 58 cases, you mean, the first batch of 25 and the 33?
CROSBIE, Q.C.:
Q. I believe it would be, yes.
DR. COOK:
A. But those were highly selected cases.
CROSBIE, Q.C.:
Q. But you knew the conversion rate was over 60 percent from those cases.
DR. COOK:
A. But again, they were highly selected cases, selectively picked out. I mean, those were cases with low grade infiltrating ductal carcinomas, lobular carcinomas. I mean, it wasn't a random population.
CROSBIE, Q.C.:
Q. The data you had, was there is over 60 percent conversion rate?
DR. COOK:
A. Yeah, based on -
CROSBIE, Q.C.:
Q. That was the only solid information you had.
DR. COOK:

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A. Based on a selected population selectivity. I mean, we -
CROSBIE, Q.C.:
Q. So what was ten percent, wishful thinking?
DR. COOK:
A. No, that was -
MR. BROWNE:
Q. Commissioner, I think that at this point in time, this is getting to the point to try to embarrass the witness in terms of the type of question. The witness has answered the question to the best of his ability. So at this point, I think -
THE COMMISSIONER:
Q. Well, the witness has certainly said why the ten percent. Mr. Crosbie, as I'm understanding, is pursuing why ten percent was considered to be the correct figure at the time.
MR. BROWNE:
Q. But I think the witness, in fairness, has answered that question.
THE COMMISSIONER:
Q. Well, he has answered the--just a moment, please, Mr. Browne. Mr. Crosbie has put to

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him two figures. I don't know whether he has any other figures to add to those, and I think we should explore that before we determine this.

MR. BROWNE:

Q. Thank you, Commissioner.

THE COMMISSIONER:

Q. Mr. Crosbie, do you have anything other than the first 55 to raise with the witness regarding the ten percent?

CROSBIE, Q.C.:

Q. I think the nature of the objection is that "objection, Mr. Crosbie is embarrassing the witness."

THE COMMISSIONER:

Q. Well, he--but that relates to the questioning based on the ten percent error, how can you arrive at that in light of the figure on the 55, which was the first numbers you had. Now, the question is whether or not the witness has to answer anything other than the results regarding the first 55, as it relates to ten percent, or if there's other information that you wish to put to the witness?

CROSBIE, Q.C.:

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Q. Well, I'd like to put it to him that he chose not to disclose the only data he did have.

THE COMMISSIONER:

Q. In respect of the first 55?

CROSBIE, Q.C.:

Q. In respect of early August, early October 2005 when they were putting about this ten percent figure.

THE COMMISSIONER:

Q. Um-hm, so you're asking the witness -

CROSBIE, Q.C.:

Q. So that's my question.

THE COMMISSIONER:

Q. Your question is why not use the 55--well, results relating to the 55, why not release the information relating to the 55?

CROSBIE, Q.C.:

Q. I guess my question is they had data, they chose not to release it. Why is that?

THE COMMISSIONER:

Q. That's the--why not release the data related to the 55?

DR. COOK:

A. Because that was possibly the worst case scenario. We didn't know. We would release

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that data, we would cause a lot of undue stress and anxiety within the population. And again, as I said before, Mr. Crosbie, that was a highly selective population. It wasn't randomized.

CROSBIE, Q.C.:

Q. So instead of release that alarming data, you chose some much more calming number for which there is little or no basis?

DR. COOK:

A. Well, we looked at the positivity rates. I mean, these were positivity rates that Dr. Williams had looked at, thinking that we were probably around 73 percent. We could be at 83 percent, and he extrapolated from that. I mean, that was a best guess estimate.

CROSBIE, Q.C.:

Q. So if someone said to you it was part of a coverup, you would disagree?

DR. COOK:

A. Well, absolutely. I mean, we had very little data to go on at that particular time.

CROSBIE, Q.C.:

Q. So you plucked ten percent?

DR. COOK:

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A. Well, that was our best estimate at that time.

CROSBIE, Q.C.:

Q. In the face of over 60 percent error rate from the day that you did that?

DR. COOK:

A. But the 65 percent error rate we had was a highly selected population and these patients were selectively picked out, lobulars and low grades.

MR. BROWNE:

Q. Commissioner -

CROSBIE, Q.C.:

Q. That's okay. I'm going to move on to another topic now. We've made our points there. 1933, please? This should be a note of your discussion with a Dr. Roch who used to work with Ventana.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. No, who used to work at a major centre in the States and then went with Ventana. I think what I'm looking for is right there, "I asked him how he could explain an increase in percentage rates. Roch was quiet until I

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suggested the system provides more standardization -" What system is that, Ventana?
DR. COOK:
A. That's the Ventana automated system.
CROSBIE, Q.C.:
Q. "-in performing the procedure, with minimal human -
DR. COOK:
A. Human variability.
CROSBIE, Q.C.:
Q. - variability. Roch replied that could be a major factor." Do you agree with that observation?
DR. COOK:
A. Well, that was the discussions we had at the time.
CROSBIE, Q.C.:
Q. Do you agree with it now?
DR. COOK:
A. It's hard to say, Mr. Crosbie. There were so many other factors in the production of those results.
CROSBIE, Q.C.:
Q. We've seen, from yesterday, if the numbers

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from Ms. Predham's affidavit and the percentage calculations are to be accepted, that prior to the Ejeckam intervention and in the period May '97 to December 2002, the average ER positivity was 58 percent. You remember looking at that yesterday?
DR. COOK:
A. But what was the total positivity? I mean, you know, it's there in Mr. Gulliver's note that the total positivity, I think, was probably in the 60 percent range, wasn't it? 60-65?
CROSBIE, Q.C.:
Q. Well, we're going to see about Mr. Gulliver's statistics in a little while. So I'm not going to dwell on this numbers at the moment. This comes, as I say, from the sworn answer.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. After the Ejeckam intervention, the ER positivity averaged 78 percent.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:

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Q. I'm going to suggest to you that the DAKO auto stainer was not the major problem. Dr. Ejeckam adjusted the antibody dilutions and adjusted the timing of the antigen--for antigen retrieval.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And Dr. Banerjee cleared the DAKO auto stainer as the cause of the problems, didn't he?
DR. COOK:
A. He did, yes, on the DAKO system, not that particular DAKO piece of equipment.
CROSBIE, Q.C.:
Q. Oh, that had been disposed of by Mr. Gulliver by the time Dr. Banerjee got involved?
DR. COOK:
A. Well, it was disposed of by the lab personnel. I don't know particularly whom had disposed of it.
CROSBIE, Q.C.:
Q. So the big difference between the DAKO auto stainer and the Ventana unit is that Ventana performs the antigen retrieval? Is that so?
DR. COOK:

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A. Onboard antigen retrieval and deparaffinization, yes.
CROSBIE, Q.C.:
Q. So therefore that would minimize human variability or the scope for human error, wouldn't it?
DR. COOK:
A. That's correct.
CROSBIE, Q.C.:
Q. Also supplies cell-ready diluted monoclonal antibodies ready for use?
DR. COOK:
A. Yes, it's already standardized and produced by that company.
CROSBIE, Q.C.:
Q. The improvement between the Ventana performance, just looking at positivity rates over the DAKO, would seem to point to deficiencies in antigen retrieval and antibody dilution or titration?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. As a problem?
DR. COOK:

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A. That's what we think, yes.
CROSBIE, Q.C.:
Q. Which went on for six years or so before it was picked up on and adjusted by Dr. Ejeckam?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. This was a problem at the technical end of the procedure, wasn't it?
DR. COOK:
A. We believe so.
CROSBIE, Q.C.:
Q. For which Mr. Gulliver and Mr. Dyer would have responsibility?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. Did you have any responsibility to make sure the ER/PR tests were being done properly?
DR. COOK:
A. I had a responsibility to make sure they were reported correctly, as every other pathologist in the organization, and we believe we were reporting them correctly. The problem was, Mr. Crosbie, we just didn't see any trends.

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CROSBIE, Q.C.:
Q. That's in part because of lack of specialization and volume?
DR. COOK:
A. Yes, I believe so.
CROSBIE, Q.C.:
Q. But you could also recognize trends by keeping good stats, couldn't you?
DR. COOK:
A. We didn't have the stats, that's the problem.
CROSBIE, Q.C.:
Q. So that's one of the factors that allowed this problem to get out of hand for so long?
DR. COOK:
A. I think the big major factor again, as I said earlier, is the lack of identifying a trend, the fact that we weren't sub-specialized, and we were seeing too few cases per month.
CROSBIE, Q.C.:
Q. On the technical end, overall the patient's screen slides were technically poor?
DR. COOK:
A. When we started looking at it from the review, yes, there were issues concerning the technical end of the slide production.

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CROSBIE, Q.C.:
Q. You had fixation artifact?
DR. COOK:
A. In a portion of the slides, yes.
CROSBIE, Q.C.:
Q. Only standing in the outside portions?
DR. COOK:
A. Not all cases, but we had it in a significant number of cases, but not all.
CROSBIE, Q.C.:
Q. Loss of pieces of the specimen, perhaps washed off during the procedure?
DR. COOK:
A. That's hard to say in what percentage of cases we had that.
CROSBIE, Q.C.:
Q. Inconsistent depth with staining of the centrals?
DR. COOK:
A. That I can't comment on.
CROSBIE, Q.C.:
Q. You didn't observe that yourself?
DR. COOK:
A. I didn't particularly observe that?
CROSBIE, Q.C.:

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Q. Bubbles, folds?
DR. COOK:
A. There were bubbles and folds.
CROSBIE, Q.C.:
Q. Well, perhaps that's a long enough list. There were technical problems with the patient's slides?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Your suggestion is that if pathologists in this province had been seeing a higher volume, they would have realized there was something going on?
DR. COOK:
A. My suggestion is if we had a core group of individuals, I think we would have picked those particular trends up quite easily quite early.
CROSBIE, Q.C.:
Q. And what I just described there, there would be consensus between Dr. Carter, Dr. Banerjee, Dr. Mullen, and you, that that existed in significant numbers of slides?
DR. COOK:

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A. I can't say as to what percentage that existed in.
CROSBIE, Q.C.:
Q. A lot, though?
DR. COOK:
A. I can't say.
CROSBIE, Q.C.:
Q. Too many?
DR. COOK:
A. I can't say, Mr. Crosbie. I mean, I simply -- until I did the review, then I found significant trends. Before that, I couldn't identify those trends.
CROSBIE, Q.C.:
Q. Remember Dr. Khalifa professionally guaranteed that no cases would be released unless the external control was positive?
DR. COOK:
A. That's correct.
CROSBIE, Q.C.:
Q. And he wasn't -- we talked about how he wasn't necessarily going to send out every -- send out all the controls. Sometimes the pathologist outside reading it may not get the control?

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DR. COOK:
A. Sometimes.
CROSBIE, Q.C.:
Q. And you said that was a problem with the budget?
DR. COOK:
A. It was mainly fiscal, if I remember in that particular case back in '97.
CROSBIE, Q.C.:
Q. Surely you can't be suggesting the price of stamps would prevent that?
DR. COOK:
A. The price of stamps? What does that have to do with --
CROSBIE, Q.C.:
Q. The price of mailing it?
DR. COOK:
A. No, Mr. Crosbie, it was the price of actually processing those slides and staining those slides that was the big problem that was put forward by the program director of the day, and the divisional manager of the day.
CROSBIE, Q.C.:
Q. To process a control, you had to bump a patient specimen?

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DR. COOK:
A. No. I mean, the other aspect of it is did we have adequate control to be able to process. I mean, there is not an infinite supply of tissue there. So in order to be able to, you know, stain those tissues, you need adequate volumes of controls, and you need again financial resources to be able to do that. The argument given to us at that particular time was due to fiscal restraint. Now if Dr. Khalifa could guarantee that those controls were read before they were shipped out, before the batches were shipped out of the Health Sciences, and guarantee that, we accepted that.
CROSBIE, Q.C.:
Q. That seemed like a reasonable compromise that still represented a guarantee of patient safety?
DR. COOK:
A. It was a compromise, and we looked at it as not compromising patient safety.
CROSBIE, Q.C.:
Q. Who was looking at the quality of the slides and the patient specimens?

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DR. COOK:
A. That would be the individual pathologist. There was no one individual at that time except for Dr. Khalifa who would have been looking at quality controls and obviously would have been looking at many of the ERs and PRs at that particular time.
CROSBIE, Q.C.:
Q. Why not have a pathologist check the patient specimen slides before sending them out just like checking the external positive controls?
DR. COOK:
A. Well, I'm sure that was done by Dr. Khalifa. That was my understanding.
CROSBIE, Q.C.:
Q. Well, then why didn't Khalifa notice the problems?
DR. COOK:
A. You'll have to ask Dr. Khalifa that.
CROSBIE, Q.C.:
Q. I'm sure we will. He's seeing the volume necessary to spot the problems.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:

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Q. We're going to be interested to find out why he didn't spot them.
DR. COOK:
A. Well, that's something you'll have to ask Dr. Khalifa.
CROSBIE, Q.C.:
Q. The argument will be, well, don't send them out unless they're good quality, repeat the testing.
DR. COOK:
A. Well, I mean, that's the -- that's the -- why we had Dr. Khalifa at that particular time, and he instituted the test, and we had the faith in him that he was monitoring what was going on with the slides.
CROSBIE, Q.C.:
Q. And then it was Dr. Parai?
DR. COOK:
A. It would have been Dr. Parai to make sure the controls were working properly, and certainly would have expected him to keep an eye on the quality of the ER and PR slides. I mean, he was site chief of the General Hospital.
CROSBIE, Q.C.:
Q. So to kind of pull this together, much of the

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problem here and the cause of the high negative rate seems to have to do with poor quality work on the part of the lab, yes?
DR. COOK:
A. We identified problems at the technical end and we identified problems at the interpretive end.
CROSBIE, Q.C.:
Q. Yeah, and the fact that most pathologists didn't seem to know what to look for?
DR. COOK:
A. Well, when you look at that situation, Mr. Crosbie, all of our pathologists are Canadian certified or American certified. Many of those individuals were trained in major schools across Canada and the United States. So were the problems unique here in this particular province, or was it system-wide problems across the country. We had individuals coming from major institutions in Canada and the United States observing the slides, and did they see anything different from the quality of our slides and what they saw in their institutions across North America.

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CROSBIE, Q.C.:
Q. Exhibit 046, page five, please. This is Dr. Banerjee's report. So the top of page five, he's talking about things that should have triggered corrective procedures, slides that should not have been released without troubleshooting, and internal control failure at all available blocks. This should have been noted in the reports as an uninterpretable case due to failure or absence of internal controls.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And your people were not sufficiently knowledgeable about this to take that step?
DR. COOK:
A. I mean, that was an observation that Dr. Banerjee identified, and reported.
CROSBIE, Q.C.:
Q. I have nothing further.
COMMISSIONER:
Q. Thank you. Mr. Pike?
MR. PIKE:
CROSBIE, Q.C.:

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Q. No questions.
COMMISSIONER:
Q. Mr. Browne.
DR. DONALD COOK, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Thank you, Commissioner. Good morning, Dr. Cook. There's some light at the end of the tunnel now that I'm up at the podium hopefully. Dr. Cook, I want to begin with, and don't be alarmed with the beginning and some questions that Mr. Coffey asked you about the structure within the lab beginning with the Health Care Corporation of St. John's, and I want to actually predate that because I believe you may have heard some evidence from Dr. Pritzker concerning Mount Sinai and the fact that Mount Sinai were able to avoid merger with other hospitals in the Toronto region.
DR. COOK:
A. Uh-hm.
MR. BROWNE:
Q. Just that observation, was that a common trend that was occurring in hospitals in the 90s across this country?

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DR. COOK:
A. What was happening across the country, there was significant reorganization of medical services, there was centralization of services, avoidance of duplication. Hospitals were being shut down, significant numbers of medical personnel and allied health professionals and nurses were being laid off across the country. So here what was happening in the St. John' area prior to '95/'96, each of the hospitals had their own separate institutions, and in regards to the laboratory structure, we had a director of labs in each of those hospital institutions where both the medical and technical arms reported to the medical authority. So we had a fairly stable structure prior to '95/'96.
MR. BROWNE:
Q. Okay, and what -- can you just indicate to the Commissioner sort of the role of the director and the managers within each -- well, I guess you can talk about St. Clare's where you were.
DR. COOK:
A. Uh-hm.
MR. BROWNE:

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Q. Comparative to the Health Care Corporation and then Eastern Health, its predecessor.
DR. COOK:
A. Well, the role was clearly defined. We knew where the buck stopped, and the buck stopped with the medical director who was able to oversee the entire operation. We had a laboratory supervisor and under him there were about four laboratory managers who reported to that supervisor, and who in turn reported to the laboratory director. So there was a fairly close communication and liaison between those individuals, but at the end of the day overall direction rested with the medical director, and he was able to have what I felt at that time was significant control over the budget, where it was to be directed, and areas of concern.
MR. BROWNE:
Q. For your institution?
DR. COOK:
A. For my institution.
MR. BROWNE:
Q. And that obviously changed post 1995/1996 with the advent of Health Care Corporation of St. John's?

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DR. COOK:
A. What happened in '95/'96, those structures were completely eliminated and we brought on what is known as program based management whereby we had formation of leadership teams where we had a program manager and a clinical chief basically on the same level, and both of whom would report to the Vice President of Medical Services.
MR. BROWNE:
Q. But within your institution of St. Clare's, were there a number of management positions that were eliminated as part of this program?
DR. COOK:
A. There was a significant number. If I remember, at that particular time we lost approximately 50 percent of our lab managers in the city with the four adult acute care hospitals.
MR. BROWNE:
Q. Now as well, Doctor, could I ask you about the accreditation process that pre-existed at the Health Care Corporation of St. John's, and do you have any reflections or observations with

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regard to that, pre and post, as it relates to the lab services component in terms of accreditation, what was going on in the lab pre Health Care Corporation and post Health Care Corporation?
DR. COOK:
A. Well, in the -- certainly during the 80s and the early 90s, accreditation was a big thing for the hospitals, and the accreditation process included much more evaluation and investigation of the labs back then than it did in a later event after '95/'96. I can remember actually we had lab technologists from other parts of Canada come in and actually go through the lab, look at the reagent bottles and what not, check the expiration dates and what not, and ask for the policies and procedural manuals and go down through those. Not only that, we had a medical component to that in which the medical side came in and looked at the quality of the laboratory reports, looked at the completeness of the reports. So I can certainly remember in one particular instance where Dr. Don Young came down, he was a physician from Montreal,

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to do an inspection of our lab at St. Clare's. After that inspection, we would have exit interviews where strengths and weaknesses were outlined, and that was important information for the laboratory director at that time because he was given indicators of where particular areas of concern lay. So those types of accreditations, those types of surveys, were very important and very informative.

MR. BROWNE:

Q. And that -- did those carry on after the Health Care Corporation of St. John's?

DR. COOK:

A. Well, what happened -- something happened with the accreditation process, and I don't know who made what decision, but certainly the lab was not involved to the same degree as it was in the earlier years, and after that -- though the hospitals got accredited, there was no one coming down to again look at the operation, look at what we had in place in terms of policies and procedures and what not. So we were sort of set adrift in that regard and again there's very little in terms of

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surveillance of what was going on in the labs in the mid to late '90s.

MR. BROWNE:

Q. And this accreditation process that you're referring to, was this part of the national program of hospitals that accredited hospitals across the country?

DR. COOK:

A. I think this was the Canadian Council of Health Services Accreditation. So there was obviously a change in the focus of accreditation.

COMMISSIONER:

Q. Just to make sure I'm clear on the point, Dr. Cook. While we're talking in terms of sort of pre Health Care Corp and after, I'm assuming your comments regarding accreditation really don't relate to the existence of Health Corp, it's just that it happens to be coincident in terms of timing?

DR. COOK:

A. It was -- it occurred all around that particular time. There were a lot of changes occuring both at the local scene and national scene. So what I referred to as the changes

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in the accreditation, I think was happening across Canada.

COMMISSIONER:

Q. Okay, thank you.

DR. COOK:

A. You're welcome, Commissioner.

MR. BROWNE:

Q. Now also around this time, Doctor, and I think we alluded to this with several witnesses, and I think you did as well with Mr. Coffey, with the advent of the JI visa pathologists, can you explain that process and how that worked in relation to the lab medicine program?

DR. COOK:

A. Well, the JI visas were international medical graduates, most of whom were training down in the United States, and once their programs were completed, they didn't have status to stay within the United States, they had to leave the country. Now they were of certain benefit to us, particularly around the late 90s when the manpower situation hit us very hard, and I can remember being acting clinical chief from '99 to 2000, the year that Dr. Haegert went on sabbatical, and that we were

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hit hard with a manpower shortage of approximately -- again I think it was around 30 percent. Now we were fortunate in being able to tap into the JI visa supply and many of our replacement positions were those with JI visas.

MR. BROWNE:

Q. And I understand that problem or that solution didn't subsist or continue on into 2000 and onward into the mid, I guess, 2003/2002 period because of opening up of licensing in other jurisdictions, is that correct?

DR. COOK:

A. Other jurisdictions relaxed their licensing procedures and protocols. So the JI's had a much wider degree of selection across Canada to tap into, so most of them ended up in centres in Ontario and BC. I'm not sure of Alberta, but certainly most of them ended up in the Province of Ontario.

MR. BROWNE:

Q. And Doctor Khalifa, who we heard about both yesterday and today, was he a J1 visa?

DR. COOK:

A. I can't say for sure, I believe--I can't say

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for sure, Mr. Browne, he did train in the United States.

MR. BROWNE:

Q. Now you were also asked about, by Mr. Coffey and Mr. Crosbie to some extent, about the switch from the ligand binding assay or, I guess, the biochemistry evaluation of ER/PR to IHC in 1998, are you aware of any limitations that were expressed surrounding the ligand binding assay process, vis-a-vis IHC?

DR. COOK:

A. Well, the ligand binding assay required a huge--significant volumes of tissue and the problem with that, as technology improved and we were identifying lesions, the size of the lesions became smaller and smaller and smaller, so if you were going to put through a tissue for the ligand binding assay, it could very well consume all available tumour. We had tumours that were, you know, small in terms of a centimeter or so, so that meant we'd lose a lot of other parameters in terms of the histological evaluation of the lesion, if there was lymphatic vascular involved, so there was quite a number of histological

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parameters that we lost if we submitted all the tissue for the ligand binding assay. The other problem -

MR. BROWNE:

Q. Sorry, Doctor, if I could stop you right there, in that process, the ligand binding assay, so I'm clear on this and hopefully the Commissioner may already be clear on this, but what was happening with the tissue? Would the tumour and the tissue be emulsified as one and then examined, is that what was occurring?

DR. COOK:

A. That's correct and in many cases you couldn't tell whether the readings reflected tumour or normal tissue.

MR. BROWNE:

Q. Sorry, I interrupted you.

DR. COOK:

A. So in regards to IHC, when that was brought in, we could actually look at the cells that were staining and identify that they were, in fact, malignant cells that were staining.

MR. BROWNE:

Q. Now, yesterday Mr. Crosbie asked you a question concerning whether the clinical chief

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and site chief at the time, 1997, Dr. Haegert who I understand was a clinical chief and Dr. Khalifa who was site chief, along with the program manager, prepared a budget surrounding the introduction of ER/PR into the service. And around that line of questioning, he showed you the proposal that both you and Mr. Gulliver prepared in October of 2005. I want to ask you some questions now about differences between 1997 and 2005. Now, did I understand you correctly yesterday that, in answer to one of the questions, I'm not sure if it was Mr. Crosbie or Mr. Coffey, that when Dr. Khalifa arrived in 1997, IHC was already being performed?

DR. COOK:

A. It was performed, yes.

MR. BROWNE:

Q. Can you recall--and if you can ballpark it, if you could, how many antibodies or stains were in existence around that time?

DR. COOK:

A. Oh certainly we didn't have many stains as compared to what we had today, these were basic stains that pathologists used to try and

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classify lesions, but certainly we didn't have the volume and the number of stains that we have today, as compared to '97.

MR. BROWNE:

Q. And I want to ask you about that in a minute, so between 1997 and 2005, the number of antibodies or stains increased?

DR. COOK:

A. Oh, increased significantly.

MR. BROWNE:

Q. Registrar, can the witness be shown P-0121 please? Now, Doctor, this is the review of the immunohistochemistry lab report prepared for Dr. Williams by both Dr. Gulliver--sorry, Mr. Gulliver and yourself. And I just want to go down into the background there, first paragraph there, you'll see that it indicates that currently--let me just start with the second line there, "Approximately a hundred antibodies are being utilized", so that in 2005 the lab was availing of 100 antibodies?

DR. COOK:

A. Yes, that's correct.

MR. BROWNE:

Q. And approximately processing 15,000 slides?

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DR. COOK:
A. That's correct.
MR. BROWNE:
Q. So that indicates the volume increased since 1997?
DR. COOK:
A. Oh there was a significant increase in the volume since '97.
MR. BROWNE:
Q. And if we can just go down further, the objective of this report, could you just have a look at that and indicate to the Commission, what was the main, the primary objective of this report?
DR. COOK:
A. Well again, to identify what resources that we would need based on what was happening in 2005 on the significant increase and volume that had taken place, particularly since '97.
MR. BROWNE:
Q. Okay, and if we look at, just go down right here, the process review, 2.1, grossing and processing, you were doing approximately 30,000 surgical samples a year, in 2005?
DR. COOK:

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A. In around 2005, yes.
MR. BROWNE:
Q. Okay. And if you see there as well, again, if you just carry on, "several years ago due to shortages of pathologists, it was decided to assign grossing duties for most small biopsy tissue samples to the technologists, the pathologists retained grossing of function of all large tissue."
DR. COOK:
A. Uh-hm.
MR. BROWNE:
Q. And then you will see there's a discussion there about the use of pathology assistants.
DR. COOK:
A. Uh-hm.
MR. BROWNE:
Q. You mentioned that in 1999 the, I guess the shortage of pathologists in your institution was handled by the use of J1 visas, is that right?
DR. COOK:
A. Yes, they provide a--they provide a significant input, yes.
MR. BROWNE:

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Q. By 2002, had that changed?
DR. COOK:
A. We still relied on J1 visas.
MR. BROWNE:
Q. Had you then started getting, I guess, shortages again among pathologists in your institution?
DR. COOK:
A. That's correct, particularly around, I believe later on during this process, we were faced with manpower problems.
MR. BROWNE:
Q. And we've seen documentation through other witnesses and I think you may have touched on this as well, around that time we had the Hay report?
DR. COOK:
A. That's correct.
MR. BROWNE:
Q. And in the Hay report, there was a reference, a recommendation concerning the use of pathology assistants?
DR. COOK:
A. That's correct.
MR. BROWNE:

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Q. And your understanding of that recommendation, how did that come about and was it supported by your department?
DR. COOK:
A. It was, it was supported by myself and it was supported by the program director.
MR. BROWNE:
Q. And in fact, was there support as well from the discipline chair, Dr. Robb?
DR. COOK:
A. That's correct.
MR. BROWNE:
Q. So there was a push among your department to get pathology assistants in place around that time?
DR. COOK:
A. Yes, a number of occasions, in '02, '03 and '04.
MR. BROWNE:
Q. Okay, so if we carry on, Doctor, and if we look at the numbers here.
DR. COOK:
A. Uh-hm.
MR. BROWNE:
Q. You'll see, I'll just come back to the--let's

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go down to the bottom line here, the 238,000 which, I mean, the full amount that's being asked for here is $282,200?

DR. COOK:

A. Yes.

MR. BROWNE:

Q. And then a major component of that is $238,200 for staffing?

DR. COOK:

A. That's correct.

MR. BROWNE:

Q. Can I suggest to you, Doctor, that that figure mostly comprises of a request for four pathology assistants, something that you had been looking for since 2002?

DR. COOK:

A. That's correct, that's where most of the funding needed to be directed at.

MR. BROWNE:

Q. Now if we go back, Doctor, there is a reference here and I'll find that--oh yes, right here, you'll see 2.2, the technical processes, the first paragraph, last line, "There's a provincial reference site, this section of the lab generates approximately

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$75,000 per year in revenue."

DR. COOK:

A. Uh-hm.

MR. BROWNE:

Q. Can you explain to the Commissioner where that money, at least to your understanding, Dr. Cook, where that figure came from and how the lab generated that money?

DR. COOK:

A. Well, when we send out slides to the other peripheral labs, there was a reimbursement that they forwarded to the General Hospital for the technical component of the staining of the slides. I can't remember any of that money being directed into the Laboratory Medicine Program, certainly my understanding is that that money went into the global budget.

MR. BROWNE:

Q. Did you ever inquire into that, why money wasn't going back into the lab, and if so, when?

DR. COOK:

A. We did around '99 and 2000, when I was acting clinical chief and Mr. Ron Whalen was program

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director, we made inquiries to the VP of Medical Services at that time to see whether we could get that funding redirected into our lab.

MR. BROWNE:

Q. And do you recall what the response was?

DR. COOK:

A. I think the VP brought it to the executive committee, if I understood, and that request was turned down, those financial resources were still directed into the global or corporate budget.

MR. BROWNE:

Q. And as well, Doctor, staying with this paragraph here, it's noted that increased demands for services, there was a twenty percent increase between 2003 and 2005 in the lab services?

DR. COOK:

A. That's correct.

MR. BROWNE:

Q. Again, that would factor into preparing the budget, would it not?

DR. COOK:

A. Yes.

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MR. BROWNE:

Q. 2005. And Doctor, if we can look at item 5, the overall impact and analysis of recommendations, you'll see there under item A, that this was looking at current volumes and looking into the future?

DR. COOK:

A. That's correct.

MR. BROWNE:

Q. Now, Doctor, you provided me with a document and Registrar, it's Exhibit P-2144. Doctor, this is a letter, well it's actually two letters, the first letter is dated February 11th, 2002 addressed to Dr. Sandik SenGupta, president of the Canadian Association of Pathologists and I believe it is from--if we go down, Roy Romanow from the Romanow Commission.

