

COMMISSION OF INQUIRY  
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

June 26, 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)
- David Eaton, Q.C.. . . . Central, Western and Labrador-Grenfell  
Regional Integrated Health Authorities
- Simon Clements . . Drs. O'Malley, Pritzker, Wegrynowski & Mullen

LIST OF EXHIBITS

- EXHIBITS P-1770 THROUGH P-1772, INCLUSIVE . . . . . Pg. 5
- EXHIBITS P-1774 THROUGH P-1840, INCLUSIVE . . . . . Pg. 5

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- 1 COMMISSIONER:
- 2 Q. Please be seated. Mr. Coffey?
- 3 COFFEY, Q.C.:
- 4 Q. Thank you, Commissioner. The next witness is
- 5 Dr. Brendan Mullen, Registrar, please?
- 6 DR. BRENDAN MULLEN (SWORN ) EXAMINATION BY BERNARD COFFEY.
- 7 Q.C.
- 8 REGISTRAR:
- 9 Q. And would you please state and spell your
- 10 complete name for the Commission?
- 11 REGISTRAR:
- 12 Q. John Brenda Morris Mullen. All names or just
- 13 the last name?
- 14 REGISTRAR:
- 15 Q. (Unintelligible ) names.
- 16 DR. MULLEN:
- 17 A. Brendan, B-r-e-n-d-a-n and last name is
- 18 Mullen, M-u-l-l-e-n.
- 19 REGISTRAR:
- 20 Q. Thank you.
- 21 COFFEY, Q.C.:
- 22 Q. Commissioner, there are some new exhibits, I'm
- 23 going to ask they be entered, please? They
- 24 are Exhibits P-1770, 1771 and 1772. Then
- 25 1774, through, I believe, P-1840, inclusive.

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1 COMMISSIONER:  
 2 Q. That accords with my list, yes.  
 3 COFFEY, Q.C.:  
 4 Q. Yes, thank you. I just want to make sure.  
 5 COMMISSIONER:  
 6 Q. Entered.  
 7 EXHIBITS P-1770 THROUGH P-1772, INCLUSIVE, ENTERED INTO  
 8 EVIDENCE.  
 9 EXHIBITS P-1774 THROUGH P-1840, INCLUSIVE, ENTERED  
 10 INTO EVIDENCE.  
 11 COFFEY, Q.C.:  
 12 Q. Thank you, Commissioner. Now, if we could,  
 13 please, Registrar, bring up Exhibit P-1770?  
 14 Now, Dr. Mullen, I take it that this is your  
 15 curriculum vitae?  
 16 DR. MULLEN:  
 17 A. That is correct.  
 18 COFFEY, Q.C.:  
 19 Q. And -  
 20 DR. MULLEN:  
 21 A. As of--preparation day was September 26th.  
 22 This was in, before your interview in Toronto.  
 23 COFFEY, Q.C.:  
 24 Q. Yes. So September of 2007?  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. It goes on for some, I believe, 20 pages,  
 4 Doctor. I'm not going to take you through all  
 5 20 pages. What I am going to ask you to do,  
 6 please, is to outline for the Commissioner  
 7 your educational background and the highlights  
 8 of your professional career?  
 9 DR. MULLEN:  
 10 A. I have an undergraduate degree from the  
 11 University of Ottawa in theoretical  
 12 mathematics. I graduated from there in 1973,  
 13 medical school in Ottawa and from '73 to '77 I  
 14 did a rotating internship in Toronto at the  
 15 Toronto East General Hospital in '77, '78, and  
 16 then a residency in anatomic pathology at the  
 17 University of Toronto from '78 to 1982.  
 18 Following that I went to the University of  
 19 British Columbia in the pulmonary research lab  
 20 to do further training in lung pathology,  
 21 particularly looking at structure function  
 22 studies of lung disease. In '84 I returned to  
 23 Toronto and went on staff at the St. Michael's  
 24 Hospital for a year and a half, about 15  
 25 months, and then moved to the Mount Sinai

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1 Hospital January 1st, 1986 where I've been on  
 2 staff since.  
 3 COFFEY, Q.C.:  
 4 Q. Are you affiliated with any medical schools?  
 5 DR. MULLEN:  
 6 A. Yes. I'm an associate professor in the  
 7 Department of Pathobiology and Laboratory  
 8 Medicine at the University of Toronto.  
 9 COFFEY, Q.C.:  
 10 Q. And you've been, had that sort of appointment  
 11 since when?  
 12 DR. MULLEN:  
 13 A. Initial appointment was at the--when I  
 14 returned to Toronto in 1982, sorry, '84 I  
 15 would have been an assistant professor and the  
 16 in 1993 I was promoted to associate professor.  
 17 And then if you notice in the CV, we changed  
 18 the department's name from Department of  
 19 Pathology to Department of Laboratory Medicine  
 20 and Pathobiology. I also have of note cross  
 21 appointments in Department of Anaesthesia and  
 22 Department of Urology because of research  
 23 interest.  
 24 COFFEY, Q.C.:  
 25 Q. Now, Doctor, just so the Commissioner kind of

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1 gets some sense of who you are and what you do  
 2 for a living, okay, I'm going to ask you to  
 3 describe for her, please, because you've been  
 4 at Mount Sinai, I take it, for effectively two  
 5 decades?  
 6 DR. MULLEN:  
 7 A. We try not to remember that.  
 8 COFFEY, Q.C.:  
 9 Q. Yes, that's about it. So, Doctor, could you  
 10 tell the Commissioner, please, because you  
 11 refer to research?  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. And I take it as well you do clinical work?  
 16 DR. MULLEN:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. How is that structured?  
 20 DR. MULLEN:  
 21 A. People who are on staff in teaching hospitals  
 22 at the University of Toronto have what are  
 23 called academic appointments, so depending on  
 24 the hospital it can range anywhere from 20  
 25 percent service to 80 percent research to

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1 basically 80 percent service, 20 percent  
 2 research. When I talk about research, I'm  
 3 talking about protected time. Nominally I  
 4 have an appointment that is 50/50, 50 percent  
 5 service, 50 percent research. And in the  
 6 service basically we're talking about  
 7 diagnostic pathology where I would cover  
 8 services such as surgical pathology, which is  
 9 the topic of interest today, I also cover the  
 10 cytopathology service and I also cover some of  
 11 the clinical laboratories, I'm in charge of  
 12 the andrology lab, which is investigation of  
 13 male infertility, then very small component of  
 14 autopsy pathology. On the--so that would be  
 15 the service side. Then there's also  
 16 administration. I'm the deputy director of  
 17 the department, so I have administrative  
 18 responsibilities, being director of the  
 19 andrology lab there are administrative  
 20 responsibilities. And then the theoretical 50  
 21 percent research time or protected time is  
 22 when you're not nominally on service, that you  
 23 have time to do academic pursuits. And my  
 24 areas of interest through the CV are mainly  
 25 structure function studies and quantitative

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1 pathology, looking initially at lung  
 2 pathology, mechanisms of lung injury, now  
 3 moving because of a change in interest and  
 4 change in focus of the hospital into male  
 5 infertility, diagnosis of trying to develop  
 6 laboratory tests for the investigation of male  
 7 infertility. The whole focus has been on  
 8 quantitation of disorders.  
 9 COFFEY, Q.C.:  
 10 Q. I believe you indicated you are an assistant  
 11 director, you said?  
 12 DR. MULLEN:  
 13 A. I'm the deputy director -  
 14 COFFEY, Q.C.:  
 15 Q. Deputy, I apologize.  
 16 DR. MULLEN:  
 17 A. Deputy director.  
 18 COFFEY, Q.C.:  
 19 Q. And deputy director of the?  
 20 DR. MULLEN:  
 21 A. Department of Pathology and Laboratory  
 22 Medicine. I believe Dr. Pritzker was here  
 23 Monday afternoon.  
 24 COFFEY, Q.C.:  
 25 Q. Yes.

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1 DR. MULLEN:  
 2 A. And he may have explained his roles.  
 3 Basically I--when he is away, I'm in charge of  
 4 the department. I also in his presence, as  
 5 he's busy with other things, I look after some  
 6 of the day-to-day operations, particularly of  
 7 the surgical pathology, cytopathology, autopsy  
 8 side.  
 9 COFFEY, Q.C.:  
 10 Q. And you've been deputy director for how long?  
 11 DR. MULLEN:  
 12 A. Let me check. Since 1998.  
 13 COFFEY, Q.C.:  
 14 Q. So, Doctor, within, then, the department of  
 15 which you're the deputy director, so you  
 16 would, in the capacity, I take it, as deputy  
 17 would report to Dr. Pritzker?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. In that capacity?  
 22 DR. MULLEN:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. As a service pathologist, in your role as a

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1 service provider, who do you report to?  
 2 DR. MULLEN:  
 3 A. Dr. Pritzker, ultimately. We have chiefs of  
 4 service, so we have a chief of surgical  
 5 pathology who is Dr. Kirsh, I would report to  
 6 him on surgical pathology issues.  
 7 COFFEY, Q.C.:  
 8 Q. Okay.  
 9 DR. MULLEN:  
 10 A. I have a head of cytology, Dr. Colgan, I would  
 11 report to him on cytology issues. We have a  
 12 head of autopsy, I'd report to him on autopsy  
 13 issues, mainly the professional issues there.  
 14 The technical issues, I would--or, sorry, we  
 15 also have a director of immunohistochemistry,  
 16 Dr. Riddell, and I report to him issues in  
 17 immunohistochemistry. We have a director of  
 18 electron microscopy. All of the areas have  
 19 medical directors as well as technical  
 20 directors, so for the medical issues I would  
 21 report to the medical director, the technical  
 22 issues usually directly to the technologists  
 23 but also to carbon copy the medical director.  
 24 COFFEY, Q.C.:  
 25 Q. And Dr. Frances O'Malley was here earlier in

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1 the week. And I understand from what she told  
 2 the Commissioner that she would be, describe  
 3 herself as a pathologist with particular  
 4 interest in breast pathology or a breast  
 5 pathologist.  
 6 DR. MULLEN:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. How is her role structured in comparison to  
 10 yours, I mean, where in the lab?  
 11 DR. MULLEN:  
 12 A. Dr. O'Malley joined us, I believe, in the late  
 13 '90s.  
 14 COFFEY, Q.C.:  
 15 Q. Yes.  
 16 DR. MULLEN:  
 17 A. At that time she was doing essentially what I  
 18 would have been doing but with special  
 19 emphasis on breast. At that time I would have  
 20 been the special emphasis on lung. Over time  
 21 her service has focused more on breast to now  
 22 that starting in July 1st that she'll be  
 23 exclusively breast. So she would be involved  
 24 in the diagnosis of breast core biopsies,  
 25 breast surgical specimens. And also we do,

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1 we're a referral service for estrogen,  
 2 progesterone receptors and HER2 analysis for  
 3 certain areas of the province, and she would  
 4 be--she's in charge of that service.  
 5 COFFEY, Q.C.:  
 6 Q. And you've just referred to a referral centre  
 7 for certain areas in the province.  
 8 DR. MULLEN:  
 9 A. Yeah.  
 10 COFFEY, Q.C.:  
 11 Q. Could you tell the Commissioner, please, how  
 12 that works within--in terms of Mount Sinai and  
 13 certain areas of the province, in particular  
 14 in relation to ER/PR, HER2/neu, if you would?  
 15 That's what I -  
 16 DR. MULLEN:  
 17 A. Can I focus mainly on the ER/PR?  
 18 COFFEY, Q.C.:  
 19 Q. Yes. That's what I'm interested in.  
 20 DR. MULLEN:  
 21 A. Okay. Estrogen--now, I'm fine to say ER/PR,  
 22 everybody knows what I'm -  
 23 COFFEY, Q.C.:  
 24 Q. Yes.  
 25 DR. MULLEN:

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1 A. Okay. The ER/PR service, we provide service  
 2 to our hospitals, both inpatient and  
 3 outpatients. We also through contracts with  
 4 other hospitals in the province provide ER/PR  
 5 service to them. Part of it is because of our  
 6 efficiency, part of it is our expertise and  
 7 part of it is just cost/benefit for the other  
 8 hospitals. So we provide services to hospital  
 9 groups within Toronto, the Humber River  
 10 Regional Hospital, which is two sites, we also  
 11 provide service to the Greater Niagara Health  
 12 System, which I believe has three or four  
 13 sites, and they're southwest part of the  
 14 province. And we also referral service for  
 15 hospitals that are doing their ER/PRs and have  
 16 technical difficulties or interpretation  
 17 difficulties, they'll send us the case. So  
 18 and so and then--sorry, I've forgotten the  
 19 major source for me is Newfoundland. We do  
 20 ER/PR for--and HER2 for Newfoundland.  
 21 COFFEY, Q.C.:  
 22 Q. Now, sir, in terms of doing ER and PR testing  
 23 and reporting and I take it HER2/neu as well  
 24 for Newfoundland and Labrador, when did you,  
 25 yourself, first get involved in that, from

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1 Newfoundland, like -  
 2 DR. MULLEN:  
 3 A. Personally or the hospital?  
 4 COFFEY, Q.C.:  
 5 Q. The hospital first of all.  
 6 DR. MULLEN:  
 7 A. Okay, okay. The hospital became involved in  
 8 October of 1999. We were approached by  
 9 Peninsulas Health Care in Carbonear to -  
 10 COFFEY, Q.C.:  
 11 Q. Actually, that's -  
 12 DR. MULLEN:  
 13 A. The Carbonear General Hospital in -  
 14 COFFEY, Q.C.:  
 15 Q. That would be Clarenville, actually.  
 16 DR. MULLEN:  
 17 A. Oh, is it?  
 18 COFFEY, Q.C.:  
 19 Q. If it's Peninsulas.  
 20 DR. MULLEN:  
 21 A. Sorry, Peninsulas Health Care, sorry.  
 22 COFFEY, Q.C.:  
 23 Q. Clarenville.  
 24 DR. MULLEN:  
 25 A. My apologies.

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1 COMMISSIONER:  
 2 Q. That's all right, we don't expect you to know  
 3 the geography.  
 4 COFFEY, Q.C.:  
 5 Q. No.  
 6 DR. MULLEN:  
 7 A. Well, I send reports to all these places, I  
 8 should--and you keep changing the names,  
 9 unfortunately. So it was, sorry, Peninsulas  
 10 Health Care.  
 11 COFFEY, Q.C.:  
 12 Q. Yes.  
 13 DR. MULLEN:  
 14 A. In October of '99 we were approached by their  
 15 pathologist to perform the ER and PR stains  
 16 and to send the case to the pathologist for  
 17 interpretation. We did not have any  
 18 interpretative role. And that continued until  
 19 we started to introduce HER2 analysis and  
 20 because HER2 analysis requires the pathologist  
 21 to reflex, you have to interpret the stains  
 22 and then if they're equivocal or there's some  
 23 technical issue, you have to do what's called  
 24 fluorescent in situ hybridization, which is a  
 25 further analysis, and for time and basically

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1 expertise we decided that it would be better  
 2 if I reported the cases and would reflex and  
 3 then speed up and send the reports. So that  
 4 started in September, I believe September of  
 5 '05. And -  
 6 COFFEY, Q.C.:  
 7 Q. That's for the Peninsulas?  
 8 DR. MULLEN:  
 9 A. That's Peninsulas. Then St. Clare's  
 10 approached us to go prospectively, I believe,  
 11 in August of '05 to do--when I talk about  
 12 prospective cases, they're current surgical  
 13 material. And we did ER and PR for St.  
 14 Clare's from August 15th of '05 to March 13th  
 15 of '07 and then we stopped and then in '08,  
 16 March 7th of '08 we again started to do them.  
 17 I'm not sure we did very many. And then I  
 18 believe about a week or two ago we were  
 19 approached by St. Clare's again to do all of  
 20 the ER/PR. So -  
 21 COFFEY, Q.C.:  
 22 Q. For what you described as St. Clare's -  
 23 DR. MULLEN:  
 24 A. Yeah, the St. Clare's site, Eastern Health.  
 25 Well, Eastern Health is multiple hospitals.

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1 COFFEY, Q.C.:  
 2 Q. Yes, I appreciate that and I'll come to that  
 3 in a moment.  
 4 DR. MULLEN:  
 5 A. Okay, so my reports always go to St. Clare's  
 6 so that's why I call it St. Clare's.  
 7 COFFEY, Q.C.:  
 8 Q. Yes. In terms of from your perspective this  
 9 is the hospital facility you're getting it  
 10 from -  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. - and wherever they get it from, they'll speak  
 15 to.  
 16 DR. MULLEN:  
 17 A. And then so that was the prospective studies.  
 18 COFFEY, Q.C.:  
 19 Q. Yes.  
 20 DR. MULLEN:  
 21 A. We've also been doing quality assurance cases  
 22 in which they would send a block for us to  
 23 stain, I would interpret the slides and send  
 24 it back. That was not a report that went to  
 25 the patient's chart, that was for their

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1 quality control.  
 2 COFFEY, Q.C.:  
 3 Q. I'm sorry, Doctor, if you could just on that  
 4 point, could you just explain that again to  
 5 the Commissioner? This is what, this is what  
 6 kind of -  
 7 DR. MULLEN:  
 8 A. When they re-instituted ER/PR testing in March  
 9 of '07, I'm not sure of the timing when we  
 10 started the QA, that they wanted external  
 11 validation that their stains were working, so  
 12 they would do the stains internally, report  
 13 the case, they would then send us the block, I  
 14 would independently stain--well, the lab would  
 15 stain the case, stain the slides and then I  
 16 would report the results on a spreadsheet and  
 17 send it back to them. So they could--looking  
 18 at the concordance, what their report was,  
 19 what my report was.  
 20 COFFEY, Q.C.:  
 21 Q. Yes. For their own purposes?  
 22 DR. MULLEN:  
 23 A. Yes, for internal purposes.  
 24 COFFEY, Q.C.:  
 25 Q. And that began, you believe, after they began

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1 to do their own cases again?  
 2 DR. MULLEN:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. Which would be early, around March of '07?  
 6 DR. MULLEN:  
 7 A. Yes, that's correct. The exact date, I would  
 8 have to look at one of my spreadsheets, but it  
 9 would be after '07, March of '07.  
 10 COFFEY, Q.C.:  
 11 Q. And that has, I take it, continued  
 12 periodically?  
 13 DR. MULLEN:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. Up until recently, relatively recently?  
 17 DR. MULLEN:  
 18 A. We would get three or four cases at a time, I  
 19 can't say every month and I--in total we  
 20 received 39 cases over that time period.  
 21 COFFEY, Q.C.:  
 22 Q. For this QA purpose?  
 23 DR. MULLEN:  
 24 A. QA purposes, yes.  
 25 COFFEY, Q.C.:

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1 Q. And then you believe that you recall that  
 2 March of this year?  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. March of 2008 you were approached about,  
 7 again, starting to do some ER and PR, not QA  
 8 cases?  
 9 DR. MULLEN:  
 10 A. No.  
 11 COFFEY, Q.C.:  
 12 Q. But actual current cases?  
 13 DR. MULLEN:  
 14 A. The diagnostic, yes.  
 15 COFFEY, Q.C.:  
 16 Q. Diagnostic cases for St. Clare's or -  
 17 DR. MULLEN:  
 18 A. Eastern Health.  
 19 COFFEY, Q.C.:  
 20 Q. What you refer to as St. Clare's, it's Eastern  
 21 Health.  
 22 DR. MULLEN:  
 23 A. Just to clarify, when you say you were  
 24 approached, it's Mount Sinai was approached.  
 25 COFFEY, Q.C.:

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1 Q. Mount Sinai, and Mount Sinai approached -  
 2 DR. MULLEN:  
 3 A. Yes. I am not the Mount Sinai Hospital.  
 4 COFFEY, Q.C.:  
 5 Q. Yes.  
 6 DR. MULLEN:  
 7 A. Ultimately, but.  
 8 COFFEY, Q.C.:  
 9 Q. But I take it the slides end up -  
 10 DR. MULLEN:  
 11 A. Yes, on my desk.  
 12 COFFEY, Q.C.:  
 13 Q. On your desk. Doctor, with respect to that  
 14 then and there were some cases, but the volume  
 15 wasn't--was it significant beginning in March  
 16 or April, did you understand you were doing  
 17 them all or just some or you didn't know?  
 18 DR. MULLEN:  
 19 A. Well, they started to trickle. I was doing  
 20 all of the HER2 cases, so every breast cancer  
 21 in Newfoundland--well, I can't, every, I can't  
 22 say it's every breast cancer, but the majority  
 23 of breast cancer. I don't know if Eastern  
 24 Health was sending anywhere else or anyone was  
 25 sending out, but every case we were doing HER2

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1 on and then we were asked to then do some  
 2 ER/PR and then it started to increase in  
 3 number.  
 4 COFFEY, Q.C.:  
 5 Q. And then -  
 6 DR. MULLEN:  
 7 A. I don't have a graph that shows the increase  
 8 in numbers, but.  
 9 COFFEY, Q.C.:  
 10 Q. And then I take it within the past week or so  
 11 you indicated you understood that Mount Sinai  
 12 was approached?  
 13 DR. MULLEN:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. To take on the St. Clare's cases?  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. At least for a period of time now, in real  
 21 time now as we speak?  
 22 DR. MULLEN:  
 23 A. On Monday I signed out 26 of them, so, yes.  
 24 COFFEY, Q.C.:  
 25 Q. Okay. That's Monday past?

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1 DR. MULLEN:  
 2 A. Yes. So there is a significant number.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, okay, that's--you say signed out, that  
 5 would be ER and PR?  
 6 DR. MULLEN:  
 7 A. Yeah, and HER2.  
 8 COFFEY, Q.C.:  
 9 Q. And HER2.  
 10 DR. MULLEN:  
 11 A. Well, it's interesting, some cases they'll  
 12 send two blocks, one they want ER/PR, another  
 13 one they'll want HER2 only and then it's a  
 14 mixture of everything. But for every case  
 15 it'll be a HER2 and now I understand it'll be  
 16 an ER/PR, as well.  
 17 COFFEY, Q.C.:  
 18 Q. And, Doctor, in terms of that most recently  
 19 coming to your attention within the past week,  
 20 how was that brought to your attention the  
 21 fact that you were going to be asked to do  
 22 this?  
 23 DR. MULLEN:  
 24 A. I received an e-mail.  
 25 COFFEY, Q.C.:

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1 Q. Okay.  
 2 DR. MULLEN:  
 3 A. From my boss, I think, or he told me I was  
 4 doing it, whichever, I'm not quite sure.  
 5 COFFEY, Q.C.:  
 6 Q. In that context, your boss in that context  
 7 would be?  
 8 DR. MULLEN:  
 9 A. Is Dr. Pritzker.  
 10 COFFEY, Q.C.:  
 11 Q. Dr. Pritzker. So that's St. Clare's, as it  
 12 were, to use your, the term you understand it  
 13 by. And you've indicated that that began in a  
 14 big way back in August of '05?  
 15 DR. MULLEN:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. In our world here I believe that would, we  
 19 would equate that with Eastern Health,  
 20 generally. I'm going to ask you then about  
 21 Western Health, the Western Regional  
 22 Integrated Health Authority, I believe is the--  
 23 -it's Corner Brook.  
 24 DR. MULLEN:  
 25 A. Western, Central, Labrador Grenfell and

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1 Eastern.  
 2 COFFEY, Q.C.:  
 3 Q. Yes.  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. So could you tell the Commissioner, please,  
 8 about Western, how that worked? Have you been  
 9 doing any work for Western, do you know?  
 10 DR. MULLEN:  
 11 A. Can I go to the next--the letters that I sent  
 12 out?  
 13 COFFEY, Q.C.:  
 14 Q. Yes.  
 15 DR. MULLEN:  
 16 A. Would that be appropriate?  
 17 COFFEY, Q.C.:  
 18 Q. Yeah, no, okay, what I'll do then is this, so  
 19 I'll ask you this, so in order to actually get  
 20 the dates and so on on that you would prefer  
 21 to refer to the actual letters. And we'll be  
 22 doing that.  
 23 DR. MULLEN:  
 24 A. Okay.  
 25 COFFEY, Q.C.:

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1 Q. But in terms of the overall kind of general  
 2 scheme of things, have you been doing work for  
 3 Western?  
 4 DR. MULLEN:  
 5 A. I've been doing, yes, Western, Central,  
 6 Labrador Grenfell, Western, Central, Eastern -  
 7 COFFEY, Q.C.:  
 8 Q. And I'll take you to those.  
 9 DR. MULLEN:  
 10 A. Yes, I'm just--so Corner Brook, James Paton -  
 11 COFFEY, Q.C.:  
 12 Q. And you can use the phrases that you're used  
 13 to -  
 14 COMMISSIONER:  
 15 Q. You can tell us where you get them from.  
 16 DR. MULLEN:  
 17 A. Yes.  
 18 COMMISSIONER:  
 19 Q. We can make the connections.  
 20 COFFEY, Q.C.:  
 21 Q. Yes.  
 22 DR. MULLEN:  
 23 A. I don't know if I brought my fax sheet. I fax  
 24 reports to people, if I have it, I can tell  
 25 you. Okay, so I send to Carbonear, I send to

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1 Corner Brook, I send to James Paton, is that  
 2 an overlap?  
 3 COFFEY, Q.C.:  
 4 Q. No, it's not.  
 5 DR. MULLEN:  
 6 A. Western Regional.  
 7 COFFEY, Q.C.:  
 8 Q. Yes.  
 9 DR. MULLEN:  
 10 A. St. Clare's and Labrador Grenfell. Yeah,  
 11 five. Am I missing one?  
 12 COFFEY, Q.C.:  
 13 Q. So Carbonear, St. Anthony?  
 14 DR. MULLEN:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Corner Brook?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. And -  
 22 COMMISSIONER:  
 23 Q. Gander?  
 24 COFFEY, Q.C.:  
 25 Q. Gander?

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1 DR. MULLEN:  
 2 A. Gander, yes.  
 3 COFFEY, Q.C.:  
 4 Q. Gander.  
 5 DR. MULLEN:  
 6 A. Gander. Am I missing -  
 7 MR. SIMMONS:  
 8 Q. Don't forget Grand Falls.  
 9 COFFEY, Q.C.:  
 10 Q. And Grand Falls.  
 11 COMMISSIONER:  
 12 Q. Thank you.  
 13 DR. MULLEN:  
 14 A. Grand Falls, yes, sorry.  
 15 COFFEY, Q.C.:  
 16 Q. Thank you. So in terms of -  
 17 DR. MULLEN:  
 18 A. Sorry, I -  
 19 COFFEY, Q.C.:  
 20 Q. No, no, no.  
 21 DR. MULLEN:  
 22 A. And I have to--and it started out very nicely  
 23 that there as a hospital attached, then it  
 24 moved to everybody was Eastern Health and -  
 25 COMMISSIONER:

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1 Q. Their names kept changing on you.  
 2 DR. MULLEN:  
 3 A. Various hospitals in that and so I'm getting  
 4 confused. I can tell you the names of the  
 5 pathologists, but I can't associate them with  
 6 the hospitals.  
 7 COFFEY, Q.C.:  
 8 Q. And I will be taking you to the actual, some  
 9 of the letters and e-mail exchanges that  
 10 could--are involved in that, but again for the  
 11 Commissioner kind of get a broad view of it,  
 12 overview, I take it that your work then for  
 13 these other regions or other hospitals outside  
 14 St. John's, other than the peninsulas which  
 15 dates back to the late '90s, they all began, I  
 16 take it, around the same time as -  
 17 DR. MULLEN:  
 18 A. Early September. I think the first report I  
 19 had was September 2nd, '05.  
 20 COFFEY, Q.C.:  
 21 Q. '05.  
 22 DR. MULLEN:  
 23 A. But that could have been the Peninsulas that I  
 24 switched over. So it would be September, mid,  
 25 sometime September, '05, early October.

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1 COFFEY, Q.C.:  
 2 Q. And in relation to those other areas, the  
 3 outside St. John's areas, what has been the  
 4 situation in relation to your, you on behalf  
 5 of Mount Sinai doing the ER and PR and  
 6 HER2/neu for those areas, how has that worked,  
 7 has that continued up until the present?  
 8 DR. MULLEN:  
 9 A. Yes, that has, to the best of my knowledge,  
 10 yes. Except one or two of the hospitals, I  
 11 believe in the spring had begun to split their  
 12 cases that I would do the HER2 and St. John  
 13 would do the ER/PR. They'd send one block to  
 14 St. John to be interpreted and one block to  
 15 me.  
 16 COFFEY, Q.C.:  
 17 Q. Yeah.  
 18 DR. MULLEN:  
 19 A. And now I would presume that starting we'll do  
 20 all of that.  
 21 COFFEY, Q.C.:  
 22 Q. Okay.  
 23 DR. MULLEN:  
 24 A. They'll combine it again.  
 25 COFFEY, Q.C.:

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1 Q. And that, your understanding then in the past  
 2 spring at least one or two hospitals within  
 3 Newfoundland that had earlier been doing ER/PR  
 4 and HER2/neu for had at least started to send  
 5 their ER and PR to St. John's, here.  
 6 DR. MULLEN:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. And but now you anticipate at least for the  
 10 foreseeable future, for a little while, you're  
 11 going to be doing them all again?  
 12 DR. MULLEN:  
 13 A. Yes. I mean, the case number won't increase  
 14 because we're doing the HER2, but we'll have  
 15 the two extra stains. The thing you have to  
 16 remember is I don't know what the output is in  
 17 St. John, I know what we receive, I don't  
 18 know--I mean, in Newfoundland, I don't know, I  
 19 mean, for all I know somebody could be sending  
 20 them to Montreal, I just don't know.  
 21 COFFEY, Q.C.:  
 22 Q. But in terms of you can--all you know is what  
 23 you get yourself?  
 24 DR. MULLEN:  
 25 A. What I receive, yes.

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1 COFFEY, Q.C.:  
 2 Q. Sure. Well, Doctor, in terms of ER and PR and  
 3 HER2/neu, well, I'll ask you about ER and PR  
 4 in particular, when did you first get  
 5 involved, I mean, looking back on it, in terms  
 6 of reporting ER and PR, not for Newfoundland  
 7 and Labrador, but just generally in your  
 8 career?  
 9 DR. MULLEN:  
 10 A. Basically the minute we started--we stopped  
 11 doing the Ligand--the biochemical assay and  
 12 started to do it in-house, which would have  
 13 probably been in the late '90s.  
 14 COFFEY, Q.C.:  
 15 Q. Okay. And within your own organization, I'll  
 16 ask you about your own experience, ER and PR  
 17 reporting, for example, in the past year or so  
 18 how many ER tests would you have interpreted?  
 19 Just to give some -  
 20 DR. MULLEN:  
 21 A. I'll have to look at my little spreadsheet.  
 22 COFFEY, Q.C.:  
 23 Q. Yes.  
 24 DR. MULLEN:  
 25 A. Can I do it by since '05?

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1 COFFEY, Q.C.:  
 2 Q. Sure.  
 3 DR. MULLEN:  
 4 A. And I can divide through.  
 5 COFFEY, Q.C.:  
 6 Q. Just to give the Commissioner some sense of  
 7 how much of this work you do?  
 8 DR. MULLEN:  
 9 A. Since '05 to June, basically June 1st of this  
 10 year I've looked at 1439 cases, so 1439.  
 11 COFFEY, Q.C.:  
 12 Q. And that would be estrogen cases?  
 13 DR. MULLEN:  
 14 A. ER/PR.  
 15 COFFEY, Q.C.:  
 16 Q. ER/PR?  
 17 DR. MULLEN:  
 18 A. Yes. Then I would have looked--because the  
 19 bulk of my work is Newfoundland, I would have  
 20 looked at more cases that had HER2 but didn't--  
 21 --more breast cases but without the ER/PR, so.  
 22 COFFEY, Q.C.:  
 23 Q. Now, before that, without getting into the  
 24 numbers, how much ER/PR work would you have  
 25 done in the years before '05?

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1 DR. MULLEN:  
 2 A. Before '05 maybe, when I'm on service, if I'm  
 3 on service once a week and depending on how  
 4 busy the breast service is, maybe two cases a  
 5 week, so maybe 50 to 100 a year.  
 6 COFFEY, Q.C.:  
 7 Q. Somewhere in that?  
 8 DR. MULLEN:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. And that would go back over the years, I take  
 12 it?  
 13 DR. MULLEN:  
 14 A. That would certainly go back over the years.  
 15 The hospital waxes and wains in the number of  
 16 cases that we do, whether we have one breast  
 17 surgeon, two breast surgeons, three breast  
 18 surgeons and the commitment of the hospital to  
 19 that service, so it would fluctuate year to  
 20 year, and then with cutbacks, how much  
 21 operating time.  
 22 COFFEY, Q.C.:  
 23 Q. Now the numbers that you--of ER/PR cases that  
 24 you've looked at in the past couple of years,  
 25 do that include the retrospective?

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1 DR. MULLEN:  
 2 A. No, no. I've kept the retro and the  
 3 Commission review and the QA separate from  
 4 that.  
 5 COFFEY, Q.C.:  
 6 Q. Okay.  
 7 DR. MULLEN:  
 8 A. Those were all diagnostic cases. When I say  
 9 diagnostic, all prospective cases for which I  
 10 issued a report.  
 11 COFFEY, Q.C.:  
 12 Q. And I'll be talking to you about this issuance  
 13 of a report, per se. Now, we have not, I just  
 14 now referred to the--I've used the word  
 15 "retrospective", and I gather in some of the  
 16 e-mails that that's the way it's referred to.  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. Here, a retrospective study or analysis  
 21 involving Newfoundland and Labrador, in  
 22 particular, St. Clare's or Eastern Health.  
 23 Could you tell the Commissioner, please, what  
 24 you recall about how you first got involved in  
 25 this?

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1 DR. MULLEN:  
 2 A. I believe it was early August, '05 Dr.  
 3 Pritzker called me into his office, said he  
 4 had been approached by Eastern Health, St.  
 5 Clare's to look at--to restrain or review, look  
 6 at, however, I can't remember the exact  
 7 terminology, about 50 to 100 cases and would I  
 8 do it, because I was back from holidays and I  
 9 was available at the time. Yes, we could do  
 10 that, bring them, stain them, issue reports  
 11 and out. So my initial impression was either  
 12 50 to 100.  
 13 COFFEY, Q.C.:  
 14 Q. And that, Dr. Pritzker lured you into his  
 15 office?  
 16 DR. MULLEN:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. And asked you to do this. And at the time,  
 20 anyway, in talking to him you understood that  
 21 this was, what -  
 22 DR. MULLEN:  
 23 A. Very time limited, this was a commitment for  
 24 100 cases.  
 25 COFFEY, Q.C.:

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1 Q. Yes. And in terms of that, just so the  
 2 Commissioner again has some sense of at the  
 3 time for Newfoundland and Labrador the only  
 4 work that you were doing on behalf of Eastern  
 5 Health was in relation to the Peninsulas -  
 6 DR. MULLEN:  
 7 A. Yes. This was the technical work only until  
 8 the HER2, so it would be basically September  
 9 of '05 when the different stain--different  
 10 ancillary test was being done, then I would  
 11 have issued reports.  
 12 COFFEY, Q.C.:  
 13 Q. So before September, '05, so August, '05, even  
 14 a month before, you were actually doing what  
 15 for Peninsulas then?  
 16 DR. MULLEN:  
 17 A. The only thing we would do, technically we  
 18 would stain the slides and send them to, send  
 19 them to Newfoundland to be interpreted.  
 20 COFFEY, Q.C.:  
 21 Q. So you weren't issuing a report?  
 22 DR. MULLEN:  
 23 A. No, no.  
 24 COFFEY, Q.C.:  
 25 Q. Okay.

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1 DR. MULLEN:  
 2 A. No, I didn't actually see the slides. My  
 3 secretary was in charge of returning them. So  
 4 that was basically my contact. And then I  
 5 kept the numbers with Ms. Wegrynowski so we  
 6 could bill, directly bill them for them.  
 7 COFFEY, Q.C.:  
 8 Q. Doctor, while I'm on the topic of the  
 9 Peninsulas, do you recall ever arriving at any  
 10 understanding as to why Peninsulas was asking  
 11 Mount Sinai to create slides?  
 12 DR. MULLEN:  
 13 A. I had a conversation at the Ontario  
 14 Association of Pathologists meeting, I believe  
 15 it was two years ago, with Dr. Yassa, who is  
 16 currently in Brockville, who was at  
 17 Peninsulas, and I asked him why he had started  
 18 to send us--because I found out that he  
 19 actually was a pathologist at the time,  
 20 because by the time I was involved in this, it  
 21 was Dr. Khan and Dr. Anwas (phonetic), I  
 22 believe.  
 23 COFFEY, Q.C.:  
 24 Q. I'm sorry, Doctor?  
 25 DR. MULLEN:

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1 A. Was it Anwas?  
 2 COFFEY, Q.C.:  
 3 Q. Okay, yes.  
 4 DR. MULLEN:  
 5 A. Who were the pathologist I would send the  
 6 reports to. And his name never -  
 7 COFFEY, Q.C.:  
 8 Q. In Clarenville?  
 9 DR. MULLEN:  
 10 A. Yes. His name had never come--Dr. Yassa's  
 11 name had never come up. So I asked, and he  
 12 said that--so in '99 he had sent cases to St.  
 13 John, he wasn't happy with the results, there  
 14 was a delay or refusal to send him the  
 15 controls, so he decided to look elsewhere.  
 16 And I can't recall where all he had looked or  
 17 we were the first institution that he had  
 18 approached, but he had spoke to Dr. Asa, who  
 19 was head of our immunohistochemistry at the  
 20 time, and she--or Doctor, I think it was Dr.  
 21 Asa, to--if we would undertake the work, and  
 22 it was a minimal amount of work so it would  
 23 have--there was no issue with doing it.  
 24 COFFEY, Q.C.:  
 25 Q. And that had been going on then since 1999?

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1 DR. MULLEN:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And into 2005, the middle of '05?  
 5 DR. MULLEN:  
 6 A. Yeah.  
 7 COFFEY, Q.C.:  
 8 Q. So in terms then of Newfoundland and Labrador,  
 9 other than the fact you were aware in the  
 10 period from '99 to '05 that Mount Sinai was  
 11 creating slides?  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. That were being simply shipped to Peninsulas  
 16 for their interpretation?  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. And you only around that time or even after  
 21 that first found out why that whole process  
 22 had started in the first place?  
 23 DR. MULLEN:  
 24 A. Yes, would have been probably '06.  
 25 COFFEY, Q.C.:

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1 Q. '06?  
 2 DR. MULLEN:  
 3 A. The meeting of--'06 meeting.  
 4 COFFEY, Q.C.:  
 5 Q. Yeah.  
 6 DR. MULLEN:  
 7 A. It was in Huntsville, so I'm just working  
 8 backward so it would be, yes, '06.  
 9 COFFEY, Q.C.:  
 10 Q. '06. It was actually before you actually  
 11 found out why Mount Sinai had been doing this  
 12 for five or six years at that point?  
 13 DR. MULLEN:  
 14 A. Yes, yes. Oh, it was years and years,  
 15 basically it would be six or seven years later  
 16 why we were doing it.  
 17 COFFEY, Q.C.:  
 18 Q. And Mount Sinai itself was not reporting the  
 19 cases -  
 20 DR. MULLEN:  
 21 A. Yeah.  
 22 COFFEY, Q.C.:  
 23 Q. - they were creating the slides? No  
 24 (inaudible) -  
 25 DR. MULLEN:

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1 A. We had no professional responsibility other  
 2 than overseeing the technical issue in the  
 3 lab. It was up to the doctors at the health  
 4 facility to report, interpret and report.  
 5 COFFEY, Q.C.:  
 6 Q. And as well, while we're at it, and I  
 7 appreciate that you've referred, occasionally,  
 8 and I'll just clarify this for the record now,  
 9 when you occasionally refer to St. John,  
 10 because you -  
 11 DR. MULLEN:  
 12 A. Oh, did I let slip there, okay?  
 13 COFFEY, Q.C.:  
 14 Q. Yes. You will be talking about St. John's.  
 15 St. John, New Brunswick has nothing to do with  
 16 anything we're -  
 17 DR. MULLEN:  
 18 A. Sorry.  
 19 COFFEY, Q.C.:  
 20 Q. No, no, just so we're clear, no, just--no, and  
 21 I appreciate that, Doctor.  
 22 DR. MULLEN:  
 23 A. I should be aware of that, my wife is from St.  
 24 John, New Brunswick.  
 25 COFFEY, Q.C.:

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1 Q. So just so we're clear.  
 2 DR. MULLEN:  
 3 A. Yes, I'm--yes, St. John, sorry, I will plural  
 4 that.  
 5 COFFEY, Q.C.:  
 6 Q. Every time you say St. John, if you do slip  
 7 into it, we are referring to St. John's?  
 8 DR. MULLEN:  
 9 A. Yes. So should I refer to -  
 10 COMMISSIONER:  
 11 Q. Except when you talk to your wife, then you  
 12 have to remember to St. John.  
 13 DR. MULLEN:  
 14 A. Well, when I was -  
 15 COMMISSIONER:  
 16 Q. Very important when you come to either city.  
 17 DR. MULLEN:  
 18 A. - at the airport, I looked at the board and,  
 19 oh, I missed my flight, and then--the SA  
 20 versus ST. No, I will--yes, I apologize, so  
 21 I'll -  
 22 COFFEY, Q.C.:  
 23 Q. No, no, no, no need to apologize. Just in  
 24 terms of that just so there's no confusion on  
 25 it.

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1 DR. MULLEN:  
 2 A. We also do work for St. John, New Brunswick.  
 3 COFFEY, Q.C.:  
 4 Q. Yeah, okay. But in this context here -  
 5 DR. MULLEN:  
 6 A. No, it's all St. John's.  
 7 COFFEY, Q.C.:  
 8 Q. St. John's, Newfoundland. Doctor, you had  
 9 been in to Dr. Pritzker's office in early  
 10 August and spoken with him. If I could,  
 11 please, Exhibit P, Registrar, P-1772? That's  
 12 it, Doctor, and it'll be there on the screen,  
 13 as well, in front of you, if you like. This  
 14 is a series of e-mails on August 10th, 2005.  
 15 The first of them is from Allan Wolff to  
 16 yourself at 5 p.m. and he writes, "I've been  
 17 asked to have these cases accessioned as both  
 18 SP and RS. Do you want the RS to show up on  
 19 your pending list?" Signed, "Allan." And  
 20 then half an hour later you responded to him  
 21 and copied Dr. Pritzker and Maria Mendes  
 22 saying, "Why are we issuing SP reports on  
 23 these specimens? They become part of the  
 24 patient's chart, ie, legal document and much  
 25 more work for me." And then, there's an e-

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1 mail from Maria Mendes on the same day,  
 2 shortly thereafter, to yourself, "Alan, just  
 3 spoke with Dr. Mullen. The samples you have  
 4 can go forward with as consults. Dr. Mullen  
 5 will call you." Signed, Maria. Now, Doctor,  
 6 I'm going to have you, for the Commissioner,  
 7 because there are certain names we're going to  
 8 be dealing with in these correspondence and e-  
 9 mails and so on, have you just explain who's  
 10 who, as it were. Who's Alan Wolff?  
 11 DR. MULLEN:  
 12 A. Alan Wolff is the head of our pathologists'  
 13 assistants. He is in charge of our  
 14 accessioning area and our specimen preparation  
 15 area. Maria Mendes is in charge of our  
 16 research services, which is a name for the  
 17 part of the laboratory that does technical  
 18 work that is not patient--on either in-  
 19 hospital or Ontario or out-of-province that's  
 20 billed through the medical system. So if it's  
 21 contracts, that type of thing, special work.  
 22 We do work for drug companies. We do work for  
 23 researchers and we'll do contract--the Eastern  
 24 Health contract would have been under her  
 25 supervision.

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1 COFFEY, Q.C.:  
 2 Q. Now the reference to the word accessioned,  
 3 what is that? What does that mean?  
 4 DR. MULLEN:  
 5 A. When a specimen is removed from a patient,  
 6 there is a requisition issued that has  
 7 patient's demographics, name, address, type of  
 8 thing. The specimen type, where the specimen  
 9 is removed, whether it was a breast, lung,  
 10 whatever, and then briefly a clinical history.  
 11 That's for an in-patient. That comes to the  
 12 pathology department with the patient specimen  
 13 and the container labelled with the same  
 14 demographics. At that time, we issue a  
 15 surgical number or here, SP refers to a  
 16 surgical pathology number and RS refers to a  
 17 research services number. So it's a unique  
 18 identifier that tags that specimen to that  
 19 patient. Now the SP is our routine clinical,  
 20 both in-hospital, out of hospital and out of  
 21 hospital Ontario, out of hospital anywhere in  
 22 Canada, out of hospital and we get cases  
 23 sometimes from outside the country, but those  
 24 are clinical specimens that are being reported  
 25 primarily for diagnosis. RS numbers are

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1 numbers that we give to specimens that are for  
 2 research or for "non-diagnostic" service. Non-  
 3 diagnostic in the sense that a report will be  
 4 issued and the patient will be--and the report  
 5 will be acted on on the patient there.  
 6 They're more for research for contracts.  
 7 COFFEY, Q.C.:  
 8 Q. And -  
 9 DR. MULLEN:  
 10 A. So just -  
 11 COFFEY, Q.C.:  
 12 Q. Sure.  
 13 DR. MULLEN:  
 14 A. So for every SP there will be a formal report  
 15 issued. For every RS, there need not be a  
 16 formal report. There may not even be any  
 17 documentation of what was done--of what the  
 18 results were. It may just be a technical  
 19 service that then the slides would be given  
 20 back to the hospital. That would--the type of  
 21 service that we were doing initially for  
 22 Peninsulas, that would be under the RS  
 23 umbrella, because at the end of the day, at  
 24 the end of the year, we have to reconcile our  
 25 surgical numbers with reports, and if you have

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1 a surgical number without a report, you have  
 2 an open turnaround time and -  
 3 COFFEY, Q.C.:  
 4 Q. And I'll be asking you a bit further about  
 5 that, this morning, a bit more with you. Now,  
 6 Doctor, you had your initial conversation with  
 7 Dr. Pritzker and you understood it was 50 to  
 8 100 cases -  
 9 DR. MULLEN:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. - that you would be--and you understood  
 13 initially that this 50 to 100, there'd be  
 14 slides created -  
 15 DR. MULLEN:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. - at Mount Sinai, and you'd be asked to  
 19 interpret them?  
 20 DR. MULLEN:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. And give whomever your interpretation?  
 24 DR. MULLEN:  
 25 A. Yes, that's correct.