DR. COOK:

A. Yes.

MR. BROWNE:

Q. And if we carry on further, there should be-- no, unfortunately it doesn't seem to have the entire report.

REGISTRAR:

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Q. The entire report of?
MR. BROWNE:
Q. Sorry, the submission of the Canadian Association of Pathologists.
THE COMMISSIONER:
Q. And you think there's something missing from this exhibit?
MR. BROWNE:
Q. There is, there is a submission dated October 21--sorry, October, 2001.
THE COMMISSIONER:
Q. Which should be attached to this?
MR. BROWNE:
Q. It should be attached to that.
THE COMMISSIONER:
Q. There's three pages here.
REGISTRAR:
Q. I think they might have put that in 0135?
MR. BROWNE:
Q. Oh, sorry, thank you. Yes, thank you so much.
THE COMMISSIONER:
Q. That's what you're looking for?
MR. BROWNE:
Q. Yes, thank you. Doctor, this is a submission that was made to the Romanow Commission and

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it's dated October 2001 and the cover letter is dated October 30, 2001, from Dr. SenGupta.
DR. COOK:
A. Right.
MR. BROWNE:
Q. Now are you able to speak to this document in terms of its contents and what the purpose of the submission was by the Canadian Association of Pathologists?
DR. COOK:
A. Well we wanted to put forth the concerns and view points that the Canadian Association of Pathologists had with the health care system and that document primarily centered in on the need to have adequate human resources, particularly in terms of pathology manpower that were deemed necessary to carry on high quality services across the country. So this was taken as an opportunity to take part in this process under Mr. Romanow. There was strong concern from the CAP executive at that time over the lack of human financial resources, the lack of funding in hospital labs right across the country, the need to have adequate funding for communication

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systems, interfacing with database systems, the need to have a process in place where there would be a plan to make sure we have adequate human financial resources for the country. So that was basically the theme and gist of the paper. There was a sixteen page brief that was submitted to the Romanow Commission
MR. BROWNE:
Q. If we turn to, this is paragraph--sorry, page 5, Doctor, the first paragraph, it says, "Another key issue discussed in this paper is the effect of a decade of unco-ordinated fiscally driven laboratory services planning." Was that another theme that was discussed in this particular paper?
DR. COOK:
A. Well that was the theme, you know, significant budgetary restraints and cutbacks were taken across, taking place across the country, there didn't seem to be any co-ordinated approach to this, nor effect or long-term effect on how this would--how this would have on pathology manpower and the ability to provide high quality laboratory services. So there was a

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concern about the slash and burn policies that were taking place in the early '90's and mid '90's.
MR. BROWNE:
Q. Do you have any further comments to make?
DR. COOK:
A. Well this, again, this sixteen page brief was submitted to the Commission and I remember I just got on the executive of the Canadian Association of Pathologists at that particular time. We received a response from the Commission thanking us for our efforts and that the brief would be used as a resource brief and providing additional information for the Commission, but basically very little came out of the brief at all and we were certainly dishearted at the executive level of what we saw as very little action to address the concerns the pathologists had, particularly in the year 2000, 2001 and many of the predictions in that report have come true.
MR. BROWNE:
Q. Doctor, also in here and I just can't seem to find the reference at all, was there any observations or comments made by the Canadian

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Association of Pathologists of again, the cost containment processes that were occurring across the country and its effect on quality assurance?

DR. COOK:

A. Oh absolutely, I mean with the reduction in financial resources, the reduction in human resources there would be a negative effect on quality assurance and quality control and quality management programs. So this was outlined in the brief and strongly expressed by the executive of the Canadian Association of Pathologists what can happen and as you have seen has taken place in a number of areas.

MR. BROWNE:

Q. Doctor, you had mentioned I believe in answer again, I'm not entirely sure whether it was a question from Mr. Crosbie or from Mr. Coffey about discretionary funding in trying to get funds for your department. Did you ever approach individuals within the executive of Health Care Corporation of Eastern Health with regard to discretionary funding prior to 2005?

DR. COOK:

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A. Well, I had a number of discussions with Dr. Williams. I remember some time in the fall of 2003 where I expressed a need to have discretionary funding for the clinical chief and to be able to direct those resources, financial resources, where the clinical chief sees fit. I think we talked about in the tune of about eighty to a hundred thousand dollars. Now, Dr. Williams was in agreement with that, but he fact of the matter was that there was simply no money available to set up such a discretionary fund for chiefs.

MR. BROWNE:

Q. Now, in terms of use of that discretionary funding, were there any particular areas where you saw that money could be used for?

DR. COOK:

A. Oh, it could be used in building up our quality assurance program, to hire quality assurance supervisors, to bring in guest speakers, for instance, to continually educate our pathologists, enhance our CME activities. Not only that, but it could be money there available for our technologists to be sent off. I mean, that was another significant

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concern that I had at that particular time. There's very little money available for technology CME. So, that could be a fund that you could use to direct towards CME, not only for the professional, but for technical components as well.

MR. BROWNE:

Q. I'll move to another topic now, Dr. Cook. Mr. Crosbie asked you about a particular patient case and the testimony from Mr. Purcell. And it was my understanding that Mr. Purcell's wife-and Mr. Crosbie can correct me if I'm wrong on this--had her ER/PR performed in July of 1998.

DR. COOK:

A. Right.

MR. BROWNE:

Q. And he asked you, I think, the question of whether or not--and I think he indicated there was a change in the results subsequently on her retest--and asked you whether or not this was a sentinel case. At that point in time, how long had IHC for ER/PR been in existence?

DR. COOK:

A. We introduced it mainly in Marc of '98.

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MR. BROWNE:

Q. So, effectively, only been a couple of month period that IHC had been -

DR. COOK:

A. That's correct.

MR. BROWNE:

Q. And if you were going to do a lookback, there wouldn't have been very much to look back, would there?

DR. COOK:

A. No, only those two months, if I remember.

MR. BROWNE:

Q. You were also asked by Mr. Coffey and again by Mr. Crosbie about internal controls. And in particular Mr. Coffey asked you, I think, a series of questions about what you observed in July and August of 2005 with Dr. Carter concerning internal controls and the absence of internal controls and so on. Can I ask you, were these cases select cases from a particular year, such as 2000 and prior to 2000?

DR. COOK:

A. Well, they were mainly 2002, there were some there from 2001 and could have been a couple

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from ’99.
MR. BROWNE:
Q. Okay. So, they’re from between 199 and 2002, is that correct?
DR. COOK:
A. That’s correct.
MR. BROWNE:
Q. So, the memo from Dr. Ejeckam concerning the relevance of internal controls came out in May of 2003.
DR. COOK:
A. That’s correct.
MR. BROWNE:
Q. There has been some discussion around proficiency testing by a number of the counsel here at the Inquiry. Doctor, from your perspective, the decision to have proficiency testing in the lab medicine program, generally whose responsibility is that for putting that in place?
DR. COOK:
A. Well, generally you have proficiency testing in the other divisions, hematology, biochemistry and those are under the control of the divisional manager.

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MR. BROWNE:
Q. You were also asked some questions about, I believe, Dr. Mullen’s slide review and perhaps, Registrar, P-1837. Registrar, I’m going to have to ask your assistance again, that’s the datasheet. Could we have, perhaps I think maybe attached to the report, the legend, the spreadsheet code that goes with that document. The letter would have been April 18, 2008, April 28.
REGISTRAR:
Q. April 28th letter.
MR. BROWNE:
Q. Yes, see if it’s there. Thank you. Here we go, Doctor. That’s it, thank you, Registrar. Now, I just want you to look at--this is the legend, the code that was prepared by Dr. Mullen and I want to draw your attention to the last item there which is comment and it says, "when a surgical pathology report was provided which include the results of Mount Sinai Hospital with respect to review, I compared the Newfoundland results with the Mount Sinai results. The results were categorized as concordant if the two results

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were in the same ER group and discordant if they were in different ER groups. Negative, less than one percent; low positive, one to ten percent; and positive, greater than ten percent".
DR. COOK:
A. Um-hm.
MR. BROWNE:
Q. Doctor, just so I’m clear, and I understand, in fact, both from the evidence of Dr. O’Malley and Dr. Mullen that they were using the Allred score. Are you generally familiar with the Allred score?
DR. COOK:
A. I am.
MR. BROWNE:
Q. Okay. Was that something that was used by pathologists in your institution or was there a different approach?
DR. COOK:
A. No, there was a different approach. We didn’t use the Allred score.
MR. BROWNE:
Q. Okay. And I understand the Allred score was introduced at Mount Sinai in 2000.

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DR. COOK:
A. I understand.
MR. BROWNE:
Q. Okay. If this score was used to evaluate cases pre 2000 for Newfoundland, would that be discordant in terms or would that be appropriate in terms of an evaluation to give us an indication.
DR. COOK:
A. Well, you were using a different standard then to evaluate the cases, particularly from the ’97, ’98 ’99 years.
MR. BROWNE:
Q. Again, this morning you were asked--Registrar, if we could see -
THE COMMISSIONER:
Q. Sorry, Mr. Browne, I think I missed something there. Where is--you’re saying particularly from ’97, ’98 and ’99 years.
DR. COOK:
A. Because he was using that standard, different standard for those particular years. I mean, he was using the Allred score which was brought in from 2000 and that was a different type of scoring method that we used for our

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own interpretation.
THE COMMISSIONER:
Q. So, why is the problem in the '90s, not after the 2000 when they started using Allred. I missed something.
DR. COOK:
A. Well, he may have been using a different criteria or a different interpretation on the stains.
THE COMMISSIONER:
Q. I think I understand your point about your position vis-a-vis, the use of Allred versus in Newfoundland, maybe my problem is just timing. When is it, your understanding, that they started to use Allred in Mount Sinai?
DR. COOK:
A. It was around 2000, I believe.
MR. BROWNE:
Q. The evidence from Dr. O'Malley and Dr. Mullen, as well, was that they introduced the Allred score, greater than one percent from 2000 onward.
THE COMMISSIONER:
Q. Yes, okay. So, for the years before 2000 -
MR. BROWNE:

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Q. Yes, I think--if that was used to call something discordant, then that may be confusing.
THE COMMISSIONER:
Q. After 2000 though, isn't it?
MR. BROWNE:
Q. No, well, if that particular scoring was used to evaluate slides between 1997 and 2000, as I understand what the witness is saying, that would--you're using -
THE COMMISSIONER:
Q. So, you're suggesting that this indicates that they went back and used Allred prior to -
MR. BROWNE:
Q. We're not able to--it seems from looking at this commentary section that this scoring may have been used for all the cases from 1997 onward.
THE COMMISSIONER:
Q. Okay. So, what you're really saying is we have to determine what that means.
MR. BROWNE:
Q. Yes, what that means. We're unclear from what that means at this point.
THE COMMISSIONER:

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Q. All right.
MR. BROWNE:
Q. When Dr. Cook looked at this, he was unclear as to whether the scoring was used across the board from 1997 onward.
THE COMMISSIONER:
Q. Okay, unfortunately, we didn't ask Dr. Mullen when he was here.
MR. BROWNE:
Q. No, we did not.
THE COMMISSIONER:
Q. All right.
MR. BROWNE:
Q. Thank you, Commissioner. Registrar, item P-0626. Doctor, you were asked by Mr. Crosbie this morning about the figure ten percent. And this was a letter, draft letter for Dr. Williams' signature in October of 2006.
DR. COOK:
A. Um-hm.
MR. BROWNE:
Q. Is it possible that that figure came from some the preliminary results that were coming back between August and September from Mount Sinai?
DR. COOK:

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A. It's possible, yes.
MR. BROWNE:
Q. Doctor, that is all the questions I have for you this morning. Ordinarily witnesses are asked whether or not they wish to make and comment, recommendations or statement to the Commissioner. This is your opportunity this morning to do so. Do you wish to avail of that opportunity?
DR. COOK:
A. Yes, I'd like to make a statement.
MR. BROWNE:
Q. Okay.
DR. COOK:
A. Commissioner, pathology is a slow meticulous process involving extensive tissue sampling, exhaustive microscopic examination and specialized testing such as ER and PR and HER2/neu. Gone are the days when a brief note describing the size and type of cancer sufficed. Unlike a clinic which may book a limited number of patients per day, pathology department cannot restrict the number of samples it receives. Despite high workload pressures, pathologists fatigue and burnout,

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our laboratories are expect to delivery high quality results. Unlike Britain, the United States and Australia, Canadian laboratories lack a national quality assurance program. These organizations oversee and administer a wide variety of quality assurance initiatives. It is strongly apparent that our laboratory must produce time critical information for patient care and even one error may have a devastating effect. By making quality assurance and patient safety a priority at all levels, we were able to restore confidence and pathology to our patients, clinicians and ourselves. But many recommendations have been implemented, I would like to make the following now.

First, the establishment of regular pathology rotations in our medical school curricula with exposure of medical school students to all aspects of the laboratory. Only then can medical students truly appreciate the laboratory and hopefully make a career choice in laboratory medicine. The long-term goal is to make Newfoundland and Labrador self sufficient in pathologists.

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Two, the establishment of a province wide laboratory accreditation program with monitoring of such activities as CME and proficiency testing. These programs must be mandatory and also include a process where technologists are regulated and licensed.

Three, maintenance of a high profile of our laboratory by greater interaction of pathologists with the general public, through discussions with advocacy groups in the form of information updates, question and answer sessions and including availability of pathologists to address individual patient concerns.

Four, laboratory and medicine program must continue to have the necessary human and financial resources to maintain high quality service.

Five, the laboratory must remain under control of a laboratory physician who has appropriate discretionary funding to allocate financial resources to where they are needed. In the past we have had two captains on the bridge, each with different directions and viewpoints. The result at times has been a

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clash of authorities and confusion over roles and responsibilities.

The service commitments, number six, of the chief of laboratory medicine must remain capped at 20 to 30 percent service load with emphasis on lab administration and quality assurance.

Seven, limits must be placed on pathology workload through implementation of workload standards currently being developed by the Canadian Association of Pathologists.

It must be noted that since I was clinical chief, there has been an infusion of human and financial resources with the addition of quality assurance co-ordinator for the lab and quality assurance supervisor for the division of pathology, the creation of four pathology assistant positions, the addition of a resource immunologist for immunohistochemistry, dedicated secretarial support for the chief of laboratory medicine, a more streamlined reporting structure under the control of the laboratory physician and an improved salary package for all pathologists, which is now one of the best in Canada. This

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has come as a result of the ER/PR issue.

There are no words that I can say to convey to the patients and their families the sadness and devastation that this has been felt throughout this difficult situation. You have been in my thoughts and prayers every waking moment for the last three years. It has been an emotional roller coaster for patients, families and all those involved. This event will remain with me for the rest of my life. On a more personal note, even though I had no intention of revealing my own health issues, it has been revealed that I have been on sick leave. In April of this year, after working ten hours and sometimes longer a day and on weekends, as I sat behind my microscope, I realized that I had become too exhausted to carry on any further. For the sake of my own health, for that of public safety which is always a priority, I went on sick leave until I could recover.

I am sure I am not alone in trying to manage the system with heavy workloads that pathologists face every day. Unless the workload situation improves, there is greater

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risk of pathology burnout and exhaustion. This will have a direct impact on patient care. Behind every slide there is a patient and family with their own hopes, dreams and aspirations. I know only too well the pain and suffering that comes with a diagnosis of cancer. It was January of 1988 I was sitting in the office of the then director of laboratory medicine at St. Clare's, Dr. John Williams, along with my colleague, Dr. Peter Roberts, we were discussing the various issues of the day when a pathologist brought in a tray of slides, a technologist, sorry. That technologist laid the tray of slides next to Dr. Williams' scope. She asked Dr. Williams could she give an urgent verbal report to the clinician. Dr. Williams got up from his chair, went over to that scope, took a slide and placed it on the stage of his microscope. After a few fine adjustments, he looked at the slide for two to three minutes. Got up from behind the microscope and beckoned my colleague, Dr. Peter Roberts to come over and have a look at the slide for a second opinion. Dr. Roberts spent out two to three to four

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minutes evaluating the slide. Then both left the office to discuss the case. Curious as to what was going on, I went over and I sat behind the scope and looked at the slide that was on the stage of the microscope. There were about four pieces of tissue on that slide, each ranging in dimension from 0.5 up to about 1.0 millimetres. One of those pieces of tissue were unremarkable gastric tissue, in other words it was a stomach biopsy. Three of the other fragments demonstrated a lesion which showed marked hypercellularity with cells that were markedly hyperchromatic in nature and pleomorphic. These was extensive microsis and breast mitotic activity. In other words, it was a stomach cancer and it was a bad cancer, it was a high grade cancer and I remember thinking that the poor individual behind this slide was going to have a hard time of it all. I just happened to look at the name of the requisition, the name that was on the requisition that was attached to the slide. The name was in the right upper hand corner of the requisition. And the name was that of Eric Thomas Cook, my father.

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That's how I discovered dad had cancer. Three months later we buried him. Five months earlier we buried my mother-in-law, age 53 on Boxing Day, December 1987, who suffered from the effects, the complications of breast cancer. I know only too well the effects of cancer, the impact that it has on patients, their lives and their families and all that is associated with it.

Commissioner, I'd like to conclude by thanking you and all those involved in the Inquiry. I hope we'll end up with a better system to serve those who are entrusted in our care. Thank you.

MR. BROWNE:

Q. Those are my questions. Thank you, Commissioner.

THE COMMISSIONER:

Q. Mr. Coffey, do you have anything?

COFFEY, Q.C.:

Q. Yes, Commissioner, the whole thing is to clarify, please.

DR. DONALD COOK, RE-EXAMINATION BY BERNARD COFFEY, Q.C.

COFFEY, Q.C.:

Q. Now Doctor, Mr. Browne asked you about

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improvements or in answer to a question of his, you referred to recent improvements in the clinical laboratory situation, locally.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And I take it, I think in passing you referred to the ER/PR matter. Would you attribute then these improvements to the fact that there was this ER/PR problem and it was discovered?

DR. COOK:

A. Those improvements, I think, came about as a result of the issues surrounding ER and PR and those were mainly, I think--came about.

COFFEY, Q.C.:

Q. Doctor, there's a reference again in answer to a question Mr. Browne asked you about proficiency testing and various parts of the labs, for pathologists, who's responsible for proficiency testing or ensuring that it occurs and what type is used?

DR. COOK:

A. There's two types of proficiency testing, those for technical and those for professional. The professional proficiency

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testing that we have evaluate pathologist interpretations and we have that from the College of American Pathologists and the American Society of Clinical Pathologists.

COFFEY, Q.C.:

Q. And who's responsible for -

DR. COOK:

A. Those would be mainly the site chiefs and clinical chiefs.

COFFEY, Q.C.:

Q. Okay. And I'm sorry, the other was? You said there was two types.

DR. COOK:

A. And the other one was the technical component and that -

COFFEY, Q.C.:

Q. The technical would be, you're talking about technologists?

DR. COOK:

A. That's right.

COFFEY, Q.C.:

Q. Okay. You've been asked somewhat by various counsel about financial or monetary issues.

DR. COOK:

A. Um-hm.

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COFFEY, Q.C.:

Q. And just in relation to the ER/PR matter itself and I appreciate your comments in relation to having someone with the time, funded time, to review matters en masse, you referred to that. But just to clarify here, at the time in 2000 when you came across the reference in a textbook to the importance of utilizing internal controls for ER/PR testing, that didn't actually cost anybody any extra money, did it?

DR. COOK:

A. Not at that particular time, no.

COFFEY, Q.C.:

Q. And as well, a memo such as Dr. Ejeckam's in May of 2003, May 2nd, 2003 memo that informative one to all pathologists throughout the province or addressed to them, that again, didn't cost any extra money.

DR. COOK:

A. Not in terms of trying to bring in--what we needed to bring in, Mr. Coffey, was continuity and stability in the system, but in terms of no actual monies, no.

COFFEY, Q.C.:

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Q. The Hay Report you referenced or were asked about in terms of pathology assistance -

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. - and as Mr. Browne just had you again, I think, point out that even in '05, October 13, '05, your report, yourself and Mr. Gulliver's report -

DR. COOK:

A. Right.

COFFEY, Q.C.:

Q. - identified that there were going to be over $200,000.00 in extra expenses in terms of personnel expenses to institute pathology assistants.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And presumably there would have been something comparable back in '02 when the Hay report recommended it. That recommendation back in 2002 then was to increase in once sense, laboratory expenses, hire pathology assistants, was there any commensurate

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suggestion by the Hay report or anyone else around that time to reduce personnel expenses by reducing the number of pathologist positions?

DR. COOK:

A. No. I don't think that was under the scope of the Hay review to look at the professional component.

COFFEY, Q.C.:

Q. In relation to that, has there been, through the 2000, like since 2000, any suggestion that you're aware of by anyone to reduce the number of pathologists?

DR. COOK:

A. There have been attempts I think in May of '04 to -

COFFEY, Q.C.:

Q. So, that was afterward.

DR. COOK:

A. That was after the fact, but not prior to that.

COFFEY, Q.C.:

Q. Okay. I just wanted to see if--just to explore with you that the idea in '02 and increased expenses in one hand, sometimes

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there's often a suggestion of commensurate decrease elsewhere, but it didn't occur.

Doctor, you were asked about the number of antibodies and the increase in the number of antibodies over time and your report, that October 13th, 2005 report, certainly refers to that and notes the number being used in 2005. Doctor, is there any way that you're aware of ascertaining in the lab, in the General Hospital, how many antibodies were in use at any particular point in time.

DR. COOK:

A. I mean, you have to go back through the records and have a look at--I'm sure that Mr. Gulliver can provide you with that.

COFFEY, Q.C.:

Q. Okay. In terms of actual records, you believe Mr. Gulliver will be able to say, like, in 2000 this is the number, January 2000.

DR. COOK:

A. He would have those records, yes.

COFFEY, Q.C.:

Q. Okay. I'll take that up with Mr. Gulliver. In terms of, you've been asked about shortages in pathology manpower, to your knowledge, has

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there ever been analysis or study undertaken as to pathologist manpower in what is now the Health Care Corporation, well what is now Eastern Health, formerly the Health Care Corporation of St. John's, pathology manpower from time to time between the period '97 and '05?

DR. COOK:

A. We have information that's provided you can get from our administrative people.

COFFEY, Q.C.:

Q. The Commission has actually seen like a sheet, the time people came on and the time they left.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. What I'm asking out about, like, from time to time, how many pathologists there were in '98; how many pathologists there were in '99; how many pathologists there were in 2000. Do you know if any analysis has been conducted in that regard?

DR. COOK:

A. I don't think there was any in-depth analysis

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regarding that.

COFFEY, Q.C.:

Q. And, in fact, Doctor, you have referred again in answer to some questions that Mr. Browne asked you, I believe you used the phrase "in terms of accreditation after the mid 90s, we were sort of set adrift", meaning the laboratories?

DR. COOK:

A. That's right.

COFFEY, Q.C.:

Q. Doctor, when did you first become consciously aware of the idea that you'd been set adrift?

DR. COOK:

A. Well, I would say probably around 2003 or 2004 that we were having discussions with Dr. Williams, myself and Mr. Gulliver, about the need of having a more thorough accreditation process.

COFFEY, Q.C.:

Q. And looking back on it from the vantage point of 2008 now, I take it that reflecting upon it now, this sort of being set adrift, to use your phrase, probably occurred in the mid 90s in terms of laboratories and accreditation?

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DR. COOK:

A. Mid to late 90s.

COFFEY, Q.C.:

Q. Mid to late 90s, but your own conscious awareness of it in terms of kind of where are we surfaced around '03/'04?

DR. COOK:

A. Well, we brought again more concerns around '03/'04.

COFFEY, Q.C.:

Q. And I believe the documentation, I think that at times when I was asking you about various things earlier, there are references then to the idea of instituting a quality assurance program for the lab?

DR. COOK:

A. We were trying to bring in QA as much as we could.

COFFEY, Q.C.:

Q. But the period then -- it took about three or four years for that kind of consciousness or awareness to set in.

DR. COOK:

A. Well, what you need to do -- I mean, you don't develop quality assurance programs overnight.

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I mean, you need to bring in the right mix of pathologists.

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

A. So those with experience and those who have the mindset.

COFFEY, Q.C.:

Q. Okay. You were asked as well about -- by Mr. Crosbie, as he suggested to you, did you agree that there was a problem with the technical end of the ER/PR process.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. For which from your perspective the technologists were responsible, and you indicated yes, and in particular he was referring you to antigen retrieval times and dilution rates?

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. In trying to arrive at the appropriate antigen retrieval time and appropriate, for example,

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dilution concentrations or rates for estrogen receptor antibody and progesterone receptor antibody. In St. John's, Newfoundland, is that something that's left to the technologist alone or is that something that, for example, now the Director of Immunohistochemistry is involved in?

DR. COOK:

A. Well, now the Director of Immunohistochemistry is involved in collaborating and working with the technical aspect.

COFFEY, Q.C.:

Q. In fact, going back to the 2003 Dr. Ejeckam intervention, I take it that whatever changes were made in antigen retrieval time and dilution rates then by the technologists were overseen by Dr. Ejeckam?

DR. COOK:

A. Well, there was consultation between the techs and Dr. Ejeckam.

COFFEY, Q.C.:

Q. And was it your understanding that -- whose final call was that it was as good as it was going to get? Was that Dr. Ejeckam's or the technologists?

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DR. COOK:

A. Well, it probably would have been Dr. Ejeckam's at that time.

COFFEY, Q.C.:

Q. You were asked about the idea of system error.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. And just -- if I could because as much as is possible, I'd like to clarify this for the Commissioner. I gather different witnesses have different understandings of what they mean by system error. When you use the word "system" in this context, okay, why do you use the word "system"?

DR. COOK:

A. Because I referred to what had happened with the tissue before it got to the lab, referred to the technical aspect of the lab that we have the appropriate control mechanisms in the technical aspect, how it was interpreted by the pathologist. So in that regard, I saw problems at every aspect of the process.

COFFEY, Q.C.:

Q. So if there was a problem -- if upon review

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the problem was limited to one part of that, say, before it ever got to the lab -- say, that was the situation, okay.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Would that then have been characterized by you as a system error?

DR. COOK:

A. No, what I characterize by system error is why wasn't it picked up, and why it went as long as it did.

COFFEY, Q.C.:

Q. Doctor, this reference to control slides -- I'm sorry, external controls and external control slides and whom they were being read by or not, and when they were being received or not by individual pathologists, what's your recollection, as a practising pathologist based at St. Clare's, as to between '97 and '05, when you got external control slides?

DR. COOK:

A. They would come with us --

COFFEY, Q.C.:

Q. For ER/PR now, of course.

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DR. COOK:
A. Yeah, we got them on a -- we didn't get them on a regular basis. If we didn't get the control slides, generally what we had was the -- on our requisition forms, names of pathologists who had checked the slides. So either took that, or at times we got the control slides when they were available.
COFFEY, Q.C.:
Q. So if there was no control slide came over and you asked and it wasn't available --
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. You would then look for the requisition to see if there was some --
DR. COOK:
A. If there was a name on the requisition, if the pathologist had overseen or checked that off.
COFFEY, Q.C.:
Q. And then he or she then would be certifying that they had, in their professional opinion, the external control work?
DR. COOK:
A. That's right.

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COFFEY, Q.C.:
Q. Doctor, in relation to that, you also referred to the idea or notion that you understood that the site chief in the General Hospital in his day would either be Dr. Khalifa or Dr. Parai?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Were also some also reviewing the ER/PR slides in general before they went out?
DR. COOK:
A. No, they would check the controls.
COFFEY, Q.C.:
Q. The controls?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. I want to clarify that. So your understanding, as a practising pathologist at St. Clare's --
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. You happen to be site chief.
DR. COOK:

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A. Uh-hm.
COFFEY, Q.C.:
Q. But a practising pathologist, was that the controls were being checked, external controls?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. By the site chief at the General?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. But how about the individual ER and PR slides themselves?
DR. COOK:
A. Well, Dr. Khalifa, I understand, may have been doing that from '97 to '99, but the individual slide itself would be checked by the pathologist.
COFFEY, Q.C.:
Q. So you'd --
DR. COOK:
A. Prior to reporting.
COFFEY, Q.C.:
Q. Yeah, I appreciate that. Well, that would

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have even in Dr. Khalifa's day would been going on too, presumably?
DR. COOK:
A. Well, my understanding was he was running checks on the ERs and PR slides to other slides.
COFFEY, Q.C.:
Q. I appreciate that, but in '97, '98, and '99, yourself at St. Clare's, you reported your own cases --
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. You would look at your own individual ER and PR individual slides?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. And Dr. Khalifa, you understood, probably already looked at them?
DR. COOK:
A. He may have -- if I remember correctly, we had discussions around whether he was periodically checking the slides.
COFFEY, Q.C.:

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Q. Okay. After Dr. Khalifa left --
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. For example, in Dr. Parai's time, did you have any understanding that the site chief, Dr. Parai, was actually looking at the ER and PR individual slides?
DR. COOK:
A. No, he was just looking at the controls.
COFFEY, Q.C.:
Q. Okay. Doctor, you were asked as well about the idea of false negatives, false negative rates.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And I believe this is a question Mr. Crosbie had for you, and he referred you to some portion of Dr. Mullen's transcript, but you did -- he asked you, and I don't know if I got this correct or not in my notes, about your own view as to the false negative rate.
DR. COOK:
A. Uh-hm.

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COFFEY, Q.C.:
Q. And I think you used around 30 percent. I think you said rough figure.
DR. COOK:
A. Roughly. These were rough calculations that I was using as the results came in.
COFFEY, Q.C.:
Q. Okay, and I just want to explore that with you, the idea of this rough figure.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Was that kind of a running total, as it were, that you were keeping?
DR. COOK:
A. Well, as the cases would come in, Dr. Williams would call me to try to ascertain where we were in terms of conversion rates based on the clinical cut offs. Those were -- again I would make a rough tally and try to tell them where we were basically in terms of the conversion rate.
COFFEY, Q.C.:
Q. And that rough figure of 30 percent, did that -- when did that begin to be used by you in

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reporting to Dr. Williams and how long did it continue for?
DR. COOK:
A. Oh, the figure -- well, we used a range of about 24 to 30 percent. I mean, I guess it started, I would say, possibly in January or early February of '06 when we had more of the specimens in from Mount Sinai.
COFFEY, Q.C.:
Q. And did you -- other than doing this rough figure, is there ever an actual -- I'll refer to it as a more precise figure, a non-rough figure?
DR. COOK:
A. No, we were trying to ascertain that -- to try to get a statistician to come in and evaluate those figures in terms of trying to get a more accurate handle on it.
COFFEY, Q.C.:
Q. I take it from what you told me earlier, that never did happen?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Okay. Finally, Doctor, Jennifer Newbury asked

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you, Ms. Newbury asked you questions about addendums and whether or not doctors might pick up -- oncologists might pick up particular additions to pathology reports.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Just in relation to the ER/PR, so the Commissioner has some understanding of this, the ER/PR retest results came back in two ways, either as consults, individual sheets of paper --
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. You would do what with that?
DR. COOK:
A. Well, the consults were mainly handled by Dr. Carter. She was issue the addendum report and send it out.
COFFEY, Q.C.:
Q. And issue the addendum report in the sense of, I take it, dictate it into Meditec?
DR. COOK:
A. Dictate it into Meditec.

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COFFEY, Q.C.:
Q. And introduce her electronic signature saying approving of it?
DR. COOK:
A. Uh-hm. Those were on the current cases, the new cases.
COFFEY, Q.C.:
Q. Yes, current cases. Well, I'm asking you too about -- there was some consultations that were retests. They were treated -- some retests were treated as urgent.
DR. COOK:
A. Right.
COFFEY, Q.C.:
Q. But they were actual retests, they were consults?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. Were they also entered in the same way?
DR. COOK:
A. Same way.
COFFEY, Q.C.:
Q. Okay, and you say sent out. How were they sent out?

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DR. COOK:
A. Oh, they were entered into the system and you had the hard copies.
COFFEY, Q.C.:
Q. Okay, that's what I want to ask you about. That hard copy would go where, your understanding was?
DR. COOK:
A. It would go to the attending physician or surgeon, or if there was any other issues concerning that, we would forward the hard copy to -- fax the hard copy to Heather Predham.
COFFEY, Q.C.:
Q. Finally then the spreadsheet retest results, which I take it primarily came to you --
DR. COOK:
A. Right.
COFFEY, Q.C.:
Q. And upon being satisfied as to the particular results for a particular patient, you would do what with it?
DR. COOK:
A. The spreadsheet would be forwarded to Heather Predham, which would be then forwarded to the

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panelling process.
COFFEY, Q.C.:
Q. And in terms of the actual result fro Mount Sinai, the ER and PR results --
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. You would enter those in Meditec?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. And you did that for all patients in Newfoundland and Labrador?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. And having entered it in Meditec and electronically signed it as an addendum, what -- was there a hard copy produced?
DR. COOK:
A. Hard copies were produced which went to the -- outside of St. John's to the laboratory directors, or inside of St. John's, it went to the attending physician whose name was on the right upper hand corner of the report.

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COFFEY, Q.C.:
Q. Okay, thank you, Commissioner. I just wanted to be clear because that may come up at some point down the road, and I wanted to make sure that everybody was -- understood, at least from your perspective, how physically this was done after the material came from Mount Sinai. Thank you very much, Commissioner.
COMMISSIONER:
Q. Thank you.
MR. SIMMONS:
Q. Commissioner, if I could, just one point of clarification. I can give you the question and you can determine if it's of interest or not.
COMMISSIONER:
Q. Sure.
MR. SIMMONS:
Q. Dr. Cook had just spoken of the 24 to 30 percent conversion rate that he roughly worked out and passed on to Dr. Williams. The question I'd be interested in is simply whether that's 24 to 30 percent of the tests that had gone to Mount Sinai or 24 to 30 percent of all ER/PR tests? In other words,

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was that the total population or just the samples --

COMMISSIONER:

Q. Did you understand the --

DR. COOK:

A. Just the tests that had gone to Mount Sinai.

COMMISSIONER:

Q. All right, thank you. Well, Dr. Cook, your stay with us has been longer than any of us had anticipated. Thank you very much for your contribution.

DR. COOK:

A. Thank you, Commissioner.

COMMISSIONER:

Q. I suggest we take the morning break and then we can begin with the new witness.

(RECESS)

COMMISSIONER:

Q. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. The next witness is Peggy Welsh. If Ms. Welsh could be sworn or affirmed, please.

MS. PEGGY WELSH (AFFIRMED) EXAMINATION BY MS. CHAYTOR

CHAYTOR, Q.C.:

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Q. Commissioner, we have a number of new exhibits which I would ask, please, to have entered. It's P-2150. I'm sorry -- it's P-2149 through to P-2157, and P-2176 and P-2177.

COMMISSIONER:

Q. Entered.

CHAYTOR, Q.C.:

Q. Thank you.

EXHIBITS ENTERED AND MARKED P-2149 THROUGH P-2157

EXHIBITS ENTERED AND MARKED P-2176 AND P-2177

CHAYTOR, Q.C.:

Q. Ms. Welsh, perhaps we could begin. Good morning.

MS. WELSH:

A. Good morning.

CHAYTOR, Q.C.:

Q. And you can tell us about your educational background?

MS. WELSH:

A. I graduated from the College of Trades and Technology in St. John's in 1974, and became registered with the Canadian Society of Laboratory Technologists as a registered technologist.

CHAYTOR, Q.C.:

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Q. And in 1974 when you did your course at the college, or the then College of Trades and Technology, what did that course involve, how long was that course, and was there any particular specialty that you concentrated on?

MS. WELSH:

A. No, I studied as a general laboratory technologist. It was a three-year course. The first year was basic sciences, senior matriculation, because at the time, we didn't have a grade 12 program in Newfoundland. Second year was theory of histology, biochemistry, microbiology, hematology and our third year was theory, as well as practical.

CHAYTOR, Q.C.:

Q. Okay, and I take it there was no such study at the time as immunohistochemistry?

MS. WELSH:

A. No, there wasn't.

CHAYTOR, Q.C.:

Q. To become then a registered technologist with the Canadian Society, did you have to take an examination?

MS. WELSH:

A. Yes, we had to write national exams from the

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Society.

CHAYTOR, Q.C.:

Q. And upon passing those exams, did that entitle you then to be able to work anywhere within Canada?

MS. WELSH:

A. Yes, it did.

CHAYTOR, Q.C.:

Q. And then in terms of your employment background, after graduating in 1974, where did you seek employment?

MS. WELSH:

A. My first position was at Memorial University in the medical school, in the teaching labs, which was basically setting up labs for first and second year medical students. In January of 1975, I went to work at the Captain William Jackman Memorial Hospital in Labrador City and I worked there until May of 1977, and then I started at the General Hospital in the histology department in June of 1977. I worked there until the end of April 2003 and started in May of 2003 at the Aberdeen Hospital, New Glasgow, Nova Scotia, which is where I'm currently employed.

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CHAYTOR, Q.C.:
Q. Okay, and in Labrador City, did you work in any particular section or area of the lab?
MS. WELSH:
A. No, Labrador City was a very small hospital, with just five technologists, and we just worked in all of the various sections of the lab.
CHAYTOR, Q.C.:
Q. So you did everything?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And here in St. John's then, you came here--or you started your position there in 1977?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And you went to the histology area?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you remain then in the histology throughout your time?
MS. WELSH:

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A. Yes, I did.
CHAYTOR, Q.C.:
Q. And currently, your position is New Glasgow, Nova Scotia, are you involved in IHC?
MS. WELSH:
A. No, I'm not.
CHAYTOR, Q.C.:
Q. At some point in St. John's, did you come to work in IHC?
MS. WELSH:
A. Yes, I did, in probably around the mid 80s, when we first started to do IHC on a very limited amount.
CHAYTOR, Q.C.:
Q. And I'll ask you a bit about those early days in a little while. So when you first went with--in 1977, when you took up your position, I take it you were a laboratory technologist one?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Is that correct?
MS. WELSH:
A. That's correct.

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CHAYTOR, Q.C.:
Q. And at some point, did you become a laboratory technologist two?
MS. WELSH:
A. Yes, I did.
CHAYTOR, Q.C.:
Q. And when was that?
MS. WELSH:
A. Probably '81 or '82.
CHAYTOR, Q.C.:
Q. Around the same time that you became involved in IHC?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And your position then, when you first joined, perhaps you could just tell us--you're the first lab technologist, by the way, that we've heard from from St. John's anyhow. We had a technologist here from Mount Sinai last week. Perhaps you could tell us about what were your duties? When you first started in 1977, what was required of you?
MS. WELSH:
A. The very first things that we were doing then,

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we would assist the pathologists or resident with the grossing of the specimens, just to write up the cassettes for them and keep records of what was being done. Then -
CHAYTOR, Q.C.:
Q. So you didn't do any of the grossing yourself?
MS. WELSH:
A. No, no, they did all the grossing, either a resident or a pathologist.
CHAYTOR, Q.C.:
Q. And at any point in time, did that change and lab technologists became involved in grossing?
MS. WELSH:
A. That changed in probably--after Dr. Khalifa came with us in probably about 1998, we started to do some, but for the first 20 years or so that I was there, we didn't do any grossing. We might have assisted with the grossing, which is just sitting there at the bench with them while they--and passing them cassettes for their tissue and things like that.
CHAYTOR, Q.C.:
Q. Okay. So other than assisting with the grossing, what else did you do?

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MS. WELSH:
A. Then we would embed the tissue. In the morning, it would be put on a processor to remove all the water from the tissue, infiltrate the tissue with wax and we would embed them into wax blocks and cut the slides. Slides were cut at five--three to five microns thickness. Stain the slides, cover slip them, bring them to the pathologist to be read.
CHAYTOR, Q.C.:
Q. Okay, and the three to five microns, that was standard throughout the time you were with Health Care Corporation and Eastern Health?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. I guess you were only there during Health Care Corporation days?
MS. WELSH:
A. Yes, it wasn't Eastern Health until after I left.
CHAYTOR, Q.C.:
Q. Okay. At the time then, what was the reporting structure within the lab? Who was your immediate supervisor?

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MS. WELSH:
A. When I first started?
CHAYTOR, Q.C.:
Q. Yes, when you first started.
MS. WELSH:
A. It was--the lab supervisor then was Mr. Felix Pittman.
CHAYTOR, Q.C.:
Q. Okay. So when you first started, it was the General Hospital?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Which was a separate entity in and of itself?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And so you reported directly to another--I take it he was a lab technologist himself, was he?
MS. WELSH:
A. Yes, he was.
CHAYTOR, Q.C.:
Q. Okay, and who did he report to?
MS. WELSH:

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A. He would have reported to Mr. Max Thornhill, who was, at the time, the director of the lab.
CHAYTOR, Q.C.:
Q. And ultimately did the lab managers report to a physician?
MS. WELSH:
A. I wouldn't--I'm not aware of who they reported to.
CHAYTOR, Q.C.:
Q. We're aware that in the Health Care Corporation days, there was a program based management structure.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. You'd be aware of that. And we've heard some evidence here about there being two streams of reporting, one for the technical side and one for the medical side.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And I'm wondering when--in the early days at the General Hospital, was there the two tiers, or was it just one tier going up through to a

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physician?
MS. WELSH:
A. I'm not sure.
CHAYTOR, Q.C.:
Q. You're not sure.
MS. WELSH:
A. I wouldn't--I just knew who I reported to.
CHAYTOR, Q.C.:
Q. That's fine.
MS. WELSH:
A. I was a very new tech then, just there for a year or two.
CHAYTOR, Q.C.:
Q. Okay. In terms then of your day-to-day work, how much interaction would you have had with pathologists?
MS. WELSH:
A. The pathologists would certainly do the grossing, so we would see them then and we would have interaction with them when they'd come in to ask us to do special stains or something like that, but other than that, we didn't have very much interaction with the pathologists back in those days.
CHAYTOR, Q.C.:

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Q. Okay, and it was the mid 1980s, you say, that the IHC was first introduced?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And however the grossing, the embedding of the tissue, the making of the paraffin blocks, all of that was part of histology in any event, so that's something that was going on from the time you first went there in 1977?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. When, in the mid 1980s then, when IHC was first introduced, do you remember who brought IHC to the General Hospital? How did it come about?
MS. WELSH:
A. Dr. Wong, who was the equivalent, I guess, of what would be the site chief now, I don't know what they called him at that point in time, he was the one who first started to do very limited immunohistochemistry, and he started to do them with Terry Gulliver.
CHAYTOR, Q.C.:

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Q. Okay, and did--how did you become introduced to it?
MS. WELSH:
A. Just shortly after that, probably a year or so later, Mr. Pittman passed away and Terry became our lab manager. So then I moved into that position.
CHAYTOR, Q.C.:
Q. Okay, and so you moved into doing IHC then?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And were you doing exclusively IHC or were you still doing other duties?
MS. WELSH:
A. Oh no, I'm still doing everything else. Our IHC then was very limited. We just did four or five antibodies.
CHAYTOR, Q.C.:
Q. So it was only four or five antibodies in the mid 1980s?
MS. WELSH:
A. Yeah.
CHAYTOR, Q.C.:
Q. And by the time you left in 2003,

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approximately how many antibodies were there?
MS. WELSH:
A. I would say we had close to 100.
CHAYTOR, Q.C.:
Q. Okay, and in those early days, in the mid 1980s, were there other technologists also moved or was it just yourself that took on IHC?
MS. WELSH:
A. I'm not sure of the exact time that Mary Butler would have started doing them as well. There were two of us, and I don't--I'm not sure of the exact year when she would have started.
CHAYTOR, Q.C.:
Q. I take it it was around the same time or shortly thereafter?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and who then taught you about IHC? You hadn't learned it in your schooling, and so how were you taught or trained to do IHC procedures?
MS. WELSH:

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A. Dr. Wong showed Terry how to do them and Terry showed me.
CHAYTOR, Q.C.:
Q. Okay, and what exactly did Mr. Gulliver show you?
MS. WELSH:
A. We just learned the basic procedure, how to--exactly what you did, we had a procedure that we followed just to make up the antibodies, put them on the slides, incubate the slides. We didn't have very much, other than just hands-on training from the person who was doing it.
CHAYTOR, Q.C.:
Q. So whatever you learned, it was through Mr. Gulliver?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And you said there was a procedure that you followed. So was there a written procedure?
MS. WELSH:
A. I don't recall if it was a written procedure or not. I probably made notes when he was teaching me, but I don't recall if there was

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ever a written procedure. I think there probably would have been, but I just don't remember that.

CHAYTOR, Q.C.:

Q. Okay, and do you recall were you provided any textbooks?

MS. WELSH:

A. No, we had no textbooks.

CHAYTOR, Q.C.:

Q. Were you provided anything in the way of a seminar or conference that you could attend where you could learn about it?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And throughout your time actually up until you left in April 2003, had you ever attended a conference or a seminar on IHC?

MS. WELSH:

A. No, not specifically.

THE COMMISSIONER:

Q. Did you say not specifically?

MS. WELSH:

A. Not specifically. I'd attended conferences through our professional society and there

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would have been maybe one or two lectures from a pathologist on immunohistochemistry, but no specific training program for IHC.

THE COMMISSIONER:

Q. Okay.

CHAYTOR, Q.C.:

Q. And your professional society being which?

MS. WELSH:

A. CSMLS, Canadian Society of Medical Laboratory Science.

CHAYTOR, Q.C.:

Q. Okay, and would those be seminars that you attended on your own accord or were they arranged through your employer?

MS. WELSH:

A. These are national--these were provincial seminars that were held every year and we went of our own accord, but our employer paid some of the registration costs, that sort of thing.

CHAYTOR, Q.C.:

Q. And would you go to those each year?

MS. WELSH:

A. I went to them most every year, but it wasn't a mandatory thing to go to.

CHAYTOR, Q.C.:

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Q. Okay, and they were here in St. John's?

MS. WELSH:

A. No, they would have been in various places around the province.

CHAYTOR, Q.C.:

Q. In the province, yes, sorry. And there were times when there were lectures by pathologists on IHC?

MS. WELSH:

A. I don't recall any.

CHAYTOR, Q.C.:

Q. No, I mean, within those -

MS. WELSH:

A. Oh, within those seminars, yes.

CHAYTOR, Q.C.:

Q. Yes, and do you recall which pathologists would have given those lectures?

MS. WELSH:

A. I remember Dr. Paul Neil gave one in Corner Brook one year. I don't recall when that was, probably early 90s, but I can't really recall exactly who would have given the lectures.

CHAYTOR, Q.C.:

Q. Okay.

MS. WELSH:

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A. They would have just been hour-long sort of information sessions.

CHAYTOR, Q.C.:

Q. And was there any concentration on the actual technical aspect of conducting IHC?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. So in terms of any training that you received from a technical point of view, did you attend any seminars or have any courses in that?

MS. WELSH:

A. No, I attended one conference in Montreal and I don't remember the year, maybe early 90s, that one of the days was spent as a workshop in IHC. It was--but it was basically on one particular instrument that somebody was trying to--was selling across the country, and so we did a seminar on how to actually use that instrument, but we never ever bought that instrument or anything.

CHAYTOR, Q.C.:

Q. That wasn't equipment that was ever used then in St. John's?

MS. WELSH:

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A. No. So that was--that's the only time that I ever did a seminar that was specifically technically -
CHAYTOR, Q.C.:
Q. IHC?
MS. WELSH:
A. - to IHC.
CHAYTOR, Q.C.:
Q. Were there other aspects though to that seminar in Montreal that were of assistance to you in carrying out IHC or was it just focused on that equipment?
MS. WELSH:
A. No, it was just focused on that actual piece of equipment.
CHAYTOR, Q.C.:
Q. And when you started doing the IHC in the mid 1980s, you indicated Dr. Wong had been involved or instrumental in bringing IHC on. Was Dr. Wong then in charge or overseeing IHC?
MS. WELSH:
A. I would imagine. I don't really recall much about that.
CHAYTOR, Q.C.:
Q. Was there anyone else? Was there any other

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pathologist then that were--for example, in terms of creating your antibodies, were you receiving any assistance from a pathologist in that time period?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. If we could look at, please, P-2150? And Ms. Welsh, these are exhibits which will come up on the screen in front of you, and you have a mouse, but I will, for the most part, be able to--I control it as well, so I'll take you to the points that we're going to talk about.
MS. WELSH:
A. Okay.
CHAYTOR, Q.C.:
Q. This is called IHC time lines and my understanding is this is a document created by Terry Gulliver or certainly Terry Gulliver is the source of the document, and the first section is about technology and equipment and it indicates from 1980s to early 1998. The first bullet is totally manual, using individual petri dishes.
MS. WELSH:

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A. Um-hm.
CHAYTOR, Q.C.:
Q. Would you have been involved at that stage?
MS. WELSH:
A. Yes, I was.
CHAYTOR, Q.C.:
Q. Okay, so tell the Commissioner, please, what exactly would you have to do in those early stages? How was the process carried out?
MS. WELSH:
A. Slides would be cut the day before and incubated, and then we would deparaffinize the slides. We used proteolytic enzyme called trypsin, I believe was the name of it, that we would then put on the slides and incubate. That was supposed to help remove formalin masking. And we made up a primary antibody. At the time when we were doing those, we were just doing probably five protein markers and we would make up the antibodies, drop them on the slides and incubate the slides. Slides, using petri dish, the slides were in a moist chamber, so we had little piece of paper towelling in the petri dish that was wet. So it would keep the slide from drying out. We

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would incubate the primary antibody for, I believe it was 30 minutes, wash the slides, include with a secondary antibody, which attaches itself to the primary antibody, incubate that for 30 minutes, wash the slides, then we incubate with a tertiary antibody, which again attaches itself to this molecule we've already attached to. It makes a molecule that's big enough to see, because otherwise you wouldn't see the antigens. Then we would cover the slides with a colouring agent called diaminobenzadine and this would change any of these molecules that we had all attached to each other with the antibodies that would turn those to brown. So you would be able to see the antigen sites in the cells.
CHAYTOR, Q.C.:
Q. Okay, and I take it during that process, the manual process, ER and PR weren't two of-- those antibodies weren't used at that time?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And then from February 1998 it's written here

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"DAKO immuno tray" in quotation marks, "replace the petri dishes".

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And what was the immuno tray? How was the process different at that point in time?

MS. WELSH:

A. The process then was that the, instead of using the individual petri dishes for each slide, we had a tray that had various slots on it that you could fill the tray with water so that you still had the moist chambers so that the slides would not dry and we would just lay the slides on this tray and put the antibodies, both primary, secondary and tertiary, on the slides at that time.

CHAYTOR, Q.C.:

Q. And was this process used for ER/PR?

MS. WELSH:

A. I think at the very beginning when we started to do ER/PR, we did that process because we didn't get the DAKO autostainer until a little later.

CHAYTOR, Q.C.:

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Q. Yes, it says "May, 1998" is the next bullet, "DAKO autostainer installed, semi-automated."

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And if we scroll down on this document under "History", we see "ER/PR kit system from 1997 through to November, 1997"?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. So it appears there was ER/PR happening in 1997?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. So that would have been through which method? How would the process have been taken place at that time?

MS. WELSH:

A. I don't remember doing the ER/PR on, in the petri dish method. I do remember doing it in the immuno tray.

CHAYTOR, Q.C.:

Q. Okay. And then the DAKO system, of course, was installed.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. What training were you given in terms of how to operate the DAKO machine?

MS. WELSH:

A. There was a service representative from the DAKO company who came to St. John's and set up the instrument and trained both Mary and I on how to operate it.

CHAYTOR, Q.C.:

Q. So it was Mary Butler and yourself, the two technologists.

MS. WELSH:

A. Mary Butler and myself.

CHAYTOR, Q.C.:

Q. And were you and Mary then, you and Mary were assigned to IHC to then use the DAKO machine and that continued on, you had been doing this through manual process for some time.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Would you also then have to still continue

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with your other duties once the DAKO machine came in or did that become more of a fulltime position for you?

MS. WELSH:

A. No, we still continued with other duties.

CHAYTOR, Q.C.:

Q. And how did you and Mary divide your time?

MS. WELSH:

A. A week about.

CHAYTOR, Q.C.:

Q. So you'd do a week--what would your rotation be?

MS. WELSH:

A. A week on the immunostainer and then the opposite we would do, immunofluorescence for kidney biopsies and skin biopsies and muscle biopsies that needed special procedures, as well as routine lab work where necessary.

CHAYTOR, Q.C.:

Q. So you'd be a week operating the machine, while Mary did the other duties and then you would alternate and the following week she would run the machine?

MS. WELSH:

A. Yeah, and it was about the same time that we

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started to do some of the grossing of the uncomplicated specimens. I'm not exactly sure what year that was, but it was either '98 or '99 that we started to do the grossing as well. So we would do that on the opposite week as well.

CHAYTOR, Q.C.:

Q. And in terms of operating the machine, where was the machine located in terms of the other duties that you and Mary had to do?

MS. WELSH:

A. It was in the back of the lab.

CHAYTOR, Q.C.:

Q. So it was all in the same general vicinity?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. But not a separate--physically separated area?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And in terms of, so I take it when you're operating the machine, you're there on your own doing it.

MS. WELSH:

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A. Uh-hm.

CHAYTOR, Q.C.:

Q. If you required assistance, what would you do?

MS. WELSH:

A. Required assistance in what way?

CHAYTOR, Q.C.:

Q. If you required assistance in what you were doing with the machine or ran into any difficulties or if you needed to take a break, what would happen? Would Mary fill in for you?

MS. WELSH:

A. You would take a break when the instrument was actually running so that you wouldn't need anyone else to come down and take over. There was a system on the machine that if something went wrong, the alarm would sound.

CHAYTOR, Q.C.:

Q. On the DAKO machine?

MS. WELSH:

A. On the DAKO machine, say if there wasn't quite enough of a reagent or a wash buffer or something, so then the other--if you weren't around at the time, the other person would look after it.

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CHAYTOR, Q.C.:

Q. Would hear the alarm?

MS. WELSH:

A. You would hear the alarm because it was there.

CHAYTOR, Q.C.:

Q. And they would be in close enough proximity, I take it that you and Mary then would co-ordinate and not both be--one of you would always be in the area.

MS. WELSH:

A. One of us was around, yes.

CHAYTOR, Q.C.:

Q. And you indicated that somebody came from DAKO, a representative came to show you how to operate the machine. And how long did that person spend with you?

MS. WELSH:

A. Maybe two days, maybe three, not--no more than three days, I don't believe.

CHAYTOR, Q.C.:

Q. And what do you recall about that training? This was, I take it, a new piece of equipment for you, you hadn't operated anything like this before?

MS. WELSH:

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A. Uh-hm.

CHAYTOR, Q.C.:

Q. What do you call in terms of how in-depth your training was?

MS. WELSH:

A. Well the first thing he did was sort of explain how the instrument operated itself, then we inputted all of our antibody protocols into the computer that came with the machine so that when we would have been doing that particular antibody, the machine would know how to, what protocols we were using, what blocking reagents or whatever, you know, antigen retrieval reagents, now they weren't called antigen retrieval reagents then. So we just learned how to basically operate the machine and how to program it to do what we wanted it to do.

CHAYTOR, Q.C.:

Q. So none of your reagents at that time required antigen retrieval when you first started using it?

MS. WELSH:

A. Not to my recollection, no.

CHAYTOR, Q.C.:

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Q. That came some time later?
MS. WELSH:
A. That came some time later, some of the newer ones that we had ordered needed the antigen retrieval.
CHAYTOR, Q.C.:
Q. Now how about, though, the ER/PRs, that would have been--they were have required antigen retrieval, were those not moved to the DAKO machine as soon as it came on?
MS. WELSH:
A. Yes, they were, yes.
CHAYTOR, Q.C.:
Q. So I take it -
MS. WELSH:
A. We were doing antigen retrieval on those, yes.
CHAYTOR, Q.C.:
Q. On those. So I take it they were somewhat unique in that regard, they were the only ones that you were doing antigen retrieval on in those -
MS. WELSH:
A. I'm not sure if they were the only ones or if--there weren't that many that required antigen retrieval right at the beginning, but the

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ER/PR always did.
CHAYTOR, Q.C.:
Q. And what were you taught or how did you learn about the antigen retrieval process?
MS. WELSH:
A. Just from the inserts that came with the antibodies, it would--it gave a brief overview of what the antibody did and then a section on how to do the procedure and the part of the procedure would have been saying that it needed antigen retrieval and to use the, whatever antigen retrieval it used. There were different types of antigen retrieval.
CHAYTOR, Q.C.:
Q. So those would be the inserts that would come with the antibody?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So were you using the manufacturer's antibodies at the time?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And were they pre-diluted?

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MS. WELSH:
A. I believe when we used the kit they were pre-diluted, but when we started to use the DAKO stainer, it was a primary--a concentrated primary antibody that we diluted, according to the spec sheets that came with the antibody.
CHAYTOR, Q.C.:
Q. Okay, and in doing then antigen retrieval, did you understand what antigen retrieval was and the importance of antigen retrieval?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And maybe you could explain that to us, why did you have to do antigen retrieval for ER/PR?
MS. WELSH:
A. Antigen retrieval was done to remove the formalin masks that would settle over issue, so when tissue is fixed with formaldehyde, sometimes the antigen sites would be masked and that was--we did that to remove those, the formalin masks, so that the antibody could attach itself to the antigen.
CHAYTOR, Q.C.:

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Q. And was there any particular method or times that you had to use in making sure that the antigen retrieval was carried out appropriately?
MS. WELSH:
A. Yes, as per the spec sheets it would have said at what temperature to do it and how long, usually it was about twenty to thirty minutes, I believe, and we used between 95 and 99 degrees.
CHAYTOR, Q.C.:
Q. Okay, and was it done--how was it done? Was it done in water baths, how was it -
MS. WELSH:
A. At first it was done on a hot plate, we had a glass dish that we would fill with water, so it would have been equivalent to a water bath, and then we would immerse the dish of slides in the antigen retrieval into this water, so that it would be kept at that temperature.
CHAYTOR, Q.C.:
Q. And so it would be kept at that temperature and for twenty to thirty -
MS. WELSH:
A. Twenty to thirty minutes, I don't recall the

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exact time.
CHAYTOR, Q.C.:
Q. And you received that instruction from the -
MS. WELSH:
A. From the insert.
CHAYTOR, Q.C.:
Q. - spec sheet. If we look back then at, to P-0150, this indicates that DAKO water baths for antigen retrieval, October, 1999, so is that the new type of water bath that you just described that came on in October of 1999?
MS. WELSH:
A. No, in '99 when we got the water bath, that's when we stopped using a hot plate and we had an actual water bath that we could set the temperature for and then we would do our antigen retrieval in that water bath.
CHAYTOR, Q.C.:
Q. Okay, and was that still the process when you left in 2003?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And the DAKO "pen", June, 1998 through April, 2004, circle tissue on slide, can you tell us

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what does that refer to?
MS. WELSH:
A. The instrument had what was called drop zones where the robotic arm would drop the antigen-- sorry, the antibodies on the sides. It had three different drop zones for a slide. We would mark the slide with this particular pen so that when we set it up to, say, use the drop zone two, that the antibody would not move up and down the slide, it would stay in that particular drop zone. So it was that the antibodies wouldn't move around.
CHAYTOR, Q.C.:
Q. And the robotic arm is on the machine, I take it?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And that was for dispensing the antibodies?
MS. WELSH:
A. That was dispensing the reagents.
CHAYTOR, Q.C.:
Q. The reagents, yes. And during your time there, did you recall any problems with the robotic arm?

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MS. WELSH:
A. I think I remember one time when it stopped that we had to get it repaired, but it's vague and I think that was the only time, though, that I remember that.
CHAYTOR, Q.C.:
Q. So it had stopped while it was on a run?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And would there be an alarm in that situation?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And so I take it that run then -
MS. WELSH:
A. The run then would be totally cancelled and redone.
CHAYTOR, Q.C.:
Q. And redone. And you recall that happening on one occasion?
MS. WELSH:
A. Only on one occasion that I remember.
CHAYTOR, Q.C.:
Q. And maintenance was carried out on the

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machine, I take it, at that time. Who would do the maintenance on the DAKO machine?
MS. WELSH:
A. Technical services from Memorial University, I believe were the ones who would do, in conjunction with DAKO, I think they had the contract from DAKO to service the machine.
CHAYTOR, Q.C.:
Q. So if any actual problems happened, would they do routine maintenance as well?
MS. WELSH:
A. Yes, they did.
CHAYTOR, Q.C.:
Q. And how often was that taking place?
MS. WELSH:
A. Probably yearly.
CHAYTOR, Q.C.:
Q. And what about in terms of within the lab itself? Did you and Ms. Butler carry out any daily checks or maintenance of the machine?
MS. WELSH:
A. Just to the point of making sure that we had all of the proper wash reagents and waste containers were emptied, that sort of thing and cleaning, there was a cleaning protocol

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that we did after.
CHAYTOR, Q.C.:
Q. And was that done every day?
MS. WELSH:
A. It was done after a certain number of slides. I don't recall exactly, I think it was 200 slides maybe, I'm not sure, and we would have to do the cleaning.
CHAYTOR, Q.C.:
Q. So when the gentleman came from DAKO, I take it he explained to you what maintenance would be required to be carried out by the technologists?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And were you also given any documentation as to what maintenance or cleaning would be necessary?
MS. WELSH:
A. No, it was just--I know it just came up on the computer screen when the cleaning was necessary to be done.
CHAYTOR, Q.C.:
Q. So the computer that was attached to the

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machine, that would remind you that it's time to do maintenance or cleaning?
MS. WELSH:
A. Yeah, and it wouldn't let you go do any more until you did the cleaning.
CHAYTOR, Q.C.:
Q. But in terms of a daily check--would there be any kind of daily check required of the machine?
MS. WELSH:
A. No, not that--other than, like I said, other than the reagents and checking the waste in the wash buffers.
CHAYTOR, Q.C.:
Q. Okay, and would you document any maintenance or cleaning on the machine?
MS. WELSH:
A. No, we didn't document anything.
CHAYTOR, Q.C.:
Q. And was that true throughout the whole time that you were there?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. When the DAKO machine was introduced, were you

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involved in it's actual set up and getting it ready, getting the antibodies ready? Were you involved in that process?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And were there any pathologists involved in that process?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And did Dr. Khalifa play any role in that at that point in time?
MS. WELSH:
A. No, not that I recall.
CHAYTOR, Q.C.:
Q. And when ER/PR was brought on to the DAKO machine, was Dr. Khalifa involved in any way with that process and in initiating ER/PR?
MS. WELSH:
A. In initiating ER/PR?
CHAYTOR, Q.C.:
Q. To the IHC method, through the DAKO machine?
MS. WELSH:
A. No, that was purely technical, we just

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transferred from one method, from doing it manually to doing it on the machine.
CHAYTOR, Q.C.:
Q. Okay. And what then did you do to test your antibodies when the new machine is up and running? What did you do to test your antibodies, to make sure your tests were running appropriately?
MS. WELSH:
A. We ran controls with every antibody.
CHAYTOR, Q.C.:
Q. And where did you get your controls?
MS. WELSH:
A. We would ask the pathologist for cases that they know would be positive for certain antibodies, especially with the ER/PR. Some of the other antibodies that we did, it would be on the spec sheets, would tell you which tissues were positive for these antibodies.
CHAYTOR, Q.C.:
Q. And then you and Mary Butler went about creating the control bank as well?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:

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Q. Control bank of slides.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Okay, and did any pathologist assist you in that, other than picking out which blocks might be good for control tissue?
MS. WELSH:
A. No, that would be their only -
CHAYTOR, Q.C.:
Q. I'm sorry?
MS. WELSH:
A. That would have been their only -
CHAYTOR, Q.C.:
Q. That was their only involvement?
MS. WELSH:
A. Their only role in that would have been to pick out the -
CHAYTOR, Q.C.:
Q. So they would identify a block for you and then you and Mary created the control slides?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And in terms of running slides, so you have

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your controls set up and then you're running your antibodies, did any pathologist then look--was there a period of time when you ran a certain number of test slides and pathologists would look at it to see if the slides were adequate, anything like that happen when the DAKO was first brought on?
MS. WELSH:
A. I don't remember.
CHAYTOR, Q.C.:
Q. Maybe we could just go back to this document for a minute then, P-2150, and the final bullet under "technology and equipment" refers to histogrip slides, 2002, prior dip slides/dried." Can you tell us what that refers to?
MS. WELSH:
A. Histogrip slides were used to cut tissue that needed the antigen retrieval, the antigen retrieval would have been sort of hard on the tissue, hard to keep the tissues on the slides because you're heating it to an almost boiling temperature. Histogrip slides were prepared to allow the tissue to adhere better to the slides.