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1 COFFEY, Q.C.:  
 2 Q. Did you have any understanding at the time as  
 3 to whether these were current cases or old  
 4 cases or -  
 5 DR. MULLEN:  
 6 A. I believe at the time, I understood that they  
 7 were--it was a retrospective. They had been  
 8 slides or cases that had been--I didn't know  
 9 the time frame, but they weren't cases for  
 10 which a report had not been issued. So it was  
 11 a review of slides--well, not review of  
 12 slides, a review of cases, new staining of old  
 13 cases.  
 14 COFFEY, Q.C.:  
 15 Q. And -  
 16 DR. MULLEN:  
 17 A. And my interpretation of the staining of the  
 18 old case.  
 19 COFFEY, Q.C.:  
 20 Q. - of the staining created at Mount Sinai?  
 21 DR. MULLEN:  
 22 A. At Mount Sinai, yes.  
 23 COFFEY, Q.C.:  
 24 Q. Okay, Doctor, so that's your first  
 25 introduction. Then what happened? Okay, you

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1 were talking to Dr. Pritzker and what's your  
 2 next memory then of this? What then happened?  
 3 DR. MULLEN:  
 4 A. Then I was approached to do the prospective or  
 5 we, I was, Mount Sinai was approached, and  
 6 again -  
 7 COFFEY, Q.C.:  
 8 Q. And that was for Eastern Health, St. Clare's?  
 9 DR. MULLEN:  
 10 A. That was for the whole of the province.  
 11 COFFEY, Q.C.:  
 12 Q. The whole of the province?  
 13 DR. MULLEN:  
 14 A. Well, sorry, no, it was--it would have been  
 15 for Eastern Health. Yes, Eastern Health, that  
 16 was August of--August 15th, that was the first  
 17 case that was accessioned. August 15th of  
 18 '05. So that would be my--I can't say  
 19 recollection, but going back and looking at  
 20 accessionings, it would have been August 15th  
 21 was the first case. So before that, we would  
 22 have agreed, we being the Mount Sinai  
 23 Hospital, would have agreed to do the Eastern  
 24 Health work, and then I then received a list  
 25 of hospitals from Dr. Cook's secretary, Judy

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1 Thomas, I believe she's his secretary, with a  
 2 list of all the hospitals and all of the fax  
 3 numbers, etcetera, etcetera, addresses, chief  
 4 pathology for the rest of the province, and  
 5 then I--which we'll see the exhibits later,  
 6 sent out the letters that yes, since Eastern  
 7 Health had temporarily ceased to do ER/PR and  
 8 HER2, that we had agreed to do it and these  
 9 are how we would like material--what material  
 10 we'd like and how we would report it and how  
 11 we would bill for it, and I believe they're  
 12 there.  
 13 COFFEY, Q.C.:  
 14 Q. Now if we could, please, Exhibit P-1699?  
 15 Doctor, these are a couple of e-mails. This  
 16 is a two-page exhibit. Just going to go to  
 17 the bottom of the first page. August 26th,  
 18 2005, there's an e-mail sent from Doctor--  
 19 well, it's a Paul name, it's Dr. Paul Neil,  
 20 the pathologist, I understand, in Corner  
 21 Brook, to Maria Mendes at Mount Sinai, copied  
 22 to Frank Holloway and the subject is ER/PR and  
 23 HER2/neu for Corner Brook, Newfoundland, and  
 24 Dr. Neil writes "Ms. Mendes, as per our  
 25 conversation, we would appreciate ER/PR and

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1 HER2/neu immunohistochemistry on our breast  
 2 tissue cases from this hospital. As you are  
 3 aware, Dr. Cook in St. John's had been doing  
 4 these for us, but has suspended this  
 5 temporarily. As you will be doing his"--I'm  
 6 sorry, this, I'm sorry, "as you will be doing  
 7 his," that would be St. John's, "we need to  
 8 send you ours as well. In 2004, we had  
 9 approximately 40 cases. We anticipate that  
 10 2005 will be no different. However, our  
 11 oncologists want HER2/neu on all cases now, so  
 12 we anticipate the same number of these. I  
 13 would appreciate more information on how to  
 14 submit these cases, as well as costs, as we  
 15 have to budget for the amount. I assume the  
 16 best mode of transport would be courier." And  
 17 then he concludes with, "if there is any more  
 18 information you require, please e-mail or  
 19 call. Thank you, Paul Neil, MD."  
 20 And then Ms. Mendes, at--on August 31st,  
 21 2005 at 2:46 p.m. sent an e-mail to yourself  
 22 and Dr. Frances O'Malley, the same subject,  
 23 saying "Hi, Dr. O'Malley and Dr. Mullen.  
 24 Wanted to let you know that I have been  
 25 contacted by Dr. Neil from Newfoundland to do

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1 the ER and PR, as well as HER2/neu, since St.  
 2 John's is not providing this service. What I  
 3 need to know is who should I refer the  
 4 consults to? Dr. Mullen or Dr. O'Malley.  
 5 Thanks, Maria."  
 6 And then there's an e-mail on the same  
 7 day from yourself to Maria Mendes and Dr.  
 8 O'Malley at 3:10 p.m., copied to Dr. Pritzker  
 9 saying "how do they want these handled? Are  
 10 they to be reported and billed to the MCP,  
 11 Newfoundland OHIP equivalent, or to be handled  
 12 as the Peninsulas cases are presently where we  
 13 stain and let them interpret the cases. That  
 14 causes a bit of a difficulty if the results  
 15 are discordant. Also, do they want a specific  
 16 HER2 stain? If they only want one stain, that  
 17 will eliminate the discordant result issue.  
 18 We also have to speak to Peninsulas concerning  
 19 their material, as they are now requesting  
 20 HER2 on all cases."  
 21 So Doctor, I take it then that as of the  
 22 end of August 2005, this indicates that in  
 23 late August, Mount Sinai had been approached  
 24 by Corner Brook?  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. Dr. Neil, to handle Corner Brook's cases on a  
 4 go-forward basis, current cases, and this  
 5 just, I take it, reflects, and correct me if  
 6 I'm wrong, this just kind of reflects the  
 7 internal handling within Mount Sinai as to how  
 8 we're going to deal with this, financially and  
 9 otherwise?  
 10 DR. MULLEN:  
 11 A. Yes, the implication here, billing the MCP,  
 12 there would be no direct cost to the hospital  
 13 other than the courier service. In Ontario,  
 14 we have--well, in every province except  
 15 Quebec, there's reciprocal billing and we're  
 16 able to bill our OHIP plan, which then  
 17 recovers from the MCP for both the  
 18 professional and technical costs.  
 19 COFFEY, Q.C.:  
 20 Q. And -  
 21 DR. MULLEN:  
 22 A. As opposed to direct billing the hospital.  
 23 COFFEY, Q.C.:  
 24 Q. Now Doctor, looking at the e-mail from  
 25 yourself at 3:10, at the top of the page there

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1 -

2 DR. MULLEN:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. - that day, you refer to "that causes a bit of

6 a difficulty if the results are discordant."

7 What are you referring to there?

8 DR. MULLEN:

9 A. Mount Sinai Hospital performs two HER2 stains

10 per case. At that time, it was a cocktail of-

11 -the first one was called AO485. The second

12 one was CB11 Tab250. Now we, being obsessive

13 compulsive, wanted to make sure that we

14 weren't over calling cases or under calling

15 cases. So both stains had to be positive for

16 us to call, or negative for us to call a case

17 either positive or negative. Discordance -

18 COFFEY, Q.C.:

19 Q. And this is for HER2/neu?

20 DR. MULLEN:

21 A. Yes, this is HER2/neu. Discordant refers to

22 if one were positive and, at that time, it was

23 staining of greater than ten percent,

24 subsequently changed to 30. If one were

25 positive and one were negative or one were

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1 equivocal, if they weren't either two

2 positives or two negatives, we would then

3 reflex to FISH and that was what I was

4 referring to about discordant, that we would

5 then--we'd then have to go on to do a reflex

6 testing. So to simplify things, it was--I was

7 trying to ask, did they want us to deviate

8 from our standard practice and give them one

9 stain or if they wanted the standard practice

10 of the two stains, then we would have to do

11 the interpretation to reflex to FISH basically

12 for two reasons. One would be time. It

13 wouldn't have to go back to Newfoundland to be

14 reinterpreted and then sent back to us, if we

15 were reporting them, and the other was, I

16 think, basically that we would have sufficient

17 numbers to--they would not have enough

18 expertise. There's certain requirements that

19 have been set down in the guidelines in a

20 number of cases that one should see a year

21 before one either does them or interprets

22 them.

23 THE COMMISSIONER:

24 Q. And who sets those guidelines?

25 DR. MULLEN:

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1 A. That's the American Society of Clinical

2 Oncology and the College of American

3 Pathologists. They were published in January

4 of, I think it was '07 or '08.

5 THE COMMISSIONER:

6 Q. And reflex to FISH?

7 DR. MULLEN:

8 A. Reflex meaning we have, I cannot sign this out

9 as either positive or negative. I have to do

10 a further test, and this is fluorescent in

11 situ hybridization.

12 THE COMMISSIONER:

13 Q. Okay.

14 DR. MULLEN:

15 A. Now, when I'm doing immunohistochemistry, I'm

16 looking at protein. When I'm doing

17 fluorescent in situ hybridization, I'm looking

18 not at the membrane of the cell, which is for

19 HER2. With ER/PR we're looking at the

20 nucleus. What I'm looking at is the number of

21 gene copies. So I'm counting the number of

22 HER2 genes and usually that there is a--and I

23 compare it to a housekeeper gene, so I can get

24 the ratio. If the number is up, it would be

25 called positive. And usually if it's up, it's

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1 reflected in the protein being up as well.

2 But because of the issues with fixation,

3 processing, slide preparation, sometimes you

4 cannot be confident with your

5 immunohistochemistry for HER2 and so we have

6 this--and so we have a test that's basically

7 the gold standard. So if initially

8 positive/negative, no further. If it's that

9 grey area, difference between the two stains

10 or technically I'm not sure or there's not

11 enough on the slide, then I'll go to

12 fluorescent in situ hybridization.

13 THE COMMISSIONER:

14 Q. So why wouldn't you go there first?

15 DR. MULLEN:

16 A. Cost.

17 THE COMMISSIONER:

18 Q. Cost issue?

19 DR. MULLEN:

20 A. Cost issues. The cost of the reagents, the

21 cost of the technical expertise. I think it's

22 in the range of about \$380 minimum for the

23 technical, by the time you have the reagents

24 and then you have to purchase the microscope

25 and not every hospital would have the quality

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1 of the microscope that you require.  
 2 THE COMMISSIONER:  
 3 Q. Okay.  
 4 COFFEY, Q.C.:  
 5 Q. And this is all--and that would be for the  
 6 FISH?  
 7 DR. MULLEN:  
 8 A. That's for, yes, HER2.  
 9 COFFEY, Q.C.:  
 10 Q. And HER2/neu?  
 11 DR. MULLEN:  
 12 A. Yes. So that was my question to them, because  
 13 they were referring to us. It was, I asked  
 14 the client what they would like, and then  
 15 trying to suggest that if we did it, that it  
 16 would facilitate speed up.  
 17 COFFEY, Q.C.:  
 18 Q. Doctor, with respect to--because by the e-mail  
 19 we looked at, 1699, if we could, please,  
 20 Registrar? Yes, it's there, particularly the  
 21 one from Dr. Neil, by that point in time, by  
 22 the end of August, I take it you understood  
 23 that at least for a period of time into the  
 24 future, you were now being--had been now  
 25 approached by Corner Brook to do their current

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1 cases?  
 2 DR. MULLEN:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. Did you have any understanding that perhaps  
 6 you would be approached by other health  
 7 authorities as well within Newfoundland at the  
 8 time?  
 9 DR. MULLEN:  
 10 A. At that time, no. I mean, I was--no, I hadn't  
 11 thought of the issue.  
 12 COFFEY, Q.C.:  
 13 Q. Okay.  
 14 DR. MULLEN:  
 15 A. Because at that time, I didn't know how many--  
 16 I wasn't very aware of the Eastern, Central,  
 17 Western and Labrador. I didn't know the set  
 18 up, so I didn't know if everything was going  
 19 to be funnelled into St. John's and then sent  
 20 to Toronto or as this e-mail and you know, the  
 21 Peninsulas issue, would be sent to us  
 22 directly. I wasn't sure if they were going to  
 23 keep their same referral pattern and then sort  
 24 of bulk ship to us or ship as they received  
 25 through St. John's or as this one, from Dr.

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1 Neil, that it would be sent to us directly.  
 2 COFFEY, Q.C.:  
 3 Q. And the retrospect--because this is current  
 4 cases -  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. - that would be. How about the retrospective  
 9 study then, by the end of the summer, what was  
 10 the--do you recall kind of where that stood by  
 11 around Labour Day, the idea of -  
 12 DR. MULLEN:  
 13 A. I think it was still 100. That was like 100  
 14 and I was going to get them out by October,  
 15 thank you.  
 16 COFFEY, Q.C.:  
 17 Q. That was your -  
 18 DR. MULLEN:  
 19 A. That was my--and then in preparation for a  
 20 meeting that we had in December in Toronto  
 21 '07, I'd asked Dr. O'Malley what her  
 22 recollection was and I believe she said we  
 23 were--they had talked about 20 or 30. So from  
 24 20 or 30 in June or July, we'd moved to 100,  
 25 50 to 100.

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1 COFFEY, Q.C.:  
 2 Q. And Commissioner, there was a letter of July  
 3 14th, I believe, I won't bring it up, ask that  
 4 it be brought up on the screen, but there was  
 5 a letter from Bev Carter to Dr. O'Malley  
 6 referring to a relatively low number of cases  
 7 that Dr. O'Malley has referred to here. So  
 8 Doctor, and again, just to have the  
 9 Commissioner get some sense of kind of your  
 10 evolving understanding, if we could bring up,  
 11 please, Exhibit P-1700? This is--again these  
 12 are two e-mails of September 1st, 2005. One is  
 13 from Beverley Stone.  
 14 DR. MULLEN:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Who's, I gather, at Peninsulas Health  
 18 Authority, what was then still described as  
 19 Peninsulas Health Authority, to yourself  
 20 involving the FISH confirmation as the  
 21 subject, and she writes "Dr. Mullen, all of  
 22 our breast cancer patients with invasive  
 23 disease now need to be tested upfront for  
 24 HER2/neu by immunohistochemistry and all cases  
 25 scores" and she goes on to talk about that.

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1 "Can you do this at your lab or should we send  
 2 these cases elsewhere? We need FISH  
 3 confirmation on a case we just got back from  
 4 you on" it's redacted, and she suggests "if  
 5 you have any questions, please call Dr.  
 6 Anwar."  
 7 And then you internally, within Mount  
 8 Sinai, that same day, e-mailed Maria Mendes  
 9 saying "this is the clerical contact in  
 10 Newfoundland. We should set up a conference  
 11 call with Anwar next week as this is getting  
 12 out of hand. We will also need to speak to  
 13 O'Malley before we proceed." So Doctor, in  
 14 the beginning of September then, what was the  
 15 state of affairs, from your perspective, in  
 16 terms of -  
 17 DR. MULLEN:  
 18 A. Well, this was the trigger case for Peninsulas  
 19 that we would then start doing the HER2 and  
 20 reporting and they had one system of reporting  
 21 there, two pluses--I forget what the, at that  
 22 time. So basically, they were asking us to do  
 23 something that we didn't feel that had to be  
 24 confirmed. So it was whose criteria were we  
 25 going to use? If they were sending to us as a

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1 reference lab, if we issued the report, and  
 2 this was--we had the same issue in Ontario  
 3 when we were doing reference, that the  
 4 oncologists had one set of criteria and it had  
 5 been established with Cancer Care Ontario,  
 6 which basically was the funding agent for  
 7 Herceptin, that if we said it was positive, it  
 8 was positive, and we didn't have to go any  
 9 further, and now Peninsulas was asking us to  
 10 do something that, first of all, was  
 11 expensive, second of all, was a resource  
 12 limited in our department at the time, for  
 13 cases that, in Ontario, would have fit our  
 14 criteria for treatment.  
 15 COFFEY, Q.C.:  
 16 Q. And this is in relation to HER2/neu?  
 17 DR. MULLEN:  
 18 A. Yes, this is HER2. This has nothing to do  
 19 with -  
 20 COFFEY, Q.C.:  
 21 Q. To do with ER/PR.  
 22 DR. MULLEN:  
 23 A. And now the other--when I mentioned Anwas  
 24 earlier, when I was setting up a reporting  
 25 system because we set up in Ontario, the

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1 doctors are under what's called CBS, which are  
 2 unique identifiers. Newfoundland didn't have  
 3 that, so I did the last name and the first  
 4 name. So ANWAS was who I referred to Dr.  
 5 Anwar, not--he wasn't Dr. Anwas. It was Syed  
 6 Anwar. So that's what I meant earlier.  
 7 COFFEY, Q.C.:  
 8 Q. Now if we could, please, Exhibit P-1707?  
 9 Doctor, this is an e-mail from Nancy Good,  
 10 September 13th, 2005, at 3:10 p.m. to  
 11 yourself. The subject is ER/PR list, and  
 12 there's an attachment, and well, first of all,  
 13 who's Nancy Good?  
 14 DR. MULLEN:  
 15 A. Nancy Good was a technologist who was in the  
 16 research services area, who was responsible  
 17 for basically the technical, the receipt of  
 18 the specimens, the opening of the packages,  
 19 the arranging for the cases to be accessioned,  
 20 in other words, given a research services  
 21 number, and then organizing that they be  
 22 stained, and then developing the spreadsheet  
 23 for the reporting, putting in the demographics  
 24 and the fields that were required, and then  
 25 basically assisting me in the reporting. So

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1 she was, shall I say, the go-to person for  
 2 this project on the technical side. She didn't  
 3 do the staining, but she did all of the pre-  
 4 analytic, and some of the post-analytic.  
 5 COFFEY, Q.C.:  
 6 Q. And who actually did the staining itself?  
 7 DR. MULLEN:  
 8 A. Initially it was done in our service  
 9 laboratory, under the direction of Ms.  
 10 Wegrynowski. There were some e-mails later  
 11 that we may touch upon. We were doing--  
 12 because it was--we thought it was time  
 13 limited, we could put them there, but as the  
 14 numbers started to increase, we found that we  
 15 were working nights and weekends, overtaxing  
 16 the machines. So we couldn't have the staff  
 17 and the machines--so it was moved over to the  
 18 research services area. Another technologist  
 19 developed and did the staining.  
 20 COFFEY, Q.C.:  
 21 Q. And who was that, do you recall?  
 22 DR. MULLEN:  
 23 A. Ryu, and it would be under his direction,  
 24 under Ms. Mendes' direction.  
 25 COFFEY, Q.C.:

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1 Q. Okay. Now here, Doctor, again to give the  
 2 Commissioner some sense of how this was  
 3 developing in Mount Sinai, here Nancy Good has  
 4 written, "Hi, Dr. Mullen. Here's the list of  
 5 all the patients we have received blocks from  
 6 so far. The ones highlighted in blue have  
 7 been stained. Thanks, Nancy." And then, of  
 8 course, when we looked at the e-mail itself,  
 9 there's an attachment, Drmullen.xls, which I  
 10 take it is a spreadsheet?  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. I'm just going to go on then here, of course  
 15 these have been redacted, RS numbers have been  
 16 redacted, patient names have been redacted.  
 17 Blocks received, and I take it this is just  
 18 the block number?  
 19 DR. MULLEN:  
 20 A. That's a block number, yes, and as you go  
 21 down, 3-5  
 22 COFFEY, Q.C.:  
 23 Q. 3-5-B-10-6 and so on.  
 24 DR. MULLEN:  
 25 A. A3. N/A, if there was no number associated

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1 with it, and I believe there's one hospital,  
 2 and I've forgotten which one, that uses  
 3 colors, and we weren't given their color  
 4 codes, so we didn't know what the block number  
 5 was, and if you look at halfway down, or no,  
 6 two-thirds of the way down, in some cases we'd  
 7 get three blocks, 1D, 2, and 3.  
 8 COFFEY, Q.C.:  
 9 Q. Yes.  
 10 DR. MULLEN:  
 11 A. And 1B, 1C, some cases that would be 99-  
 12 SU7788.  
 13 COFFEY, Q.C.:  
 14 Q. So 99-SU7788  
 15 DR. MULLEN:  
 16 A. With two blocks, 1B and -  
 17 COFFEY, Q.C.:  
 18 Q. Yes, with a block 1B and 1C, and so on. So as  
 19 well, this is labelled, all samples received  
 20 August 2005 from St. Clare's site, St. John's  
 21 Hospitals for ER and PR receptors.  
 22 DR. MULLEN:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. And going down through this, there's a second

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1 page. There's a third, a fourth, a fifth, a  
 2 sixth, a seventh, an eighth, a ninth and a  
 3 tenth page, and I take it, Doctor, by then,  
 4 mid September or by September 13th, 2005 -  
 5 DR. MULLEN:  
 6 A. I'm just--this was dated, sorry, I've  
 7 forgotten the -  
 8 COFFEY, Q.C.:  
 9 Q. This was dated, we'll go back up, it's  
 10 September 13th, 2005.  
 11 DR. MULLEN:  
 12 A. Okay, all right.  
 13 COFFEY, Q.C.:  
 14 Q. So just get back right up there.  
 15 DR. MULLEN:  
 16 A. Sorry, yes, okay.  
 17 COFFEY, Q.C.:  
 18 Q. And so I take it then, and again, I -  
 19 DR. MULLEN:  
 20 A. Probably about 18th page.  
 21 COFFEY, Q.C.:  
 22 Q. Yes, actually -  
 23 DR. MULLEN:  
 24 A. Or 20?  
 25 COFFEY, Q.C.:

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1 Q. 38 actually.  
 2 DR. MULLEN:  
 3 A. Oh, sorry, okay.  
 4 COFFEY, Q.C.:  
 5 Q. There's quite a number of them.  
 6 DR. MULLEN:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. By this point in time, when you just do the  
 10 arithmetic, multiple it out.  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, I take it then that by the middle of  
 15 September, you would have realized that there  
 16 are a lot of cases here that -  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. - you're being asked to look at.  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Now by then, you understood what about--did  
 25 you have any understanding by that point in

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1 time about the years involved, like the number  
 2 of years that this number of cases came out  
 3 of?  
 4 DR. MULLEN:  
 5 A. I may have, but I don't recall. In our  
 6 conversations, I wasn't even aware of what the  
 7 material was I was receiving. The key--I  
 8 didn't know if I was receiving all breast  
 9 cases from Newfoundland from A to B time  
 10 period, whether I was receiving things that  
 11 were positive, things that were negative, a  
 12 mix. I wasn't--I did not know going into this  
 13 project, and until we met, I really didn't  
 14 know what I had seen.  
 15 COFFEY, Q.C.:  
 16 Q. Doctor, on that point, and when you say "we"  
 17 you're talking about yourself and myself and  
 18 Mr. Simmons?  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And Mr. Simmons and Mr. Simon Clements and  
 23 Sandra Chaytor and I?  
 24 DR. MULLEN:  
 25 A. Yes, this was the interview in Toronto.