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CHAYTOR, Q.C.:
Q. So that came on sometime in 2002, at least according to what we have here, is that in keeping with your recollection as well?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. So that was only about a year before you left that you had that type of slide?
MS. WELSH:
A. That histogrip slides, I think for 2002, they probably bought slides that were already covered with that, it seems like I recall preparing histogrip slides longer than a year.
CHAYTOR, Q.C.:
Q. And then the Ventana fully automated, that's after your time, so we'll skip that.
MS. WELSH:
A. Okay.
CHAYTOR, Q.C.:
Q. Number two talks about the antibodies used and under the DAKO, there's a number of clones indicated for ER and PR.
MS. WELSH:
A. Uh-hm.

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CHAYTOR, Q.C.:
Q. And different clones that were used for different periods of time. And then again the history, "ER/PR kit system, 1997 through to November, 1997." What do you recall about the kit system, what did that mean?
MS. WELSH:
A. The kit system is just that all of the reagents for one particular antibody would have come in one box with everything that you needed to do that particular antibody.
CHAYTOR, Q.C.:
Q. So everything that you needed came within a -
MS. WELSH:
A. Came within one kit.
CHAYTOR, Q.C.:
Q. And then in 1998, you moved off that, so how did it differ? Once the kit system was no longer in use, what did you have to do differently?
MS. WELSH:
A. Then we received--it says there "pre-diluted antibodies for October until April", I don't really remember all those dates, those would have come in as antibodies that were already

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pre-diluted that we would have just used our, used those and then our regular, secondary and tertiary antibodies that we were using for other immunohistochemistry. And then when the primary antibodies came in, we would have diluted them as per the spec sheets and used the secondary and tertiary antibodies that we had.

CHAYTOR, Q.C.:

Q. Okay, so for a brief period of time, this indicates anyhow, October 1997 through April 1998, the antibodies, ER/PR, were pre-diluted.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And after that then, you and Mary would have been diluting?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And well, I guess, also come long Ken and Les, so for that period of time then, you would dilute your own antibodies?

MS. WELSH:

A. Yes.

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CHAYTOR, Q.C.:

Q. And what did that involve? How did you actually go about diluting antibodies?

MS. WELSH:

A. We would pipette a primary antibody and dilute it in phosphate buffered saline, so if it was a one in fifty dilution, we'd use one microlitre of antibody for every 50 microlitres of the phosphate buffer.

CHAYTOR, Q.C.:

Q. Okay, and in terms of your pipettes, we heard some--or the Commissioner has heard some evidence in terms of calibrating the pipettes, was that done on a regular basis?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Did you ever calibrate your pipettes?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Did anyone ever tell you that that might be a good thing to do?

MS. WELSH:

A. No.

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CHAYTOR, Q.C.:

Q. You were never instructed in that?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And the pipettes that you were using, were they replaced from time to time?

MS. WELSH:

A. From time to time, yeah.

CHAYTOR, Q.C.:

Q. And I take it from your answer, your hesitation in answering, not very often.

MS. WELSH:

A. Not very often, no.

CHAYTOR, Q.C.:

Q. And then we have clones for Ventana, then reagent solutions--actually before I leave the dilution of the antibodies, when you--so you're actually creating then your own antibody, where would you store your antibody after it's created?

MS. WELSH:

A. At first, from '97 to--until we got the DAKO machine, we would only make up enough that we used, we would only dilute as much as we were

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going to use that day or on that run and the primary antibody would be stored in the refrigerator. When we got the DAKO instrument, we would make up a larger amount and they would be stored in the refrigerator.

CHAYTOR, Q.C.:

Q. Okay, and where was this refrigerator?

MS. WELSH:

A. About halfway up the lab.

CHAYTOR, Q.C.:

Q. And was it in your section where the IHC was actually taking place?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And were there other things also stored in that refrigerator?

MS. WELSH:

A. Oh yes, we had one shelf.

CHAYTOR, Q.C.:

Q. And do you know whether or not that refrigerator had an alarm?

MS. WELSH:

A. I don't think it did.

CHAYTOR, Q.C.:

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Q. And do you know whether or not there was, that certain antibodies required different temperatures for storage?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And would the antibodies have expiry dates?
MS. WELSH:
A. Yes, they would.
CHAYTOR, Q.C.:
Q. Okay, and how would you determine what the expiry date should be?
MS. WELSH:
A. The expiry date would be written on, would be on the label of the antibody.
CHAYTOR, Q.C.:
Q. So you would make up your own antibody.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. It would be stored in the fridge and you would note on the label in the storage container the expiry date, is that how that would work?
MS. WELSH:
A. No, it already would have been printed on the

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label that came with the antibody.
CHAYTOR, Q.C.:
Q. Okay, so it would come from the manufacturer?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And how would you then, prior to using an antibody, would you check the expiration date?
MS. WELSH:
A. No, because if they were there, we periodically went through the antibodies and checked them, so anything that was there would have been up to date.
CHAYTOR, Q.C.:
Q. So you periodically checked and cleaned out anything that was expired?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. But on a day to day basis of picking an antibody out of the fridge and using it, you didn't have a practice of checking the expiration date?
MS. WELSH:
A. No.

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CHAYTOR, Q.C.:
Q. Do you know whether or not you ever used antibodies that had expired?
MS. WELSH:
A. I don't think so.
CHAYTOR, Q.C.:
Q. Was there ever any concern expressed as to the cost of antibodies and using antibodies even if they had been expired by a short period?
MS. WELSH:
A. Not that I recall. I'm -- I'm trying to think. There may have been an occasion we used an expired antibody, but then the controls would have been run and it would have only been -- and it would have been checked out, but I'm not even 100 percent sure of that.
CHAYTOR, Q.C.:
Q. You have some vague recollection?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And you recall that only happening on one occasion?
MS. WELSH:

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A. Yeah.
CHAYTOR, Q.C.:
Q. But in terms of the resources and the costing of resources, was that ever expressed to you or within your earshot that these reagents are expensive and to use them up? Any expression of anything like that?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. If we could look then, please, at -- I didn't finish the next page, sorry. The reagents and solutions, and other, and then there's a list here of those. Then we have staffing, technologists. This indicates here that you were there from 1987 to October, 2003. I take it that's an error? You weren't there in October, 2003?
MS. WELSH:
A. No, I left in April of 2003.
CHAYTOR, Q.C.:
Q. Do you remember which date you left in April, 2003?
MS. WELSH:
A. The 25th/26th.

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CHAYTOR, Q.C.:
Q. So it was late in the month?
MS. WELSH:
A. It was late in the month.
CHAYTOR, Q.C.:
Q. And you worked right up until the time that -- your resignation date?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And then Mr Green joined in March of 2002, according to this document?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And he had transferred from, I understand, St. Clare's Mercy, to start training on that date?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And then March, 2003, Peggy Welsh resigned?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. So this is saying that you resigned on that

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date, but I take it you actually worked until late April, 2003?
MS. WELSH:
A. Uh-hm. That would have been probably when I put in my resignation.
CHAYTOR, Q.C.:
Q. That might be your resignation letter, okay. Then also in that same month, March, 2003, Les Simms transferred from St. Clare's Mercy to start training?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And were you involved then in the training of both Mr. Green and Mr. Simms?
MS. WELSH:
A. Yes, I was.
CHAYTOR, Q.C.:
Q. Perhaps you could tell the Commissioner what did that involve? For example, with Mr Green in March of 2002, how did you train him?
MS. WELSH:
A. I would have had him spend his time with me when we were doing histochemistry or grossing, whichever. He would have spent a few days

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watching me, and I would be explaining to him what I was doing, and then he would have been actually doing -- we would have done them in conjunction and then he would have done them on his own with me supervising him.
CHAYTOR, Q.C.:
Q. Okay, and so he basically job shadowed you for a few days?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And in the IHC portion, you would be doing that on a weekly rotation at that point in time?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So would he have spent the full week job shadowing you that you were there?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and then when would he be left to do the IHC on his own?
MS. WELSH:

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A. I'm not exactly sure how long he was in training. Several weeks probably.
CHAYTOR, Q.C.:
Q. Several weeks?
MS. WELSH:
A. That we worked together. Several weeks that we worked together. When I was training both Ken and Les, and when I was training them with the IHC, we would have continued, I believe, with the IHC instead of doing any other training. So Mary and I would probably not have alternated on that time, so I would have spent two weeks with Ken and two weeks with Les.
CHAYTOR, Q.C.:
Q. Okay, so you spent two weeks in the IHC with Ken?
MS. WELSH:
A. Probably about that time, yes.
CHAYTOR, Q.C.:
Q. And about the same with Les when he came?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And were they -- other than job shadow or

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watching you, observing you carry out the IHC test, were they given anything to read in terms of how to carry out the tests?

MS. WELSH:

A. They would have been given the procedure, the spec sheets to look at, but basically it was just me teaching them what I knew.

CHAYTOR, Q.C.:

Q. And the spec sheets were the manufacturer's spec sheets?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. Were there other standard operating procedures besides the spec sheets or were those your SOPs?

MS. WELSH:

A. That was basically it.

CHAYTOR, Q.C.:

Q. That was it.

MS. WELSH:

A. Uh-hm. We had a -- we had some procedures that were written down when we were doing the manual procedures, but there was really no procedure manual for how to do them on the

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DAKO machine.

CHAYTOR, Q.C.:

Q. On the DAKO machine there wasn't?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. So you relied on the spec sheets from the manufacturer?

MS. WELSH:

A. Uh-hm, and the operation of the machine. We entered everything in the computer, so then the computer prompted you to continue to do --

CHAYTOR, Q.C.:

Q. So you entered into the computer the information that was on the spec sheet, is that right?

MS. WELSH:

A. When we first set up a new antibody, yes, then we would enter in the computer what was on the spec sheet, what dilutions to use and the timing, whether or not it needed hydrogen blocking, things like that.

CHAYTOR, Q.C.:

Q. And then that would come up on the computer screen, I take it, and so anybody running the

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machine would have then the procedure?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. On the computer, and could refer to it that way?

MS. WELSH:

A. Yes, if they went into each individual antibody.

CHAYTOR, Q.C.:

Q. So if Mr. Green, for example, was going to run ER/PR, he could go into the machine and it would come up and tell him what procedure to follow?

MS. WELSH:

A. Well, the procedure was basically the same for all antibodies. The only thing that was different was dilutions and antigen retrieval.

CHAYTOR, Q.C.:

Q. Yes. So for him to know that, he would have to either have the physical spec sheet --

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Or the information from the spec sheet which

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was put into the computer?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. Do you recall was there any tweaking done to what was on the spec sheets?

MS. WELSH:

A. Not really. We followed the spec sheets pretty well. They would sometimes have a range of dilutions. So when we would get a new antibody that was, say, a range of 1 in 20 to 1 in 50, we would start it with 1 in 50 and get the pathologist to look at it and see what they thought, and maybe it wasn't concentrated enough, we would then try the different dilution.

CHAYTOR, Q.C.:

Q. So if you were given a range on your spec sheets, you would run different slides and in those cases you would take it to the pathologist?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And ask the pathologist for his or her input?

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MS. WELSH:
A. That was only when we would get a new antibody. Once it was decided which one -- which dilution to use, that's that dilution we would continue to use.
CHAYTOR, Q.C.:
Q. Okay. This just indicates then who were the managers at the time?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Just continue on here, and then the physical space, and I think you've described for us -- first of all, it says, "The IHC testing, both manual and semi-manual with the DAKO System, was performed in the main pathology laboratory space".
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And you indicated it was at the back of the lab?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:

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Q. And your fridge -- your fridge was up more in the middle of the pathology lab?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. What about your other equipment? For example, did you have a microscope available to you?
MS. WELSH:
A. We had a microscope available. That was the same microscope that everybody in the pathology lab would have used to check slides. That wasn't in our -- in our area. It was further up the lab.
CHAYTOR, Q.C.:
Q. And that was for everyone in the pathology lab to use?
MS. WELSH:
A. Uh-hm, yeah, and incubators were in our area.
CHAYTOR, Q.C.:
Q. What about the tissue processor?
MS. WELSH:
A. Tissue processor was in a different room.
CHAYTOR, Q.C.:
Q. A different room altogether?
MS. WELSH:

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A. Uh-hm.
CHAYTOR, Q.C.:
Q. If we can look, please, at P-1850. Now, Ms. Welsh, I don't know if you've seen this before, but it's a memorandum which went from Dr. Khalifa to all Newfoundland pathologists in February, February 16th, 1998.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And it's in reference -- reporting of estrogen and progesterone receptor immunohistochemical results.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And he's attached here to this memo at page four what appears to be somewhat of a concordant study.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And this we understand is the switching from the immunohistochemistry -- sorry, from the biochemistry method to the immunohistochemical

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method of doing ER/PR?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Do you recall being involved with Dr. Khalifa at all in that process?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. What do you recall about that?
MS. WELSH:
A. We would have just done the immunohistochemical staining for ER and PR on cases -- on these cases that he would have given us. We would have given the slides back to him, and he would have been the one who was doing this correlation.
CHAYTOR, Q.C.:
Q. So Dr. Khalifa would have identified which test to have carried out?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And you and Mary would have --
MS. WELSH:

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A. We would have performed the tests and gave the slides back to him.
CHAYTOR, Q.C.:
Q. And there seems to be about a total number here indicated to be -- appears to be 19 for estrogen, and 17 for progesterone.
MS. WELSH:
A. Okay.
CHAYTOR, Q.C.:
Q. Is that in keeping with your recollection or were there -- did there seem to be more or less?
MS. WELSH:
A. No, that seems to be about right.
CHAYTOR, Q.C.:
Q. That's about right?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Is there anything else then that you recall about this period of time before the ER/PR got brought on to the IHC method? Do you recall anything else in terms of any validation or concordant studies that were carried out?
MS. WELSH:

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A. No.
CHAYTOR, Q.C.:
Q. You indicated that a gentleman came from DAKO to show you how to use the machine, and by the end of his couple of days with you, did you feel comfortable in operating the DAKO machine?
MS. WELSH:
A. Yes, I did.
CHAYTOR, Q.C.:
Q. Did you ever experience any difficulties afterwards with operating the machine?
MS. WELSH:
A. No, not to my recollection.
CHAYTOR, Q.C.:
Q. And did you have -- was there anyone available to you that you could pick up the phone and call if you did run into any problems?
MS. WELSH:
A. Yes, you could call him. We had his number and his card on the machine and we could call him if we had any trouble.
CHAYTOR, Q.C.:
Q. Do you happen to remember who he was?
MS. WELSH:

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A. Dan Belkowski.
CHAYTOR, Q.C.:
Q. Sorry, Dan --
MS. WELSH:
A. Belkowski (phonetic).
CHAYTOR, Q.C.:
Q. Do you know how to spell that?
MS. WELSH:
A. Heavens, no. I'm surprised I remembered.
CHAYTOR, Q.C.:
Q. Me too. Okay, and did you have occasion to call Mr. Belkowski after he left Newfoundland?
MS. WELSH:
A. I called him a couple of times, yes.
CHAYTOR, Q.C.:
Q. Okay, and what was the nature of your inquiries?
MS. WELSH:
A. I have no idea . I really don't remember. It would have probably been just after he had left, you know, within the first few months if we had come up with anything we weren't sure of, but I don't recall any specifics.
CHAYTOR, Q.C.:
Q. And in the time period, I believe we saw, it

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was 1997, the early days of doing ER/PR, the kit system, 1997 through to November, 1997.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So most of what was done in 1997 appears to have been the kit system. Whose responsibility would it be to order new antibodies when they were getting low?
MS. WELSH:
A. That would have been our responsibility.
CHAYTOR, Q.C.:
Q. And was that also true then after you move on to the diluted antibodies and the pre-diluted antibodies?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. This is the responsibility of the technologist?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So I take it you would notice when it was getting low and then order more?

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MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could look, please, at P-1889. This is another document that you're perhaps not familiar with, but this is a letter with two dates; March 12, 1997, and February 27, 1997, and it's written to Mr. Gulliver from Dr. Khalifa. He writes that, "The estrogen and progesterone kit that we have tried and which offered us very good and reliable results has been totally consumed by last week, as of February 20th, 1997. You knew this and you were trying to use a new detection system in combination with an old primary antibody that the laboratory had for some time. This combination did not work. I called you on Monday morning at the Janeway Hospital site and told you that we were having an emergency situation. Any trial of a new technique need to be done in parallel with a well established one before a switch could be safely made. I thought I conveyed to you this message clearly and asked you to replace the ER/PR kit as soon as possible", and he goes on to write further

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on that, and clearly not happy with Mr. Gulliver over this issue. Do you recall yourself anything about this, any discussion from Mr. Gulliver to the technologists then about the kit having been consumed?
MS. WELSH:
A. I don't recall this, no.
CHAYTOR, Q.C.:
Q. Do you recall any issue ever coming up that antibodies had run out and had not been replaced prior to running out?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. What would you do if -- you get low on antibody, so you order more in, and how would you -- then would you do anything to compare or run any kind of validation to make sure that the new antibody is performing the same and of the same quality as your prior antibody?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. You wouldn't do anything like that?

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MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. So I take it you would then just follow whatever spec sheet came?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And would the antibody sometimes have -- would they have different lot numbers, though?
MS. WELSH:
A. I don't know. Probably over time they would have had different lot numbers. I think we just trusted the company to have checked out all the antibodies before they were sending them out.
CHAYTOR, Q.C.:
Q. You didn't make any particular adjustments for your lab?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. If we could look, please, at P-2176. This is a -- actually this exhibit has a number -- Ms. Welsh, I'll just show you a number of spec

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sheets or what we understand -- are these spec sheets?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So these are the types of spec sheets that you --
MS. WELSH:
A. These are spec sheets for reagents, not antibodies.
CHAYTOR, Q.C.:
Q. Okay.
COMMISSIONER:
Q. Sorry, you said these are specs sheets for?
MS. WELSH:
A. For reagents that we would have used in conjunction with the antibodies. These are not the actual antibody spec sheets.
CHAYTOR, Q.C.:
Q. Okay, and perhaps then you can explain that to us. What would you have to do with--was there anything you had to do with the reagents when you received them? Was there any dilution or anything that had to happen or they just -
MS. WELSH:

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A. No, these were usually -
CHAYTOR, Q.C.:
Q. Used -
MS. WELSH:
A. Well, the -
CHAYTOR, Q.C.:
Q. Sorry?
MS. WELSH:
A. I'm looking at the target retrieval 500 mils of ready to use. So when we got these, they were already pre-diluted.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. And you see the procedure is there for them, what to do with them.
CHAYTOR, Q.C.:
Q. Yes. And so again, you would just follow the spec sheet?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And where would those spec sheets be kept?
MS. WELSH:
A. They were kept in an accordion folder in the

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cupboard next to where we worked.
CHAYTOR, Q.C.:
Q. And were they kept in any particular order?
MS. WELSH:
A. In a semi-alphabetical, the As with the As and the Bs with the Bs.
CHAYTOR, Q.C.:
Q. And when you would get a new spec sheet in on a particular reagent, would it replace the old or would you keep them all?
MS. WELSH:
A. We would probably keep them for a little while, but then it would replace the old. We would clean out the folder on occasion.
CHAYTOR, Q.C.:
Q. And then was there any particular record kept otherwise than through the spec sheet, once the spec sheet was discarded? Was there any particular record kept of what reagent was used for what time period?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And these are all reagents, are they, we have here at this exhibit?

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MS. WELSH:
A. Yeah, the one that just went by there, I didn't see what it was.
CHAYTOR, Q.C.:
Q. I'm sorry. Here we go.
MS. WELSH:
A. Yeah, um-hm.
CHAYTOR, Q.C.:
Q. Okay, if we could have then, please, 2177? Those were the solutions and -
MS. WELSH:
A. Yeah, these -
CHAYTOR, Q.C.:
Q. - these are your -
MS. WELSH:
A. These would be the antibodies.
CHAYTOR, Q.C.:
Q. These are your antibodies, right. So these are the types of spec sheets then you've indicated that you would follow?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And what information, for example, on this spec sheet, what information would have been

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put into the computer?
MS. WELSH:
A. The information would have gone into the computer only the very first time that we used it.
CHAYTOR, Q.C.:
Q. Right, okay.
MS. WELSH:
A. So the very first estrogen receptor that we had gotten, we would have--that would have been inputted into the computer, and when we got new antibodies--each time a spec sheet came in, unless there was something changed, nothing would have been -
CHAYTOR, Q.C.:
Q. You didn't necessarily change it?
MS. WELSH:
A. No, nothing would have had to have been inputted.
CHAYTOR, Q.C.:
Q. Okay, and -
MS. WELSH:
A. Input, sorry.
CHAYTOR, Q.C.:
Q. And would all of this information though go

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into the computer or just -
MS. WELSH:
A. No, it would have just been--all that went into the computer was dilution and timing, incubation timing.
CHAYTOR, Q.C.:
Q. When you started doing ER/PR tests, did you understand the purpose of an ER/PR test?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you understand that it had--it was a diagnostic test?
MS. WELSH:
A. No, I understood it was a test to determine treatment.
CHAYTOR, Q.C.:
Q. To determine treatment, sorry, yes, okay. And was anything else explained to you about ER/PR in particular?
MS. WELSH:
A. No, other than it was just to determine what kind of treatment the patient would receive.
CHAYTOR, Q.C.:
Q. Okay. If we could look at P-2152, please?

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And this is called a special procedure request form, and it's early days. It's May 12th, 1998, but I take it that the DAKO machine is up and running at this point, and the pathologist is indicated to be P. Neil, we understand is Dr. Paul Neil, Western Memorial?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And you are the histotech indicated. This is your signature?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And then it's completed June 3rd, 2008.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. So is this a standard--and I just pick this one out. Is this a standard special procedure request one, is this a standard form that would come to you when an ER/PR test was requested?
MS. WELSH:
A. Um-hm.

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CHAYTOR, Q.C.:
Q. And we see down here under carcinoma, estrogen and progesterone receptor is circled.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. So this is what you would receive, I take it?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And what would you do then? It says up here at the top, there's no surgical path number on this, but there's a block number. So what would you do upon receipt of this, a request form such as this?
MS. WELSH:
A. Well, this would have come in from Corner Brook, so it would have come accompanied by block three, surgical number 3325-98 of Western Memorial. You see up on the top, there's another number there, 4425-98?
CHAYTOR, Q.C.:
Q. Yes.
MS. WELSH:
A. That would have been--I would have entered it

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in our computer and given it our surgical number, and for consult. We would have cut the slides and incubated the slides overnight and then did the estrogen and progesterone receptor.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. And -
CHAYTOR, Q.C.:
Q. Sorry, go ahead.
MS. WELSH:
A. When it was finished, we would send it back to Dr. Neil.
CHAYTOR, Q.C.:
Q. Okay, and what would go back to Dr. Neil?
MS. WELSH:
A. At the very beginning, probably with this number, Dr. Khalifa was reading all the ERs and PRs, so I don't know--right at the beginning, the slides went back to--didn't go back to them for interpretation. Dr. Khalifa did it, but then after a while, he sent this memo to all the pathologists that they would be getting their slides themselves. So then

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we would send a copy of this. We would send their slides. We would send them back their block and we would sent them controls.

CHAYTOR, Q.C.:

Q. And when it was a request such as this one from outside St. John's, would there always be a control slide sent back with the patient slides?

MS. WELSH:

A. Once they stopped reporting them at the Health Science, yes.

CHAYTOR, Q.C.:

Q. So I take it as long as Dr. Khalifa was there and interpreting them, the only thing that went back to the pathologist ordering the test was the result of the test?

MS. WELSH:

A. At first, when we first started, when he was actually resulting them, yes.

CHAYTOR, Q.C.:

Q. And then what about this form itself. Would this form go back?

MS. WELSH:

A. Yes, it would.

CHAYTOR, Q.C.:

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Q. Okay.

MS. WELSH:

A. Or a copy of it.

CHAYTOR, Q.C.:

Q. Or a copy of it, okay, and once Dr. Khalifa stopped reading or interpreting the slides, then the slides, the patient slides were sent back to the requesting pathologist along with this form, I take it?

MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And the control slides?

MS. WELSH:

A. And the control slides.

CHAYTOR, Q.C.:

Q. And were there always control slides sent to the authority outside the General Hospital? So for example, this is Western Memorial. Would they always get a control slide back?

MS. WELSH:

A. Yes. There was probably an occasion or two that there were--if we didn't have enough control slides that it may not have gotten sent back to different hospitals, but then

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they would have--the slides themselves would not have gone back until one of our pathologists had okayed the controls.

CHAYTOR, Q.C.:

Q. Okay. So in terms of then running control slides, perhaps you can explain to us how many control slides would be run per batch? And when I say per batch, even maybe you can take us back before that. On the DAKO machine, how many slides would fit on the DAKO machine?

MS. WELSH:

A. 48.

CHAYTOR, Q.C.:

Q. 48 slides, and I take it there were 48 spaces for slides which would include your control slide?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And there were days when it wasn't just ER/PR on the machine?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. There could be numerous other stains as well,

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or antibodies as well. So how would--would there always be a control run for ER and PR?

MS. WELSH:

A. There would be a number of ER/PR controls done, one for every institution that had requested them. We usually did the--a lot of times, did the--if we had a lot of ER and PR requests, we did those as a separate run. We would do all of the other antibodies on the first--on one run and then the ERs and PRs just by themselves with all the controls. We tried as often as possible to do a control for every institution.

CHAYTOR, Q.C.:

Q. So if you had--for example, at the time, the Grace would still be in operation, the Grace Hospital. So if you had a request from the Grace, a request from St. Clare's, several from within the Health Sciences, one from Western, one from Carbonear, you would run a control for each of those institutions?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And would be sent then out to St. Clare's, the

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Grace, they would get their own controls?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And you've indicated those, there were occasions when you didn't have enough controls, a pathologist within the Health Science would read the controls?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. So why would that ever happen? Why would it ever be a case that you didn't have enough controls to sent out to the pathologists who ordered the test?
MS. WELSH:
A. If we were just extremely busy and didn't get new controls, if we ran out of controls. It didn't happen very often. Most times we did controls for every institution. It would have been rare.
CHAYTOR, Q.C.:
Q. So were there times that your control bank became low -
MS. WELSH:

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A. Yes.
CHAYTOR, Q.C.:
Q. - and you didn't have many controls left?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And then there was a period of time -
MS. WELSH:
A. Then we would have to get somebody to give us new blocks to make controls from. The pathologists would do that.
CHAYTOR, Q.C.:
Q. But you're confident that before the patient slides ever went back to another institution -
MS. WELSH:
A. The controls were looked at.
CHAYTOR, Q.C.:
Q. - the controls were read by a pathologist?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And would that be signed off on the document?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:

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Q. So there wouldn't be any indication that the controls had been read?
MS. WELSH:
A. I think it was--there were times when you could write it -
CHAYTOR, Q.C.:
Q. Down here in the comment section.
MS. WELSH:
A. - you could write it down there, that the slides were -
CHAYTOR, Q.C.:
Q. Yes, and I'll show you a few forms where that in fact appears to be what's happened, and there's comments made.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And within then the Health Sciences, if you had three or four different pathologists ordering ER/PR tests, would there be a control slide produced for each of them or just -
MS. WELSH:
A. No, just one.
CHAYTOR, Q.C.:
Q. Just one. So one per institution?

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MS. WELSH:
A. One per institution.
CHAYTOR, Q.C.:
Q. And where would the control slide go then? How would all of the pathologists know that it's there ready to be read. What would happen to it?
MS. WELSH:
A. There was a reading room, it was called at the Health Science, in the pathology area, where all the pathologists were supposed to read their slides and there was one particular shelf that was marked controls. So that was where we would put all the control slides. So they would know that they were there.
CHAYTOR, Q.C.:
Q. Okay, and so I take it that the patient slides and the control slides were laid into the reading room?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And how would you know then when it was ready--the control slides could be removed? Would you do that?

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MS. WELSH:
A. Yeah, but they would--there was also another shelf where they would put slides to be filed, and they would put their slides back in there when they were done with them. Until then, we didn't take them back.
CHAYTOR, Q.C.:
Q. And was there any documentation or a sheet where people could check off to indicate that they had now read the control or anything like that?
MS. WELSH:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. And how would the next pathologist coming in know whether there's anyone else that needs to look at the control slide?
MS. WELSH:
A. I don't know. We just did what--that's what we were told to do with the slides, was to put them out there.
CHAYTOR, Q.C.:
Q. Okay, and was it also then the job of the technologist or the responsibility of the technologist to file the controls away after

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they had been read?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and if there were four or five patients, for example, who had slides run in that batch, how would the control slides be filed? Would they be filed with a particular patient?
MS. WELSH:
A. I'm not exactly sure how they would have been filed. I didn't really do the filing. That would have been some of the other technologists. I'm thinking they were filed with one--maybe with one particular patient and dated.
CHAYTOR, Q.C.:
Q. Okay, and was there a log kept of all the patients that would have been involved in that particular run of tests?
MS. WELSH:
A. We would have kept a copy of these request forms.
CHAYTOR, Q.C.:
Q. So the forms with the date? And I take it the date at the top is the date of request?

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MS. WELSH:
A. Yes, and the date at the bottom is -
CHAYTOR, Q.C.:
Q. So May 12th, and down here, June 3rd is when the test was run?
MS. WELSH:
A. When the test was run.
CHAYTOR, Q.C.:
Q. And when do you sign it?
MS. WELSH:
A. At the very end, just before I send it out.
CHAYTOR, Q.C.:
Q. So you sign it when it's ready to go back?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Or ready to go out, okay. And so this, the control slide for any particular run, if we were to try and trace back, we would have to look at these sheets and figure out the dates and find patients that all had their tests conducted on the same date?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:

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Q. And there would be no other record other than doing -
MS. WELSH:
A. There was no documentation back then.
CHAYTOR, Q.C.:
Q. Okay, and is that true right up until you left in April 2003?
MS. WELSH:
A. Until I left, yes.
CHAYTOR, Q.C.:
Q. So same process?
MS. WELSH:
A. It was, yeah. It's changed now, I believe.
CHAYTOR, Q.C.:
Q. Yes, I understand there's been some changes.
THE COMMISSIONER:
Q. Excuse me. How would you know, if you were a pathologist coming into the room, which control slides related to your slides? Was there something on the--I'm assuming, for example, there might be, in the control slide area, several control slides.
MS. WELSH:
A. Um-hm.
THE COMMISSIONER:

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Q. How would a pathologist know which control slide related to what he or she might be reading by way of slides -
MS. WELSH:
A. The control slides, I believe, if I remember correctly, were dated so that, say, the controls that I did on June 3rd would have said June 3rd and if their request form was dated June 3rd, well then they would know that those were their control slides.
THE COMMISSIONER:
Q. Okay.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. Ms. Welsh, did you ever check the control slides before putting them in the reading room or sending them out?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. So you would do that?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And did Ms. Butler also do that?
MS. WELSH:

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A. I can't speak for what she did. I'm assuming she did.
CHAYTOR, Q.C.:
Q. So you were trained though that that was part of your responsibility to check the external control before it was passed on to pathologists?
MS. WELSH:
A. I don't know if it was part of our responsibility. We just--Dr. Khalifa showed us, when we were first starting it, what it looked like and we did it just so that we wouldn't bring out slides that the controls didn't work, then why sent out all those slides to all those people and then realize that the controls didn't work. So that's why we looked at them first.
CHAYTOR, Q.C.:
Q. And what did Dr. Khalifa teach you to look for?
MS. WELSH:
A. The brown staining of the--in the tumour cells.
CHAYTOR, Q.C.:
Q. So he taught you to look for brown staining in the tumour cells?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay, and so I take it he looked through--he looked through the microscope with you?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Did you have a double-headed microscope at that time?
MS. WELSH:
A. Yes, we did. We did in the reading room.
CHAYTOR, Q.C.:
Q. In the reading room.
MS. WELSH:
A. We didn't in the lab.
CHAYTOR, Q.C.:
Q. Okay. So he spent some time with you there and showed you what to look for in your controls?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Is that the first time anyone had done that?

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MS. WELSH:
A. Yeah, pretty much.
CHAYTOR, Q.C.:
Q. And after Dr. Khalifa left, did anyone else spend time showing you what to look for in slides or how to run the testing?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. So Dr. Khalifa taught you to look for the brown staining?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay, and you would do that before you put the stains out or the slides, sorry, out. If we could look at P-2149, please, and page 14, please? And this again is the similar type of procedure request form, and this one, you'll see, has your name at the bottom, June 14th, 2002, and this one says the controls are checked by Dr. S. Parai, and they're positive.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:

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Q. And this is going out to--it's difficult to read.
MS. WELSH:
A. Paul Neil, I believe, Corner Brook.
CHAYTOR, Q.C.:
Q. Yes, it looks like it's Dr. Neil again in Corner Brook. So I take it this would be an occasion when there wasn't a control to send to Dr. Neil and so Dr. Parai checked.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And what do you recall of Dr. Parai's involvement in that regard?
MS. WELSH:
A. I don't have any recollection of--I don't know what you mean by -
CHAYTOR, Q.C.:
Q. Do you recall -
MS. WELSH:
A. - just with the--in this sort of an incident?
CHAYTOR, Q.C.:
Q. Yes.
MS. WELSH:
A. Not this incident in specific?

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CHAYTOR, Q.C.:
Q. I'm just wondering generally was any particular person assigned the responsibility for reading the controls?
MS. WELSH:
A. No. Not that I was aware of, no.
CHAYTOR, Q.C.:
Q. So you didn't understand that Dr. Parai, as site chief, would do that?
MS. WELSH:
A. No, I probably would have just given them to him because maybe when I took them out to the room, he was the person who was there.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. I would have given them to any of the--any pathologist who had ordered them themselves.
CHAYTOR, Q.C.:
Q. So you didn't have any sense, as a technologist working in the lab, you didn't have any sense that there was any particular pathologist that was overseeing this, the IHC issue that you could go to?
MS. WELSH:

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A. No.
CHAYTOR, Q.C.:
Q. And so you would just ask whoever was -
MS. WELSH:
A. Yeah, someone who had probably ordered ERs and PRs themselves, when I brought theirs out, and said "could you get back to me about the controls because I don't have any to send to Corner Brook" or whatever.
CHAYTOR, Q.C.:
Q. Okay, and this handwriting, is this your handwriting?
MS. WELSH:
A. That's mine, yes.
CHAYTOR, Q.C.:
Q. In the comments section?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay, and how would you know that Dr. Parai had checked the slides?
MS. WELSH:
A. He would tell me.
CHAYTOR, Q.C.:
Q. He would tell you?

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MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And then you would document it?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay. I'm just going to go back a page to page 13, and this one is also yours and this one is June 12th '02.
MS. WELSH:
A. It's probably the same--looks like the same day.
CHAYTOR, Q.C.:
Q. June 12th, yeah, same month, and so that's Dr. Parai checked the slides that day for you as well?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And June 12th again, and this one is--can you read the -
MS. WELSH:
A. It's Dr. Wadhwa from the Grace.
CHAYTOR, Q.C.:

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Q. He's from the Grace, is he?
MS. WELSH:
A. She.
CHAYTOR, Q.C.:
Q. Or she, I'm sorry.
MS. WELSH:
A. These are all the same day, June 14th.
CHAYTOR, Q.C.:
Q. June 14th, okay, and Dr. Parai checked them again that day?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And if we could have page 25 please and this one is ordered on June 27 and Dr. Ismil, is it?
MS. WELSH:
A. Ismil.
CHAYTOR, Q.C.:
Q. And where was Dr. Ismil?
MS. WELSH:
A. I'm not sure where she was.
CHAYTOR, Q.C.:
Q. Okay, but not at the Health Science Centre.
MS. WELSH:

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A. Not at the Health Science, no.
CHAYTOR, Q.C.:
Q. And again, this is faint, but it appears to be your signature and you've signed over in the corner that the controls checked -
MS. WELSH:
A. At Health Science.
CHAYTOR, Q.C.:
Q. - and positive.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay. And there's no name of a doctor?
MS. WELSH:
A. No, I didn't put that down there, no.
CHAYTOR, Q.C.:
Q. But it would have been a physician I take it or a pathologist would have -
MS. WELSH:
A. Oh yes.
CHAYTOR, Q.C.:
Q. And then page 26 of the same exhibit, Dr. Dankwa.
MS. WELSH:
A. He was in St. Anthony.

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CHAYTOR, Q.C.:
Q. Yes. And this is--down on the bottom again it says "ER/PR controls checked at Health Science and positive" and again your signature.
MS. WELSH:
A. Um-hm. I believe this is the same date as the one from Dr. Ismil.
CHAYTOR, Q.C.:
Q. They're both -
MS. WELSH:
A. July 3rd and July 4th.
CHAYTOR, Q.C.:
Q. This one is July 3rd and then this one is July 4th.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. Okay. On the side here it says, "NB, please return the block".
MS. WELSH:
A. That would have been his writing that he would have -
CHAYTOR, Q.C.:
Q. Dr. Dankwa.
MS. WELSH:

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A. Dr. Dankwa would have wanted the block returned.
CHAYTOR, Q.C.:
Q. And were the blocks normally returned?
MS. WELSH:
A. Yes, they were.
CHAYTOR, Q.C.:
Q. So, he's just giving a notice that--were there ever any complaints that blocks weren't returned?
MS. WELSH:
A. No. There may have been on occasion that a block wasn't returned -
CHAYTOR, Q.C.:
Q. But he's just giving a reminder.
MS. WELSH:
A. I think he was just reminding, maybe he had had one of those.
CHAYTOR, Q.C.:
Q. Okay. And then page 28, again, controls checked and this is July 18 now.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And this is your initials, I take it, PW.

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MS. WELSH:
A. Yes, it is.
CHAYTOR, Q.C.:
Q. And this is going out to Dr. Gallagher, it appears.
MS. WELSH:
A. In Gander.
CHAYTOR, Q.C.:
Q. And again, there's no physician noted, no pathologist, but would it have been a pathologist that -
MS. WELSH:
A. There would have been a pathologist who would have--it wouldn't just be me looking at them.
CHAYTOR, Q.C.:
Q. And in terms of running external controls on the DAKO machine, was there always at least one control per antibody?
MS. WELSH:
A. Yes.
THE COMMISSIONER:
Q. Ms. Chaytor, wherever you can find a spot, we'll take the luncheon break.
CHAYTOR, Q.C.:
Q. Okay, thank you. And did the control slides

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have any particular, other that you said there would be a date on the control slide, would there be any other identifying information on the control slide?
MS. WELSH:
A. Just what the control--what antibody was done. It would be labelled ER control, PR control.
CHAYTOR, Q.C.:
Q. And the date?
MS. WELSH:
A. And the date.
CHAYTOR, Q.C.:
Q. Do you recall a pathologist ever complaining that they'd received a control slide and it hadn't worked or that they weren't satisfied with it?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. That did happen?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And do you recall any specifics around that?
MS. WELSH:

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A. No.
CHAYTOR, Q.C.:
Q. Did it happen very often?
MS. WELSH:
A. No, it didn't happen very often, but it did happen on occasion and then things would be repeated.
CHAYTOR, Q.C.:
Q. And then it would be repeated?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. So, they would come back with the control slide had not worked and ask that it be -
MS. WELSH:
A. And then it would be repeated.
CHAYTOR, Q.C.:
Q. And do you recall any particular pathologist who brought that to your attention?
MS. WELSH:
A. No, I don't.
CHAYTOR, Q.C.:
Q. And do you recall, was that any particular time period or something that happened occasionally -

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MS. WELSH:
A. That's something that happened occasionally throughout the whole time I was there.
CHAYTOR, Q.C.:
Q. Okay. Did you know about internal controls? Did you know -
MS. WELSH:
A. No, I heard the words, but never really discussed internal controls.
CHAYTOR, Q.C.:
Q. And did you ever--what did you understand an internal control was?
MS. WELSH:
A. I understood them just to be portion of the tissue that would normally stain positive so that you would--it would be then a piece of tissue that was treated the same control as a different piece of tissue. So, it would have been the same piece of tissue, but -
CHAYTOR, Q.C.:
Q. So, part of the patient's tissue?
MS. WELSH:
A. Part of the patient's tissue, but I'd never really heard it in regard to ER and PR.
CHAYTOR, Q.C.:

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Q. Where did you learn about internal controls at all, even to know that there was--a control that would normally stain?
MS. WELSH:
A. I don't know, I just know it. I heard it somewhere, somewhere in my career.
CHAYTOR, Q.C.:
Q. So, it wasn't something you studied at school, I take it?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. It was during your work life.
MS. WELSH:
A. Yes, it was just something that I had heard at some point.
CHAYTOR, Q.C.:
Q. And if you had heard that at some point, what likely or who likely was the source of that information?
MS. WELSH:
A. Probably would have been a pathologist, I would assume, who would have mentioned it.
CHAYTOR, Q.C.:
Q. Okay. So, likely it would have come from a

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pathologist as opposed to another lab technologist?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Was it something that Dr. Khalifa pointed out to you?
MS. WELSH:
A. It could be. I don't know. I don't know exactly where I heard it. It was never made that big -- you know, it wasn't that big a discussion. It was just something that I remember hearing about, but I don't really know much about them.
CHAYTOR, Q.C.:
Q. And in relation to IHC stains --
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. Did you hear about it in relation to IHC stains, but not ER/PR specifically?
MS. WELSH:
A. I don't know where I heard it. I just know I remember hearing about them. I think some of the -- some of our other special stains that

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we would do on normal tissue you would have, but they were internal controls as well. So it could have been very well related to those special stains as well.
CHAYTOR, Q.C.:
Q. So it's something wherever you picked up the bit of knowledge that you have on it, it's something that you knew for a long time?
MS. WELSH:
A. Uh-hm. Well, I don't know how long. I don't know when I picked it up. I just remember hearing the words. I remember when you asked me about that. So I just know I heard the words.
CHAYTOR, Q.C.:
Q. And do you know if you knew that in -- well, you left in 2003.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So was that something you had learned only a year before, two years before, or something much longer?
MS. WELSH:
A. Oh, I don't know. Probably just a few years

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before.
CHAYTOR, Q.C.:
Q. Sorry?
MS. WELSH:
A. Probably just a few years before.
CHAYTOR, Q.C.:
Q. A few years before that?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Okay. It's a good place, please, Commissioner.
COMMISSIONER:
Q. We'll take the luncheon break. We'll meet again at five after two.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Please be seated. Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. Good afternoon, Ms. Welsh.
MS. WELSH:
A. Good afternoon.
CHAYTOR, Q.C.:
Q. If I could have please, P-2177 and it's page

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three, Registrar. These are the specification sheets I bought you to earlier, Ms. Welsh and this one here has a date written at the top, November 15th, 2000. It's probably difficult to tell just from that small handwriting, but do you know is that your handwriting?

MS. WELSH:

A. No, I believe that's Mary's.

CHAYTOR, Q.C.:

Q. Mary's, okay.

MS. WELSH:

A. It's just a -

CHAYTOR, Q.C.:

Q. That's a guess?

MS. WELSH:

A. Yeah, pretty sure.

CHAYTOR, Q.C.:

Q. And then if we go over to page four at the top it says, "the antibody gives an optimal staining at a dilution of 1 to 50 through to 1 to 100".

MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And I take it that's the type of range that

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you would be looking in diluting your antibody.

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. "And with the LSAB methods, when tested on formalin fixed paraffin embedded sections of human breast carcinoma", were you using the LSAB methods?

MS. WELSH:

A. I'm not sure what that stands for, I don't remember.

CHAYTOR, Q.C.:

Q. Okay. And then there's some other handwriting on the bottom of this page and it's 1 to 10, 1 to 20 right on up through to 1 to 50.

MS. WELSH:

A. That looks like it would have been a titration where we would have stained the slides with those different concentrations to see which worked the best.

CHAYTOR, Q.C.:

Q. To see which one would be the best. And then 1 to 10 is circled and the word "best" is written there.

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MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And again, is that your handwriting?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Okay. You think that's Mary's?

MS. WELSH:

A. I think that's Mary's.

CHAYTOR, Q.C.:

Q. Okay. And then on the document itself then is written on the first page of the document, "1" -

MS. WELSH:

A. 1 and 10.

CHAYTOR, Q.C.:

Q. - "1 and 10". So that would be the dilution that was determined, I take it, at this point in time, November 2000.

MS. WELSH:

A. That's what it looks like.

CHAYTOR, Q.C.:

Q. And the range that the manufacturer gave was 1 to 50 to 1 to 100, at least with the LSAB

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methods and you're not sure what that is and whether you've been using that method.

MS. WELSH:

A. We did peroxidase, antiperoxidase methods, and I don't know if that's the same thing or not.

CHAYTOR, Q.C.:

Q. Okay. So, insofar, as this is not within the range that's given by the manufacturer's spec sheets, were there times that you went outside the range noted on the spec sheet?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And this appears to be -

MS. WELSH:

A. This appears to be one of them.

CHAYTOR, Q.C.:

Q. - one of those times.

MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. And who would be involved then in making the determination that the best is 1 to 10 as opposed to anything else?

MS. WELSH:

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A. That would be the pathologist.
CHAYTOR, Q.C.:
Q. And who, in November of 2000 would be the pathologist that you would be consulting on that?
MS. WELSH:
A. I don't know, it could have been any of them. There's no one who was--Dr. Khalifa had already left by that time.
CHAYTOR, Q.C.:
Q. Yes. And then on page 7, I believe it is, this April 3, 2003. So, this is the month that you actually left.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And it looks like here it's indicated to be 1 to 50.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. So, those numbers that we see, those would be the actual -
MS. WELSH:
A. Those would be the dilutions.

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CHAYTOR, Q.C.:
Q. That's the dilutions, okay. And then at page 11, this is probably around the time that you're leaving, April 28, 2003, it's 1 to 20 as of that date.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. You also indicated this morning that Dr. Khalifa showed you how to look for external controls.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And I'm wondering, and you said you would look for the brown staining. What, in particular, would you be looking to see what had been stained?
MS. WELSH:
A. The nuclear staining of the tumour cells.
CHAYTOR, Q.C.:
Q. Okay. And were you able to identify what was tumour versus what was just regular tissue?
MS. WELSH:
A. Just barely. You had just--they would have

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been a very deep blue. This was how he showed them to us, is that they would be the deeper blue and a different size than the other cells rather and they would have the dark brown staining. We would just be looking at them for our own interest to make sure that they worked before we sent them out. We still depended upon the pathologists to let us know if the controls worked. So, I could have looked at a control, say, and thought it worked and the pathologist could say that it didn't. The ultimate responsibility was with the pathologist, not with me.
CHAYTOR, Q.C.:
Q. Okay. And I think then I had asked you, just before we broke for lunch, whether or not a pathologist had ever complained that a control slide hadn't worked and you had remembered some instances where that had been the case. In that situation, what would happen? I understood you to say that you would repeat the tests.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:

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Q. Would all of the tests for that day, all of the ER/PR tests for that day be re-ran?
MS. WELSH:
A. Yes, they would.
CHAYTOR, Q.C.:
Q. And how would you go about determining which ones needed to be redone?
MS. WELSH:
A. We would just redo all the ones that were done on that day. There was a spreadsheet of what would have been done on that particular day. We would have just repeated all of those. So, we made up a work sheet every day or what went on every run of every day. So, all of the surgical numbers would have been there and we just would have taken those out and repeated them.
CHAYTOR, Q.C.:
Q. Okay. So, how long would you keep those spreadsheets?
MS. WELSH:
A. I don't think there was any set amount of time that we would have kept them.
CHAYTOR, Q.C.:
Q. Was it ever a case that a pathologist from

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outside St. John's would complain that the control hadn't worked and get back to you to do a repeat?

MS. WELSH:

A. I don't recall any specific instance, no, because usually they were read at the Health Science before they were sent out.

CHAYTOR, Q.C.:

Q. During Dr. Khalifa's day -

MS. WELSH:

A. No, no, I mean, if I did them for Corner Brook, Grand Falls, Gander and the Health Science, by the time we packed them up and sent them out to those other hospitals, it probably would have been the next day and someone would have already looked at them at the Health Science.

CHAYTOR, Q.C.:

Q. So, the control for it, if there had been any done in house or for pathologists in house at the Health Sciences, that pathologist would have looked at his or her control before the test went out to the other regions or the other hospitals. And was that a practice, would you hold back on sending them until you

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heard back from -

MS. WELSH:

A. No, because we were sending controls anyway. So, if the controls didn't work, the onus would have been on the pathologist from the other hospital to send them back and say that they didn't work.

CHAYTOR, Q.C.:

Q. I'm just wondering if you had any recollection of that and then how you would identify what else needed to -

MS. WELSH:

A. I don't really have any recollection of that happening.

CHAYTOR, Q.C.:

Q. Okay. And what about in terms of, so if a pathologist came back and told you that a control hadn't worked, a pathologist from within Health Science, you remember that happened occasionally, would that be documented, that the test had to be re-run?

MS. WELSH:

A. No, I would have been just on the--we would probably have just used the same order form and would have signed it for the second time

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on the bottom saying "repeated".

CHAYTOR, Q.C.:

Q. Okay. And would any investigation be carried out to determine why did the control not work?

MS. WELSH:

A. No, because sometimes things just happened that there could have been any number of -- like, a step that got missed or something like that that you would investigate -- you would probably only investigate if it continued to happen. If you had somebody come back once in a three month period that something didn't work, you'd just repeat it and redo it, and if it worked the next time, that was fine.

CHAYTOR, Q.C.:

Q. So if you had a situation where in the three or four month period there were several repeats necessary, would that have been investigated?

MS. WELSH:

A. I don't remember that ever happening

CHAYTOR, Q.C.:

Q. So when -- your recollection of that, it was a very infrequent thing that a test would have to be repeated?

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MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And in any event there was no documentation, for example, nothing in the way of an occurrence report filled out saying that a test needed to be repeated?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And no log of any correction action taken to rectify the problem, nothing like that?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Would any pathologists ever complain that they hadn't received control slides?

MS. WELSH:

A. Not that I remember, no.

CHAYTOR, Q.C.:

Q. If we could look, please, at 2154, Registrar. Ms. Welsh, this is a fax from DAKO Diagnostics Canada Inc to yourself, and it's dated quite some time ago, from a David Brown of DAKO Diagnostics.

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MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And I believe it's July 15th, 1998, and it's re; final concentration of --
MS. WELSH:
A. PBS.
CHAYTOR, Q.C.:
Q. PBS reagents. What's PBS?
MS. WELSH:
A. Phosphate buffered saline.
CHAYTOR, Q.C.:
Q. And, "Hi, Peggy; As I mentioned, here are the final concentrations for the constituent reagents at single one times working strength. If you wish to make a 10 times or 20 times stock solution, just make that stock solution 100 mils or 50 mils and bring to litre with water. Please feel free to call me at any time if you have any questions", and then there's some calculations here.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Do you remember -- I don't know if you

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remember specifically what this is about, or perhaps you could explain to us what this would be about?
MS. WELSH:
A. Phosphate buffered saline was the solution that we used for making up the reagents, the antibody dilutions, and for the washing of slides, and this was the procedure for making that buffer.
CHAYTOR, Q.C.:
Q. And so were there any -- were there any particular problems that you had encountered at this time? Why are you asking Mr. Brown for assistance?
MS. WELSH:
A. Because we had just started using the DAKO machine, I think just before that, if I remember correctly, and I think we were -- I believe we were purchasing it already pre-made, and then we found out how to make it up and I believe it was less expensive to make it up ourselves.
CHAYTOR, Q.C.:
Q. So now you're making it up yourselves?
MS. WELSH:

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A. I'm not 100 percent sure. This is ten years ago, so it's --
CHAYTOR, Q.C.:
Q. And in terms of making it up yourselves, again I take it you would use your pipettes to do that, to try to --
MS. WELSH:
A. No, this would have been chemicals that we would have weighed out.
CHAYTOR, Q.C.:
Q. Okay. So it's nothing in terms of any volume that you would be measuring?
MS. WELSH:
A. It would have been volume, but we would be talking volumes of probably -- what does it say here. We were making a litre, 1000 mils, and we had volume metric cylinders for measuring those.
CHAYTOR, Q.C.:
Q. When you were doing your antibodies, would you make up a batch as you go or would you make it up for a period of time? How much would you normally make up?
MS. WELSH:
A. Probably make up about five millilitres at a

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time.
CHAYTOR, Q.C.:
Q. Five millilitres.
MS. WELSH:
A. When we were using the auto stainer, yes.
CHAYTOR, Q.C.:
Q. Okay, and so in terms of a concentration of one to ten, for example, like we saw on the spec sheet that I just showed you, what measurements then would that involve?
MS. WELSH:
A. Well, if I made five millilitres, that would -- I would use --
CHAYTOR, Q.C.:
Q. That's fine.
MS. WELSH:
A. Yeah.
CHAYTOR, Q.C.:
Q. One to ten is easier.
MS. WELSH:
A. One to ten, yeah, would be 500 -- no, that would be one to two. Fifteen microlitres for 1000. No, I can't remember. My figuring, you're in a bad spot to try to think the things out.

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CHAYTOR, Q.C.:
Q. Fair enough.
MS. WELSH:
A. I think it's probably -- one in ten would be ten microlitres of the antibody per millilitre of PBS.
CHAYTOR, Q.C.:
Q. So it's pretty --
MS. WELSH:
A. So it would be 50 in 5000.
CHAYTOR, Q.C.:
Q. Okay. So it's pretty minuscule in terms of what we're talking about in volume?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. If we could look, please, at 2156, Registrar, and I'll just take you through. This is a three page document and there's numbers up to 33. Are you familiar with -- do you recognize or remember this document?
MS. WELSH:
A. Yes, I do.
CHAYTOR, Q.C.:
Q. And perhaps you can tell us what does PAP

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stand for?
MS. WELSH:
A. Peroxidase anti-peroxidase.
CHAYTOR, Q.C.:
Q. Okay, and what is this document?
MS. WELSH:
A. That's the procedure for doing immunohistochemistry. Back when we started doing it, it was called peroxidase anti-peroxidase because that was the method that we -- that was used.
CHAYTOR, Q.C.:
Q. So this was what was used for doing all IHC?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Stains, and this was what was initiated when you started doing it?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Which would be back in the mid 1980s?
MS. WELSH:
A. No, this would have been --
CHAYTOR, Q.C.:

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Q. On the DAKO machine, is it?
MS. WELSH:
A. No, before that. This would have been when we started doing them -- when Dr. Chittal, one of our pathologists had gone to France for a sabbatical, and he had been working with IHC over there, and when he came back after his year sabbatical, that's when we started to do the procedure this way as opposed to the way we had been doing it from the mid 80s on. There are a few different procedures in here.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. From the way we used to do them. This is the procedure that he brought back.
CHAYTOR, Q.C.:
Q. And perhaps then you can just scroll down through it and tell us what ones the DAKO machine was in. Would all of this still pertain to the time when the DAKO came in in February or March of 1998?
MS. WELSH:
A. The reagents are pretty much the same. It's just the procedure would have changed a little

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in that they -- things were done on the machine itself. Like, it would say to put the slides for six minutes at 37. That would have been done on the machine.
CHAYTOR, Q.C.:
Q. Right.
MS. WELSH:
A. Transfer slides to 200 mils of methanol, and that should be 3 percent hydrogen peroxide, I think -- 30 percent hydrogen peroxide for 30 minutes.
CHAYTOR, Q.C.:
Q. So the 30 percent is correct?
MS. WELSH:
A. 30 percent is correct, yes. That would have been done actually on the machine itself. So we wouldn't have been transferring slides ourselves, the machine would have been doing it. We weren't doing this absolute alcohol chloroform acetone.
CHAYTOR, Q.C.:
Q. So now -- sorry, go ahead.
MS. WELSH:
A. When we started using the machine, we didn't use this any more.

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CHAYTOR, Q.C.:
Q. So was that why it's crossed out or do you know why there's certain portions here crossed out? Do you know anything about that?
MS. WELSH:
A. Those would be the things that weren't done on the machine, I'm assuming. I don't remember crossing these out, but --
CHAYTOR, Q.C.:
Q. So when the machine was brought in, was there an updated version of this document? Was the document updated?
MS. WELSH:
A. No, not to my knowledge.
CHAYTOR, Q.C.:
Q. So when you left in 2003, this was the same document?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And this was what was in effect in terms of your procedures for IHC?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:

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Q. This is it?
MS. WELSH:
A. Uh-hm. Yeah, this was the manual method, but the instrument was semi-automated, so it still did the same -- things were done in the same way pretty much.
CHAYTOR, Q.C.:
Q. And so when you were training then Mr. Green and Mr. Simms, would you have shown them this document in 2002/2003?
MS. WELSH:
A. I really don't remember. I may have showed it to them as in explaining the step by step thing that the machine would have done, but we wouldn't have followed this procedure.
CHAYTOR, Q.C.:
Q. And other than this then and the -- and samples of the spec sheet, such as the ones we've looked at, were there any other documents pertaining to IHC procedures and how they were to be carried out?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. If I could have, please, 2149, and page nine,

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please. Ms. Welsh, this is the same forms that I was taking you through this morning and we pointed out who was reading controls.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And this is just a sample of some of these forms that we've been provided with, excuse me, and they all pertain to ER/PR testing.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So special procedure request form, and it appears this one is from Dr. Denic, March 13th, 2002.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And this one is signed by you, P. Welsh.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. March -- it looks like 17th, '02, and this one has written in the comment section, "repeat", with an explanation point.

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MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. I take it, who would be writing this, is that you or Dr. Denic?
MS. WELSH:
A. That would have probably been Dr. Denic.
CHAYTOR, Q.C.:
Q. Okay, and note "block sent to Mayo Clinic. These are the only unstained slides we have", and it's Mary Butler's signature, April 3rd, 2002.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So this is a situation where, I take it, the pathologist was looking for a repeat, but the blocks had been sent off to the Mayo Clinic, it appears?
MS. WELSH:
A. But Mary would have repeated it because her name and the date is signed on the bottom, so --
CHAYTOR, Q.C.:
Q. Okay, her name --

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MS. WELSH:
A. She probably would have used whatever -- if we had extra unstained slides there, but we obviously didn't have the blocks. This writing that's there that says, "Blocks sent to Mayo Clinic", I don't even recognize that writing. That's not Mary's or mine.
CHAYTOR, Q.C.:
Q. And it's not yours, I take it?
MS. WELSH:
A. No, it's not mine.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. So I -- I'm thinking this looks like it was sent from -- maybe Dr. Denic wrote that or one of his secretaries who sent it over, so we could -- it would have been repeated on the slides that -- unstained slides that we had. It doesn't look like the slides were sent to -- that the blocks were sent to the Mayo Clinic for the ER/PR. It looks like they were sent for consult, and, therefore, the blocks weren't there for us to recut.
CHAYTOR, Q.C.:

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Q. Okay. You're thinking that Mary has signed here with a date --
MS. WELSH:
A. She would have repeated. She would have repeated it.
CHAYTOR, Q.C.:
Q. That the repeat would have taken place on April 3rd?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And we can certainly ask her to clarify that as well. There's another form here, and this is May 17th '02, and this doctor again --
MS. WELSH:
A. Wadhwa.
CHAYTOR, Q.C.:
Q. Thank you, and I believe this one is yours as well?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And you've signed it May 22nd, '02.
MS. WELSH:
A. Uh-hm.

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CHAYTOR, Q.C.:
Q. And this one in comments also indicates "repeat"?
MS. WELSH:
A. It was a repeat.
CHAYTOR, Q.C.:
Q. So that's a repeat of the prior test, I take it?
MS. WELSH:
A. That's what it looks like to be, because there's only one signature on it.
CHAYTOR, Q.C.:
Q. Yes. If I can have page 36, please, and this is Dr. Elms.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And the date appears to be -- I think we can get it better from the --
MS. WELSH:
A. July '02.
CHAYTOR, Q.C.:
Q. July, okay, July 2nd -- July 25th, I believe, '02.
MS. WELSH:

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A. Uh-hm.
CHAYTOR, Q.C.:
Q. And then you sign it July 30th '02?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And on this one we can also see that there are two signatures; yourself, July 30th '02, and then Mary Butler, please repeat ER/PR, and then it's signed August 28th '02?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So it looks like almost a month later this was repeated and Mary did the repeat, I take it, and that was Dr. Elms. If we could go back to page 10, please. Mr. Coffey is just pointing out that the surgical pathology number that we see here, which is May 13th, '02.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And it was a test run by Ms. Butler.
MS. WELSH:
A. Uh-hm.

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CHAYTOR, Q.C.:
Q. Signed May 16th, and then if we go ahead to page 12, it's the same surgical number.
MS. WELSH:
A. Okay.
CHAYTOR, Q.C.:
Q. And this is one which is repeated then on May 22nd by yourself.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So that seems to be the test which was repeated, okay, the same block.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Also the same block. Let's have a look; block 1D.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Block 1D. That appears to be the repeat that you did on the 22nd of May?
MS. WELSH:
A. Uh-hm.

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CHAYTOR, Q.C.:
Q. If we could go then, please, to page 37. Page 37, this is Dr Elms. I believe that's one I just showed you isn't it?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Thank you. Actually, no, it's not.
MS. WELSH:
A. Oh!
CHAYTOR, Q.C.:
Q. No, it's a different one. So we blocked out, obviously, the patient's name, but this is Dr Elms, though.
MS. WELSH:
A. Uh-hm
CHAYTOR, Q.C.:
Q. The same date. So that one was repeated, and then this is a new block, again repeated on the same date, and then page 38 should be a different lot number, but again Dr. Elms, same date, and a repeat then on August 28th '02.
MS. WELSH:
A. It looks like there's quite a bit of difference in the timing there.