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1 COFFEY, Q.C.:  
 2 Q. In Toronto in December of -  
 3 DR. MULLEN:  
 4 A. '07, yes.  
 5 COFFEY, Q.C.:  
 6 Q. Could you just explain to the Commissioner  
 7 what you're referring to there, in terms of  
 8 you didn't know until you actually met with us  
 9 what it was you--that had actually been sent  
 10 to you in the sense of the parameters used?  
 11 DR. MULLEN:  
 12 A. I received--let me just see. I need my little  
 13 cheat sheet, okay. By the time we had met, I  
 14 had received 997, almost 1,000 blocks, and in  
 15 preparation for our meeting, I was trying to  
 16 determine whether--what the positivity rate,  
 17 what the negativity rate was in the cases and  
 18 because the material, and we'll discuss this  
 19 later, was not the quality that I was used to.  
 20 So every time I was looking at a case--I  
 21 shouldn't say every time, I would say the  
 22 majority of the cases, the baseline kept  
 23 changing. It wasn't something that I--that if  
 24 it were internal case from the Mount Sinai,  
 25 this is what I would expect for a positive,

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1 this is what I expect for negative. So each  
 2 time, so I was trying to--and I do positivity  
 3 rates, negativity rates for all of my cases  
 4 for ER/PR just to make sure that I'm within  
 5 the gold standard, both the technical side and  
 6 the professional interpretation or the  
 7 suggested standards. So in preparation for  
 8 the meeting, for the deposition, I wanted to  
 9 see what my positivity rate, what my  
 10 negativity rate was, and they were slightly--  
 11 there was a deviation from what I would have  
 12 expected if I had gotten all of the cases from  
 13 Newfoundland. It was much lower positivity  
 14 rate than I get internally, and that's in the  
 15 literature.  
 16 COFFEY, Q.C.:  
 17 Q. So that was -  
 18 DR. MULLEN:  
 19 A. That was a bit upsetting to me.  
 20 COFFEY, Q.C.:  
 21 Q. So just in terms of that, the positivity rate  
 22 you're referring to here is -  
 23 DR. MULLEN:  
 24 A. What I -  
 25 COFFEY, Q.C.:

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1 Q. - on the 1,000 blocks that you had done at  
 2 Mount Sinai -  
 3 DR. MULLEN:  
 4 A. Yes, the staining at Mount Sinai and the  
 5 interpretation at Mount Sinai. So because we  
 6 were reporting in spreadsheet, it's easy for  
 7 me to go in and pull what the positivity rate  
 8 was, what the negativity rate, and I  
 9 restricted it to cases of invasive tumor that  
 10 were primary to breast, not metastases and  
 11 then try to manipulate every combination and  
 12 permutation to see--try to explain why my--  
 13 explain in my mind why I would be lower than  
 14 what the rate was. So naively, I asked counsel  
 15 what had they sent me, and then they told me  
 16 what they had sent me. So my discrepancy,  
 17 from my positivity rate and what's in the  
 18 literature and what I'd get on my service  
 19 side, all prospective cases, it was easy to  
 20 explain.  
 21 COFFEY, Q.C.:  
 22 Q. Now could you just indicate then, to the  
 23 Commissioner, why, from your perspective then,  
 24 it was easy to explain?  
 25 DR. MULLEN:

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1 A. Because I believe the conversation was that up  
 2 to a certain time, any case that would--now,  
 3 we're always referring to ER, not the PR. ER  
 4 positive less than 30 was sent to me and then  
 5 it was switched to less than ten, I believe.  
 6 So I was getting a mixture of what initially  
 7 had been called less than 30 and less than  
 8 ten. So in which I believe at one time, ER  
 9 less than 30 was considered negative here and  
 10 then switched to less than ten, so that  
 11 combination. So basically, I was getting what  
 12 initially had been called negative cases.  
 13 COFFEY, Q.C.:  
 14 Q. And all negative--what initially in  
 15 Newfoundland and Labrador had all been called  
 16 all negative?  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. Classified as negative cases, and it was only  
 21 in December of '07 -  
 22 DR. MULLEN:  
 23 A. That I, yes.  
 24 COFFEY, Q.C.:  
 25 Q. - that you realized that, okay, everything

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1 that I have--that we've retested at Mount  
 2 Sinai for ER was originally classified in  
 3 Newfoundland as a negative?  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. And so your positivity rate then made sense in  
 8 the sense of you were only re-examining  
 9 within--re-examining at Mount Sinai, retesting  
 10 at Mount Sinai, what had originally been  
 11 classified in Newfoundland as negatives?  
 12 DR. MULLEN:  
 13 A. Negatives, yes, and just to clarify that we  
 14 used different cut-off points.  
 15 COFFEY, Q.C.:  
 16 Q. Yes.  
 17 DR. MULLEN:  
 18 A. Positive, we have positive as anything greater  
 19 than one percent and so a low positive would  
 20 be one to ten basically. Anything over ten  
 21 would be a straight positive.  
 22 COFFEY, Q.C.:  
 23 Q. Now, Doctor -  
 24 DR. MULLEN:  
 25 A. So then when I was giving--doing my

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1 percentages, I was breaking them down as to  
 2 positive, anything over ten low positive, and  
 3 then combining everything.  
 4 COFFEY, Q.C.:  
 5 Q. Doctor, in relation to the retrospective  
 6 study, which is the look back that was done,  
 7 you were involved in, involving the material  
 8 from Newfoundland and Labrador, could you tell  
 9 us, please, what your approach was in terms of  
 10 information gathering at the time? How much  
 11 did you, yourself, want to know about the  
 12 prior history of any one case?  
 13 DR. MULLEN:  
 14 A. I wanted -  
 15 COFFEY, Q.C.:  
 16 Q. And what your approach was and why you adopted  
 17 the approach you did?  
 18 DR. MULLEN:  
 19 A. I wanted to know nothing. I didn't want to be  
 20 biased. Basically what I wanted to do was  
 21 take each slide as I received it, make--as  
 22 though it were a new case at the Mount Sinai  
 23 Hospital, that I would make the diagnosis of  
 24 the tumor type, presence or absence of tumor,  
 25 and then I would interpret the ER, I would

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1 interpret the PR and report, and because  
 2 pathologists like to agree, some of us do, and  
 3 if I had looked at the report and found that  
 4 they had issued a report with such and such,  
 5 consciously or subconsciously, I would have  
 6 looked back or had been going forward, I would  
 7 have tried to meet in the middle or--so I  
 8 basically wanted to do, this is untouched  
 9 work. This is what I found, and then let them,  
 10 them being Dr. Cook and associates, let them  
 11 deal with the consequences or deal with the  
 12 report.  
 13 COFFEY, Q.C.:  
 14 Q. The report, so whatever--so from your  
 15 perspective, in terms of doing--approaching  
 16 the retrospective study, you understood that  
 17 these had all been interpreted at some--tested  
 18 and interpreted in Newfoundland.  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. But whether they were negatives, positives,  
 23 some combination thereof -  
 24 DR. MULLEN:  
 25 A. I had no -

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1 COFFEY, Q.C.:

2 Q. - you chose not--you didn't want to know?

3 DR. MULLEN:

4 A. I didn't want to know at all. I didn't want

5 that bias.

6 COFFEY, Q.C.:

7 Q. Yes, and so, you understood that simply the

8 blocks, it ended up being almost 1,000 blocks.

9 DR. MULLEN:

10 A. Well, at the very end, 1160.

11 COFFEY, Q.C.:

12 Q. It was just over -

13 DR. MULLEN:

14 A. We won't quibble.

15 COFFEY, Q.C.:

16 Q. But approximately 1,000 blocks would have come

17 into Mount Sinai. Mount Sinai's technologists

18 would have prepared slides for you to review?

19 DR. MULLEN:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. You would review the slides, just knowing that

23 Mount Sinai had created the slides?

24 DR. MULLEN:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. Would call them as you saw them?

3 DR. MULLEN:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. Or not, as the case might be. You would call

7 them as to, from your perspective, what type

8 of tumor it was, the diagnosis?

9 DR. MULLEN:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. In terms of everything from DCIS to ductal to

13 lobular and so on.

14 DR. MULLEN:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. And we'll be talking about some of that. And

18 then, if it was possible, from your

19 perspective, you would give a percentage for

20 ER and a percentage for PR?

21 DR. MULLEN:

22 A. Yes.

23 COFFEY, Q.C.:

24 Q. For those cases.

25 DR. MULLEN:

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. And report it to St. John's to Dr. Cook.

4 DR. MULLEN:

5 A. The prospective for St. John's from August and

6 the rest of the province from September, I

7 would issue a report using our criteria.

8 COFFEY, Q.C.:

9 Q. Yes.

10 DR. MULLEN:

11 A. So the diagnosis would be what the sample was,

12 what type of tumor.

13 COFFEY, Q.C.:

14 Q. And I'll be coming to that in a moment, okay.

15 DR. MULLEN:

16 A. Okay.

17 COFFEY, Q.C.:

18 Q. So to differentiate, but from the

19 retrospective study -

20 DR. MULLEN:

21 A. I gave a raw number, and it was up to St.

22 John's to interpret however they wished.

23 COFFEY, Q.C.:

24 Q. We just looked at, I think, 1707, which is

25 there on the screen. That's a spreadsheet

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1 attached to an e-mail, September 13th 2005.

2 If we could bring up, please, Exhibit 1774,

3 please?

4 Now Doctor, this is an e-mail from Nancy

5 Good, September 20th, 2005 at 10:12 a.m. to

6 yourself. The subject is--if you look at it,

7 it's described as updated ER/PR list. The

8 attachment is Dr.Mullen.xls and she writes,

9 "Hi, Dr. Mullen. Here's an updated list of RS

10 number for the ER/PR staining." Signed Nancy.

11 And I take it this is just an updated list.

12 If we could bring up, please, Exhibit P-

13 1775? These are two e-mails. One is from

14 Nancy Good to Dr. Donald Cook, Wednesday

15 September 21st, 2005, 5:13 p.m. Subject is

16 ER/PR reports. She writes "Hi, Dr. Cook. I

17 spoke to Dr. Mullen and he will read the

18 slides on the weekend and have reports for you

19 early next week. Bye for now, Nancy." And

20 then there's an internal e-mail within Eastern

21 Health. Dr. Cook is forwarding that to Dr.

22 Williams.

23 So I take it then, Doctor, by September,

24 Thursday September 22nd--I'm sorry, Wednesday,

25 September 21st, 2005, during that second last

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1 weekend or so, or last weekend of September of  
 2 2005, a batch of slides was going to be ready  
 3 for you to review?  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. And interpret and report on.  
 8 DR. MULLEN:  
 9 A. That's correct.  
 10 COFFEY, Q.C.:  
 11 Q. If we could, please, Registrar, bring up  
 12 Exhibit P-0597? This is an e-mail from  
 13 yourself, Doctor, on Monday, September 26th  
 14 2005, at 6:09 p.m. to Dr. Donald Cook. It's  
 15 copied to Nancy Good and Maria Mendes. The  
 16 subject is ER/PR results and the attachment is  
 17 labelled results1.xls and an ER/PR co.doc.  
 18 There are two, obviously two attachments, and  
 19 you write "if you have any questions, please  
 20 do not hesitate to call me." Signed, Dr.  
 21 Brendan Mullen. If we could just turn the  
 22 page there, Doctor, on page two of this, it  
 23 writes "attached"--you've written here,  
 24 "attached please find the first set of ER/PR  
 25 results. The code I use is as follows:" and

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1 then there's an RS number, our research  
 2 number, specimen number, your case number,  
 3 patient name, which is obviously the patient's  
 4 name, a block, which is the block numbers  
 5 supplied, comments, discrepancies and block  
 6 information. So I take it that under that  
 7 column, you would -  
 8 DR. MULLEN:  
 9 A. These first five would have been identical to  
 10 the spreadsheets we've seen. Nancy Good would  
 11 have prepared that. So the RS number is our  
 12 accession number and then the specimen would  
 13 have been the original number from the  
 14 referring hospital, patient name and block.  
 15 COFFEY, Q.C.:  
 16 Q. And then -  
 17 DR. MULLEN:  
 18 A. Discrepancies was a column if it's a different  
 19 number or something.  
 20 COFFEY, Q.C.:  
 21 Q. And then there's, you've written here, tumor  
 22 type with D for ductal, DL for ductal with  
 23 lobular features, DT ductal with tubular  
 24 features, L for lobular, PAP for papillary and  
 25 MCA for -

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1 DR. MULLEN:  
 2 A. Metastatic.  
 3 COFFEY, Q.C.:  
 4 Q. - metastatic cancer, CA. And then there's ER  
 5 percentage cells positive, PR percentage cells  
 6 positive. IC for internal controls with P  
 7 meaning present but not stained, PS meaning  
 8 present and stained, PSW meaning present and  
 9 stained weakly, and A meaning absent, and then  
 10 F/P for fixation and processing with A meaning  
 11 adequate and P meaning poor, and then a  
 12 threshold for positive ER/PR result, staining  
 13 of any intensity in greater than one percent  
 14 invasive tumor cells, and then positive and  
 15 negative laboratory external controls stained  
 16 appropriately. So I take it that that's an  
 17 explanation, a key, as it were?  
 18 DR. MULLEN:  
 19 A. Yes, and I think during the day we'll see more  
 20 of these and as we went along, the tumor type  
 21 would increase, you know, subclassification.  
 22 As I saw more, I'd have to add. But  
 23 everything else stayed the same, and  
 24 basically, the last two columns were that the  
 25 controls, those are standard in all our

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1 reports and that was a threshold I was using,  
 2 but I didn't report whether it was positive or  
 3 negative. And the fixation processing was  
 4 subjective. I would look and try to assess,  
 5 and the internal controls was objective,  
 6 whether they're present or absent, and then  
 7 subjective, whether they stained or stained  
 8 weakly or didn't stain. I mean, these are--  
 9 the middle two, the internal control and  
 10 fixation processing are features that we look  
 11 at on each case in the block to make sure that  
 12 what we're getting is adequate.  
 13 COFFEY, Q.C.:  
 14 Q. And I'm going to be taking you through that,  
 15 Doctor. So here, as of then, September,  
 16 Monday, September 26th 2005, and I don't know  
 17 whether the 6:09 p.m. is local St. John's time  
 18 or -  
 19 DR. MULLEN:  
 20 A. This is the same exhibit?  
 21 COFFEY, Q.C.:  
 22 Q. Yes, but it's printed off from Dr. Donald  
 23 Cook, so--and nothing really falls on that.  
 24 DR. MULLEN:  
 25 A. No, the sent time is all at my time, yes.

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1 COFFEY, Q.C.:

2 Q. And from--the Commissioner's understanding

3 then, by the last Monday of September of 2005,

4 the first grouping or wave of reports on the

5 retrospective study was sent by e-mail to St.

6 John's, Newfoundland?

7 DR. MULLEN:

8 A. Yes. I think the e-mail the previous week

9 said I'd do it on the weekend and we did it on

10 the weekend.

11 COFFEY, Q.C.:

12 Q. Now if we could, please, Exhibit P-1783?

13 Doctor, this is again a series of e-mails.

14 The first of them in time is -

15 DR. MULLEN:

16 A. 28th?

17 COFFEY, Q.C.:

18 Q. Yes, it's September 28th 2005, 11:47 a.m.

19 It's from Dr. Cook to yourself. The subject

20 is ER and PRs and the 28th would be a

21 Wednesday or would have been a Wednesday. Dr.

22 Cook writes "Hi, Dr. Mullen. I received the

23 results of the first batch of ERS and PRs.

24 Could you let me know how quickly we can

25 receive the results of the remaining cases?

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1 We would appreciate these results as soon as

2 possible. Thanks for all your help. Regards,

3 Dr. Cook."

4 And then you responded the same day, 1:19

5 p.m., saying "the slides are stained on the

6 weekends and I try to read them the following

7 week. I have a second similar size batch that

8 I will read tomorrow" and internally within

9 Eastern Health, Dr. Cook forwarded your

10 response to Dr. Williams.

11 So if we could, please, Registrar,

12 Exhibit P-1784? Now this is an e-mail from

13 yourself, Wednesday, September 28th, 2005,

14 3:39 p.m. to Dr. Cook, copied to Nancy Good

15 and Maria Mendes, and the attachment is

16 results2.xls and the ER/PR code, and you write

17 here "the four cases are DCIS times three, and

18 DCIS with 0.4 millimetres focus of

19 microinvasion." I believe that's -

20 DR. MULLEN:

21 A. One, times one.

22 COFFEY, Q.C.:

23 Q. Times one.

24 DR. MULLEN:

25 A. So one case.

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1 COFFEY, Q.C.:

2 Q. One case with that and three with DCIS.

3 "ER/PR assessment is not valid in the

4 microinvasive component. Please review the

5 cases and then forward blocks with invasive

6 tumor." Signed Brendan Mullen. And there is,

7 attached here there's just again the RS number

8 and the classification as to DCIS or DCIS/M

9 which would be microinvasive, I take it.

10 DR. MULLEN:

11 A. Yes. Yes, and then if you go ER/PR ICNF/P is

12 covered, those were the others.

13 COFFEY, Q.C.:

14 Q. Because here we'll be -

15 DR. MULLEN:

16 A. Okay.

17 COFFEY, Q.C.:

18 Q. - we go on to the page three of the exhibit,

19 in the middle code there, you've now entered

20 in DCI, ductal carcinoma in situ, and DCIS/M.

21 DR. MULLEN:

22 A. Yes, microinvasion, which is defined in less

23 than one millimetre.

24 COFFEY, Q.C.:

25 Q. Now Doctor, why the different--why the

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1 singling out, I suppose, or identification of

2 those four particular cases? Can you explain

3 that to the Commissioner?

4 DR. MULLEN:

5 A. If I'm too basic, please -

6 COFFEY, Q.C.:

7 Q. Never assume you're too basic, okay.

8 DR. MULLEN:

9 A. Has the concept of in situ carcinoma versus

10 invasive carcinoma been explained to the

11 Commission?

12 COFFEY, Q.C.:

13 Q. Perhaps you could just -

14 THE COMMISSIONER:

15 Q. It wouldn't hurt to repeat it.

16 DR. MULLEN:

17 A. All right, okay. In the spectrum of

18 carcinomas, there are carcinomas that are

19 called ductal carcinoma in situ or lobular

20 carcinoma in situ, where one has malignant

21 cells, but they haven't broken through the

22 basement membrane, and the concept is that if

23 they haven't broken through or invaded the

24 adjacent stroma, then they will not

25 metastasise. So basically, they're a

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1 carcinoma in situ where cells that have the  
 2 features of carcinoma, but don't have the  
 3 potential to metastasise, so therefore  
 4 excision or less radical therapy is warranted.  
 5 Then the next invasive cancer, there are  
 6 two types. Lobular, which constitutes about  
 7 ten percent, and then ductal, and ductal would  
 8 be the 90 percent in various subtypes,  
 9 depending on how many pathologists, you'll get  
 10 different classifications, but the main is  
 11 ductal with no special features and not  
 12 otherwise specified. So the DCIS, it's not  
 13 our policy, at Sinai, to report estrogen  
 14 progesterone receptor values for ductal  
 15 carcinoma in situ. In the ductal carcinoma in  
 16 situ, or lobular carcinoma in situ, there's a  
 17 whole spectrum. The very high grade, it's  
 18 easy to say this is a malignant cell, this is  
 19 not, and you can do a percentage. In the  
 20 less, in the lower grades, it's very difficult  
 21 to tell where an atypical cell becomes a  
 22 malignant cell. So it's a--part of it is a  
 23 recognition issue, but also, to the best of my  
 24 knowledge, there are no studies suggesting  
 25 what the cut-off value or not just what the

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1 cut-off value, what the incremental value of  
 2 hormone therapy would be. So it's not our  
 3 policy unless directly requested by the  
 4 Commission to report these.  
 5 And then the microinvasive issue is in  
 6 this 0.4 millimetre, there may have been six  
 7 or eight cells. So it's very difficult to say  
 8 what the percentage is and plus, these cases,  
 9 the microinvasions, are essentially treated,  
 10 my understanding, oncologists correct me if  
 11 I'm wrong, as equivalent to in situ.  
 12 COFFEY, Q.C.:  
 13 Q. And Doctor, here, you conclude by saying  
 14 "please review the cases and forward blocks  
 15 with invasive tumor." So -  
 16 DR. MULLEN:  
 17 A. The one thing that I want to make very clear  
 18 to the Commission is that what I was seeing  
 19 was one slide prepared from one block that had  
 20 been selected by the St. John's. I did not  
 21 see the original slides, did not receive all  
 22 of the blocks, and so one of the issues that  
 23 if I'm seeing ductal carcinoma in situ, that's  
 24 not to say that in another block, or even in  
 25 the original block, but not in the section

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1 that I had, that there may have been invasive  
 2 tumor. So I want to make very clear that what  
 3 I'm calling ductal carcinoma in situ does not  
 4 necessarily mean that that was the final  
 5 diagnosis. There may have been invasive  
 6 carcinoma elsewhere in that block that we  
 7 didn't get, basically, so if we get a block  
 8 like this, we're doing sections, and if this--  
 9 or we'll call the white swan is the invasive  
 10 portion, that St. John's may have seen that,  
 11 but then when I--that was no longer--probably  
 12 I would get something like that, and I  
 13 wouldn't have it.  
 14 COFFEY, Q.C.:  
 15 Q. You wouldn't get the slice with the invasive?  
 16 DR. MULLEN:  
 17 A. Yes, it would be a sampling issue. I'm not  
 18 suggesting, by any of--for any of these cases,  
 19 that it was a diagnostic issue. In my mind,  
 20 it would have been either clerical, sending  
 21 the wrong block, or it might have been a  
 22 sampling issue.  
 23 COFFEY, Q.C.:  
 24 Q. And so here then, when you're asking "please  
 25 review the cases," these four individual cases

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1 you've identified here "and forward blocks  
 2 with invasive tumor" -  
 3 DR. MULLEN:  
 4 A. Yes, that's correct.  
 5 COFFEY, Q.C.:  
 6 Q. In other words, you're just saying "look, send  
 7 me--look for your--look amongst your blocks,  
 8 find me one with -  
 9 DR. MULLEN:  
 10 A. Invasive tumor.  
 11 COFFEY, Q.C.:  
 12 Q. - invasive tumor in it and send it up.  
 13 DR. MULLEN:  
 14 A. Unequivocal.  
 15 COFFEY, Q.C.:  
 16 Q. And we will then process a new slide out of  
 17 that block?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. And I will be able to do an ER and PR report  
 22 on those?  
 23 DR. MULLEN:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. Okay. Doctor, if we could, please, Exhibit P-  
 2 1785? And it's--the bottom e-mail, we've just  
 3 looked at. The top e-mail is one at 4:01 p.m.  
 4 from yourself to Dr. Cook and you write "I  
 5 inadvertently sent you the file with the  
 6 'hidden' data." What does that mean?  
 7 DR. MULLEN:  
 8 A. Do we have the spreadsheet? Okay.  
 9 COFFEY, Q.C.:  
 10 Q. Yes.  
 11 DR. MULLEN:  
 12 A. If you look at--what I was interested in was  
 13 the RS number and--because when I receive the  
 14 slide, it's labelled with the RS number and  
 15 then the ER, whether it was ER or PR or  
 16 control. So to save me having to go through  
 17 specimen number, patient number, block number,  
 18 etcetera, all of those, when I was reporting,  
 19 I would collapse the spreadsheet down so I  
 20 would have the RS number and then the tumor. I  
 21 wasn't interested in discrepancies. So  
 22 basically, it was I could go RS, tumor, ER/PR,  
 23 ICFP. It was more for clerical. So when I  
 24 sent it to him, I had sent it--those of you  
 25 familiar with Excel, you can hide columns. So

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1 that basically, so then, I unhid or revealed  
 2 the columns and sent it back.  
 3 COFFEY, Q.C.:  
 4 Q. And in terms of that, just to show one, I take  
 5 it, with the--Exhibit P-1784, page two,  
 6 please? Page two.  
 7 DR. MULLEN:  
 8 A. Yes, that's the hidden. So it was easier for  
 9 me to see the RS number and then--or Nancy, as  
 10 she was entering them, to--rather than having  
 11 to scroll across.  
 12 COFFEY, Q.C.:  
 13 Q. And this now, you were just sending back the  
 14 entire spreadsheet across here now, looking at  
 15 1785, if we could, please?  
 16 DR. MULLEN:  
 17 A. Yes. So column two, the specimen number,  
 18 comments would be suppressed or hidden, and  
 19 then I would just look at RS, tumor, and then  
 20 do those.  
 21 COFFEY, Q.C.:  
 22 Q. Again, just to--I wanted to have that  
 23 explained to the Commissioner, like the  
 24 reference to hidden, that was all.  
 25 DR. MULLEN:

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1 A. It wasn't hiding data. It was for technical  
 2 reasons, for clerical reasons more than  
 3 anything.  
 4 COFFEY, Q.C.:  
 5 Q. And if we could, please, Exhibit P-1786? Now  
 6 here, Dr. Mullen, again it's two e-mails. One  
 7 in particular in respect of yourself, you've  
 8 sent one September 28th, 2005, that evening,  
 9 7:18 p.m. to Dr. Cook, and the subject is  
 10 ER/PR results, and you just simply write "one  
 11 half of the next batch." So I take it that--  
 12 and as well, there were results attached here.  
 13 This is results3.xls and the ER/PR code. So  
 14 again, you're -  
 15 DR. MULLEN:  
 16 A. What I was trying to do, rather than wait  
 17 until the very end, was to move them out as  
 18 fast as I could. So we would do a--we would  
 19 do them in batches, and then I think I would  
 20 cut and then send.  
 21 COFFEY, Q.C.:  
 22 Q. And here, Exhibit P-1787.  
 23 DR. MULLEN:  
 24 A. Okay.  
 25 COFFEY, Q.C.:

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1 Q. Now here, Doctor, again, I just--I can advise  
 2 the Commissioner, of course, there is quite a  
 3 number of other e-mails and stuff and I'm not  
 4 going to be going through every--or taking the  
 5 witness through each individual e-mail or  
 6 communication between Mount Sinai and Eastern  
 7 Health, but I refer to this here, Doctor, just  
 8 to give the Commissioner some sense of what  
 9 was kind of the nitty gritty of actually doing  
 10 this at times. This is an e-mail from  
 11 yourself, Thursday, September 29th, 2005 at  
 12 7:06 p.m. to Dr. Cook. It's copied to Nancy  
 13 Good. The subject is a request for additional  
 14 block, and there are numbers and I gather  
 15 probably names and so on redacted, but it says  
 16 "the block, which is a section of the nipple,  
 17 does not contain tumor. Please submit an  
 18 appropriate block for ER/PR staining."  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. So again, I take it -  
 23 DR. MULLEN:  
 24 A. We're trying to, once we identified that there  
 25 was no tumor, that we would say--we knew that

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1 that was a definite, for want of a better  
 2 word, miss, that please send so we can get  
 3 going. The DCIS issue was slightly different  
 4 because that could have been what the tumor  
 5 was, and so that, they had to sort out.  
 6 COFFEY, Q.C.:  
 7 Q. If we could, Exhibit 1788, please? This is an  
 8 e-mail of September 30th, 2005. That's a  
 9 Friday, 4:25 p.m. It's from Dr. Cook to  
 10 yourself. Subject is ER/PRs and it says "Dr.  
 11 Mullen, I have received the results of the  
 12 second batch and the note regarding the DCIS's  
 13 and the block without the tumor," which I  
 14 presume was the e-mail I just referred to?  
 15 DR. MULLEN:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. "We will be sending up more cases next week.  
 19 I would appreciate if these cases could be  
 20 handled as quickly as possible as this story  
 21 is breaking in the news and patients will be  
 22 asking questions on their ER and PR status.  
 23 Regards, Dr. Cook."  
 24 And then if we could bring up, please,  
 25 Exhibit P-1789? This is, at the bottom of the

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1 page there, Doctor, this is the -  
 2 DR. MULLEN:  
 3 A. My response.  
 4 COFFEY, Q.C.:  
 5 Q. - this is your response overall, at the top of  
 6 the page. At the bottom of the page, of  
 7 course, is the -  
 8 DR. MULLEN:  
 9 A. The original.  
 10 COFFEY, Q.C.:  
 11 Q. - the original e-mail, and just on that point,  
 12 and again, just for the sake of clarifying  
 13 this for you, Commissioner, when we look here,  
 14 the time sent on Don Cook's e-mail of Friday,  
 15 September 30th, 2005, is indicated to be 2:55  
 16 p.m. to Brendan Mullen, and that's 2:55 p.m.,  
 17 and we look at the text of that, this is the  
 18 e-mail referring to "the story is breaking in  
 19 the news and patients will be asking questions  
 20 on their ER and PR status." If we could just  
 21 go back, please, to Exhibit P-1788, and that  
 22 is that same e-mail, except that here it's  
 23 indicated--because it's from--it's indicated  
 24 to be 4:25 p.m., so there's the hour and a  
 25 half difference.

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1 DR. MULLEN:  
 2 A. Sorry, can -  
 3 COFFEY, Q.C.:  
 4 Q. It's 4:25 p.m., Doctor.  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. I don't know if you -  
 9 DR. MULLEN:  
 10 A. Yes, I saw that, and now -  
 11 COFFEY, Q.C.:  
 12 Q. And when we look back at 1789, that same e-  
 13 mail, the time frame is 2:55 p.m.  
 14 DR. MULLEN:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Just so the Commissioner understands and in  
 18 fact, yourself, if you look at these very  
 19 closely, you can see actual differences in  
 20 time frames and it is an hour and a half  
 21 difference, and I presume computer types could  
 22 explain why, and which clock is used on a  
 23 print-out.  
 24 DR. MULLEN:  
 25 A. It resets.

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1 COFFEY, Q.C.:  
 2 Q. But here then, in particular here, Doctor,  
 3 looking at your e-mail from yourself, Friday,  
 4 September 30th, 2005 at 10:54 p.m. to Dr. Cook  
 5 has results5.xls and you write "sorry I missed  
 6 your call today. I was at a biotech symposium  
 7 outside the hospital. We will expedite the  
 8 cases as much as our capacity permits. I have  
 9 attached the results for two cases that I was  
 10 missing the demographics for." Signed by  
 11 yourself.  
 12 So I take it then, Doctor, and I'm going  
 13 to ask you about this, when you are involved  
 14 in September--during September of 2005, did  
 15 you have any understanding at all as to what  
 16 the situation was in Newfoundland, in terms of  
 17 whether the public was aware of this or not or  
 18 anything like that? Had anybody communicated  
 19 that to you?  
 20 DR. MULLEN:  
 21 A. No.  
 22 COFFEY, Q.C.:  
 23 Q. So in terms of -  
 24 DR. MULLEN:  
 25 A. My entire understanding of the situation,

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1 until it became a national story, was they  
 2 wanted to review the staining and it was  
 3 basically whether it was research or service  
 4 or however you want to phrase it. I didn't  
 5 know what the whole situation was.  
 6 COFFEY, Q.C.:  
 7 Q. And then here, on Friday, September 30th, when  
 8 Dr. Cook was e-mailing you and of course, you  
 9 did respond later, late that--or later on  
 10 that, much later that evening with results5 -  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. - which you've indicated, as the attachment,  
 15 when he wrote "I would appreciate if these  
 16 cases could be handled as quickly as possible,  
 17 as this story is breaking in the news and  
 18 patients will be asking questions on their ER  
 19 and PR status," did you make any inquiries  
 20 about what that was about at the time?  
 21 DR. MULLEN:  
 22 A. I can't remember. I mean, and to be quite  
 23 honest, it wouldn't have made any difference  
 24 to me. I mean, we were contracted to do a job  
 25 and we were trying to do it as quickly as

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1 possible.  
 2 COFFEY, Q.C.:  
 3 Q. Sure.  
 4 DR. MULLEN:  
 5 A. And as quickly as our capacity permitted us.  
 6 COFFEY, Q.C.:  
 7 Q. Doctor, we understand from Trish Wegrynowski  
 8 that she had been here already by then. She  
 9 had been here in St. John's, you know, the  
 10 middle of September, September 20th or so,  
 11 2005. Had you been aware that Ms. Wegrynowski  
 12 had been asked to come here and review the lab  
 13 at that time, do you know?  
 14 DR. MULLEN:  
 15 A. I probably was, but I honestly can't recall.  
 16 COFFEY, Q.C.:  
 17 Q. And you would--if you were aware of it, you  
 18 would be aware why? Why would it come to your  
 19 attention?  
 20 DR. MULLEN:  
 21 A. Because I'm in and out of her lab like three,  
 22 four, five times a day.  
 23 COFFEY, Q.C.:  
 24 Q. Okay.  
 25 DR. MULLEN:

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1 A. And where is she?  
 2 COFFEY, Q.C.:  
 3 Q. And somebody might have said to you that she's  
 4 gone to Newfoundland?  
 5 DR. MULLEN:  
 6 A. To Newfoundland to review--whatever, they may  
 7 have said to review or whatever she was doing.  
 8 Ms. Wegrynowski is a very highly regarded  
 9 technologist in the area of the  
 10 immunohistochemistry, as well as  
 11 histopathology, and she provides technical  
 12 consultation to many hospitals within our  
 13 region. Some of the hospitals that refer to  
 14 us, she's been there to help them.  
 15 COFFEY, Q.C.:  
 16 Q. So at the time, the idea that she was--if she  
 17 was out of--if you were told at the time  
 18 "she's gone to Newfoundland," it wouldn't have  
 19 -  
 20 DR. MULLEN:  
 21 A. I would, for technical assistance probably.  
 22 THE COMMISSIONER:  
 23 Q. Mr. Coffey, can you--two things.  
 24 COFFEY, Q.C.:  
 25 Q. Sure.

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1 THE COMMISSIONER:  
 2 Q. Can we clarify the business of the knowledge  
 3 of how many were coming and how that  
 4 progressed?  
 5 COFFEY, Q.C.:  
 6 Q. Well, actually, the next exhibit,  
 7 Commissioner, actually will help, I think.  
 8 THE COMMISSIONER:  
 9 Q. All right.  
 10 COFFEY, Q.C.:  
 11 Q. In that regard.  
 12 THE COMMISSIONER:  
 13 Q. Okay, thank you.  
 14 COFFEY, Q.C.:  
 15 Q. Actually, no.  
 16 THE COMMISSIONER:  
 17 Q. Well, the one after.  
 18 COFFEY, Q.C.:  
 19 Q. There's one later.  
 20 THE COMMISSIONER:  
 21 Q. As long as you're getting to it.  
 22 COFFEY, Q.C.:  
 23 Q. Oh yes, I will be, Commissioner. If we could,  
 24 perhaps take the morning break? I believe  
 25 it's -

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1 THE COMMISSIONER:  
 2 Q. Yes, it's about that time, if you wish to do  
 3 so, sure.  
 4 COFFEY, Q.C.:  
 5 Q. - it's about that time, and I want to take up  
 6 then October of '05.  
 7 THE COMMISSIONER:  
 8 Q. Mr. Pike seems to be on this feet.  
 9 MR. PIKE:  
 10 Q. Sorry, Commissioner, there was a matter I  
 11 should have attended to earlier, but I was  
 12 late coming in this morning. With me this  
 13 morning is Mr. Christian Hurley, who's a  
 14 student at law with our law firm, and I wanted  
 15 to introduce you to him, and have him sit up  
 16 with me for the balance of the day, with your  
 17 permission.  
 18 THE COMMISSIONER:  
 19 Q. Indeed. Welcome, Mr. Hurley.  
 20 MR. PIKE:  
 21 Q. Thank you.  
 22 THE COMMISSIONER:  
 23 Q. We'll take the morning break.  
 24 (RECESS)  
 25 THE COMMISSIONER:

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1 Q. Please be seated. Mr. Coffey.  
 2 COFFEY, Q.C.:  
 3 Q. Thank you, Commissioner. Registrar, could we  
 4 bring up, please, Exhibit P-0592? Now Doctor,  
 5 again, this is a couple of different e-mails,  
 6 but I'm going to refer you to it and then  
 7 perhaps have you utilize it to explain  
 8 something to the Commissioner. There's an e-  
 9 mail of September 9th, 2005 from Nancy Good to  
 10 Dr. Cook.  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. At 4:54 p.m., subject is ER/PR staining, and  
 15 she writes "Hi, Dr. Cook. I just wanted to  
 16 let you know that we have started cutting the  
 17 blocks and staining will begin next week."  
 18 Now this would be, as I indicated, at the end  
 19 of the first full week of September of '05.  
 20 "The machine can handle 48 samples, which is  
 21 16 complete cases ER/PR and negative control,  
 22 and will be run after hours. We will keep you  
 23 posted on the progress. Thanks, Nancy." And  
 24 I gather that by the end of September, they  
 25 had the first grouping of slides for you to

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1 look at.  
 2 DR. MULLEN:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. This reference to 16 complete cases, the  
 6 machine can handle 48 samples, and I take it  
 7 three times 16 is 48, 16 complete cases. Can  
 8 you tell us, please, about that? What is  
 9 involved in a physical way?  
 10 DR. MULLEN:  
 11 A. The machine that we're referring to is our--at  
 12 this time, was our DAKO autostainer, which is  
 13 a robotic system for immunohistochemistry, and  
 14 it has 48 slots. It has a capacity for 48  
 15 slides. Physically, the capacity is 48  
 16 slides. So it would run the 16 cases and  
 17 there's a time for--there's a--I won't be able  
 18 to tell you the exact number of hours that are  
 19 required, but there's an extensive time period  
 20 that it's being stained, washed, and then  
 21 counterstained. So that was our capacity on  
 22 that one machine. At the time, we had three  
 23 machines in the department and one was  
 24 dedicated to ER/PR because we had validated  
 25 every position on the autostainer for ER and

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1 PR.  
 2 COFFEY, Q.C.:  
 3 Q. Now the positive controls, where would they  
 4 be?  
 5 DR. MULLEN:  
 6 A. The positive -  
 7 COFFEY, Q.C.:  
 8 Q. Now this says negative control. Was that -  
 9 DR. MULLEN:  
 10 A. I'm sorry, the four other slots, I believe,  
 11 that would--no, that I can't answer, sorry.  
 12 COFFEY, Q.C.:  
 13 Q. Okay, that's fine, and I'll--the thing is,  
 14 from your perspective though, you understood  
 15 at the time you were getting an ER slide, a  
 16 PR slide and what else?  
 17 DR. MULLEN:  
 18 A. And a negative control for each case, plus a  
 19 positive control for the run.  
 20 COFFEY, Q.C.:  
 21 Q. For the run. And -  
 22 DR. MULLEN:  
 23 A. For both positive ER, positive PR, so yes, two  
 24 slides.  
 25 COFFEY, Q.C.:

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1 Q. And again, this is not copied to you, this e-  
 2 mail. I just bring it up, whether it's 16  
 3 times three or 15 times three, plus some other  
 4 slides, I can take up with someone else, but  
 5 from your perspective at the time, and I  
 6 guess, just for the Commissioner, because I  
 7 want to get some--take you through them and  
 8 kind of have some sense of what it was you  
 9 were getting to examine in September.

10 DR. MULLEN:  
 11 A. So the -  
 12 COFFEY, Q.C.:  
 13 Q. For any one case then, one patient or one  
 14 block, what would happen, in terms of what  
 15 would you--what would come to you?

16 DR. MULLEN:  
 17 A. I would receive the routine slide, which was  
 18 called a haematoxylin and eosin stain slide,  
 19 and HNE slide, which is our standard  
 20 diagnostic slide, and accompanying it would be  
 21 the estrogen stained slide--receptor stained  
 22 slide, the progesterone stained slide, and  
 23 then the negative control, and for that run,  
 24 that group of 15 or 16 cases, there would also  
 25 be a positive control that the lab would have

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1 had.  
 2 COFFEY, Q.C.:  
 3 Q. And the HNE slide that would come forward, I  
 4 take it that would be in relation to a  
 5 particular block?

6 DR. MULLEN:  
 7 A. It would be the block that matched the ER and  
 8 PR. If you recall either the spreadsheet or  
 9 the code, when I said tumor, the tumor would  
 10 be diagnosed on the HNE. That's the gold--  
 11 what I use and what every pathologist uses to  
 12 make the diagnosis and that's the  
 13 interpretation of the tumor, whether it was  
 14 present or absent and if it was present,  
 15 whether it was in situ or invasive and then if  
 16 it was invasive, what type of invasive tumor,  
 17 and they were broad categories. I wasn't  
 18 micro diagnosing. It was--I shouldn't say  
 19 micro diagnosing. I wasn't micro classifying.  
 20 I was trying to do broad categories. And then  
 21 in the next column would be the ER, which  
 22 would be the next slide, and then the PR,  
 23 which would be the subsequent slide. It was  
 24 always in that sequence, ER, PR, and then if  
 25 you recall from the spreadsheet, there was the

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1 internal control. I would go back to--or at  
 2 the same time I was doing the HNE, I would  
 3 look at the block and decide whether there was  
 4 an internal control.  
 5 Now by the term "internal control" I'm  
 6 referring to the presence of benign  
 7 epithelium. So benign breast tissue, either  
 8 within the tumor or adjacent to the tumor, and  
 9 then I would comment whether it was present or  
 10 absent and if it was present, whether it  
 11 stained or stained weakly. That was the PSW  
 12 or A. And then the final thing that I did was  
 13 very subjective interpretation of the quality  
 14 of the material, whether it was adequate or  
 15 poor, and adequate, essentially by the--after  
 16 one or two cases or one or two runs was there  
 17 a tumor that I could assess. That's basically  
 18 what it boiled down to at the very end. It  
 19 wasn't a very strict criteria. Whether there  
 20 was tumor on the slide and I could assess it,  
 21 then it was adequate.

22 COFFEY, Q.C.:  
 23 Q. And this is for the retrospective?  
 24 DR. MULLEN:  
 25 A. Yes, that's retrospective. That was the

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1 spreadsheet, those broad categories.  
 2 COFFEY, Q.C.:  
 3 Q. And this, and you say after two or three runs,  
 4 and what are you referring to there?

5 DR. MULLEN:  
 6 A. Two or three. I sat down with a series of  
 7 cases, I can't tell you how many, and I went  
 8 through them and went--trying to get a  
 9 baseline, what I was going to have to  
 10 evaluate.

11 COFFEY, Q.C.:  
 12 Q. And these are cases, the slides had been  
 13 prepared by Mount Sinai from the blocks from  
 14 Newfoundland?

15 DR. MULLEN:  
 16 A. Yes, this would have been the first, we'll  
 17 say, maybe ten or so. Don't quote me on the  
 18 exact number, but whenever you're doing, for  
 19 want of a better term, research project or  
 20 project, you want to see what the range is  
 21 going to be. So what is it that I'm going to  
 22 have to assess. So what are the adequacies  
 23 and what are sort of the range, and so I'd  
 24 look at them and try to figure out what would  
 25 be the easiest and best way to assess them and

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1 what criteria I should use. So I did that and  
 2 then I went back a second time and then just  
 3 to reconfirm that, you know, that would be  
 4 adequate for me, and I think for the patient,  
 5 and then the question, I think, to put to  
 6 Eastern Health or St. John's was whether a  
 7 spreadsheet would be adequate, and they were  
 8 in agreement and those criteria were adequate  
 9 for them, and so then, I did the actual  
 10 interpretation. So two times, sort of to  
 11 familiarize myself with the quality of the  
 12 material, the staining, the range of the  
 13 staining, as well as one can with ten slides  
 14 or ten cases, I should say.  
 15 COFFEY, Q.C.:  
 16 Q. Doctor, if we could, Exhibit P-1776?  
 17 THE COMMISSIONER:  
 18 Q. Sorry, before we leave that, just to make sure  
 19 I'm not missing something here or  
 20 misinterpreting what you're saying. Just in  
 21 terms of the process you went through. So do  
 22 I take it that for some cases you got one  
 23 block, some cases you got two or -  
 24 DR. MULLEN:  
 25 A. Three, yes.

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1 THE COMMISSIONER:  
 2 Q. - or three blocks?  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 THE COMMISSIONER:  
 6 Q. Would you cut your slides from each of the  
 7 blocks you got?  
 8 DR. MULLEN:  
 9 A. Yes.  
 10 THE COMMISSIONER:  
 11 Q. So if you got a case with two blocks, in fact,  
 12 you would run two -  
 13 DR. MULLEN:  
 14 A. We would do a -  
 15 THE COMMISSIONER:  
 16 Q. - what I would call a run, based on each of  
 17 those blocks?  
 18 DR. MULLEN:  
 19 A. We would--depending on the number of blocks,  
 20 we would do--we would replicate the staining,  
 21 everything. The interpretation would--it would  
 22 all be done independently. So I would have  
 23 one block, I would report that. I'd move on  
 24 to the next, whether I recalled it was the  
 25 same case or you know, matched, it would--and

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1 they may not have been in that order, that  
 2 sequence, but everything was--and they would  
 3 be reported independently. So if one case was  
 4 no tumor, and so nothing was reported, and  
 5 then the next block had tumor, it would be  
 6 reported independently.  
 7 THE COMMISSIONER:  
 8 Q. Okay.  
 9 DR. MULLEN:  
 10 A. So you would get--you could get, and often,  
 11 and I would be surprised if you ever got the  
 12 same result, unless it was completely absent,  
 13 you would get different ER and PR results  
 14 because of the heterogeneity, both within one  
 15 section and between sections.  
 16 COFFEY, Q.C.:  
 17 Q. I will be getting to that.  
 18 THE COMMISSIONER:  
 19 Q. Okay, thank you. And do I take it then, in  
 20 fact, there are three slides created for every  
 21 block?  
 22 DR. MULLEN:  
 23 A. Four, one would be the routine, the H--the  
 24 routine is done on a different machine.  
 25 THE COMMISSIONER:

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1 Q. Okay.  
 2 DR. MULLEN:  
 3 A. Because it's not immunohistochemistry, it's  
 4 routine histochemistry.  
 5 THE COMMISSIONER:  
 6 Q. And that's the one you used to determine the  
 7 diagnosis?  
 8 DR. MULLEN:  
 9 A. Yes, that's correct, and what area I should  
 10 assess.  
 11 THE COMMISSIONER:  
 12 Q. Okay, and then the other three -  
 13 DR. MULLEN:  
 14 A. Yes.  
 15 THE COMMISSIONER:  
 16 Q. - would be your ER, your PR and your negative  
 17 slide?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 THE COMMISSIONER:  
 21 Q. All of which are done on the same machine?  
 22 DR. MULLEN:  
 23 A. Yes.  
 24 THE COMMISSIONER:  
 25 Q. And can you tell me again the business of

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1 checking for the normal tissue near your  
 2 tumor?  
 3 DR. MULLEN:  
 4 A. Okay. Do you want me to do that now or are  
 5 you going to -  
 6 COFFEY, Q.C.:  
 7 Q. Yes. No, you go ahead and do it now.  
 8 DR. MULLEN:  
 9 A. Sorry, I didn't mean to--because -  
 10 THE COMMISSIONER:  
 11 Q. No, no. Yes, sometimes Mr. Coffey has grand  
 12 plans which I don't know about. I only see  
 13 them later, so--and I have a tendency to jump  
 14 in.  
 15 DR. MULLEN:  
 16 A. All right. One of the--the major issue in all  
 17 of diagnostic pathology or  
 18 immunohistochemistry is the processing and  
 19 fixation of--fixation first, processing of  
 20 tissue. So you're trying to base the reaction  
 21 in the tumor to what actually goes on in the  
 22 normal. So normal in patient women in the  
 23 breast, patients who have breast cancer, if  
 24 they're pre-menopausal, about 80 percent of  
 25 their epithelium or 80 percent of women will

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1 have positive estrogen receptor in the benign  
 2 epithelium. So that I use as an internal  
 3 control. In women, post-menopausal who have  
 4 malignancy, it's up to 88 percent. So you  
 5 know, in almost 90 percent and 80 percent of  
 6 women, there is a built--there should be a  
 7 built-in internal control, and the standard  
 8 for an internal control, the study that I'm  
 9 quoting the 80 and 90 percent is they just  
 10 required one percent to be positive.  
 11 THE COMMISSIONER:  
 12 Q. Okay.  
 13 DR. MULLEN:  
 14 A. So that--so it's a very low standard, but  
 15 there is that built-in safety net for me. Now  
 16 if you have a second piece of--you have a  
 17 tumor you're using as a control, whether you  
 18 use tumor or you use normal endometrium or  
 19 endocervix which we use as a control, if you  
 20 haven't processed it at the same time as you  
 21 process the tissue or if that tissue hasn't  
 22 been processed and fixed the same way, you  
 23 have no idea--you can have an external control  
 24 that reacts quite nicely, but it has no  
 25 relevance to what you're actually looking at.