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CHAYTOR, Q.C.:
Q. Yes.
MS. WELSH:
A. It was first done on the 30th and not repeated until the 28th of August.
CHAYTOR, Q.C.:
Q. Now this would have been about -- less than a year, eight or nine months, I guess, before you left your employ.
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Six to eight month perhaps. Do you recall anything about this time period of having any repeats shortly before you left?
MS. WELSH:
A. No, I don't.
CHAYTOR, Q.C.:
Q. And when a repeat would occur, for example, the --it's quite a bit of time period, as you say, and I'm just wondering about what would have happened in terms of tracking down the other tests which were also run on July 30th, 2002, to repeat those as well?
MS. WELSH:

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A. They probably would not have been tracked down with that much of a --
CHAYTOR, Q.C.:
Q. Time difference?
MS. WELSH:
A. Time difference, because we would not have known that there would have been that problem with them, and sometimes -- maybe they just hadn't been repeated. We can only go by what the pathologist would tell us about the controls.
CHAYTOR, Q.C.:
Q. If we could go back --
MS. WELSH:
A. So that was a month later.
CHAYTOR, Q.C.:
Q. Sorry, yes, and if we could go back, please, to page nine. This original test, it appears, was done March 17th and a repeat on April 3rd.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. What about a two week difference? Would the tests that were also run on March 17th, if there were any other ER/PRs, would they also

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have been repeated?
MS. WELSH:
A. I don't think so because we would have at that time sent controls with all of the slides to the other hospitals. We can't just automatically assume that because it was repeated that the controls didn't work. They just may not have been happy with the quality of the section or something like that, but we would have -- because every hospital would have gotten their own set of controls.
CHAYTOR, Q.C.:
Q. Would any inquiry be made or any communication as to whether or not, well, what was the reason for the repeat?
MS. WELSH:
A. Probably not. You would have to--we were doing tens of thousands of slides and they just would have come to us and we just would have repeated them.
CHAYTOR, Q.C.:
Q. And again, there would be no document filled out which would indicate the reason for the-- or any inquiries made as to why, so that it could be determined if other tests needed to

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be redone as well?
MS. WELSH:
A. No, there was no documentation required.
CHAYTOR, Q.C.:
Q. And if we could go back, please, to page 36, and I'm just bringing to your attention, Ms. Welsh, ones which you are involved in signing off on.
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And this is again just for a limited period of time in 2002, and this certainly appears to be that these would have been all the same batch. So on July 30th '02, certainly any that Dr. Elms ordered, at least three anyhow that he ordered that day, were repeated then August 28th?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And whether or not there were other pathologists who had tests on July 30th, you don't think that would have been checked at the time?

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MS. WELSH:
A. Probably not, no.
CHAYTOR, Q.C.:
Q. Because this certainly didn't--it seems to-- may indicate that there was a problem with the controls for him and certainly it was three different surgical numbers. So it wasn't just something peculiar to a particular test, according to what we're looking at here. It was something that -
MS. WELSH:
A. I can't give you any explanation for that. I don't know what his reasoning would be.
CHAYTOR, Q.C.:
Q. And again now, I just brought you to the ones in which your name appeared, but this is a period of time in '02 from, I believe the first one that I brought you to was around March, middle of March, March 17th, 2002 up until July 2002, and there's 1-2, two and then three on the 30th. So certainly five tests in that time period which you yourself were involved in.
MS. WELSH:
A. Um-hm.

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CHAYTOR, Q.C.:
Q. Does that seem to be an inordinately high number of repeats on ER/PR in that time period, from March to July of 2002?
MS. WELSH:
A. I don't know, probably. I don't remember having to repeat all that many. There seems to be five in--what's that, a four-month period?
CHAYTOR, Q.C.:
Q. Yes. For just yours, yes, okay, so that would be about the rate of repeats, would be around--that would be in keeping with your recollection, probably five in a four-month period, for yourself personally?
MS. WELSH:
A. I don't know. I don't remember how many repeats we would have done prior to or after that, because there was no documentation of things like that and we were running hundreds of slides per week.
CHAYTOR, Q.C.:
Q. And nobody was keeping track?
MS. WELSH:
A. There was no record keeping of that. This was

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it, as far as record keeping was.
CHAYTOR, Q.C.:
Q. Do you recall any interruptions in the lab while you were there? Were there any--for example, were there any labour strikes?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And when do you recall that happening?
MS. WELSH:
A. When I was--in my whole time there?
CHAYTOR, Q.C.:
Q. Well, at this--from when you went with IHC.
MS. WELSH:
A. Okay, so that would have been '97. We went--we were on strike in--I don't know if it was the--2000 maybe, and I know in 2002. I can't remember the exact dates. I know there were several strikes. We had a--there was a wildcat strike at one point. I think that was in 2001 maybe, probably three times.
CHAYTOR, Q.C.:
Q. And what would happen then, particularly with you and Mary assigned to the IHC lab, what would happen in those situations? Would one

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of you have to remain on the job or what happened? Who filled in for you, if anyone?
MS. WELSH:
A. In the labour disputes, there was--for those, after we started doing those, one of us was on call for emergency situations. So if they needed to have an immunoperoxidase done, they called us in to do it. We weren't actually on the job, but we were there if we needed to go in. I remember going in once or twice for one of the strikes, but I don't remember exactly which one it was.
CHAYTOR, Q.C.:
Q. So otherwise testing, IHC testing was on hold -
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. - unless it was an emergency?
MS. WELSH:
A. Because there was very little surgery or pathology being done anyway when the labs weren't operating.
CHAYTOR, Q.C.:
Q. And what about did any manager ever fill in?

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Did Mr. Gulliver or Mr. Dyer, to your knowledge, ever carry out the IHC testing?
MS. WELSH:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. And any other--anything else that would have interrupted the working of the lab while you were there?
MS. WELSH:
A. No, not that I recall.
CHAYTOR, Q.C.:
Q. Were you there when--we've heard reference to a flood. Were you there then or is that -
MS. WELSH:
A. No, that was after.
CHAYTOR, Q.C.:
Q. That's after your time. Do you recall, while you were in the IHC lab, any issues being brought forward of problems with fixation of the tissue?
MS. WELSH:
A. Breast tissue is one of the tissues that there was always problems with fixation, because of the nature of the tissue itself. It was fatty tissue and then the tumour would have been

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hard tissue, and fatty tissue never fixed very well. It's very difficult to get good fixation in breast. So that was an issue.
CHAYTOR, Q.C.:
Q. Okay, and was that discussed amongst you and Mary and the lab techs that eventually come on? Was that an issue, for example, that was discussed with Mr. Green and with Mr. Simms when they came on?
MS. WELSH:
A. We weren't responsible for the fixation, so it may have been discussed in that--in just saying that sometimes the breast tissue is very difficult to cut and they would have known that because having worked at St. Clare's, they would have done a lot of cutting of breast tissue anyway. Pathologists or residents did the grossing on the breast tissues and they were the ones who took the sections. So if the sections were too thick and didn't fix properly, we had no control over that.
CHAYTOR, Q.C.:
Q. Okay. So what you're saying is in terms of the fixation issue, it was well known amongst

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the lab technologists that there was a fixation issue, that it wasn't--you had no control over it, either it was something that originated outside the lab in the OR -

MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. - and that also there may have been fixation issues because of the thickness of the slices at the--when the tissue was grossed by the pathologist?

MS. WELSH:

A. Um-hm.

CHAYTOR, Q.C.:

Q. Okay, and was it something that was also well known then amongst the pathologists?

MS. WELSH:

A. I can't speak for what was known among pathologists.

CHAYTOR, Q.C.:

Q. Okay. So you didn't hear anything discussed or any discussion around that?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

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Q. And in terms of any times when you would have been assisting with the grossing, do you recall any pathologist bringing it to your attention or making any comment?

MS. WELSH:

A. I hadn't assisted with grossing for probably 12 to 15 years since I left, before I left.

CHAYTOR, Q.C.:

Q. So that's not something that you were ever involved in after?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Okay. But it's something that should have been apparent in the grossing of the specimen, the fixation issue?

MS. WELSH:

A. Sorry, I don't understand?

CHAYTOR, Q.C.:

Q. When the specimen is being grossed, would the fixation issue be apparent at that point?

MS. WELSH:

A. Would the fixation issue be apparent? I'm not understanding what you're trying to ask.

CHAYTOR, Q.C.:

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Q. That's fine. I'm just wondering if at the time when the tissue is being grossed, and you talked about the thickness of the slices, would any issue of fixation be apparent? Would you expect any issue of fixation to be apparent at that point in time?

MS. WELSH:

A. No, that would be--the only thing that would be apparent at that time would be that the section was too thick. Sometimes when the grossing was done, the tissue was not always completely fixed at the time. It would fix afterwards as well, after it was sliced. It went into fixation on the tissue processor as well.

CHAYTOR, Q.C.:

Q. Okay, and how would it be apparent to you then as a lab technologist that there's a fixation issue?

MS. WELSH:

A. Well, if you try to cut the section and it's not properly fixed, it's very difficult to cut a section, especially fatty tissue. It doesn't hold together in the wax.

CHAYTOR, Q.C.:

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Q. And what would you do in that situation?

MS. WELSH:

A. We'd do the best that we could.

CHAYTOR, Q.C.:

Q. And when you're actually beyond the cutting and making the blocks and at the stage you're making the slide, was there also times when fixation was an issue at that stage?

MS. WELSH:

A. Well, that was what I was talking about, we're cutting the slides.

CHAYTOR, Q.C.:

Q. Oh, cutting the slides.

MS. WELSH:

A. That was when you would--that's what I meant by difficult to cut.

CHAYTOR, Q.C.:

Q. Yes, okay.

MS. WELSH:

A. When you're cutting sections.

CHAYTOR, Q.C.:

Q. So at that point in time, would you go back to the pathologist and, for example, ask for another block, a different block?

MS. WELSH:

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A. I've done that.
CHAYTOR, Q.C.:
Q. And did you explain to the pathologist why another block was necessary?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And what would you tell him or her?
MS. WELSH:
A. That the tissue wasn't fixed and I needed another block because I couldn't get a section. But we would only go back if we couldn't get a section. Sometimes we could still--we would manage to cut a section.
CHAYTOR, Q.C.:
Q. And was there ever any documentation of that, of problems with -
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. So that wasn't recorded anywhere?
MS. WELSH:
A. No, there was very little documentation of anything.
CHAYTOR, Q.C.:

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Q. And so whether then you may go back and tell the pathologist that you need another block, if necessary, other than that, there'd be no communication further on the fixation issue?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. Did you also have experience with tissue washing off slides?
MS. WELSH:
A. Yes, that happened sometimes.
CHAYTOR, Q.C.:
Q. Okay, and what would cause that?
MS. WELSH:
A. That would be caused by several things. One could be improper fixation or processing of the tissue. Another could be if the tissue was mostly all fatty tissue and didn't adhere to the slides. The antigen retrieval itself was very difficult on the tissues. We were pretty well boiling tissue in a hot acid. So sometimes the tissue could certainly wash off the slides then.
CHAYTOR, Q.C.:
Q. And were you aware of the significance or

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importance of fixation for the tissue? Would that be something that you would have been taught?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and was that--were you particularly aware of that for ER/PR?
MS. WELSH:
A. No, not any more than any other stain that we were doing.
CHAYTOR, Q.C.:
Q. Would you also have occasion to observe any bubbling of the tissue on the slides?
MS. WELSH:
A. No, not really. I don't recall. I don't really even understand what you're meaning by bubbling of tissue.
CHAYTOR, Q.C.:
Q. Of any folding or any -
MS. WELSH:
A. There's a difference in a fold and a bubble.
CHAYTOR, Q.C.:
Q. Okay, so no bubbles, but -
MS. WELSH:

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A. No bubbles that I can recall.
CHAYTOR, Q.C.:
Q. But you can recall folds?
MS. WELSH:
A. Sometimes there would be folding in the tissue. You have to appreciate, you're cutting a piece of fat that has been infiltrated with wax and sits in a wax block and we're cutting at three microns, which is three one-thousandth of a millimetre. So when you're trying to cut a piece of tissue that thin and pick it up on a slide, sometimes there is going to be some folding.
CHAYTOR, Q.C.:
Q. So it would fold through that process?
MS. WELSH:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And what about any holes in the tissue?
MS. WELSH:
A. You would get holes in the tissue if it's not properly processed or fixed, and that usually happened when the section was a bit too thick.
CHAYTOR, Q.C.:
Q. When it was -

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MS. WELSH:
A. When it was grossed at first, if it was a bit thick.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. That was usually in the fatty part of the tissue and we were--or I was unaware that that was all that important, the fatty part of the tissue. I always thought it was the tumour tissue that they were really interested in.
CHAYTOR, Q.C.:
Q. Okay. So did anyone explain to you any importance to having both normal tissue and the tumour on the slide?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. So you weren't aware of that?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And I take it you've since become aware of that?
MS. WELSH:

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A. Yes.
CHAYTOR, Q.C.:
Q. And when did you learn that?
MS. WELSH:
A. From reading things on the transcripts from here.
CHAYTOR, Q.C.:
Q. From here?
MS. WELSH:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. When you talked about internal controls and breast epithelium and stuff, but I had no knowledge of that before that.
CHAYTOR, Q.C.:
Q. So in preparing the slides at the time, that wasn't something that you were aware that you should be trying to concentrate on?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and with respect to any issue of fixation, do you recall whether or not there

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was any steps or measures implemented to try and deal with the issue, while you were there?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. Did you, as a technologist, other than go back to the pathologist and ask occasionally for a different block, was there anything else that you could do in the technical end to try and address poor fixation?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. Was there times when reprocessing took place?
MS. WELSH:
A. I believe there was. I know St. Clare's would reprocess some blocks, but I don't believe at the Health Science that we reprocessed very many.
CHAYTOR, Q.C.:
Q. And how would you know that St. Clare's would do that?
MS. WELSH:
A. I think I read that somewhere too.
CHAYTOR, Q.C.:

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Q. Oh, okay. So you don't recall it being a common occurrence at -
MS. WELSH:
A. At the Health Science, no.
CHAYTOR, Q.C.:
Q. - at the Health Sciences, and when it would occur, what would be the purpose? Why would you reprocess a block?
MS. WELSH:
A. To cut a better section. Reprocessing, to put it back through the processing machine would be so basically taking the water out and putting wax in, so I guess it would just have been done to try to cut a better section than you could get the first time. I'm not sure if it was--if the fixation would have changed or not, because the initial fixation would have already taken place and the processing would have taken place and then if you just went back to reprocess, you're starting right at alcohol as opposed to formalin.
CHAYTOR, Q.C.:
Q. And were you aware of any dangers or damage that could be caused to the tissue in doing--in reprocessing?

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MS. WELSH:
A. Not at the time, no.
CHAYTOR, Q.C.:
Q. Okay, and when did you become aware of that?
MS. WELSH:
A. In reading the things from here.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:
A. I've learned a lot in the last month that I had never heard in all the time I was doing the work.
CHAYTOR, Q.C.:
Q. And Ms. Welsh, where, in particular, have you learned that? Is it through anybody's evidence in particular that you've listened to?
MS. WELSH:
A. Probably the woman from Mount Sinai.
CHAYTOR, Q.C.:
Q. Trish Wegrynowski?
MS. WELSH:
A. Yeah. Things that she had talked about, I had never heard about before.
CHAYTOR, Q.C.:

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Q. Do you recall pathologists ever complaining about--other than the control issues, did pathologists ever complain about the quality of the slides?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. No complaints about -
MS. WELSH:
A. I mean, I'm sure they did at some particular time, but nothing stands out.
CHAYTOR, Q.C.:
Q. So nothing of such frequency -
MS. WELSH:
A. Nothing of such frequency that it would have caused any concern, because when we would do the procedure, we would send the slides out and we'd send the controls out, and unless someone came back to us and said "there's something wrong with this," we assumed everything was fine. People tend to always tell you when you do a bad job, but they don't tell you when you do a good job, so you assume you're doing a good job if you don't hear anything opposite.

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CHAYTOR, Q.C.:
Q. And that's true in whatever profession.
MS. WELSH:
A. Exactly.
CHAYTOR, Q.C.:
Q. Okay. So nothing of a frequency in terms of complaints that would stand in your mind -
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. - or of a severity, I would take it -
MS. WELSH:
A. No, we thought we were doing a wonderful job.
CHAYTOR, Q.C.:
Q. And I take it based on what you've heard in the past couple of weeks, you have some concern about that now?
MS. WELSH:
A. Well, I don't feel--yes, I do have. I did the best I could, what I thought was the best I could do at the time.
CHAYTOR, Q.C.:
Q. And with the knowledge that you had.
MS. WELSH:
A. With the knowledge that I had and the training

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that I had.
CHAYTOR, Q.C.:
Q. Once Dr. Khalifa left, was there anyone else that you could go to as a resource person in IHC?
MS. WELSH:
A. There probably, if I would have had a problem with anything, I probably would have spoken to Dr. Chittal because he was the one who sort of introduced this method that we were using when he came back from France. So I kind of thought of him as being a little more knowledgeable about the technical aspect of it.
CHAYTOR, Q.C.:
Q. And overall or in general, how were the relations between the technical and the medical staff? Were there any issues or did it appear to be a good cordial working relationship?
MS. WELSH:
A. I think it was a cordial working relationship. We didn't interact all that much, everybody was busy doing their part of the job.
CHAYTOR, Q.C.:

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Q. So no issues or tension that you were aware of?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And if you did have a question or a problem regarding the test or even, for example, in coming up with new material for control slides, were the pathologists approachable?
MS. WELSH:
A. Yes, they were.
CHAYTOR, Q.C.:
Q. And helpful if you raised any questions?
MS. WELSH:
A. Well, it was hard to get control slides sometimes, control tissue sometimes, we would ask them to pick out some cases for us and we may have had to wait awhile before they would get back to us on those, so that would have been times that we may have been very short on controls.
CHAYTOR, Q.C.:
Q. But other than that?
MS. WELSH:
A. No, our working relationship seemed to be

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quite good.
CHAYTOR, Q.C.:
Q. Okay, and do you recall Dr. Ejeckam?
MS. WELSH:
A. Vaguely.
CHAYTOR, Q.C.:
Q. Okay, and did you actually work with him?
MS. WELSH:
A. I worked with him many years ago when he was there, decades ago I remember him. I didn't-- I don't think I actually worked with him, he came just a few months before I left and I said this even when I talked to you before, I don't have much recollection of him being there. I was busy at that time for the last couple of months in training Les and I think Dr. Ejeckam worked mostly with Mary. I remember seeing him there, but I didn't realize that he was as involved as he was.
CHAYTOR, Q.C.:
Q. And when you worked with him decades before, that was at the General Hospital?
MS. WELSH:
A. I just remember him from decades--from about twenty years before. I don't know if he was

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at St. Clare's or at the General, I just remember him.
CHAYTOR, Q.C.:
Q. And he came then six months or so before, then you leave in April of 2003?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So you don't remember much interaction with him in that time period?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And did you have any sense that he was more involved in the IHC lab than other pathologists?
MS. WELSH:
A. No, because I don't really remember him.
CHAYTOR, Q.C.:
Q. So you think if that were the case, you would see him around?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. The quality of control slides in picking

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control slides or the quantity, sorry, I should say of control slides and that becoming low, whose responsibility was that, to make sure you had a good bank of control slides?
MS. WELSH:
A. I guess that would have been our responsibility, the technologists, to make sure that we kept up, but if we asked the pathologists to give us a list of the good ER/PR controls and we didn't get any back from them for awhile, well you keep depleting what you had.
CHAYTOR, Q.C.:
Q. And the Commissioner has heard, I think, with respect to Dr. Ejeckam that he had raised some issues with certain stains, I believe there were eight of them and two of which were ER/PR in April of 2003. And I realize again that's the same month that you left your employment, do you have any recollection of those issues that were raised at that time?
MS. WELSH:
A. No, I don't and that would have been the time that I was training Mr. Simms because he had come over to work in our hospital in March, so

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my last five or six weeks of work was spent just with him. So I believe Mary would have been more involved with Dr. Ejeckam and that-- I don't even remember hearing that.

CHAYTOR, Q.C.:

Q. So you don't even remember hearing any issue.

MS. WELSH:

A. I don't.

CHAYTOR, Q.C.:

Q. And in terms of your training of Mr. Simms at that time, how long would you have spent with him in terms of the IHC component of your work?

MS. WELSH:

A. Probably two to three weeks.

CHAYTOR, Q.C.:

Q. In the IHC portion of the lab?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. If we could look at P-0113 please? So I take it then, Ms. Welsh, you don't recall any suspension in those stains at the time?

MS. WELSH:

A. No.

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CHAYTOR, Q.C.:

Q. There are three memos that were written by Dr. Ejeckam and this is the first one, which would be April 4th, 2003, and you would be in your job at that time?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And this was written to the pathologists, St. Clare's and out of town hospitals, and this is the notification that the stains have remained unreliable, erratic, and therefore unhelpful.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And that's copied, it says, to Barry Dyer and all technical staff on immunohistochemistry.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Did you receive a copy of the memo?

MS. WELSH:

A. No, I did not.

CHAYTOR, Q.C.:

Q. You did not?

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MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Do you know if any of the technologists -

MS. WELSH:

A. I can't speak for any of the others, but I know I didn't.

CHAYTOR, Q.C.:

Q. And you were also unaware that this had taken place?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And if we could look, please, at P-2155? April 22nd, 2003, so it's probably down to your last couple of days of work and I realize this is not written to you, it's written to Barry Dyer, Mary Butler and it's not signed. You see we do have LSAB written here. This is not signed but it comes from DAKO, you see up here?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And this talks about, "I have taken the time

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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'm sure we can have this whole situation ironed out in no time."

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. He goes on to say "As a general comment, it is going to be important for the future of consistently standardized results that all tissues and fixed and processed with identically as possible. Since your control tissues appear to be staining excessively, it is reasonable to think that variability in staining is due to a variability in tissue preparation." And it goes on to say, "However, it might be a good idea to get some guidelines for the other hospitals, so that you always know what you are dealing with, for example, send a letter saying that all specimens must be fixed between 18 to 24 hours in 10 percent neutral buffered formalin." And it goes on to the next page--it deals with different stains which include the ER/PR and

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"as discussed with these three antibodies, extend all primary antibody dilutions to 60 minutes, perform antigen retrieval using target retrieval solution by your previously employed vision where a boiling method, both ER and PR should work at one to fifty." And over here we see "97 degrees". The idea of extend all primary antibody dilutions to 60 minutes, how did that compare to what you had been doing?

MS. WELSH:

A. I think we had been using 30 minutes.

CHAYTOR, Q.C.:

Q. Thirty minutes, so it should work, it says, at one to fifty.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And then that's another stain, should be at one to twenty. "If the staining is still inadequate, you should try using the high pH target retrieval solution for antigen retrieval. The high pH buffer produces the best results for all three of these antibodies." I take it are all three of

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these--well the first one is obviously ER/PR and what's the third one?

MS. WELSH:

A. Cylin D1, that's not a breast -

CHAYTOR, Q.C.:

Q. That's not a breast, okay, right. It goes on to say, "The high pH buffer produces the best results for all three of these antibodies, although tissue damage or loss can occur if the tissues are improperly fixed or improperly trimmed of fat. It is important to note that all three of these antibodies are nuclear markers. It has been our experience that while a poor antigen retrieval can yield successful results with the EnVision polymer, K1491, other methods of detection can yield better results for these nuclear markers." What would you have been using?

MS. WELSH:

A. We used the EnVision polymer.

CHAYTOR, Q.C.:

Q. Okay, and did you not know that these antibodies were nuclear markers?

MS. WELSH:

A. Yes.

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CHAYTOR, Q.C.:

Q. So any -

MS. WELSH:

A. That just means that that's where the staining would occur, would be in the nucleus of the cell, as opposed to the cytoplasm.

CHAYTOR, Q.C.:

Q. And you were aware of that?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And so in terms of whatever tweaking took place and advice received by Mary and Mr. Dyer back in 2003 from DAKO, you weren't aware that any of this was taking place?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. You were aware, however, the issue that there's some discussion in here of fixation issues and you were aware of some issues of fixation have been identified prior to this?

MS. WELSH:

A. This is all -

CHAYTOR, Q.C.:

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Q. If the issue of fixation in terms of your own experience.

MS. WELSH:

A. Yes, from my own experience.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-2151? And this is a performance development form, we understand this would be a performance evaluation -

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. That you would have had during your employ and this one is for the time period, January 1st, 1999 to December 31st, 1999.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And it says next evaluation day, it looks like January, 2003, and you will see that we just include this to get an idea of the same, the kinds of issues on which you would have been evaluated.

MS. WELSH:

A. Uh-hm.

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CHAYTOR, Q.C.:
Q. And there's been a redaction of any personal information. And this is signed by yourself, January 11th, 2000 and by Mr. Gulliver and is this Mr. Whalen?
MS. WELSH:
A. Yes, he would have been--that, if I recall, was a glowing recommendation.
CHAYTOR, Q.C.:
Q. I'm sorry?
MS. WELSH:
A. That was a glowing performance evaluation, yes.
CHAYTOR, Q.C.:
Q. And it's tri-annual, so every three years that you would have one.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And did they happen? Did you have an evaluation every three years?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And this is the only one that we have, did you

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have others?
MS. WELSH:
A. Not that I recall.
CHAYTOR, Q.C.:
Q. This was it, and it was a good one.
MS. WELSH:
A. And it was a good one.
CHAYTOR, Q.C.:
Q. Okay, and in terms of the kinds of things that--so in terms though, Ms. Welsh, you had quite a length employment.
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. You had one evaluation.
MS. WELSH:
A. I had one evaluation probably right after my third year probationary period and then I remember having this one.
CHAYTOR, Q.C.:
Q. And in terms of clients then to provide care service which is centered on the client identifies the client served by the individual group team, monitors outcomes of care service, evaluates how well the care of service

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provided meets the needs of clients, what did you understand that you had to do to meet those objectives?
MS. WELSH:
A. I would take that as just doing the best job I was able to do for the care of the patients. You can see there wasn't much written there under, where Terry would have written his comments. We really weren't a client centred sort of -
CHAYTOR, Q.C.:
Q. So maybe that didn't pertain to you?
MS. WELSH:
A. Yeah, that wouldn't pertain, I don't think, because we didn't deal actually with the client.
CHAYTOR, Q.C.:
Q. And learning and development, maintains the knowledge, skills and abilities necessary to perform job responsibilities. And I take it that was a--that was part of your glowing evaluation?
MS. WELSH:
A. Well I would have attended the annual conferences and that sort of thing, but that

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would have been the only extra training that we would have gotten, other than what we just learned on the job.
CHAYTOR, Q.C.:
Q. And I take it nobody, there was no feedback given to you to do anything more than what you had done?
MS. WELSH:
A. Oh no, no.
CHAYTOR, Q.C.:
Q. And was there any opportunity provided to you -
MS. WELSH:
A. That was none.
CHAYTOR, Q.C.:
Q. Or suggestions that there's other things you should be doing?
MS. WELSH:
A. Oh no, had there been, we would have all jumped at the chance of it, but there was never any offered to us, there was no money for that sort of thing.
CHAYTOR, Q.C.:
Q. So was that something that you brought up from time to time and were told the resources

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weren't there?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. So you would ask for additional training and were told -
MS. WELSH:
A. Well it was just sort of common knowledge that it was no good to ask to go on any kind of courses or anything because there just was no money. We saw the kind of meetings that they had, the administration and management were just trying to save money, as opposed to spend it on sending us off for any kind of educational thing.
CHAYTOR, Q.C.:
Q. And was that discussed with your manager?
MS. WELSH:
A. I don't remember a specific discussion with managers, no, I know we sort of talked about it amongst ourselves.
CHAYTOR, Q.C.:
Q. And the quality focus portion, the eight dimensions of quality provided framework for the quality focus competency, the eight

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dimensions of quality are continuity, safety, competence, acceptability, effectiveness, appropriateness, efficiency and accessibility.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And what, in terms of your role in the lab, what kinds of things could that be referring to?
MS. WELSH:
A. I don't know, I guess the competence would be that I was competent to do the work. And efficiency and accessibility, well we know what those mean, but as for the rest of it, I don't remember. It obviously wasn't very much written in that spot either.
CHAYTOR, Q.C.:
Q. And again, I take it there was no concerns expressed to you?
MS. WELSH:
A. No, no.
CHAYTOR, Q.C.:
Q. And did you raise any concern? Did you raise any concern about whether or not, for example, learning and development, whether or not there

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were extra things that you should or could be doing?
MS. WELSH:
A. No, probably not.
CHAYTOR, Q.C.:
Q. And I take it while I hear what you're saying today, having heard Ms. Wegrynowski, I take it at the time when you're carrying out your job, you felt that you were knowledgeable and well qualified to do the IHC testing at the time.
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. Based on the knowledge that you -
MS. WELSH:
A. Based on the knowledge that I had, the reading that I had done myself, I felt quite competent.
CHAYTOR, Q.C.:
Q. And any quality control or quality assurance measures that were in place in the lab during your time there, can you speak to that? What quality assurance or quality assurance took place?
MS. WELSH:

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A. I wouldn't say there was any quality assurance. There was quality control in that we ran controls with our immunostains and we ran controls with our other special stains, that would have been it.
CHAYTOR, Q.C.:
Q. That was it?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. So the running of your external controls were a form of quality control?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. But no quality assurance measures that you're aware of?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. I think you were here this morning when Dr. Cook mentioned that in St. Clare's, and I realize you were at the Health Science, but he had said prior to the amalgamation of the Health Care Corporation there had been

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external people come in and expect the lab at St. Clare's.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Did anything like that happen at the Health Sciences Centre?

MS. WELSH:

A. I don't recall anyone being there, no.

CHAYTOR, Q.C.:

Q. So you don't remember any external people coming in and doing an inspection or accreditation of the Health Science's lab?

MS. WELSH:

A. Not to be inspecting the lab, no.

CHAYTOR, Q.C.:

Q. And in terms of other quality control measures, like documenting issues, anything like that, were those things happening? Documenting any problems with the testing, for example, anything like that?

MS. WELSH:

A. No, the only documentation that I remember doing before I left was documenting receipt of specimens and documentation of specimens were

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labelled incorrectly, that sort of thing, but not with any technical problems.

CHAYTOR, Q.C.:

Q. Did you have the internet available to you?

MS. WELSH:

A. No, we did not.

CHAYTOR, Q.C.:

Q. Up until you left in 2003?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Did you have any journals or reference materials available?

MS. WELSH:

A. I remember one reference textbook that we had for immunopathology was one that I had asked Terry to order a few years before and it was just a book of antibodies and what they stained for, what they were used for. So we had that textbook, that's the only books I remember having.

CHAYTOR, Q.C.:

Q. So it was a textbook on antibodies and the purpose of the antibodies.

MS. WELSH:

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A. Just on antibodies and their purposes.

THE COMMISSIONER:

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

CHAYTOR, Q.C.:

Q. Thank you. Perhaps then this would be a convenient place then, Commissioner, I'm not going to be much longer.

THE COMMISSIONER:

Q. All right then, we'll take the afternoon break.

(RECESS)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor?

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. If we could have, please, P-1853, page 13. Now I don't know if there's any way, can we turn that around? Thank you, perfect. This is called a "reagent layout map". Perhaps, Ms. Welsh, you can explain to us what this document is.

MS. WELSH:

A. This would be the document that would print out from the computer when we had entered in

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the stains that we were going to do on this particular run of the analyzer. And there were 24 slides for different cases. It would tell us up in the left-hand corner that we needed 2.5 litres of buffer and 1.5 litres of deionized water, left-hand side.

CHAYTOR, Q.C.:

Q. Okay, right-hand, yes.

MS. WELSH:

A. And then it would tell us how much of each of the reagents that we needed along the left-hand side would be the hydrogen peroxide trypsin protein block, Envisn and diaminobenzadine and I would have needed that amount of reagent, and then on the other circles, would be the antibodies that we needed and how much of each of those we needed.

CHAYTOR, Q.C.:

Q. And is this then the map, is this how it's then laid out in the machine?

MS. WELSH:

A. Yes, it is. We had a rectangular shape tray that had holes in it and we would put the reagents in the, like the hydro peroxide would

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go in A1 and the DAB would go in A2.
CHAYTOR, Q.C.:
Q. And who would be responsible for making sure that you have the appropriate amount of reagent?
MS. WELSH:
A. That would be our responsibility.
CHAYTOR, Q.C.:
Q. And what if there was insufficient amount of reagent and it ran out before it got to all the patient slides, would you have any way of knowing that?
MS. WELSH:
A. Yes, an alarm would sound to let you know that there was insufficient amount of a reagent and would come up on the screen that there was an insufficient amount of a reagent and you could add more reagent and continue along.
CHAYTOR, Q.C.:
Q. So there was an alarm -
MS. WELSH:
A. There was, but the reason we printed this out was that so when we loaded up this rack to put in there, we knew exactly how much we needed. So you would make sure before you put it on

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that you had enough of all of the reagent on there.
CHAYTOR, Q.C.:
Q. And was there any particular place that, in the 48 slots, was there any particular place where the control slides would go?
MS. WELSH:
A. Usually put the control slides at the end of the--this doesn't show whether it's controls, this just shows that we would have done those, five, seven antibodies.
CHAYTOR, Q.C.:
Q. Yes, and this is only for, well this is 32, I guess.
MS. WELSH:
A. Pardon me?
CHAYTOR, Q.C.:
Q. This shows 32 here, in terms of the layout map, there's four times eight, I think, right? So there's 32 spaces here.
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And there would be 48 slide sections on the machine.

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MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Would the controls always go in one particular area? For example, if you had ER/PRs, would the controls go immediately after the ER/PRs or would it go at the very end of all of it? Like, would all the controls be at the -
MS. WELSH:
A. I usually put all the controls on at the end.
CHAYTOR, Q.C.:
Q. At the very end.
MS. WELSH:
A. Uh-hm, you would put a case on at a time and a surgical number, 1420 had, say this Vimentin and KI67 and S100, I would put all those on together. The way the instrument worked is say if it was doing the first one, the Vimentin, it would take up so much, as much Vimentin reagent as it needed and then it would go around to all of the different spots on the machine and dispense the reagent, so it didn't really matter where the slides were, they were all done at the same time.
CHAYTOR, Q.C.:

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Q. And if the alarm went to indicate that there was insufficient reagent, what would you do in terms of your run?
MS. WELSH:
A. You would add more reagent and continue on.
CHAYTOR, Q.C.:
Q. And continue on.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And how would you know whether or not then all of the slides had received the appropriate amount?
MS. WELSH:
A. The instrument knew that, if the slides had received the appropriate amount, so it would go back to the one that it had realized it didn't have enough reagent. That happened very infrequently because, as I say, we printed this off first, so we were, made sure that when we put the reagents on, that there was enough in each of the reagent cups.
CHAYTOR, Q.C.:
Q. Okay, and if we could go back, please, to P-2177? And these were the specification sheets

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that we referred to earlier and I'm just wondering who would, where would the specification sheets, you told me they would be kept in a binder, but would they be distributed to anyone else? Who would get the specification sheets other than the lab technologists?

MS. WELSH:

A. The only time anyone else would get them was if one of the pathologists asked us for a copy, that happened occasionally that they would ask for a copy of it, maybe they wanted to read the specs on it. But other than that, it was just for us.

CHAYTOR, Q.C.:

Q. So they weren't automatically distributed to any pathologist?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And the pathologists who requested a copy, were they within the Health Sciences Centre or were they from outside?

MS. WELSH:

A. It could have been either.

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CHAYTOR, Q.C.:

Q. And do you have any specific recollection of that, pathologists from outside Health Science requesting copies -

MS. WELSH:

A. Nothing specific, I couldn't tell you who, but I do remember printing off copies and sending them out to the pathologists at the various hospitals.

CHAYTOR, Q.C.:

Q. And you don't know when that would have happened?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Or why the request was made?

MS. WELSH:

A. I probably wouldn't have had any indication as to why it was made. They would have asked for it, I just would have done it and sent it to them.

CHAYTOR, Q.C.:

Q. And if we could go back, please, to P-2149? Page 36, please? This is the special procedure request forms that I brought you to

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before and here's one with your signature, July 30th, '02, and on the bottom here, there's "for a complete listing of immunoglobulins available in our laboratory, consult the bound collection of the product monographs in the reporting room." Do you know what that's referring to?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Do you know the bound collection of the product monographs in the reporting room, do you know was there a bound copy, for example, of the spec sheets left in--the reporting room, I take it, is the reading room, is that right?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. And do you know if there was a bound collection of the spec sheets in the reading room?

MS. WELSH:

A. No, I don't have a recollection of that, maybe.

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CHAYTOR, Q.C.:

Q. And this appears on a number.

MS. WELSH:

A. It's on all of them, it's on the -

CHAYTOR, Q.C.:

Q. It's not on all of them, it's on some in the certain time period, so you have no recollection of such a bound volume?

MS. WELSH:

A. No, I don't remember that.

CHAYTOR, Q.C.:

Q. And it looks like there's actually a different form here, this one here, the immunoperoxidase request form?

MS. WELSH:

A. That was the form that we, I believe Doctor--I don't know who did that one up, I believe it was Dr. Parai. That was when we had so many antibodies that they couldn't all fit on the other--the other form had regular, I'll call histology special stains, as well as immunohistochemistry.

CHAYTOR, Q.C.:

Q. Okay, so this was a new form?

MS. WELSH:

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A. So this was a newer form that listed all the antibodies that we had at the time.

CHAYTOR, Q.C.:

Q. Okay. And if I could have P-0047 please? And this is not a document I would expect you to be familiar with, but this is a the report of Ms. Wegrynowski which was done, it's her first report, November 9th, 2005. And I just want to take you to a couple of things here. On page 5, she has a number of recommendations throughout her report and if you've listened, as you've indicated to some of her evidence, you probably would have heard this, her first recommendation would be "standard operating procedures relating specifically to the grossing fixation procedures must exist for each tissue type to ensure the reproducibility and reliability of results."

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. And I take it, Ms. Welsh, based on what you've told us, there was no such standard operating procedures during your time with, at any point in time with the General Hospital?

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MS. WELSH:

A. No, there wasn't.

CHAYTOR, Q.C.:

Q. And page six, number five, she recommended that "signed daily cleaning and maintenance schedules for the tissue processors must be maintained and retained".

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. "Temperature of the paraffin wax must be recorded daily. This is especially important as some antibodies are heat labile."

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Was any of that taking place during your time in your employment?

MS. WELSH:

A. No, we did it, but it wasn't documented.

CHAYTOR, Q.C.:

Q. Okay, so you did daily cleaning and maintenance schedules of the tissue processors?

MS. WELSH:

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A. It wasn't cleaned daily. It was cleaned weekly.

CHAYTOR, Q.C.:

Q. And temperature of the paraffin wax, was that recorded daily?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. Was it taken, was it actually -- apart from it being recorded, was it done?

MS. WELSH:

A. I don't think the temperature of the paraffin wax was done.

CHAYTOR, Q.C.:

Q. Was it --

MS. WELSH:

A. I don't remember ever --

CHAYTOR, Q.C.:

Q. Ever doing it?

MS. WELSH:

A. Ever checking the temperature of the wax. The processor had the temperature there, so we just assumed that was the --

CHAYTOR, Q.C.:

Q. And you relied on that?

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MS. WELSH:

A. Relied on that.

CHAYTOR, Q.C.:

Q. Okay. On page nine, number 14, she refers to a procedure manual outlining the standard operating procedures is to be created outlining all methods and antibodies currently in use, and it should be in compliance with the Clinical and Laboratory Standard Institute, and I take it you didn't have a procedure manual outlining standard operating procedures while you were there?

MS. WELSH:

A. No, we did not.

CHAYTOR, Q.C.:

Q. Okay. Number 15 on page 10, she refers to the antibody data specification sheets to be available for all antibodies currently in use. The data sheets should be kept in alphabetical order and be available at the work bench for both technical and professional reference, and I understand from your evidence that --

MS. WELSH:

A. That was done.

CHAYTOR, Q.C.:

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Q. That was done, or certainly attempted to be kept in alphabetical order?
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. "And it would be prudent to maintain the specifics of the lot number in use, such as the clone expiry date, storage conditions, and specific staining instructions with the data sheet for easy reference". Was that done?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. "And the routine equipment maintenance must be performed and documented", and she refers to both internal check, and again this is the Ventana equipment she would be talking about. In your day it would have been the DAKO.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And the external check then, annual preventative maintenance records must be maintained, and I think you've already told us about what was happening in terms of

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maintenance and documentation.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. "Guarantee pipette and temperature accuracy and calibration", and you've told us that you did not calibrate the pipettes?
MS. WELSH:
A. No, we did not.
CHAYTOR, Q.C.:
Q. And she refers to the standard thermometric device or reference thermometer is to be available to check thermometers used on all temperature controlled instruments. Digital temperature readings do not suffice. So I take it there was no standard thermometric device available to you?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. "And documented evaluation must be performed to ensure the sensitivity and specificity of the test results. Each component used in IHC staining must be optimized and validated individually to ensure outcome and to assist

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in troubleshooting", and certainly at the time she was there, she said it wasn't being done. Do you recall that ever having been done during your time?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. "For all system components, match lot reagents must be tested in unison. Parallel testing of old versus new lots suffices".
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. "Reagents with a predefined Ph should be monitored. The Ph must be taken and recorded when a new lot is received". Was that being done?
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And under primary antibodies, she writes, "Pre-diluted and concentrated. Any change in lot number of concentration, the specificity of the antibody must be verified prior to use. The staining results should be compared to the

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previous lot using the appropriate controls". Was that being done at any point?
MS. WELSH:
A. Well, we would have used the appropriate controls if we had a new lot number.
COMMISSIONER:
Q. I beg your pardon, I didn't catch the last sentence.
MS. WELSH:
A. I said if we had a new lot number, we would have still used the appropriate controls, but there wouldn't have been -- I don't think we would have done any actual comparison between one or the other.
CHAYTOR, Q.C.:
Q. Okay. "The validation documentation must be approved and signed off by medical section head prior to use in routine service", and I take it that wasn't happening?
MS. WELSH:
A. That wasn't done, no.
CHAYTOR, Q.C.:
Q. Page 18, and there are -- I'm just going to take you to certain portions here, and under competency testing, "Presently no

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documentation exists relating to the training of staff to perform their assigned duties. Competency assessment for all staff is not performed in the pathology division laboratory program. The pathology manager has begun to investigate this process. Staff must be provided with training and given a documented performance appraisal prior to working without supervision", and then number 38, "staff to be assessed for competence to perform tasks following training, identify requirements of a task, to perform GAP analysis, and develop action plans". Did you have any competency testing while you were in your position?

MS. WELSH:

A. No, I did not.

CHAYTOR, Q.C.:

Q. I don't get that complaint very often, but apparently they can't hear me. I'll speak up. Thank you, Mr. Coffey. It's the wind I'm competing with, I think, today. If we can have then, please, 2157, and I understand, Ms. Welsh, that since you've come to Newfoundland to give your evidence, you have been by for a visit to the IHC lab?

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MS. WELSH:

A. Yes, I went yesterday.

CHAYTOR, Q.C.:

Q. Perhaps you can tell us about your observations on how the lab compares to when you left it in April of 2003?

MS. WELSH:

A. It's a totally different place.

CHAYTOR, Q.C.:

Q. Okay.

MS. WELSH:

A. There was equipment, more equipment than we had had before. The IHC is actually in its own separate room. The people who are doing it are dedicated to doing just IHC. There are books everywhere, documentation and papers everywhere with temperature recordings, and things like that. It was an amazing difference. I didn't recognize the place at all.

CHAYTOR, Q.C.:

Q. So you were pleased, I take it?

MS. WELSH:

A. Yes, a lot has changed in those five years.

CHAYTOR, Q.C.:

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Q. And here, I think, you will see a change as well. This is a -- this exhibit here, and I'm not going to take you through all of this by any stretch, but you can see that there's 382 pages, and this is documentation that's just -- well, on Friday that we've received here at the Commission, and most of which is quite recent, but it is a pathology policies and procedures manual, and it's 382 pages. I take it there was no such manual in existence when you were in your position?

MS. WELSH:

A. No, we had a manual that was a procedure manual, but it was basically just a procedure for doing routine histological stains, all the different -- we used to call them special stains because they were something different from just your regular hematoxylin and eosin stain.

CHAYTOR, Q.C.:

Q. And nothing for IHC?

MS. WELSH:

A. Nothing for IHC.

CHAYTOR, Q.C.:

Q. If we could look, please, at page 17,

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Registrar. This is a policy which is handling sub-optimal specimens in pathology. It's approved April 16th, 2008; effective April 21st, 2008, and it defines a sub-optimal pathology specimen and what that may include, and then what happens, procedure in terms of dealing with a sub-optimal --

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Did you have anything like that available to you at the time?

MS. WELSH:

A. No, we did not.

CHAYTOR, Q.C.:

Q. And if we -- I'll just go back here, actually. Page nine is a fixation policy. Do you remember seeing any fixation policy during your time?

MS. WELSH:

A. No, there was no policy.

CHAYTOR, Q.C.:

Q. And if we could have 0135, please. This refers to tissue tech, VIP5 processor troubleshooting. I'm not sure -- was that the

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equipment, the tissue processor that would have been --

MS. WELSH:

A. We had a tissue tech VIP. I don't know if it was the VIP5.

CHAYTOR, Q.C.:

Q. But it would have been a similar processor?

MS. WELSH:

A. But it was a similar tissue processor.

CHAYTOR, Q.C.:

Q. Okay, and in terms of -- we saw a recommendation that I just brought you to from Ms. Wegrynowski where she was recommending in terms of maintenance and cleaning of the -- what was the regular, or how often should the tissue processors -- how often were they supposed to be cleaned, do you know?

MS. WELSH:

A. We did them -- we cleaned them once a week. We did a complete change of reagents and put all fresh reagents and fresh wax on it, and cleaned it with a hot water flush, I remember, but that was done once a week, and other days it would just have been physically wiped down to clean up the excess wax and top up reagents

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if necessary.

CHAYTOR, Q.C.:

Q. I know you said it was done weekly, but do you know was it supposed to be done weekly or daily?

MS. WELSH:

A. I thought it was supposed to be done weekly. We got -- when we first got the processor, we were told to clean it weekly, so we did.

CHAYTOR, Q.C.:

Q. And this is a procedure then which is fairly detailed.

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Sixteen steps, if you encounter -- to identify and correct problems or errors during tissue processing on the VIP5. Was there any such procedure in place for you during your time?

MS. WELSH:

A. No, there wasn't, and there were times that the processor would break down and we wouldn't know until the next morning. There was no alarm system on it, and I know we did express concern -- the technologists did express

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concern that there should be an alarm system that would ring somewhere where someone was. The pathology lab wasn't occupied in the evenings or overnight. The processing was an overnight procedure. There were times that the processor did actually break down in mid cycle. We wouldn't know until we got in the next morning.

CHAYTOR, Q.C.:

Q. And then what would happen?

MS. WELSH:

A. Well, then we would be delayed. The tissue would be still sitting in the solution that it was in when the processor decided to stop.

CHAYTOR, Q.C.:

Q. And if overnight the tissue processor had broken down, and then started up again, would you have --

MS. WELSH:

A. It wouldn't start up again.

CHAYTOR, Q.C.:

Q. But if that had happened, would you know?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

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Q. So could --

MS. WELSH:

A. It wouldn't start up against once it broke.

CHAYTOR, Q.C.:

Q. Was it subject to power failures?

MS. WELSH:

A. No, there was a battery on it as well, so it wasn't subject to power failures. It would have had to have been a mechanical problem.

CHAYTOR, Q.C.:

Q. And what checks were carried out in terms of the battery?

MS. WELSH:

A. I don't think there were any. I don't recall ever checking it.

CHAYTOR, Q.C.:

Q. So in terms of the processor breaking down, if you arrive in the next morning and you realize it hadn't finished, you'd have to start over, I take it?

MS. WELSH:

A. Well, we would start from where we were. First we would try to figure out what went wrong with the processor, fix it if we could, and continue on from the step that it was in

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at the time.
CHAYTOR, Q.C.:
Q. And could that damage the tissue if it had been sitting there overnight?
MS. WELSH:
A. Depending on what it was sitting in. Usually when the processor broke, it usually was sitting in formula, so that would not have really affected the tissue.
CHAYTOR, Q.C.:
Q. So there were occasions that happened?
MS. WELSH:
A. But there were occasions when it did happen, yes.
CHAYTOR, Q.C.:
Q. And then you raised that issue. Who would you raise that issue with that it needs to be alarmed?
MS. WELSH:
A. That had been raised several times, I think, with supervisors and --
CHAYTOR, Q.C.:
Q. And up until you left --
MS. WELSH:
A. Up until I left, there was no alarm system.

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CHAYTOR, Q.C.:
Q. No alarm system, okay.
MS. WELSH:
A. No.
CHAYTOR, Q.C.:
Q. And to your knowledge, if there were a problem with the processor and it broke down, it couldn't stop for -- momentarily or stop in the process and then start itself up again?
MS. WELSH:
A. Not to my knowledge.
CHAYTOR, Q.C.:
Q. If we could have, please, 237. So I take it, this procedure that I showed you here, that would have been useful to have -- it would have been useful in terms of how to deal with issues regarding the tissue processor?
MS. WELSH:
A. Yes.
CHAYTOR, Q.C.:
Q. And this is a procedure for troubleshooting immunohistochemistry staining, and this again is new, three years after you left your employ, March 19th, 2008, or thereabouts. This gives some indication; follow the

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activities below to troubleshoot any sub-optimal immunohistochemistry staining.
MS. WELSH:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Was there any such procedure in place during your time with -- in St. John's?
MS. WELSH:
A. No, there wasn't. Our only troubleshooting for sub-optimal would have been if the pathologist would have told us that it wasn't good enough.
CHAYTOR, Q.C.:
Q. So did you see yourself -- you did tell us -- in fairness, you told us that you would look at external controls and sometimes you were able to identify and rerun. Other than that, did you see your role or see yourself as having any role in troubleshooting in this procedure?
MS. WELSH:
A. No. We left that to the pathologists. We made the slides, we sent the slides to them, and like I said to you earlier, if we didn't hear anything from them that there was

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anything wrong, we just assumed that everything was fine.
CHAYTOR, Q.C.:
Q. Did you have -- did you -- in terms of the control slides that you came up with, did you have any understanding how strong the staining should be, or whether or not you should pick a control which was going to be a strong positive or a weak positive, what did you understand?
MS. WELSH:
A. Well, we tried to pick controls. We asked the pathologist to pick the controls for us for the ERs and PRs, and the stronger the staining, the better.
CHAYTOR, Q.C.:
Q. And if it stained weakly, what did you understand the implications of that to be?
MS. WELSH:
A. If it stained weakly, I would understand that it would have been what you would call a sub-optimal stain.
CHAYTOR, Q.C.:
Q. Okay.
MS. WELSH:

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A. But then again that would have been -- we would have waited for the pathologist to come and tell us that it was because it wasn't our role to decide if something was a weak positive or a strong positive.

CHAYTOR, Q.C.:

Q. So if you saw any staining at all, you would release the stains?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. Release the slides --

MS. WELSH:

A. Yes, release the slides to the pathologists for their interpretation.

CHAYTOR, Q.C.:

Q. I'll just show you a couple more -- one more, anyhow. This was an immunohistochemistry run log procedure, and again it's March 19th, 2008, effective date, and this notes, "To enter the following information on the immunohistochemistry run log, and antibodies used, machine used, date, total number of slides, technologist initials, quality control number, notes, calculations, dilutions, error

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codes or alarms". Was any of that information recorded during your time?

MS. WELSH:

A. The only thing that we had was a run log that would have had the total number of slides per case and the antibodies used on that case, and that log would not necessarily have been retained for very long.

CHAYTOR, Q.C.:

Q. And this is just a sample I've showed you, Ms. Welsh. How does this documentation, these various procedures and policies, how does that compare to what was in place when you were in your job?

MS. WELSH:

A. Oh, my, apples and oranges. This is a really good thing, and we had nothing. We had no documentation at all and there was no real procedure manual. I think this looks like a very good thing. If anyone has any trouble with anything, they know where to go and what to do about it.

CHAYTOR, Q.C.:

Q. The whole issue that brings us here today, ER/PR, how did you hear about it? You were

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actually living in Nova Scotia by the time it would have come out publicly.

MS. WELSH:

A. I heard it on the CBC supper hour news.

CHAYTOR, Q.C.:

Q. Is that right? So you heard about it then -- that would have probably been October, 2005?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. So you had no inkling that there was any issue prior to that?

MS. WELSH:

A. No.

CHAYTOR, Q.C.:

Q. And what did you think when you heard about it?

MS. WELSH:

A. Oh, my God, I was shocked, devastated. All I kept thinking about was with the timing that they were giving, that they said it was from '97 to 2005, that's what I was doing, and I thought I was doing everything to my best ability, and since then I've just been thinking about it constantly.

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CHAYTOR, Q.C.:

Q. And did you contact anyone, any of your former colleagues or anyone else to make inquiries as to what this was all about?

MS. WELSH:

A. I talked to a few of my friends who worked in the lab, yes, but not to any great extent. I just followed it on the news.

CHAYTOR, Q.C.:

Q. And other than getting involved then in this process, did anyone contact you to make any inquiries as to what was happening in the lab during your time there?

MS. WELSH:

A. No, the first people who contacted me were you and Mr. Coffey when we talked on the phone.

CHAYTOR, Q.C.:

Q. Thank you, Ms. Welsh, for coming. Those are all my questions. Some of my fellow lawyers may have questions for you. Thank you for your time.

THE COMMISSIONER:

Q. Ms. Brazil?

MS. BRAZIL:

Q. I have no questions for the witness,

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Commissioner.
THE COMMISSIONER:
Q. Thank you. Mr. Browne?
MS. PEGGY WELSH, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Just a couple questions. Good afternoon, Ms. Welsh. We met this morning. My name is Peter Browne. I represent a number of the physicians who have been asked to testify before the Commissioner. I just have a couple of questions I want to follow up on some of the points you made this morning. First of all, we have heard and I'm sure--you've indicated you've followed some of this. We've heard some evidence and seen some documents that pathologists had site meetings. In particular, we saw some documents there many of the pathologists met at the Health Sciences and discussed various topics in their division. Was there such a process within--for technologists, where technologists would come together, discuss issues pertinent to their work with their respective managers?
MS. WELSH:
A. No.

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MR. BROWNE:
Q. We also heard some evidence, and I think you were at the Health Sciences during the relevant time period, about the fact that formalin was made in house. Do you have any knowledge about that and were you involved in any of that process? I think it was the--the evidence we have so far was that it was stopped in, I think, early 2003, January 2003.
MS. WELSH:
A. Um-hm.
MR. BROWNE:
Q. Yes?
MS. WELSH:
A. Yes.
MR. BROWNE:
Q. Were there any--well, let me ask you, what's your recollection about that? How was that prepared? Was there any sort of documentation surrounding its preparation?
MS. WELSH:
A. There was no documentation other than the--would have probably been a piece of paper somewhere with the concentrations of reagents on it. We made two separate buffers and mixed

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those two buffers together with formalin and water and made buffer formalin.
MR. BROWNE:
Q. Okay. Was there any sort of particular training that you had -
MS. WELSH:
A. No, that kind of training would have been the kind of training we would have received as medical laboratory technologists anyway in how to prepare a buffer.
MR. BROWNE:
Q. And was there any particular--this piece of paper, to indicate what sort of concentration percentage or anything?
MS. WELSH:
A. It would have been--it was a actual weight per volume. So it would have been 400 grams of something mixed with two litres of water. That would have been -
MR. BROWNE:
Q. But beyond--do you--beyond that, do you recall sort of the--any of the details of what was in that sheet, in terms of the percentage of buffered formalin that it created?
MS. WELSH:

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A. Oh, it created ten percent buffered formalin.
MR. BROWNE:
Q. And were there particular group of technologists who were involved in that or were all technologists?
MS. WELSH:
A. Oh no, everybody did that.
MR. BROWNE:
Q. Okay, thank you. You were shown--and it's not necessary to bring this up, but if you wish, Ms. Welsh, you can refer to it. It was a number of requisition forms Ms. Chaytor showed you this morning with--and I think several included your name with requests for repeating of the test by pathologists. Was there ever any occasion where a pathologist would call over and ask for a repeat or comment on about the quality of the stain, while you were there?
MS. WELSH:
A. I don't remember anything specific, but I'm sure there probably were a couple of times I remember talking to someone.
MR. BROWNE:
Q. If there were any complaints about, I guess,

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the quality of the stains or the particular test, did you or your colleagues ever refer pathologists to managers to deal with any particular problems?

MS. WELSH:

A. Not to my knowledge.

MR. BROWNE:

Q. I guess you don't recall any particular instance where you referred a pathologist to your superiors to deal with the problem?

MS. WELSH:

A. No, I don't.

MR. BROWNE:

Q. That's all the questions. Thank you very much.

MS. WELSH:

A. Thank you.

THE COMMISSIONER:

Q. Mr. Pritchett?

MR. PRITCHETT:

Q. We have no questions, Commissioner.

THE COMMISSIONER:

Q. Ms. Newbury?

MS. NEWBURY:

Q. I don't have questions, thank you.

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THE COMMISSIONER:

Q. Ms. Russell?

MS. RUSSELL:

Q. No questions.

THE COMMISSIONER:

Q. Mr. Simmons?

MR. SIMMONS:

Q. Thank you.

THE COMMISSIONER:

Q. I'm sorry, just that I've skipped one person who just seems to be absent from the room, but since the computer is there, I assume he's somewhere in the neighbourhood.

MR. BROWNE:

Q. I think he's taking--I think Mr. Pike (inaudible).

THE COMMISSIONER:

Q. Well, he's left his computer in any event or somebody has.

MR. SIMMONS:

Q. If he comes back and he has any questions, I have no problem -

THE COMMISSIONER:

Q. Thank you, Mr. Simmons. Would you check and see if Mr. Pike is left?

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MR. LEN THORNE:

Q. He is left, Commissioner.

THE COMMISSIONER:

Q. Okay, thank you. Now, Mr. Simmons?

MS. PEGGY WELSH, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Thank you. Ms. Welsh, I'm going to take the opportunity, while you're here, to go through with you a little more of the detail about how some of these IHC procedures were performed when you were doing them. So I think it might be helpful if we understood a little bit more about some of the steps. So can I have Exhibit P-2156, please? You've identified this before as a typewritten version of the peroxidase antiperoxidase protocol. It's shorthand here PAP for it.

MS. WELSH:

A. Um-hm.

MR. SIMMONS:

Q. You've had a chance to look at this, I think, before you came here today.

MS. WELSH:

A. Um-hm.

MR. SIMMONS:

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Q. And you'd mentioned when this exhibit was up before that Dr. Chittal, who was one of the pathologists at the General Hospital, had had a sabbatical in France where he'd worked with immunohistochemistry?

MS. WELSH:

A. Um-hm.

MR. SIMMONS:

Q. And that when he'd come back, he brought back a different way, I understood, of doing IHC procedures for the lab?

MS. WELSH:

A. Um-hm, that's correct.

MR. SIMMONS:

Q. So from that, do I understand that there are-- there is more than one process that you could use if you're manually doing an immunohistochemical procedure?

MS. WELSH:

A. I'm -

MR. SIMMONS:

Q. Had you been doing it -

MS. WELSH:

A. We had been doing it one particular way, which was the old way that we started in the mid

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80s.
MR. SIMMONS:
Q. Yes.
MS. WELSH:
A. And then when Dr. Chittal came back, there were a few extra steps. The basic procedure was still the same, the triple bridge antibody reaction, but it was--he had added a few different stains, few different steps to the procedure.
MR. SIMMONS:
Q. So the basic procedure was the same as when you first started it, but there were some other enhancements, and I take it that those were understood perhaps to be improvements to the way it was being done?
MS. WELSH:
A. Yes, they were.
MR. SIMMONS:
Q. In the time that you were involved in doing IHC, were there periodically changes in the procedures like that?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:

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Q. And when those changes took place, were they presented--who would initiate a change like that, if you were going to change the procedure you were using?
MS. WELSH:
A. The biggest change would have been this procedure which Dr. Chittal would have initiated and then the next biggest change would have been the introduction of the semi-automated DAKO stainer. I don't remember if when Dr. Khalifa started doing things, if he had any real changes in the procedure or not, or just changes in antibody. When we started doing ER/PR, it was just sort of thought to be two more antibodies.
MR. SIMMONS:
Q. Two more antibodies.
MS. WELSH:
A. That we added to the list.
MR. SIMMONS:
Q. Right, so aside from the change in procedure made necessary by the introduction of the semi-automated DAKO machine, other changes in the procedure, would it be fair to say, would be initiated by a pathologist involved in the

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process, other than by the technologist?
MS. WELSH:
A. Yeah, if there were any changes.
MR. SIMMONS:
Q. Okay, and this typewritten procedure that we have here, does this represent the way that the procedure was done manually before the DAKO semi-automated machine was introduced?
MS. WELSH:
A. Yes, it does.
MR. SIMMONS:
Q. Okay, I'd like to take a couple of minutes and we'll go through it a little bit, just so we can understand what was involved in that. It starts out by referring to day one, and it says "prepare the slides, cut sections at three microns on clear glass slide, place in 58 to 60 degree Celsius incubator overnight."
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. So you would have to take the blocks that had previously been prepared?
MS. WELSH:
A. Um-hm.