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1 THE COMMISSIONER:  
 2 Q. Okay.  
 3 DR. MULLEN:  
 4 A. So what I want--the external control is  
 5 basically for did our process work? Yes, it  
 6 did. But the actual--I would not--I couldn't  
 7 use our external control as a control for  
 8 assessing the breast cancer cases. I knew  
 9 that stained, but what we would call a  
 10 positive would be much stronger than any of  
 11 the cases that I ever saw from Newfoundland,  
 12 because of the processing and fixation issues.  
 13 THE COMMISSIONER:  
 14 Q. Okay, which we will come to.  
 15 DR. MULLEN:  
 16 A. And I have--I think later, I have slides  
 17 demonstrating that issue.  
 18 THE COMMISSIONER:  
 19 Q. Okay.  
 20 DR. MULLEN:  
 21 A. Graphically, it's much easier than verbally.  
 22 THE COMMISSIONER:  
 23 Q. Okay, thank you.  
 24 COFFEY, Q.C.:  
 25 Q. And so the Commissioner is aware, so that

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1 you'd have a particular patient--well, a  
 2 particular identified with an RS number and an  
 3 SP number, I believe -  
 4 DR. MULLEN:  
 5 A. No, it was--for the retrospective, it was  
 6 always RS.  
 7 COFFEY, Q.C.:  
 8 Q. RS numbers, internally for yourselves?  
 9 DR. MULLEN:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Okay, whatever the number Newfoundland  
 13 assigned to them, you had your own numbers.  
 14 The RS number, and that RS number, as we  
 15 looked at some of the spreadsheets earlier--  
 16 I'll just perhaps go back to--put one up here,  
 17 just to illustrate the point maybe.  
 18 THE COMMISSIONER:  
 19 Q. I take it from this, the choice of blocks is  
 20 also fairly critical in this process?  
 21 DR. MULLEN:  
 22 A. Yes. The Mount Sinai cases I have complete  
 23 control over the selection of the block, I  
 24 make the diagnosis and I always try to ensure,  
 25 it's not always possible, it's not 100

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1 percent, I always try to ensure that I have  
 2 benign breast tissue within the block.  
 3 Ideally it's within the tumor, but it can be  
 4 adjacent to or even on the block, that I can  
 5 use as the internal control. So in 90 percent  
 6 of the cases postmenopausal, 80 percent of  
 7 premenopausal I have that built-in internal  
 8 control.  
 9 COMMISSIONER:  
 10 Q. Okay.  
 11 COFFEY, Q.C.:  
 12 Q. And here, for example, if we could bring up  
 13 again Exhibit P-1707? And this is that  
 14 September 13th, 2005 e-mail from Nancy Good to  
 15 yourself, Doctor, we've looked at earlier.  
 16 I'm just going to go to, if I could, the  
 17 spreadsheet attached. And in looking at this  
 18 earlier, for example, it's an RS number that's  
 19 been redacted here, but the specimen number,  
 20 which would be, I take it, the -  
 21 DR. MULLEN:  
 22 A. The submitting hospital.  
 23 COFFEY, Q.C.:  
 24 Q. Submitting hospital is SU number. And for  
 25 example, here, the ones we looked at below,

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1 earlier -  
 2 DR. MULLEN:  
 3 A. 997806 would have three cases.  
 4 COFFEY, Q.C.:  
 5 Q. Yes. 7806 would actually have three blocks?  
 6 DR. MULLEN:  
 7 A. Three, yes.  
 8 COFFEY, Q.C.:  
 9 Q. Associated, Mount Sinai would have received  
 10 block label 1D, block label 2 and a block  
 11 labelled 3?  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COMMISSIONER:  
 15 Q. And in this case you would have run all three  
 16 blocks?  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 COMMISSIONER:  
 20 Q. As opposed to choosing the particular block  
 21 because you might do -  
 22 DR. MULLEN:  
 23 A. They would have gotten three results.  
 24 COMMISSIONER:  
 25 Q. Yes.

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1 DR. MULLEN:  
 2 A. Now, here I would have not because I didn't  
 3 want to know the source of material. This  
 4 could have been a right breast, left breast,  
 5 it could have been two different tumors within  
 6 the breast, two different operations the same  
 7 time. So I really, what I was presented with,  
 8 stained and reported.  
 9 COMMISSIONER:  
 10 Q. All right. Thank you.  
 11 COFFEY, Q.C.:  
 12 Q. And so for any one block, whether it came  
 13 from--and whether you had multiple blocks from  
 14 the same patient or not, for any one block  
 15 that Mount Sinai received and did this--was  
 16 involved in this retrospective analysis or  
 17 study, any one block you would have received a  
 18 HNE slide, HNE stain, slide -  
 19 DR. MULLEN:  
 20 A. Prepared at -  
 21 COFFEY, Q.C.:  
 22 Q. Prepared at Mount Sinai?  
 23 DR. MULLEN:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. And looked at that and made your diagnosis?  
 2 DR. MULLEN:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And recorded it?  
 6 DR. MULLEN:  
 7 A. Yeah, that would have been the column that had  
 8 the tumor type, ductal, the majority would be  
 9 ductal. I mean, I can give you the breakdown.  
 10 Invasive tumor we had 997 of them and the  
 11 majority of those would be ductal.  
 12 COFFEY, Q.C.:  
 13 Q. And you, as well, though, indicated to the  
 14 Commissioner that in looking at the HNE slide  
 15 you would utilize what you saw to determine  
 16 what else? You said area to examine in  
 17 particular?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. Could you explain that?  
 22 DR. MULLEN:  
 23 A. And I believe you'll be leading me to this  
 24 later, one of the major issues that I had in  
 25 reviewing the material was the issue of the ER

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1 and the PR stain material not adhering to the  
 2 slide. So basically, and I have pictures to  
 3 show later what we call exploding sections or  
 4 the section would not stain--it would not stay  
 5 on the slide. Because of the preprocessing  
 6 required for ER and PR staining it requires  
 7 heating in an acid solution, the tissue would  
 8 just, if it's not properly processed, would  
 9 basically blow apart and you would end up with  
 10 either a little bit and in some cases nothing  
 11 on the slide. So these, if you--some of the  
 12 e-mails that we'll see that we kept repeating  
 13 to try to get them to stay on. I mean, there  
 14 are tricks in processing, or tricks in--but  
 15 ultimately it's the quality of the material  
 16 that you put on the slide that when you're  
 17 going through antigen retrieval dictates  
 18 whether there's anything left.

19 COFFEY, Q.C.:

20 Q. By the time the antigen retrieval process is  
 21 over?

22 DR. MULLEN:

23 A. Yes. So the HNE, by and large, not in 100  
 24 percent of cases, but by and large, was  
 25 adequate to read, so I would look--I would--to

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1 see where the tumor was so that when I went to  
 2 assess what percentage was positive, I knew  
 3 what part of the slide to look at. And then  
 4 in some cases the internal control and not  
 5 unexpectedly may be just one duct. I wanted  
 6 to see where I should look for on the slide.  
 7 But that didn't -

8 COFFEY, Q.C.:

9 Q. Oh, the ER slide -

10 DR. MULLEN:

11 A. Yes, I would try to match. Now, the issue  
 12 became sometimes, if you remember my example  
 13 of the Kleenex box, not every section has the  
 14 same material and so some things may pop up in  
 15 the ER slide that wasn't in the HNE, so I may  
 16 end up with an internal control that was there  
 17 but wasn't in the HNE. So basically the last  
 18 two--the column on the internal control was  
 19 the combination of the HNE and the estrogen  
 20 and progesterone. And if the estrogen--it was  
 21 either one or the other was positive.

22 COFFEY, Q.C.:

23 Q. And I will be exploring some of this in more  
 24 detail with you later. Exhibit P-1776?  
 25 Doctor, again, to help the Commissioner to put

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1 some of this in temporal context, this is a  
 2 letter of September 26th, 2005. It's from  
 3 yourself, copied to Dr. Donald Cook. It's  
 4 addressed to Dr. Maurice Dalton, Central  
 5 Newfoundland Regional Health Centre, Grand  
 6 Falls-Windsor. You write, it's "Re: ER/PR  
 7 HER2/neu assessment." And you write, "Dr. Dr.  
 8 Dalton, At the request of Dr. Donald Cook,  
 9 Clinical Chief, Laboratory Medicine Program,  
 10 St. John's, Eastern Health, the Department of  
 11 Pathology and Laboratory Medicine at Mount  
 12 Sinai Hospital is providing temporary coverage  
 13 for the performance and interpretation of ER  
 14 and PR receptors and HER2/neu assessment. To  
 15 refer a case, please send to my attention a  
 16 paraffin block, preferably including normal  
 17 breast tissue with the accompanying pathology  
 18 report and a covering letter to include the  
 19 patient's name, MCP number and date of birth.  
 20 The ER/PR in immunohistochemical HER2/neu  
 21 assessment will be billed using the MCP  
 22 number. For cases requiring FISH assessment  
 23 of the HER2/neu status. The hospital will be  
 24 billed \$400. Based on our experience, less  
 25 than 20 percent of cases require a FISH

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1 confirmation. To expedite the reporting of  
 2 cases please provide the fax number for your  
 3 facility. If you have any questions please do  
 4 not hesitate to contact me. Yours sincerely,  
 5 Brendan Mullen." And I'm just going to--if we  
 6 could bring up, please, then, Exhibit P-1777?  
 7 This is, I gather, Doctor, in effect, the same  
 8 letter, it's the same date -

9 DR. MULLEN:

10 A. The same, yes, it's the same letter.

11 COFFEY, Q.C.:

12 Q. - same text, to Dr. B. Gallagher, that would  
 13 be Barry Gallagher at James Paton Memorial  
 14 Hospital. Exhibit P-1778? That's again the  
 15 same text, same date, except this one is  
 16 addressed to Dr. G. Baker at Carbonear General  
 17 Hospital. Exhibit P-1779? And this is again  
 18 a letter of same date, same text, I believe,  
 19 to Dr. K. Dankwa at the Charles S. Curtis  
 20 Memorial Hospital and this is Labrador  
 21 Grenfell in St. Anthony. And finally, Exhibit  
 22 P-1780? This is a letter of the same date,  
 23 again, same text, addressed by yourself to Dr.  
 24 Paul Neil at Western Memorial in Corner Brook.  
 25 I'm sorry, and there's one other. I said the

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1 final and, of course, the final is Exhibit P-  
 2 1781.  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. This is at letter dated -  
 7 DR. MULLEN:  
 8 A. - (inaudible), yes.  
 9 COFFEY, Q.C.:  
 10 Q. - September 26th, 2005, same date, same text,  
 11 but this one is addressed to Dr. S. Anwar at  
 12 the Peninsulas Health Care Corporation. So I  
 13 take it, Doctor, that all of those letters, in  
 14 effect, were confirming that as of September  
 15 26th, 2005 Mount Sinai was going to report  
 16 current cases on a go-forward basis for ER/PR  
 17 and HER2/neu for, well, what we understand  
 18 would be Newfoundland?  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. Period?  
 23 DR. MULLEN:  
 24 A. Yes, that's my understanding. This was my  
 25 request to please look at the slide before you

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1 send it so I'd have an internal control.  
 2 COFFEY, Q.C.:  
 3 Q. Yes.  
 4 DR. MULLEN:  
 5 A. And just to tell them what we were going to--  
 6 how we were going to process and proceed.  
 7 COFFEY, Q.C.:  
 8 Q. I'm going to use Exhibit P-1781, the text of  
 9 it, because the text of the others I've looked  
 10 at is the same.  
 11 DR. MULLEN:  
 12 A. Okay.  
 13 COFFEY, Q.C.:  
 14 Q. The body of the text. Here, Doctor, in  
 15 respect of the current cases on a kind of a  
 16 go-forward basis.  
 17 DR. MULLEN:  
 18 A. The prospective cases, okay.  
 19 COFFEY, Q.C.:  
 20 Q. Here, though, you are actually looking for and  
 21 requesting not only, of course, the paraffin  
 22 block and as you point out, preferably  
 23 including normal breast tissue which allows or  
 24 provides an internal control, I gather?  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. That's the point?  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. But as well you're looking here for the  
 8 accompanying pathology report and covering  
 9 letter to include the patient's name, MCP  
 10 number and date of birth?  
 11 DR. MULLEN:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. So here as opposed to the retrospective study  
 15 where, I gather, you were not looking at the  
 16 pathology reports and so on, could you explain  
 17 why the different approach?  
 18 DR. MULLEN:  
 19 A. Would it possible for you to pull up and  
 20 exhibit of one of my reports? I believe -  
 21 COFFEY, Q.C.:  
 22 Q. I certainly can.  
 23 DR. MULLEN:  
 24 A. It's not in my package, but I believe you have  
 25 a copy. And I'll step you through it.

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1 COFFEY, Q.C.:  
 2 Q. Sure. If we could, please, and I would point  
 3 out, Commissioner, this is one of those C  
 4 exhibits.  
 5 COMMISSIONER:  
 6 Q. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. I have a number of them, actually, but one in  
 9 particular I'll just ask the Registrar to  
 10 bring up C-0057, please?  
 11 COMMISSIONER:  
 12 Q. In our coding, Doctor, the C exhibits are -  
 13 DR. MULLEN:  
 14 A. Confidential.  
 15 COFFEY, Q.C.:  
 16 Q. Confidential. Now, Doctor, here this  
 17 particular exhibit, would you just take us  
 18 through the form? Well, first of all, this is  
 19 on Mount Sinai Hospital letterhead?  
 20 DR. MULLEN:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. And just kind of take us down through the form  
 24 and what the various listings mean?  
 25 DR. MULLEN:

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1 A. First of all, this report was dated 2006,  
 2 March 17th it was received, St. Patrick's Day.  
 3 Okay. So this was the form that we had at  
 4 that time. We've changed our logo because  
 5 we've had a major donor, so we now have  
 6 changed basically the name of the hospital. I  
 7 have to put that plug in. So if you look at  
 8 the top, part of the College of American  
 9 Pathologists Ontario lab accreditation is that  
 10 you require contact numbers, so who we are,  
 11 Mount Sinai Hospital on the upper left,  
 12 Pathology Laboratory Medicine, our address,  
 13 both a telephone number and a fax number.  
 14 Location, we, for our cases that are referred  
 15 in, we use the term "Pathology referred in  
 16 specimen." If it were a outpatient, it would  
 17 be whatever the--it would be POP. If it were  
 18 inpatient, whether it was from the OR, it'd be  
 19 operating room or something like that. The  
 20 room number is the patient's room. The  
 21 physician is the referring physician. In this  
 22 case at the time all cases from St. John's  
 23 were sent to--were referred to me under Dr.  
 24 Carter's name. The date of the procedure is  
 25 the next column, that's the date, in this case

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1 it's the date we received it. And the  
 2 accession date, in the hospital, the date of  
 3 procedure, the time the operation would be,  
 4 we'll say it was 17th, if we received it the  
 5 same day, it would be the 17th, received it  
 6 the next day would be the 18th or whatever, in  
 7 over the weekend. You can tell the time from  
 8 the procedure--the date of the procedure to  
 9 the time we've actually accessioned it. And  
 10 then the date and time of the final report,  
 11 again the date and the actual time. If we go  
 12 down the next side on the right-hand side,  
 13 medical record number is a unique identifier.  
 14 Visit is for when we send it to our lab  
 15 information system, it has to have a unique  
 16 visit number so it would be accessible.  
 17 Patient's last name, first name, date of birth  
 18 and sex. And then below the line the title of  
 19 the report is the final surgical pathology and  
 20 that's we have finals. We have another  
 21 category, if I have to change something, it  
 22 will be called revised final surgical  
 23 pathology report. Then it has our hospital  
 24 unique surgical pathology number, SP meaning  
 25 surgical pathology, '06, the year, 4713 would

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1 be what number we were up to on March 17th.  
 2 Then if we go down the left-hand side, the  
 3 copies to, if there was copy, this is more for  
 4 internal, if another clinician or another  
 5 physician, clinician or cancer centre required  
 6 a copy, we'd send it to them and it would be  
 7 indicated there. Then the clinical history,  
 8 this is for--this is my template for the ER/PR  
 9 HER2 from Newfoundland, for clinical history  
 10 if they wanted ER/PR, if they wanted HER2,  
 11 whatever it was, I would put in that comment  
 12 ER/PR, HER2 assessment. And then the gross  
 13 description basically is my standard received  
 14 from Department of Pathology, St. Clare's site  
 15 is a paraffin block labelled, and that was  
 16 their number, SS, SS and SUs, I'm not sure  
 17 which site here uses which. 62--SU might be  
 18 university and SS might be St. Clare's.  
 19 SS6242-01-2L, so the year. So their SS is  
 20 their hospital indicator; 6242 would be their  
 21 accession number; 01 would be their year. So  
 22 this was, in fact, a retrospective that was  
 23 coming after the fact--well, I shouldn't say  
 24 retrospective, but a case from '01, dash 2L  
 25 would be second specimen and L would be the

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1 number of the block that they were sending to  
 2 me. So from each specimen you can have  
 3 anywhere from one block to basically  
 4 unlimited. If it's a large tumor, you can  
 5 have 40, 50 blocks. So that's that indicator.  
 6 And from a breast specimen, type and site  
 7 unspecified. St. Clare's or when I say St.  
 8 Clare's, St. John's, when they send me  
 9 material, just send me a sheet with the  
 10 patient's name, MCP, I think date of birth and  
 11 then the block number. They don't indicate  
 12 whether it's right or left or whatever. So  
 13 that's there. And if it were coming from one  
 14 of the other sites that I had a path report,  
 15 it would say from a right breast specimen or  
 16 left breast specimen. So I--okay. So then  
 17 the microscopic description, this is a  
 18 template we use: estrogen receptor protein;  
 19 percent positive cells, 95. The antibody used  
 20 in this case is, and it's the antibody we use  
 21 for all of our cases is 6F11 and the  
 22 procedure, Linked Striped Avidin Biotin  
 23 procedure, they're multiple procedures.  
 24 Progesterone receptor protein, percentage  
 25 positive cells, antibody--in this case it's

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1 less than one. PGR1294 is the antibody we use  
 2 for progesterone. Line Striped Avidin Biotin  
 3 procedure. HER2/neu protein, here percentage  
 4 positive cells. And the requirements for HER2  
 5 protein require that we give the percentage  
 6 and the staining intensity, absent or not  
 7 applicable depending on what you want to say,  
 8 weak, moderate or strong. So less than one,  
 9 weak. And then the antibody used, as I  
 10 mentioned, the AO485, this LSAB procedure.  
 11 Percentage positive cells, again, less than  
 12 one, staining intensity weak, antibody used,  
 13 TAB250 CD11, that's a cocktail, and LSAB,  
 14 procedure. And then this is the, what--not  
 15 everybody is familiar with our threshold, so  
 16 we always state what our threshold is,  
 17 threshold for positive ER/PR result, staining  
 18 of any intensity greater than one percent of  
 19 invasive tumor cells. So you have more than  
 20 one percent, one in 100 cells that stain  
 21 weakly, we call that positive. We may call it  
 22 low--we'll call it low positive if it's less  
 23 than 10, but if it's over 10 percent, it's--  
 24 both for all intents and purposes are  
 25 positive, one is low, one is normal positive.

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1 And we can discuss the clinical significance  
 2 of that later, if required. Then the  
 3 threshold for HER2 result, moderate to strong,  
 4 complete membrane--now, this is what was  
 5 applicable in '06. It's changed slightly in  
 6 '07, to strong, complete membrane staining in  
 7 greater than 10 percent of invasive tumor  
 8 cells. Now it's greater than 30 percent,  
 9 strong, is the cutoff. Positive and negative  
 10 laboratory external control stained  
 11 appropriately. And then the normal breast  
 12 tissue reacted appropriately with estrogen and  
 13 progesterone stains. Now, I would modify that  
 14 statement in metastatic tumors to state and  
 15 tumors that, the cases that did not have  
 16 internal controls to state normal breast  
 17 tissue is not present, just to indicate to the  
 18 clinician and to the pathologist that if  
 19 you're worried, send me something else. But  
 20 in this case we know that the estrogen  
 21 receptors is positive so that would have been--  
 22 wouldn't have necessarily flagged them to do  
 23 anything. And when I mention metastatic,  
 24 those are tumors that have--not in breast but  
 25 outside of breast, so they wouldn't have

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1 normal breast tissue there, you wouldn't  
 2 expect to have it. So it's tumor to bone,  
 3 tumor to lung, tumor to brain, that type of  
 4 thing. And then the next page, this is why I  
 5 really wanted the -  
 6 COFFEY, Q.C.:  
 7 Q. Yeah, before we go on.  
 8 DR. MULLEN:  
 9 A. Sorry.  
 10 COFFEY, Q.C.:  
 11 Q. There's a note here at the bottom left-hand  
 12 side, I take it, printed in 2006/03/20 at  
 13 17:52 hours, so it actually keeps track of -  
 14 DR. MULLEN:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. - when it's printed, yes. Go ahead, sir.  
 18 DR. MULLEN:  
 19 A. And then a reference -  
 20 COFFEY, Q.C.:  
 21 Q. Page 2.  
 22 DR. MULLEN:  
 23 A. This is the reference we had in '06--sorry.  
 24 Yes, in '06. Our subsequent reports now also  
 25 include the HER2 and the--don't know why I

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1 didn't include it there, but the HER2 and new  
 2 ASCO guidelines, the reference is there. And  
 3 so my diagnosis--and this is critical for me  
 4 keeping track of what I do, the breast, and I  
 5 like to tell which breast it is because if we  
 6 get two blocks and one is right, one is left,  
 7 we--and they may be separate. Specimen type  
 8 and--in this case from St. Clare's I never  
 9 know which--whether it's mastectomy,  
 10 lumpectomy, whatever, so it always goes--and I  
 11 don't know the side, so it has that default.  
 12 And here I made a diagnosis, invasive ductal  
 13 carcinoma, no special type, which is the vast  
 14 majority of the tumors we see. And I state  
 15 "Positive for estrogen receptor protein"  
 16 because it was greater than one. Negative for  
 17 progesterone receptor, which is because it was  
 18 less than one. And negative for HER2/neu  
 19 protein be over expression because it was, I  
 20 believe, less than one in both cases. Sorry,  
 21 I didn't realize I control this. So that's  
 22 the format. And the reason I wanted, as I  
 23 mentioned, to see the report, was to be able  
 24 to tell the Commission if it's right side,  
 25 left side, that type of thing. It's more for

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1 completeness.

2 COFFEY, Q.C.:

3 Q. Now, Doctor, now this particular exhibit, C-

4 0057, it's, the date of your report is March

5 20th, 2006?

6 DR. MULLEN:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. And this would not be a report for surgery

10 done within Mount Sinai?