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MR. SIMMONS:
Q. With the tissue fixed, processed, cut, put in a cassette, paraffin added to make the block?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. That would happen before it reached you at the IHC lab, would it?
MS. WELSH:
A. They would already have been cut for H & E stains and sent to the pathologist for diagnosis. Then they would have asked to do immunoperoxidase staining on that particular block, so it would have--they would have sent the request form.
MR. SIMMONS:
Q. Right.
MS. WELSH:
A. We would dig the block out of the files and then cut the section.
MR. SIMMONS:
Q. Yes, so for specimens that originated within the General Hospital, if I understand correctly, those cases, those specimens would come assigned to a pathologist at the General

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Hospital, correct?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. That pathologist would be responsible for the gross examination and the selection of tissue to be embedded in these cassettes?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And that the routine H & E stain would be done and a slide prepared and given to the pathologist to look at?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And is it then that the pathologist would choose to order an ER/PR stain, if that's what they wished to order?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Okay, and the requisition forms we've seen are the ones the pathologists would complete and give to you when they requisitioned that

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stain?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Okay. For specimens originating at other sites in St. John's, the Grace Hospital and St. Clare's that were within the Health Care Corporation, would the process be essentially the same, except that the blocks would be made at those institutions?
MS. WELSH:
A. Exactly, yes.
MR. SIMMONS:
Q. Would the process be essentially the same, except that the blocks would be made at those institutions?
MS. WELSH:
A. Exactly, yes.
MR. SIMMONS:
Q. And the request for a pathologist would come from a pathology--request for the stain would come from the pathologist at that institution?
MS. WELSH:
A. Yes, and they would send over the form and their paraffin blocks.

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MR. SIMMONS:
Q. Right, and then also there would be blocks that would come in from pathologists at hospitals elsewhere in the province that were not part of the Health Care Corporation at all?
MS. WELSH:
A. That's correct.
MR. SIMMONS:
Q. And would be a similar process, a requisition would come with the block?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. So you would get blocks from all these different sources. Now when the section is cut and placed on the slide, what's the purpose of putting it in the incubator overnight at 58 to 60 degrees Celsius?
MS. WELSH:
A. We wish to melt the wax that is around the tissue.
MR. SIMMONS:
Q. Yes.
MS. WELSH:

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A. And adhere the sections to the slide.
MR. SIMMONS:
Q. Okay, the next step then begins on day two, and it says to place, is that 200 millilitres of one-tenth -
MS. WELSH:
A. Phosphate buffered saline.
MR. SIMMONS:
Q. - phosphate buffered saline, in a 37 degree Celsius incubator. Then it talks about weighing out trypsin and making up something called albuminized -
MS. WELSH:
A. PBS.
MR. SIMMONS:
Q. PBS, okay.
MS. WELSH:
A. Phosphate buffered saline.
MR. SIMMONS:
Q. What are those steps for?
MS. WELSH:
A. Trypsin is a proteolytic enzyme that we used to reduce the formalin mask over the antigen site, which is basically the same sort of thing that antigen retrieval did, but this was

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just--say, this was the way it used to be done before antigen retrieval was dreamt up, and so we would put the slides in there for, I believe it was about six minutes or something like that. Albuminized PBS was just the regular phosphate buffered saline with bovine albumin in it. We used that so that when we washed the slides and wiped the slides off in a later part of the procedure, it sort of made a little bubble over the slide so that the sections would not dry out. That is the only reason for having a little albumin. We put one mil in a 100 mils of buffer. So it was just -

MR. SIMMONS:

Q. So on day two then, the first three items there are to prepare these materials for use in the procedural steps that then follow on this sheet?

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. And the first one then says to transfer slides directly from the incubator where they were at 58 to 60 degrees Celsius, and there's a series

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of seven steps there referring to time in xylene, time in 95 percent alcohol, time in tap water, and time in 37 degree tap water. What's the purpose of that step?

MS. WELSH:

A. Those are called--that's rehydration. When tissue is processed, it's dehydrated. All of the water is taken out of the tissue so that it can be made miscible with wax, so that we can cut it. When we want to do our staining procedures, we have to rehydrate the specimens, put water back in. So these steps are what is the protocol for rehydration. Xylene removes the paraffin from the cells and from the tissue. 95 percent alcohol replaces the xylene in the tissue and then we go to water.

MR. SIMMONS:

Q. Okay.

MS. WELSH:

A. And we use cold tap water, just as a wash, to make sure that the tissue is fully permeated with water. We use 37 degree tap water because we were going to put the slides in the trypsin, which was incubated at 37. So we

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didn't want to put cold slides in 37 degree trypsin because then you would bring the temperature of your trypsin down. So we would use warm water.

MR. SIMMONS:

Q. So these processes now of putting the slides through the xylene and the alcohol and the tap water, were they automated in any way?

MS. WELSH:

A. No, they were all manual.

MR. SIMMONS:

Q. You did that manually in dishes?

MS. WELSH:

A. In staining dishes with a timer.

MR. SIMMONS:

Q. Right, okay. So you'd have a timer on your bench. You'd use the timer and set the timer for each step in the procedure to time it correctly?

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. Okay. The second step is to add trypsin to the phosphate buffered solution in the 37 degree Celsius incubator, then you'd transfer

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the slides to the solution for six minutes at 37 degrees and then rinse in cold tap water for five minutes?

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. And the purpose again of that step, of putting it in the trypsin was?

MS. WELSH:

A. To remove formalin masking of the antigen sites.

MR. SIMMONS:

Q. Okay. Now, is that a step that was done for all the different antibodies that you processed or -

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. It was, okay. Then there's a heading which says, "inhibition of endogenous peroxidase" and there's a series of steps there that appear to involve transferring the slides to a solution of methanol and hydrogen peroxide, rinsing and putting it through alcohol, chloroform, acetin, tap water and then the

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albuminized phosphate buffered solution. So, what is all that process for?

MS. WELSH:

A. Inhibition of endogenous peroxidase means that we want to remove any peroxidase that is normally occurring in the cell because if we don't, then that would be called endogenous peroxidase. It's peroxidase that is in your cells in your body. If we didn't remove those cells, those peroxidase that was in the cells, then when we did the staining, we counterstained for peroxidase. So, they would have showed up as being positive. So, we removed--that was the method for removing the endogenous peroxidase from the cells so that whatever stained was the antigen site.

MR. SIMMONS:

Q. Okay. And this portion of the process was common to other antibodies as well as ER/PR -

MS. WELSH:

A. All the antibodies.

MR. SIMMONS:

Q. Okay. The next heading then says, "primary antibody" and it has steps 13 to 17 there. Number 13 being to prepare dilutions of

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primary antibody using the albuminized PBS and it says, "140 to 200 ul", is that microlitres?

MS. WELSH:

A. That's microlitres.

MR. SIMMONS:

Q. "Per slide", so that's telling you what quantity of antibody to have prepared and ready.

MS. WELSH:

A. Exactly, if we had to do five, let's say, ERs, we would make up about 1000 microlitres so that we would have enough for every slide.

MR. SIMMONS:

Q. Okay. Now, you've told us already, I think, that early one when you were doing this testing manually, you would just mix up the dilutions of antibodies each time you have a run of slides to do.

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. Later you would mix up a batch and keep it in a bottle in the refrigerator.

MS. WELSH:

A. Yeah.

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MR. SIMMONS:

Q. We've also seen some of the specifications sheets that came with the antibody with the dilutions written on it. Was the dilution recorded in any way other than on the specification sheet when you mixed up these antibodies?

MS. WELSH:

A. We would write it on the side of the bottle that the antibody came in.

MR. SIMMONS:

Q. So, if you took the antibody bottle out of the fridge, the dilution that you had determined was going to be used for that antibody was written on the label?

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. And that's the you'd use when you'd mix up the dilution.

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. Can you just go through the next steps there, 14 to 17 and just tell me what those are.

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MS. WELSH:

A. We would dry the slides with a paper towel, tissue thing, we would dry the back and the tops and leave a film of albuminized PBS around the section itself, making sure that there were no air bubbles. And you notice there in big letters, it says, "do not let the sections dry".

MR. SIMMONS:

Q. So, this is -

MS. WELSH:

A. That was why we used albuminized PBS, so that the PBS when we were rinse--when we were wiping it off the slides, it would stay around the section.

MR. SIMMONS:

Q. So you had to manually -

MS. WELSH:

A. Manually wipe -

MR. SIMMONS:

Q. - wipe each slide -

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. - around the edges, but avoiding -

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MS. WELSH:
A. Avoiding the tissue.
MR. SIMMONS:
Q. - taking the moisture from the tissue?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Okay.
MS. WELSH:
A. Then we would cover these tissue with the primary antibody that we had just prepared in step 13, did them one slide at a time obviously and let them incubate for 30 minutes in humidification chamber, either the little petri dish with the wet paper towel, or the immuno tray that we got a little later that had the water in it.
MR. SIMMONS:
Q. And how would you time the 30 minutes?
MS. WELSH:
A. With a clock.
MR. SIMMONS:
Q. Okay, a timer of some sort?
MS. WELSH:
A. Timer, um-hm.

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MR. SIMMONS:
Q. Okay, and then the next step?
MS. WELSH:
A. The next step then was to wash each slide with the PBS. We used a squeeze bottle, a wash bottle, so we would hold the slide physically in your hand and wash off all of the primary antibody after the 30 minute incubation and when it was adequately washed, we would transfer it to a staining dish of albuminized PBS, to sit in the PBS while we washed all the rest of the slides, so that none of the slides would dry.
MR. SIMMONS:
Q. Okay. The next heading is secondary antibody.
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. And there's a series of--there's three steps described there, and if I understand from what you've said before, the secondary antibody is one that attaches to the primary antibody -
MS. WELSH:
A. Yes.
MR. SIMMONS:

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Q. - and helps build a larger molecule that will eventually be easier to see when it's stained?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Okay, and there's a similar--is it a generally similar process described here for applying the secondary antibody?
MS. WELSH:
A. Yes, it is. It's done exactly the same, and then there was also--then there would be a tertiary antibody, a third one.
MR. SIMMONS:
Q. So the next heading there, which is steps 21 to 23, is the tertiary antibody?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. And then the next heading says "revelation of peroxidase staining" and there are steps 24 to 27 there. Can you tell me what was involved in that, please?
MS. WELSH:
A. Well, once we've made this molecule of primary, secondary and tertiary antibodies,

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which is now large enough to see under a microscope, we had to colour that, because it's just a reaction taking place. So we used what was called diaminobenzadine and we put that on a -
MR. SIMMONS:
Q. And diaminobenzadine, otherwise known as DAB?
MS. WELSH:
A. DAB. We called it DAB because you didn't want to use that big word all the time. So we put that on all the slides and that would reveal the peroxidase staining. That's why it says revelation.
MR. SIMMONS:
Q. Okay.
MS. WELSH:
A. It would reveal the peroxidase stain. Then when you looked at it, there would -
MR. SIMMONS:
Q. And was there any particular care that had to be taken in mixing and applying the DAB?
MS. WELSH:
A. Yes, the DAB was supposed to be made up immediately before use. It had to be kept in the dark when you weren't using it, so we only

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made up enough to do maybe 10 to 15 slides at a time, and then when we revealed those 10 to 15 slides, we'd make up some more and reveal the next 10 to 15 slides.

MR. SIMMONS:

Q. Okay, and step 24 there describes what you've just told us about making up the DAB. 25 says to arrange the slides in the humidification chamber, and has a time there for -

MS. WELSH:

A. Yes, three to five minutes.

MR. SIMMONS:

Q. - three to five minutes exposure.

MS. WELSH:

A. Yeah.

MR. SIMMONS:

Q. And then 26 is to rinse to stop the reaction and then return to a staining jar of water?

MS. WELSH:

A. Yes.

MR. SIMMONS:

Q. And then the last heading here, second last heading, which has steps 28 to 33, is counterstaining?

MS. WELSH:

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A. Counterstaining, yes. We want to--now what we would have would be a slide with just brown spots. So you'd need to use a stain that we use a tissue stain which is haematoxylin. It's a nuclear stain. So we want to be able to stain up the rest of the tissue so that the pathologist could see the cells with the reaction taking place in them.

MR. SIMMONS:

Q. And then the very last one is just mount -

MS. WELSH:

A. To mount them, that's put a cover slip on them so that it's protected.

MR. SIMMONS:

Q. Okay. Now when Dr. Chittal came back from France, were you involved with him in putting together this procedure that we see here?

MS. WELSH:

A. Well, this--I was involved with him when we started doing this procedure, yes, but I wasn't involved with putting it together. He came back with this procedure in a little notebook, handwritten notes from when he was in France.

MR. SIMMONS:

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Q. And do you know how this particular document came to be prepared?

MS. WELSH:

A. I believe I prepared it, from his notebook.

MR. SIMMONS:

Q. Right, and would he have seen this or approved it or reviewed it in any way at the time?

MS. WELSH:

A. Yes, I'm sure he would have. I don't recall bringing it to him to see, but I can't imagine that I wouldn't.

MR. SIMMONS:

Q. Okay. Now eventually then the DAKO auto stainer was acquired and the process had to change then because a number of these steps we see here became automated?

MS. WELSH:

A. Yes, they did.

MR. SIMMONS:

Q. Okay. I'm going to take you back to the beginning now and just see if we can identify what you still did manually with the DAKO machine and what became automated.

MS. WELSH:

A. Okay.

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MR. SIMMONS:

Q. And how that worked. So if we go back to day one, preparing and cutting the slides, that would be the same?

MS. WELSH:

A. We still did that.

MR. SIMMONS:

Q. In procedure, step one which was rehydrating the slides using xylene and alcohol and water -

MS. WELSH:

A. We would have done that.

MR. SIMMONS:

Q. Was that automated on the auto stainer?

MS. WELSH:

A. No, that wasn't automated. That was still done manually.

MR. SIMMONS:

Q. Exposure to the trypsin?

MS. WELSH:

A. That was done on the auto stainer.

MR. SIMMONS:

Q. So this is where the--you would be able to put the slides on the auto stainer and the trypsin would be one of the reagents that the auto

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stainer would apply, would it?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Was the inhibition of endogenous peroxidase still a step that was carried out?
MS. WELSH:
A. That was carried out on the auto stainer.
MR. SIMMONS:
Q. On the auto stainer, and the application of the primary, secondary and tertiary antibodies?
MS. WELSH:
A. That was on the auto stainer as well, except we didn't use tertiary antibodies by that time. I think we had gone to using this polymer that we had talked about.
MR. SIMMONS:
Q. Okay.
MS. WELSH:
A. I talked about with Sandra Chaytor earlier.
MR. SIMMONS:
Q. Okay, so this was the detection kit you -
MS. WELSH:
A. The detection kit, the EnVision.

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MR. SIMMONS:
Q. - that had replaced some of these?
MS. WELSH:
A. Yes, this polymer included both the secondary and the tertiary antibodies, so it cut down on time.
MR. SIMMONS:
Q. Right, okay. And when you get then to the steps of the counterstain, for example, is that now incorporated--did that become incorporated in the detection kit also, or did you -
MS. WELSH:
A. No, that was done manually.
MR. SIMMONS:
Q. - still have to do that? That was done manually. Was it done on the auto stainer or after the slides came off the auto stainer?
MS. WELSH:
A. After the slides came off.
MR. SIMMONS:
Q. Now with the ER testing and the PR testing, at some point antigen retrieval became part of the process.
MS. WELSH:

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A. Um-hm.
MR. SIMMONS:
Q. Had you started doing antigen retrieval before the introduction of the DAKO auto stainer?
MS. WELSH:
A. Yes, I think so.
MR. SIMMONS:
Q. And the performance of the antigen retrieval you understood--the purpose of it, you understood to be what?
MS. WELSH:
A. To remove the formalin mask. I understood it to be a better method than just the proteolytic enzyme, the trypsin.
MR. SIMMONS:
Q. So when you had first started doing ER and PR stains using the immunohistochemical method as introduced by Dr. Khalifa, was antigen retrieval part of that initial process or was it introduced later?
MS. WELSH:
A. No, it was part of the process.
MR. SIMMONS:
Q. Part of the original process.
MS. WELSH:

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A. Um-hm.
MR. SIMMONS:
Q. And you told us that in order to do it, you would have a hot plate with a container that would hold heated water?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. And you would have another container that you would place in the heated water, which would have a solution of some sort in it?
MS. WELSH:
A. Um-hm.
MR. SIMMONS:
Q. And the slides would be placed in that solution?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. What was the solution that the slides were placed in?
MS. WELSH:
A. It was a citrate buffer.
MR. SIMMONS:
Q. Okay, and was that a material that was

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supplied from some supplier?
MS. WELSH:
A. That was supplied, um-hm.
MR. SIMMONS:
Q. So earlier today, you were shown a number of specification sheets for things other than antibodies. Would the citrate buffer be one of those items for which there would be a specification sheet like that?
MS. WELSH:
A. It would, yes.
MR. SIMMONS:
Q. It would, all right. So can you just tell me now, what the mechanics would be of the process of doing the antigen retrieval?
MS. WELSH:
A. We would just heat the water until it got to the desired temperature. We would put the staining -
MR. SIMMONS:
Q. How would you -
MS. WELSH:
A. With a thermometer.
MR. SIMMONS:
Q. - measure the temperature?

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MS. WELSH:
A. With a thermometer.
MR. SIMMONS:
Q. Immersed in the liquid?
MS. WELSH:
A. Immersed in the water. We would put the citrate buffer in a staining dish, put that in the heated water and then check the temperature on that and then when that reached 95 to 97 degrees, we would put the slides in, time them for 20 to 30 minutes, I'm not exactly sure any more what the timing was.
MR. SIMMONS:
Q. And then once that time was up?
MS. WELSH:
A. We would take them out and let them--and just stand them on the bench to let them cool down to room temperature.
MR. SIMMONS:
Q. Okay. So was that process introduced as part of the work Dr.Khalifa did?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And eventually, instead of using the hot plate

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and the dish, there was a custom piece of equipment acquired?
MS. WELSH:
A. There was a water bath.
MR. SIMMONS:
Q. A water bath?
MS. WELSH:
A. Yeah, a water bath that was always at that temperature, so you didn't have to wait for the hot plate to heat up.
MR. SIMMONS:
Q. Okay.
MS. WELSH:
A. But we would still put the buffer in the water bath and allow the buffer itself to come to that temperature.
MR. SIMMONS:
Q. Right, okay, and after the DAKO auto stainer was acquired, you had to continue doing the antigen retrieval by that same method?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And continued to do so up until the time you left in 2003?

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MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Okay. Exhibit 1853, page 13, please, and if you can rotate that 90 degrees? Good. This is the reagent layout map that you were shown earlier for the DAKO machine. I want to go through with you now a little bit about some of the mechanics of how the DAKO auto stainer worked and what you did with it.
MS. WELSH:
A. Okay.
MR. SIMMONS:
Q. And do I understand you to say that it could process 48 slides at a time?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And we don't have a picture of it, unfortunately, I don't think, but I take it to be a device, machine that would sit on a tabletop, probably twice as big as this podium that we have here.
MS. WELSH:
A. Probably bigger than that.

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MR. SIMMONS:
Q. Probably larger than that?
MS. WELSH:
A. Probably about the size of the table there, from the podium to the end maybe.
MR. SIMMONS:
Q. Okay, and in it there would be a space in it where you would put those 48 slides?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And there would be another space in it where you would -
MS. WELSH:
A. Where you would put the reagents.
MR. SIMMONS:
Q. - vials or bottles of reagents.
MS. WELSH:
A. Uh-hm.
MR. SIMMONS:
Q. There was a computer associated with it?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And you told us that when the technician from

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DAKO came in and set it up at first, one of the things that was done was that protocols were entered for the different antibodies that you would process?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And that would involve, I think you said putting in the dilution that you would use?
MS. WELSH:
A. And the time.
MR. SIMMONS:
Q. And the times for what?
MS. WELSH:
A. For incubation.
MR. SIMMONS:
Q. For incubation of the antibody?
MS. WELSH:
A. Of the antibody on the slide.
MR. SIMMONS:
Q. On the slide.
MS. WELSH:
A. Yeah, for the amount of time that the antibody would have remained on the slide.
MR. SIMMONS:

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Q. Right, and once that was entered into the computer, would the machine then have a number or some indicator or sign so that you could select ER/PR and it would run the same protocol for an ER/PR slide each time?
MS. WELSH:
A. Just whenever you entered--when we entered, it would always run the same protocol, there was only one protocol in there for, say, ER/PR and when you entered it into the computer in the morning or late afternoon, whenever you did it from your work list, enter in the surgical number, what stains were required and then that's when the computer would print out this map. And it would do the -
MR. SIMMONS:
Q. So you'd start with a work list.
MS. WELSH:
A. Uh-hm.
MR. SIMMONS:
Q. That would be a list of the specimen numbers and the stains that were to be applied to those specimen numbers, would it?
MS. WELSH:
A. Yes.

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MR. SIMMONS:
Q. And you would have to enter those on a computer key board into the machine, would you?
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And one of the things it would print then would be this reagent layout map?
MS. WELSH:
A. Uh-hm.
MR. SIMMONS:
Q. And would it print something else? Would you also have a map for where the slides went?
MS. WELSH:
A. Yes, well you could print it out, we didn't usually print it, it came up on the screen and we did it from the screen because the machine was right here, the screen was right there, so rather than having to pick up a piece of paper every time, it would be space one was for this certain slide and -
MR. SIMMONS:
Q. Right, so the spaces in the machine where the slides went were numbered?

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MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. And the computer screen would tell you numbers one to so on it had assigned to ER/PR -
MS. WELSH:
A. It did.
MR. SIMMONS:
Q. Or to a particular specimen number.
MS. WELSH:
A. It would have--the computer screen would have a picture -
MR. SIMMONS:
Q. Yes.
MS. WELSH:
A. - of the 48 spaces and on each one there would be the surgical number and the antibody that was being done on that particular slide. So when you pick up your slide, you check one against the other.
MR. SIMMONS:
Q. And you put it in the right spot.
MS. WELSH:
A. And you put it into its correct spot.
MR. SIMMONS:

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Q. And you would print the reagent layout map and do the same thing with that, you would use the reagent layout map to put the materials -
MS. WELSH:
A. To put the materials on.
MR. SIMMONS:
Q. - in the right spots.
MS. WELSH:
A. Yes.
MR. SIMMONS:
Q. Then you would start the machine?
MS. WELSH:
A. Uh-hm.
MR. SIMMONS:
Q. It would take how long to run?
MS. WELSH:
A. Three hours, three and a half hours, depending on how many slides were on and also depending on how many different antibodies. Sometimes this reagent map was two pages because there was a space for two of these racks, so it would depend if you were running twenty different antibodies or twenty-five different antibodies, would obviously take more room and would take a little longer.

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MR. SIMMONS:
Q. And we've heard I think the machine described as a robot or a robotic arm?
MS. WELSH:
A. It had a robotic arm.
MR. SIMMONS:
Q. So I would picture that as just a mechanical device that takes the reagents and puts it on the slides and after a particular period of time, rinses it or adds another reagent?
MS. WELSH:
A. Yeah, rinses it and then adds another reagent.
MR. SIMMONS:
Q. Okay.
MS. WELSH:
A. And it was timed so that it would, timed from the first slide, so if there were 25 of the same test, it would always rinse the first one off after 30 minutes; the second one, thirty minutes; the third one, thirty minutes, so it wasn't like if you were doing them manually, you would have set your timer for 30 minutes and then had to try to watch them. Some would have been on longer.
MR. SIMMONS:

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Q. Yes.
MS. WELSH:
A. But this didn't do it that way.
MR. SIMMONS:
Q. Okay.
THE COMMISSIONER:
Q. Ms. Welsh, we have this particular document is up and since I have a question about it, I-- what does each of these circles actually represent?
MS. WELSH:
A. A space in the reagent rack.
THE COMMISSIONER:
Q. Okay, so what we have here is a representation of 32 of your spaces?
MS. WELSH:
A. Yes, a while plastic rack that would have had four, one, two, three, four--32 holes in it.
THE COMMISSIONER:
Q. Okay.
MS. WELSH:
A. And the rows were numbered across one way and letters down the other, so -
THE COMMISSIONER:
Q. Okay, so if there are blank spaces here, does

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that mean you weren't using those particular ones that day?
MS. WELSH:
A. We didn't use that space that day.
THE COMMISSIONER:
Q. Okay, and by looking at A4, Vim .5 millilitres, I presume, that is a signal-- that's a record of what your machine was instructed to do in respect of that particular slide?
MS. WELSH:
A. Well for that particular reagent, that would mean that, this is not for the slides, this is just for the reagents. That A4 would mean that we needed 0.5 millilitres of Vimentin, which was one of the antibodies because we probably had three slides of Vimentin, so we needed .5 millilitres of Vimentin. The next one -
THE COMMISSIONER:
Q. Well that's my problem, see, I'm not understanding this because -
MR. SIMMONS:
Q. If I can be of help, maybe, would be what happens that the robotic arm would take

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Vimentin from the A4 slot and move it across the machine to where the slide is, apply it to one side -
MS. WELSH:
A. And then go back and get some more.
MR. SIMMONS:
Q. Take some more Vimentin and apply it to another slide.
THE COMMISSIONER:
Q. So this has nothing to do with slides?
MR. SIMMONS:
Q. This is not the mapping slide.
MS. WELSH:
A. No, this is just reagents.
THE COMMISSIONER:
Q. Okay, that's where--all right, so what we have here is really just a depository for material that you want to apply the slides.
MS. WELSH:
A. Yes.
THE COMMISSIONER:
Q. And this is just a record of how much that you happen to have when you add up all the little bits and pieces you need for each of your 48 slides, assuming that you have a full

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complement that day.
MS. WELSH:
A. Yes.
THE COMMISSIONER:
Q. To accomplish all of the tests that you're required to do that day of each little bit of whatever.
MS. WELSH:
A. And it would show you exactly where to put them on the analyzer. This is like a picture of the rack, so all of our antibodies would have had to have been in the actual spot that they're written there, so the vial of Vimentin would be placed in space A4; the vial of KI-67 would -
THE COMMISSIONER:
Q. Which you would do manually.
MS. WELSH:
A. Which I would do manually, yes.
THE COMMISSIONER:
Q. So you have to make sure that the vials are in the correct spots to make sure that the robotic arm actually takes it out of the right container and puts it on the slide?
MS. WELSH:

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A. Exactly, yes.
THE COMMISSIONER:
Q. Okay, thank you. Now at last, I think the light has gone on, thank you.
MR. SIMMONS:
Q. Now I have a few other questions for you just arising out of some of the things Ms. Chaytor asked you, a few points just to pick up on. One of the things you were asked about was the histogrip slides and you describe that as being a particular type of slide that tissue would adhere to better?
MS. WELSH:
A. Uh-hm.
MR. SIMMONS:
Q. And I thought you also said something about, something you would do to slides before you had the histogrip slides?
MS. WELSH:
A. We prepared them, we bought a--there was a reagent that you bought that was called histogrip, sort of speaks for itself, histo meaning tissue and grip meaning grip. So that it would help the tissue to stick to the slides better. We made that reagent up with,

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I don't know what was in it, I'm sure that that was a trade secret.

MR. SIMMONS:

Q. Uh-hm.

MS. WELSH:

A. We mix that with acetone and we physically dipped slides in that and allowed them to dry and then use them.

MR. SIMMONS:

Q. And we have the document that says when the purchase of the histogrip slides, the treated slides, started. How long before that were you treating your own slides with the solution?

MS. WELSH:

A. I have no--I don't remember. Probably a few years. I know we used the histogrip slides for anything that required antigen retrieval because of the heating process in the citric acid buffer.

MR. SIMMONS:

Q. When you first became involved in doing the immunohistochemical testing, I think you said initially there were only four or five antibodies?

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MS. WELSH:

A. Uh-hm.

MR. SIMMONS:

Q. That you would do, so I presume that for the technologists involved in it, it didn't take up a very big part of your day?

MS. WELSH:

A. No, no, not then.

MR. SIMMONS:

Q. Initially it was Mr. Gulliver and then you took over from him.

MS. WELSH:

A. Uh-hm.

MR. SIMMONS:

Q. Up until the time you left in 2003, how did the volume and work load grow over time?

MS. WELSH:

A. Oh exponentially. It was--we did at least two full runs of 48 every day, sometimes we would put the instrument on overnight to do a run overnight while we were gone. And the number of antibodies went to, probably close to a hundred by the time I left.

MR. SIMMONS:

Q. Thank you very much, I don't have any other

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questions for you.

MS. WELSH:

A. Thank you.

THE COMMISSIONER:

Q. Thank you, Mr. Simmons. I've received a message from Mr. Pike to the effect that he has no questions, so we've solved that problem. Ms. Chaytor, do you have anything arising?

MS. PEGGY WELSH, RE-EXAMINATION BY SANDRA CHAYTOR, Q.C.

CHAYTOR, Q.C.:

Q. Just a couple, if we could just leave the reagent map open there, what would happen if the reagent is put in the wrong place? What if your--then the wrong doesn't end up at A4?

MS. WELSH:

A. Then the wrong reagent would be applied to the slides.

CHAYTOR, Q.C.:

Q. What would happen if your slide was not put in the appropriate slot on the machine?

MS. WELSH:

A. Then the wrong reagent would be applied to the slide again.

CHAYTOR, Q.C.:

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Q. So either slide placement or reagent placement could mean that a slide would not come in contact with the appropriate reagent.

MS. WELSH:

A. It could.

CHAYTOR, Q.C.:

Q. And in the case of ER/PR, that would mean you could get a false negative?

MS. WELSH:

A. It the case of any antibody, yes, that could theoretically happen.

CHAYTOR, Q.C.:

Q. That could be the result?

MS. WELSH:

A. Yes.

CHAYTOR, Q.C.:

Q. I think you mentioned in terms of measurements and one microlitre?

MS. WELSH:

A. Uh-hm.

CHAYTOR, Q.C.:

Q. Could you just tell us -

MS. WELSH:

A. A microlitre is a thousandth of a -

CHAYTOR, Q.C.:

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Q. Is it a thousandth?
MS. WELSH:
A. One one hundredth of a millilitre or is it? I -
CHAYTOR, Q.C.:
Q. One one millionth maybe?
MS. WELSH:
A. No, it's not one one millionth.
CHAYTOR, Q.C.:
Q. Of a litre.
MS. WELSH:
A. Of a millilitre, but of a litre it would be one one millionth.
CHAYTOR, Q.C.:
Q. Yes, so that's what we're talking, had some small volume.
MS. WELSH:
A. Yes, we're talking very small amounts of tissue--of fluid.
CHAYTOR, Q.C.:
Q. And just one other point, I had understood that Mr. Simmons was asking you about antigen retrieval and that not being something new. When the DAKO machine came on you had been doing antigen retrieval before, but did I

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understand from what you told me earlier today that ER/PR was the first IHC process that involved the antigen retrieval.
MS. WELSH:
A. But we had been doing ER/PR by the kit method, which would have still required antigen retrieval before we started to use the DAKO autostainer.
CHAYTOR, Q.C.:
Q. Yes, and ER/PR was the first?
MS. WELSH:
A. I'm not one hundred percent sure on that, but I'm thinking it probably was.
CHAYTOR, Q.C.:
Q. Okay, thank you, those are my questions.
THE COMMISSIONER:
Q. Thank you very much. Thank you very much, Ms. Welsh, for coming from Nova Scotia to assist us. I very much appreciate it. It's five minutes to the hour -
CHAYTOR, Q.C.:
Q. Well let's start the next witness. I don't know about the rest of my colleagues, but I'm kind of warm.
THE COMMISSIONER:

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Q. Why don't we just break for the day and meet tomorrow morning at 9:30 and I have a message from administration to the effect that there will be envelops for all at the close of the day. So thank you.
CHAYTOR, Q.C.:
Q. Thank you.
Upon conclusion.

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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 8th 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 8th day of July, A.D., 2008
Judy Moss

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