11 DR. MULLEN:

12 A. No.

13 COFFEY, Q.C.:

14 Q. It's is probably, looking at the number here,

15 SS6242-01, it's probably a 2001 case?

16 DR. MULLEN:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. And so the date of procedure here and

20 accession date of March 17th, 2006, I take it,

21 would be -

22 DR. MULLEN:

23 A. They're all internal.

24 COFFEY, Q.C.:

25 Q. For Mount Sinai, Mount Sinai is dealing with a

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1 -

2 DR. MULLEN:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. - block which probably dates back to 2001?

6 DR. MULLEN:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. Surgery. Now, Doctor, on that point, if I

10 could ask you, because you, of course, I

11 gather were involved in a retrospective study,

12 were there ever situations where blocks were

13 sent up as part of the retrospective study,

14 but they ended up being dealt with as consults

15 with individual reports such as, for example,

16 this particular one?

17 DR. MULLEN:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Did that ever happen, and if so, how did it

21 come about?

22 DR. MULLEN:

23 A. I believe Dr. Cook or somebody from St.

24 Clare's would contact either Maria Mendes or

25 Nancy Good and state that this case with this

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1 block number they want done immediately or

2 done stat, so or they'd want a HER2 on it,

3 HER2 analysis, and that wasn't part of the

4 retro, so we would take--remove the block or

5 the case from the retro study and move it into

6 our surgical, so it would get priority, it

7 would be done immediately, both ER/PR and HER2

8 within the lab. So you can see here it came

9 on the 17th and so accession, it would be cut

10 probably the 18th and stained the 19th and I

11 would report out the 20th, so tried to, we

12 tried to expedite, unless, I'm not sure if

13 that was a weekend, but that type, within a

14 day or two, at most.

15 COFFEY, Q.C.:

16 Q. In terms of that, if we could, Registrar,

17 Exhibit C-0073? Now, Doctor, this is again

18 one of those, I will refer to it as a consult

19 report.

20 DR. MULLEN:

21 A. Yes.

22 COFFEY, Q.C.:

23 Q. This particular patient has, in fact,

24 testified here before the Commissioner. And

25 this, the Commissioner has heard evidence that

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1 this particular patient, in fact, had, if I

2 recall it correctly, metastasis and while she

3 was being treated for a complication or a

4 symptom related to that there was a request

5 made to have her test result expedited.

6 DR. MULLEN:

7 A. Okay.

8 COFFEY, Q.C.:

9 Q. Her retest, I'm sorry, the retest result in

10 the retrospective. So this -

11 DR. MULLEN:

12 A. And to add, I believe here to add HER2, as

13 well.

14 COFFEY, Q.C.:

15 Q. Yes, as well, and HER2 was added, as well,

16 here. So if during the retrospective analysis

17 a request was done for HER2/neu in respect of

18 any one of those particular patients that

19 would otherwise be in the retrospective study

20 -

21 DR. MULLEN:

22 A. Retrospective.

23 COFFEY, Q.C.:

24 Q. - they got pulled out -

25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. - they were dealt with as a consult, reported  
 4 separately ER/PR and HER2/neu?  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Or even without, perhaps, HER2/neu, even if  
 9 there was just some urgency -  
 10 DR. MULLEN:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. - they would be -  
 14 DR. MULLEN:  
 15 A. Unless I--if it were ready, if it were ready  
 16 to be reported on the spreadsheet, it might  
 17 have been that way, but for most of them  
 18 weren't ready so they'd be pulled out and  
 19 done. I think you would have the final  
 20 number, but I--it was a limited number, I  
 21 think 12 or 15, at most.  
 22 COFFEY, Q.C.:  
 23 Q. That kind of got pulled out, as it were?  
 24 DR. MULLEN:  
 25 A. Yes, out of the 11, so less than one percent.

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1 COFFEY, Q.C.:  
 2 Q. And, now, Doctor, with respect to, if we just  
 3 go back then to Exhibit P-1781, please, P-  
 4 1781? And this is that kind of--it appears,  
 5 in effect, it's form letter for this  
 6 particular purpose, to Dr. Anwar. Here you  
 7 had requested certain things for the ongoing  
 8 consults, the current consult cases be sent to  
 9 you. The accompanying pathology report, I  
 10 believe you indicated that in respect of the  
 11 material coming from St. John's on current  
 12 cases would you get, for the current cases,  
 13 that pathology report?  
 14 DR. MULLEN:  
 15 A. No, I did not. As I mentioned, I request  
 16 whatever the appropriate--whatever the stain  
 17 was, whether ER/PR or HER2, combination HER2,  
 18 ER/PR, I would receive basically a table,  
 19 patient's name, MCP, date of birth and then  
 20 block number.  
 21 COFFEY, Q.C.:  
 22 Q. And that was for the current cases?  
 23 DR. MULLEN:  
 24 A. Yes, that was all prospective cases.  
 25 COFFEY, Q.C.:

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1 Q. Yeah.  
 2 COMMISSIONER:  
 3 Q. When you say accompanying pathology report,  
 4 are you referring to the kind of things that  
 5 are noted on the--aside from, I presume,  
 6 whether it was right breast or left breast,  
 7 for the kind of thing that they see?  
 8 DR. MULLEN:  
 9 A. No, I would--that would be the requisition.  
 10 COMMISSIONER:  
 11 Q. Okay.  
 12 DR. MULLEN:  
 13 A. The pathology report would be the final report  
 14 where the--do you have an example of one of  
 15 those from, it would be easy to pull up? You  
 16 don't have one of mine.  
 17 COMMISSIONER:  
 18 Q. Well, yes, okay. But we're dealing with  
 19 current, are we not?  
 20 DR. MULLEN:  
 21 A. Yes.  
 22 COMMISSIONER:  
 23 Q. Okay. With the accompanying pathology report.  
 24 And I'm just wondering what one would expect  
 25 to see in an accompanying pathology report on

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1 a current case?  
 2 DR. MULLEN:  
 3 A. I would expect to see the clinical history  
 4 with--basically if you go back to my--can we  
 5 pull up one of my previous?  
 6 COMMISSIONER:  
 7 Q. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. Yes. Perhaps we'll use, if I could, please,  
 10 Exhibit C-0073?  
 11 COMMISSIONER:  
 12 Q. Clinical history.  
 13 DR. MULLEN:  
 14 A. So the clinical history there would be breast  
 15 cancer, breast mass, whatever, not stated.  
 16 Most of the clinicians don't state. The  
 17 specimen would be whether it was a lumpectomy,  
 18 mastectomy or core biopsy and might indicate  
 19 side and if you're very lucky might indicate  
 20 the quadrant.  
 21 COMMISSIONER:  
 22 Q. Okay.  
 23 DR. MULLEN:  
 24 A. And the gross description would be the  
 25 description of the specimen that was received

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1 in pathology. So our standard would, and this  
 2 would be done by the pathologist or the  
 3 pathologist assistant. So basically it would  
 4 state something to the effect, specimen  
 5 container is labelled the patient's  
 6 identification and as, whatever the specimen  
 7 was and contains a portion of breast tissue,  
 8 you give the measurements.  
 9 COMMISSIONER:  
 10 Q. Um-hm.  
 11 DR. MULLEN:  
 12 A. Whether--then you describe the skin, if  
 13 there's skin present. Then you make serial  
 14 sections through it and describe if there's a  
 15 tumor. And then you--so basically for all  
 16 intents and purposes breast cancer is presence  
 17 of a sphere within a sphere. So you're trying  
 18 to, on your gross description is to indicate  
 19 the size of the tumor.  
 20 COMMISSIONER:  
 21 Q. Um-hm.  
 22 DR. MULLEN:  
 23 A. First of all the size of the specimen, the  
 24 size of the tumor and then the relationship  
 25 of the tumor to the margins because that

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1 becomes very important for the surgeon and the  
 2 radiotherapist to know whether they're  
 3 completely excised.  
 4 COMMISSIONER:  
 5 Q. Um-hm.  
 6 DR. MULLEN:  
 7 A. So that would be that. And then you would--  
 8 the next would be the table of the sections.  
 9 So we have standard margins that we take, so--  
 10 and then sections of the tumor. And then you  
 11 also want to sample the normal breast tissue  
 12 as independents to see if there's other  
 13 coexistent diseases. And then that would be  
 14 what would be under the gross description.  
 15 And then microscopic description we at the  
 16 moment use synoptic reports for breast cancer  
 17 so there are College of American Pathologist  
 18 have a form that basically--there are multiple  
 19 criteria that you fill in, so it's to ensure  
 20 completeness of the report and so they're  
 21 basically the microscopic findings and then in  
 22 our hospital we would add the estrogen,  
 23 progesterone and HER2. And then finally you  
 24 would have a--then your references and then  
 25 you would have a diagnosis. And the diagnosis

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1 in the equivalent for the primary would be  
 2 breast, whatever the specimen was, invasive  
 3 ductal carcinoma. You would comment on  
 4 resection margins or any other findings. So  
 5 it would be this format, but much more text  
 6 and much more descriptive than I have.  
 7 COMMISSIONER:  
 8 Q. All right. Thank you.  
 9 DR. MULLEN:  
 10 A. And I was using that basically so I'd know--  
 11 for completely, whether one tumour, two  
 12 tumours, that type of thing.  
 13 COFFEY, Q.C.:  
 14 Q. If we could, please, Exhibit P-1790, doctor,  
 15 this is an e-mail of October 3, 2005, at 3: 59  
 16 P.M. to yourself and Dr. Cook. The subject is  
 17 ER/PR and he writes, "Hi, Dr. Mullen, could  
 18 you follow up on RS" - and a particular number  
 19 and the SU number is there - "which was  
 20 reported in the first half of the second batch  
 21 as ER zero percent and PR zero percent of  
 22 Block B, Tumour D on September 28th. The same  
 23 case was reported in the remaining cases of  
 24 the same batch, Line Number 10, as ER 50  
 25 percent and PR zero percent, Block B, Tumour C

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1 on, September 29th. The patient's name is" -  
 2 and we've redacted it. "Regards, Don Cook."  
 3 DR. MULLEN:  
 4 A. I was -  
 5 COFFEY, Q.C.:  
 6 Q. Yes?  
 7 DR. MULLEN:  
 8 A. If you pull up the original spreadsheet, I'm  
 9 sure one of those had two blocks, and as I was  
 10 going through that was the issue. I put the  
 11 wrong number in.  
 12 COFFEY, Q.C.:  
 13 Q. Yes, and again in respect of this, you  
 14 responded at 6:04 that same day and this  
 15 relates to attachments as results.  
 16 DR. MULLEN:  
 17 A. Yeah.  
 18 COFFEY, Q.C.:  
 19 Q. Eight by this point. "I transposed our 528 on  
 20 one of my 536. The correct interpretation is  
 21 appended."  
 22 DR. MULLEN:  
 23 A. Yeah.  
 24 COFFEY, Q.C.:  
 25 Q. And that is at a second page of this. So,

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1 doctor, I take it then - and I just simply  
 2 referred to it - because, I take it, that at  
 3 times just because of the sheer amount of data  
 4 involved here that it was possible to at times  
 5 transpose things.  
 6 DR. MULLEN:  
 7 A. Yes. Yes, by this time--I don't know if this  
 8 time or shortly thereafter, but probably at  
 9 this time I would have my--Nancy Good - I  
 10 would be interpreting the slide. She would  
 11 have the spreadsheet open. We would have  
 12 collapsed it or had the hidden columns. I  
 13 would go across. She would enter the data.  
 14 She would either repeat or I would repeat just  
 15 to make double sure that we had the same. It  
 16 was trying to minimize any clerical errors.  
 17 COFFEY, Q.C.:  
 18 Q. And to illustrate something for the  
 19 Commissioner, Exhibit P-1791 - now this is an  
 20 e-mail of the same day, Monday, October 30,  
 21 2005, 12:34 P.M., from yourself to Dr. Cook.  
 22 This particular attachment is Result 6. "Two  
 23 more cases. One needed to be re"--  
 24 DR. MULLEN:  
 25 A. Coverslipped.

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1 COFFEY, Q.C.:  
 2 Q. "--coverslipped. The other needed further  
 3 sections. No tumour left in the block in the  
 4 end." Two points - one is what is  
 5 recoverslipped? What is that?  
 6 DR. MULLEN:  
 7 A. In the preparation of a slide, the material--  
 8 or the section is cut. It's put on a slide.  
 9 It's either stained with immunohistochemistry  
 10 or stained with the routine chemistry. It's  
 11 taken through a series of stains and then at  
 12 the end--first of all to preserve but second  
 13 of all because of the optics, you have to use  
 14 an imbedding medium on top of the tissue, and  
 15 then you put a piece of glass on top that  
 16 covers the entire slide--or section rather,  
 17 and then you look at with your microscope. So  
 18 in this one, it would have--because possibly  
 19 problems with our coverslipper or because the  
 20 section was very thick or irregular, air would  
 21 have gotten underneath it. I would have had  
 22 to take it off, recoverslip so I could  
 23 interpret it because you have to--if you have  
 24 air trapped underneath, you just can't see the  
 25 the material. And the other would have been

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1 one of my cases where I had no tumour, and  
 2 just to ensure - this one would not have had  
 3 DCIS either because I would have stopped if it  
 4 had DCIS and it had no tumour. Basically  
 5 stepped through the block again - again my  
 6 white swan analogy - stepped through to see if  
 7 I could come up with something. If I could  
 8 come up with something, then I would go  
 9 forward and do the ER/PR.  
 10 COFFEY, Q.C.:  
 11 Q. And Exhibit P-1792, please. This is an e-mail  
 12 of October 4, 2005, 3:02 P.M., from Nancy Good  
 13 to Dr. Cook. It's copied to Maria Mendes.  
 14 The subject is an updated ER/PR list, and the  
 15 attachments are drmullen.xls and  
 16 stclaessite.xls and she writes, "Hi, Dr.  
 17 Cook, please find attached the list of blocks  
 18 cut and stained so far. I have also attached  
 19 a list of all the blocks we have received so  
 20 far. (There are no envelopes left to open)" -  
 21 and that's in brackets. "The list is divided  
 22 into years. I hope this helps. Thanks,  
 23 Nancy." And again there are as part of the  
 24 attachment a series of a spreadsheet, two  
 25 spreadsheets in effect - and "we'll hold a

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1 series of RS numbers, specimen numbers,  
 2 patient names, blocks received, comments and -  
 3 DR. MULLEN:  
 4 A. "Reporting."  
 5 COFFEY, Q.C.:  
 6 Q. "Reporting last" - there's a text here,  
 7 "Reported the last number of stain, the last  
 8 number cut," and, sorry, it just goes on for a  
 9 number of pages.  
 10 DR. MULLEN:  
 11 A. Uh-hm. If you go back - just as you clicked,  
 12 you'll see a note, request for HER2 block,  
 13 given to immuno, no RS given.  
 14 COFFEY, Q.C.:  
 15 Q. That's at Page 8 of the exhibit, for the  
 16 record, Commissioner, 99SG4055.  
 17 DR. MULLEN:  
 18 A. Yes. That would have indicated that that  
 19 would have been taken out and done as one of  
 20 the consults that we showed.  
 21 THE COMMISSIONER:  
 22 Q. Okay.  
 23 DR. MULLEN:  
 24 A. Because they asked for HER2, and then the  
 25 other in here, if you look at - where is it,

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1 the comment SMMS P63 - those are stains that  
 2 would have been done to differentiate whether  
 3 there was invasion or not invasion. In some  
 4 cases that I - they're ancillary tests,  
 5 immunohistochemical tests that help me assess  
 6 whether there's invasion or not invasion -  
 7 again, the issue of whether it's DCIS or not.  
 8 COFFEY, Q.C.:  
 9 Q. Can we go for example to Page 7 in the  
 10 exhibit.  
 11 DR. MULLEN:  
 12 A. Sorry.  
 13 COFFEY, Q.C.:  
 14 Q. Uh-hm.  
 15 DR. MULLEN:  
 16 A. And just here again under the comments column,  
 17 the third-last entry under--well, third-last  
 18 entry for a specimen number, it's the only  
 19 entry in the comments column here. "\* Two  
 20 blocks received, one block not labelled."  
 21 DR. MULLEN:  
 22 A. Now that would--doesn't refer to the 99SS1628.  
 23 It would have referred to the fact that one  
 24 block would say that number -2 and the other  
 25 one would have not had a number. It was not

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1 uncommon - and I can't speak for the rest of  
 2 the country - it was not uncommon in those  
 3 days that the first block of any case was left  
 4 as a blank because the vast majority - I  
 5 shouldn't say "the vast majority" - a large  
 6 number of cases in pathology are biopsies and  
 7 they don't go beyond a zero or a -1, so you  
 8 wouldn't--rather than putting -1 - if you saw  
 9 a -1, you'd expect there to be -2. They were  
 10 at those days left as a plain number or zero  
 11 so that's what that's referring to, not that  
 12 it wasn't labelled with the year or the  
 13 surgical number.  
 14 COFFEY, Q.C.:  
 15 Q. And here if we could look, please, at - just  
 16 see, say Page 2 of the exhibit, and all this  
 17 here--the specimen numbers on the first of  
 18 them is 00SS5977.  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And then it goes on for a number of 00's and  
 23 then we go to a--begins a series of 99's and  
 24 then we go back to 0's, and then at the bottom  
 25 of the page there's a 02 and when you go

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1 through this first grouping, there's a mixture  
 2 of specimen numbers in terms of years.  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. If we could go, please, to exhibit--I'm sorry,  
 7 the same exhibit, Page 10, and here then when  
 8 we're looking under specimen numbers - and  
 9 again the label here is "Samples received  
 10 August 2005 from St. Clare's site, St. John's  
 11 hospitals, for ER and PR receptors," and  
 12 there's an actual--under specimen number in  
 13 bold print, 1997.  
 14 DR. MULLEN:  
 15 A. Yeah.  
 16 COFFEY, Q.C.:  
 17 Q. And there are a series of - there's nothing  
 18 there, and then there's 99, series of numbers,  
 19 and then 2000 and a whole series of specimen  
 20 numbers with 1000, and then we go on to Page  
 21 14. It's a series of SS numbers beginning 01.  
 22 DR. MULLEN:  
 23 A. Uh-hm.  
 24 COFFEY, Q.C.:  
 25 Q. So this appears then, at this point - some of

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1 this at least anyway is ordered in terms of  
 2 the years.  
 3 DR. MULLEN:  
 4 A. I happen to notice that one case we were  
 5 referring to previously, 1D, 2 and 3 -  
 6 COFFEY, Q.C.:  
 7 Q. Yes.  
 8 DR. MULLEN:  
 9 A. I think this is just a spreadsheet set up by  
 10 year.  
 11 COFFEY, Q.C.:  
 12 Q. Yes. She did indicate in the e-mail that this  
 13 is divided into years.  
 14 DR. MULLEN:  
 15 A. Yes. And it's not in numerical sequence  
 16 either. It's just within the year because  
 17 it's very difficult to order an SU and SS, and  
 18 the different ways of doing things, so this is  
 19 all by year.  
 20 COFFEY, Q.C.:  
 21 Q. And I raise that, Commissioner - just from  
 22 your own perspective and looking at this  
 23 you'll be able to tell, as of that point in  
 24 time, the slides or specimens that were at  
 25 Mount Sinai in terms of the kind of mixture of

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1 years as indicated from the St. Clare's site  
 2 August 2005 and the different years reflected  
 3 there. Exhibit, please, P-1793.  
 4 THE COMMISSIONER:  
 5 Q. I'm sorry, Mr. Coffey, just before you leave  
 6 that last--can we go back to the - that's  
 7 1792, to the e-mail from Nancy Good.  
 8 COFFEY, Q.C.:  
 9 Q. Yes, it's Page 1, yes.  
 10 THE COMMISSIONER:  
 11 Q. Yes. She says "I have also attached the list  
 12 of all blocks we have received so far," and  
 13 then she says, "There are no envelopes left to  
 14 open. The list is divided into years,  
 15 etcetera." When she says "There is no  
 16 envelopes left to open," does that mean you've  
 17 done everything that you then had, or what  
 18 does that mean?  
 19 DR. MULLEN:  
 20 A. Basically, we had accessioned everything.  
 21 THE COMMISSIONER:  
 22 Q. Okay.  
 23 DR. MULLEN:  
 24 A. Yes, we had accessioned everything. We hadn't  
 25 cut. We hadn't necessarily cut and stained,

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1 but everything had been opened, sorted and put  
 2 in a spreadsheet and the process was -  
 3 THE COMMISSIONER:  
 4 Q. Ongoing.  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 THE COMMISSIONER:  
 8 Q. All right, thank you.  
 9 COFFEY, Q.C.:  
 10 Q. It had been entered into your Mount Sinai's  
 11 record-keeping, sort of?  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Yes, in terms of identification. By that  
 16 point in time - and we looked at some of the  
 17 earlier e-mails this morning - you had already  
 18 reported certain batches.  
 19 DR. MULLEN:  
 20 A. Yeah. But you know that some of those--the  
 21 batches I was reporting were one or two cases  
 22 so -  
 23 COFFEY, Q.C.:  
 24 Q. Yes, some were batches and some were -  
 25 DR. MULLEN:

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1 A. The dribs and drabs, if you want to call them  
 2 that.  
 3 COFFEY, Q.C.:  
 4 Q. Yes, but some of them were significant, I  
 5 think fairly significant numbers.  
 6 DR. MULLEN:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. In the first couple of groupings. Exhibit P-  
 10 1793 - I'm just going to go to, well, the  
 11 bottom of the page first. The first page,  
 12 there's an e-mail from Dr. Cook, September 21,  
 13 2005, 8:02 A.M., to Nancy Good, and he had  
 14 written back then, "Could you please advise me  
 15 on the status of the ER and PR slides and when  
 16 we can expect some reports in regards to Dr.  
 17 Cook," and on September 21 she had forwarded  
 18 that. Ms. Good had forwarded to you asking  
 19 "What should I reply to Dr. Cook?," and you  
 20 had indicated to Ms. Good "Early next week,  
 21 I'm going to do it on the weekend," and then,  
 22 I take it, again that's that stream of e-mails  
 23 we had looked at earlier and you had already  
 24 reported by then.  
 25 DR. MULLEN:

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1 A. Yeah.  
 2 COFFEY, Q.C.:  
 3 Q. So Ms. Good then, by October 5, is letting  
 4 Maria Mendes know that that's a -  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. That--oh, just forwarding that for FYI.  
 9 DR. MULLEN:  
 10 A. What had happened.  
 11 COFFEY, Q.C.:  
 12 Q. If we could, please, Registrar, Exhibit P-  
 13 1794, and the second e-mail was one of October  
 14 5, 2005. That's the one at the top of the  
 15 page from Nancy Good to Maria Mendes and the  
 16 attachment, Results 1. She apparently was  
 17 here forwarding the e-mail we looked at  
 18 earlier that you had sent September 26, 2005,  
 19 to Dr. Cook saying, "If you have any  
 20 questions, please do not hesitate to call me,"  
 21 and this was where you were forwarding Results  
 22 1, the first of the spreadsheets. And to give  
 23 the Commissioner some sense of this, Page 2 of  
 24 this and 3 are a spreadsheet with a number of  
 25 specimens with RS numbers. Patient names, of

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1 course, are redacted. The block as identified  
 2 - there's a comment section space. There's a  
 3 tumour, any of which are labelled "D", which I  
 4 gather is ductal.  
 5 DR. MULLEN:  
 6 A. Ductal.  
 7 COFFEY, Q.C.:  
 8 Q. And then there's a column for ER which, I take  
 9 it, is your -  
 10 DR. MULLEN:  
 11 A. My interpretation.  
 12 COFFEY, Q.C.:  
 13 Q. Interpretation of the ER status--or  
 14 percentage, I'm sorry.  
 15 DR. MULLEN:  
 16 A. Uh-hm.  
 17 COFFEY, Q.C.:  
 18 Q. PR, the percentage for PR and IC, to be  
 19 internal control and -  
 20 DR. MULLEN:  
 21 A. Presence and absence - present stained,  
 22 present stained weekly.  
 23 COFFEY, Q.C.:  
 24 Q. And then there's a final column.  
 25 DR. MULLEN:

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1 A. The adequacy fixation processing - adequate,  
 2 inadequate.  
 3 COFFEY, Q.C.:  
 4 Q. Now that would refer to, I take it, the  
 5 adequacy of what had been done in respect of  
 6 the fixation of the tissue before they even  
 7 made it into being a block.  
 8 DR. MULLEN:  
 9 A. Yes. Basically, when I receive - my  
 10 assessment of the slides were prepared in  
 11 Mount Sinai Hospital as a reflection of the  
 12 fixation processing issue. I didn't have the  
 13 original slides from Newfoundland to assess.  
 14 Basically, it was my interpretation based on  
 15 what I was seeing that we had stained and cut.  
 16 COFFEY, Q.C.:  
 17 Q. Okay. In terms of that in relation to that,  
 18 if I could - I'm just going to, well, the  
 19 fourth page of this exhibit, 794, that's the  
 20 code.  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Which -  
 25 DR. MULLEN:

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1 A. Can be used to interpret the spreadsheet.  
 2 COFFEY, Q.C.:  
 3 Q. Yes.  
 4 DR. MULLEN:  
 5 A. And we saw one subsequently--whereas it kept  
 6 growing as the types of the tumours I saw kept  
 7 growing.  
 8 COFFEY, Q.C.:  
 9 Q. Please, Registrar, Exhibit P-1796, and this  
 10 exhibit is two e-mails. The first of them is  
 11 from Dr. Cook, October 9, 2005, 10:06 A.M., to  
 12 yourself. The subject is ER's/PR's, and he  
 13 writes, "Hi, Dr. Mullen, could you follow up  
 14 and comment on RS" - and the number is  
 15 redacted - and it's "03SS9561," I take it,  
 16 it's a surgical number - name redacted - "this  
 17 case was sent up as a consultation in mid-  
 18 August 2005 and reported as ER 1 to 5 percent,  
 19 PR less than 1 percent on Block 2E, Report,  
 20 SP0512331. On the retro-master list, she is  
 21 reported as ER 20 percent, PR 2 percent on  
 22 Block 2F. She has been told that she has not  
 23 converted on repeat testing, based on the  
 24 results of SP0512331, which is the results ER  
 25 here indicated, ER 1 to 5 percent, PR less

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1 than 1 percent. Thanks, regards, Dr. Cook."  
 2 And then in the same exhibit there's an e-mail  
 3 from your yourself Tuesday, October 11, 2005,  
 4 at 10:51 A.M., to Dr. Cook, and you write,  
 5 "Dr. Cook, SP05-12331 - there are large areas  
 6 that poorly fixed/processed in the center of  
 7 the slide and the staining reflects this with  
 8 the ER and PR positive cells present at the  
 9 periphery. ER was greater than 1 percent and  
 10 is considered positive as stated in the  
 11 report. RS" - blank, redacted - "this slide  
 12 appears better fixed/processed with the ER and  
 13 PR positive cells present throughout the  
 14 slide, although again a majority are at the  
 15 periphery. Both slides are positive for ER  
 16 and RS - number redacted - is positive for PR.  
 17 Thanks, Brendan Mullen." So, doctor, what was  
 18 this about?  
 19 DR. MULLEN:  
 20 A. This is a reflection of the fact that - well,  
 21 the question was--I had reported one slide--  
 22 one block or one block from the same surgical  
 23 specimen. So they set up two slides - we'll  
 24 say Block 1 and Block 2 for want of a better  
 25 term. In Block 1, basically all I had that

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1 was valuable--that I was able to evaluate, was  
 2 very periphery. It's basically what we call a  
 3 doughnut effect. The center was not  
 4 interpretable because it was pretty fixed. It  
 5 may have fallen out or it was necrotic.  
 6 Nothing stained, and you knew that it wasn't  
 7 staining because of the biology, the fact it  
 8 was an ER/PR. It's the fact that cells were  
 9 necrotic. It was just dead, poorly fixed, and  
 10 so I was left with a rim at the periphery. In  
 11 the other block that he sent up, some of the  
 12 cells within the center were viable and they  
 13 stained. So the percentages varied between  
 14 the two. Now in breast cancer, both within  
 15 the same block, within the same section,  
 16 there's heterogeneity. It's not a uniform--  
 17 areas can be poorly--can be negative. Other  
 18 areas can be positive. Cells side by side -  
 19 one can be positive, one can be negative.  
 20 This reflects the percentages that we give.  
 21 And then between blocks, Block 1 and Block 2,  
 22 you would not expect necessarily to have the  
 23 same result, so there's heterogeneity both  
 24 within and between blocks.  
 25 COFFEY, Q.C.:

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1 Q. And what about the matter of even fixation of  
 2 the tissue even within the same block? Can  
 3 that vary?  
 4 DR. MULLEN:  
 5 A. Now if you recall my analogy that a tumour is  
 6 a sphere within a sphere, that if the tissue -  
 7 think of a peach - if the peach is the outer  
 8 side--if the peach is the lumpectomy, the pit  
 9 is the tumour. If you put the whole peach  
 10 into a fixative, formalin penetrates at the  
 11 rate of one millimetre per hour. Now  
 12 depending on how big the tumour - and I'll be  
 13 showing that in a little presentation sometime  
 14 later. Depending on how thick the section is-  
 15 -this is the specimen penetrating one  
 16 millimetre an hour and the tumour is that size  
 17 you will not get well-fixed tissue, and if you  
 18 take the outside of the tumour it will be  
 19 better fixed than the inside of the tumour.  
 20 So to get around that issue, it's standard  
 21 procedure to serially section the specimen,  
 22 put paper towels in to allow the formalin to  
 23 penetrate to keep the sections aside, allow  
 24 the formalin to penetrate and get fixation  
 25 that way. So there are ways of working that

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1 the people, who actually grow specimens or  
 2 prepare the specimens, have a way of getting  
 3 around that issue of penetration.  
 4 COFFEY, Q.C.:  
 5 Q. And what you found here and reported on here  
 6 on October 11, 2005, I take it, it's fair to  
 7 say that you wouldn't find it surprising that  
 8 there might be a difference between one block  
 9 and another.  
 10 DR. MULLEN:  
 11 A. No, not at all.  
 12 COFFEY, Q.C.:  
 13 Q. Even from the same surgical specimen?  
 14 DR. MULLEN:  
 15 A. Nope, not at al, not at all.  
 16 COFFEY, Q.C.:  
 17 Q. And I take it, would that be particularly so  
 18 if there were fixation problems?  
 19 DR. MULLEN:  
 20 A. It might magnify it, yes. I would be--unless  
 21 they were all positive or all negative, I  
 22 would be very surprised that you would have  
 23 from area to area, that you'd have the same -  
 24 COFFEY, Q.C.:  
 25 Q. Same result.

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1 DR. MULLEN:  
 2 A. Yes, same result.  
 3 COFFEY, Q.C.:  
 4 Q. If we could, please, Exhibit P-1797. Perhaps  
 5 I could bring up instead, Exhibit P-1798  
 6 because it's go that one and more. Doctor,  
 7 this is a series of e-mails on October 17,  
 8 2005. The first of them is from Doctor Cook  
 9 to yourself at 7:40 a.m., status of ER/PR  
 10 reports. He says, "Hi Doctor Mullen, I wonder  
 11 if you could advise me of the status of our  
 12 repeat ERS and PRS and when we can expect  
 13 additional report. We certainly appreciate  
 14 all your efforts in this situation. Many  
 15 thanks, regards, Doctor Cook". And you  
 16 responded later the same day, "I'm out of the  
 17 city, I'm sorry, except for brief stop  
 18 tomorrow until Saturday. I will do what is  
 19 available on Sunday". And then that same day,  
 20 Maria Mendes e-mailed you saying, "Hi Doctor  
 21 Mullen"--I'm sorry, the name is pronounced?  
 22 DR. MULLEN:  
 23 A. Ruoyu and Muntajib.  
 24 COFFEY, Q.C.:  
 25 Q. "Re-ran the negatives you and I had picked and

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1 is ready for you to look at and I have asked  
 2 Muntajib"?

3 DR. MULLEN:  
 4 A. Muntajib.  
 5 COFFEY, Q.C.:  
 6 Q. Muntajib, sorry--"to put the first and second  
 7 slide together so that you can compare the two  
 8 slides. From what Ruoyu can see, one case is  
 9 now positive where it was previously negative.  
 10 Also, at the moment we have not stained any  
 11 further cases since we are now down to one  
 12 staining machine because the other instrument  
 13 is non-operational. Signed, Maria". And  
 14 again, to put that in perspective, while we're  
 15 on it, P-1799. This an e-mail, the bottom of  
 16 the page, Doctor, the same day, October 17,  
 17 2005, 11:03 a.m. to Doctor Cook to yourself,  
 18 follow up on RS and the numbers redacted. "Hi  
 19 Doctor Mullen, could you follow up and comment  
 20 on redacted" particular SP "reported as ER 70  
 21 percent, PR less than two percent, Block G and  
 22 retro number"--there's an RS number there--"ER  
 23 less than one percent, PR less than one  
 24 percent, Block C. Our numbering is"--there's  
 25 a surgical number there--"many thanks, Don

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1 Cook". And then the same day at 9:54 p.m. you  
 2 sent Doctor Cook an e-mail, the subject is the  
 3 follow-up on that, "I will look at the case  
 4 tomorrow to ensure that our negatives are true  
 5 negatives. Will also repeat all cases that  
 6 are negative (0 or less that one percent) with  
 7 no internal control and internal control that  
 8 did not stain or stain weakly. We will never  
 9 be able to eliminate the fixation problem, but  
 10 this double check should minimize any staining  
 11 anomalies. Signed, Brendan". So, Doctor, a  
 12 couple of different questions I have then in  
 13 relation to those series of e-mails, I'll deal  
 14 with P-1799 first. Could you explain then  
 15 what was going on in your reply here to Doctor  
 16 Cook on October 17, what's that about?

17 DR. MULLEN:  
 18 A. I was very concerned about the quality of the  
 19 material that I was looking at. As I  
 20 mentioned earlier, the issue of external  
 21 control is really not a valid--well, the  
 22 external controls showed that we stained, but  
 23 I couldn't use that as a base line for the  
 24 material I was reviewing. So, I was trying to  
 25 use the internal control as my baseline, that

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1 if I had normal breast tissue that stained  
 2 strongly, I was happy that the case had  
 3 stained and the biology would be adequate to  
 4 assess. The ones I was very concerned about  
 5 were the negatives or, I should say, and then  
 6 if the tumor was positive, that was fine as  
 7 well. The ones I was very concerned about  
 8 were the cases that were negative and when I  
 9 use the term negative, it's 0 or less than one  
 10 percent, that had no internal control or the  
 11 control didn't--did have an internal control  
 12 and did stain or stained very weakly. I was  
 13 trying to make sure that there was something  
 14 in our--that there was nothing in our stainer  
 15 that was causing them to be negative. So, I  
 16 asked them to be repeated. I just wanted to  
 17 make sure that our technique was going to pick  
 18 up all of the positives, that we weren't going  
 19 to call negatives because of the issues of the  
 20 internal control.

21 COFFEY, Q.C.:  
 22 Q. On that point and I just ask you to elaborate  
 23 on something you referred to earlier and you  
 24 just referred to it again. The external  
 25 control which would, Mount Sinai would run

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1 with -

2 DR. MULLEN:  
 3 A. Every run.  
 4 COFFEY, Q.C.:  
 5 Q. - with this, each time ERS and PRS were run  
 6 here, you said that it would indicate, well,  
 7 it stained.

8 DR. MULLEN:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. - ie., the stainer is working in the sense of  
 12 for our external control.

13 DR. MULLEN:  
 14 A. For our external control. First of all, it  
 15 indicated the stainer was working, that we're  
 16 using the right antibody, you know, all of  
 17 those issues that we were dispensing,  
 18 theoretically--we were dispensing the right  
 19 antibody.

20 COFFEY, Q.C.:  
 21 Q. Now, Doctor, with respect to that though, I  
 22 believe earlier you referred to the fact that  
 23 your own external control was fixed in a  
 24 particular manner -

25 DR. MULLEN:

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. - you would know, but this tissue from

4 Newfoundland, would you have any way of

5 knowing how that was fixed, what process was

6 used?

7 DR. MULLEN:

8 A. For each specific, no, but in general, we

9 would assume that the fixative was neutral

10 buffered formalin, that tended to be the

11 standard fixative. But you would have to ask

12 each individual hospital what fixative they

13 used. And as I mentioned, the sectioning--how

14 they process the specimen before it was even

15 put through any of our tissue analyzers. In

16 other words, did they cut--did they allow the

17 fixative for the right requisite amount of

18 time, all of those issues are very critical.

19 I mean, you have to ensure that the material,

20 after it's removed from the patient, before

21 it's processed--I mean, it's fine we have all

22 our fancy stainers, but if that's not working,

23 there's nothing you can do after the fact to

24 retrieve the material. And that's what I was

25 trying to get at, that I was trying to be

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1 extremely careful that I wasn't under calling

2 cases because of the issue of the poor

3 fixation, processing.

4 COFFEY, Q.C.:

5 Q. And this poor fixation, I take it, would have

6 occurred--if it occurred, would have occurred

7 before the block was made?

8 DR. MULLEN:

9 A. Yes, yes.

10 COFFEY, Q.C.:

11 Q. In Newfoundland or wherever the block was

12 made.

13 DR. MULLEN:

14 A. I use the term fixation, processing almost

15 interchangeably, but they're really not.

16 Fixation refers to the presence of formalin,

17 the ten percent neutral buffered formalin.

18 Small specimens can be placed directly into

19 the formalin because again the penetration

20 because if you have a core biopsy, they're one

21 or two millimetres. So, it will penetrate

22 very quickly. If you have a large specimen, a

23 large breast specimen, they're fatty, the

24 tumor is--for the surgeon, is within the

25 tumor, is not on the surface. So, you have to

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1 section it to allow the formalin to penetrate.

2 So, if you have a poorly fixed specimen, if

3 you're processing which refers to taking the

4 fixed specimen through to a slide, is perfect,

5 you cannot retrieve--you can't undo the poor

6 fixation. But on the other hand, if you have

7 good fixation, poor processing, the two will

8 end up with a bad slide. So, you need good

9 fixation/good processing or excellent

10 fixation/excellent processing to end up with

11 material that you can go forward with.

12 COFFEY, Q.C.:

13 Q. And that's -

14 DR. MULLEN:

15 A. Otherwise you're working at a disadvantage.

16 COFFEY, Q.C.:

17 Q. And that would be--the processing in this

18 context would be processing the tissue into a

19 block?

20 DR. MULLEN:

21 A. Yes. So, did somebody explain that process?

22 COFFEY, Q.C.:

23 Q. Perhaps if you could again, it can't hurt

24 here.

25 DR. MULLEN:

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1 A. So, we have our peach. We've section it and

2 we'll assume that we can cut the pit. So, the

3 pit is sectioned. We take material, two to

4 three millimetres in thickness, they're placed

5 in what is called a cassette which is

6 basically a holder and this--when we talk

7 about block numbers, this is ultimately what

8 we do. And we take them through graded series

9 of alcohol. We dehydrate them. We then

10 change from alcohol into other chemicals and

11 at the end of the day, we have a piece of

12 tissue that's impregnated with paraffin and

13 makes a solid block. That is the bedrock of

14 diagnostic pathology throughout the world.

15 And from that block, we cut section which

16 refer to the five micron sections, basically

17 the thickness of a hair, put them on slides

18 and then stain them, in this case, for

19 hematoxylineosin in a routine histochemical

20 lab. Then take a section for estrogen

21 receptor, a section for progesterone receptor

22 and then HER2 as well and they're done in

23 immunohistochemistry. So, unless everything

24 is done properly, fixation, processing to the

25 time it's received in immunohistochemistry,

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1 then you have great difficulty in analyzing  
 2 and being confident in your results unless  
 3 you--I mean, all of the steps have to be  
 4 safeguarded.  
 5 COFFEY, Q.C.:  
 6 Q. If we could go back, please, to Exhibit P-  
 7 1798. Now, there's a reference here to, "also  
 8 at the moment, we have not stained any further  
 9 cases since we are down to one staining  
 10 machine because the other instrument is non-  
 11 operational". So, I take it, what had  
 12 happened then in the middle of October of '05,  
 13 that there was a problem with one of the  
 14 machines?  
 15 DR. MULLEN:  
 16 A. Yes. We have--I think at that time we had  
 17 three DAKO machines and we were running, I  
 18 believe, ER/PRs on two of them, one for some  
 19 reason broke or we weren't confident that it  
 20 was dispensing properly. So, it was taken out  
 21 of operation. So, we were down to one  
 22 machine. So, we were limited to 48 slides per  
 23 day.  
 24 COFFEY, Q.C.:  
 25 Q. The exhibit 1800, P-1800, please. Now, this

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1 again is an exchange of e-mails between  
 2 yourself and Doctor Cook. Doctor Cook wrote  
 3 to you on October 17, 2005 at 11:03 a.m.,  
 4 referring to or asking you to follow up and  
 5 comment on a particular result, reported at  
 6 ER, 70 percent; PR less than 2 percent on  
 7 Block G and the retro number, he gives it ER  
 8 less than one percent, PR less than one  
 9 percent, Block C and he refers to their own  
 10 surgical number. Many thanks. And then you  
 11 respond the next day at 12:57 p.m. saying,  
 12 "this is the same issue as the previous case  
 13 review. There's a disparity in the degree of  
 14 fixation/processing with the G block having  
 15 approximately 50 percent of the service  
 16 showing adequate fixation/processing and this  
 17 is the area with the ER reactivity. The C  
 18 block is a rim that shows adequate  
 19 fixation/processing and this again, is the  
 20 area with ER reactivity. Based on  
 21 fixation/processing present, I would trust the  
 22 results in G over the results in C". So, I  
 23 take it again this is one of those -  
 24 DR. MULLEN:  
 25 A. Well, if you--and again, going back to my

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1 peach--if we haven't processed it properly, if  
 2 we haven't sectioned it to allow the formalin  
 3 in, if you take the tip, you know, skim the  
 4 tip of the pit, that would be hopefully better  
 5 fixed. And then as you moved in the centre, it  
 6 would be less well fixed because it's a  
 7 further distance from the edge. And again  
 8 formalin, one millimetre per hour.  
 9 COFFEY, Q.C.:  
 10 Q. And just then in answering you said "if we",  
 11 in this context, it would actually be "if  
 12 Newfoundland" -  
 13 DR. MULLEN:  
 14 A. Well, we, pathology in general.  
 15 COFFEY, Q.C.:  
 16 Q. Pathology in general and in this particular  
 17 case it would be someone in Newfoundland.  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. If we could please, Exhibit P-1708. Here,  
 22 Doctor, there's an e-mail from Nancy Good,  
 23 October 20, 2005, 10:07 a.m. to Doctor Cook,  
 24 it's copied to yourself and others including  
 25 Doctor Pritzker, the attachments are, referred

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1 to, are labelled block discrepancies.xls. And  
 2 Nancy writes, "Hi Doctor Cook, Maria would  
 3 like to know if we will be receiving any more  
 4 blocks for retesting and if so, approximately  
 5 how many more. Everything is being logged  
 6 into our database (we have approximately 547  
 7 patients), although some don't have a RS  
 8 number yet. Please find the attached list of  
 9 block discrepancies and other notes. If you  
 10 have any questions, please give me a call".  
 11 And if we could just look at the spreadsheet  
 12 attached. It's labelled block discrepancies.  
 13 And I take it, after identifying the  
 14 particular patient, specimen number and block  
 15 number, there are just various comments,  
 16 trying to clarify, I take it, certain things  
 17 about particular blocks.  
 18 DR. MULLEN:  
 19 A. Yes. The pathology report may have been a--or  
 20 the accompanying letter said we were sending  
 21 in--sorry, I'm just trying to find an example.  
 22 COFFEY, Q.C.:  
 23 Q. Here would be an example.  
 24 DR. MULLEN:

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1 A. The second case, it had '01, the year was '01,  
 2 01SS8489, Block J.  
 3 COFFEY, Q.C.:  
 4 Q. Yes.  
 5 DR. MULLEN:  
 6 A. But it was actually SS848903, so it was the  
 7 wrong year. So, we wanted to make very sure--  
 8 I shouldn't say it's unlikely, but it'd be  
 9 unlikely unless this was a hospital that only  
 10 did breast, that the same case number and two  
 11 different years would both be breast, but we  
 12 want that clarified. And then this one, the  
 13 next case would have gone to, was taken out  
 14 for HER2. And then the--it's not very clear,  
 15 S18 -  
 16 COFFEY, Q.C.:  
 17 Q. There's one here, S1602-03, the third entry.  
 18 The block number is 2.  
 19 DR. MULLEN:  
 20 A. Yes. Here it's written at 1661. So, before  
 21 we go forward, which is the correct?  
 22 COFFEY, Q.C.:  
 23 Q. So, generally dealing with clerical, potential  
 24 clerical errors or to indicate to St. John's  
 25 that some of these had been pulled out for

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1 HER2/neu.  
 2 DR. MULLEN:  
 3 A. Yes, yes, in this case there is one.  
 4 COFFEY, Q.C.:  
 5 Q. Okay, this particular instance.  
 6 DR. MULLEN:  
 7 A. And then spelling, those types of things.  
 8 COFFEY, Q.C.:  
 9 Q. Exhibit P-1801. This is an e-mail, October  
 10 25, 2005, 10:12 a.m to yourself, status of ER  
 11 and PR review and Doctor Cook has e-mailed you  
 12 saying, "Hi Brendan, I'm wondering how it's  
 13 going with the review and when we can expect  
 14 some more results. I can appreciate that  
 15 Mount Sinai is probably at capacity levels,  
 16 could you update me. Regards, Don Cook". And  
 17 then, if we could please, Exhibit P-1802.  
 18 It's an e-mail from yourself, October 27, 2005  
 19 at 1:29 p.m. to Doctor Cook, the attachment is  
 20 results 9. You write, "this is the next set  
 21 of results. I am waiting for the blocks which  
 22 have been cut to be stained. I will read them  
 23 as soon as they are available. The only other  
 24 material I have to review are the previous  
 25 negatives (0 or less than one percent with no

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1 internal control and internal control that did  
 2 not stain or stain weakly) which were repeated  
 3 to ensure that we did not miss any positives.  
 4 They should be available early next week.  
 5 Signed, Brendan Mullen".  
 6 So, as of the end of October then,  
 7 Doctor, looking at what we've just reviewed  
 8 this morning, what status was this at that  
 9 point in time overall? Do you recall--in the  
 10 sense of, like, so much had been reported.  
 11 There were blocks to be stained. From your  
 12 perspective at the time, by late October, what  
 13 was the situation?  
 14 DR. MULLEN:  
 15 A. I think one of my previous e-mails, or Nancy's  
 16 e-mails, we had 547.  
 17 COFFEY, Q.C.:  
 18 Q. Yes, I believe around that.  
 19 DR. MULLEN:  
 20 A. Well, I really can't answer.  
 21 COFFEY, Q.C.:  
 22 Q. You'd actually have to look at the spreadsheet  
 23 and add them up and -  
 24 DR. MULLEN:  
 25 A. Yes.

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1 DR. MULLEN:  
 2 A. - kind of see where you were. What I'm asking  
 3 you is more, not so much in particular,  
 4 Doctor, it's kind of overall, in terms of at  
 5 that point, in terms of your own expectation  
 6 or view as to when you might be able to get  
 7 through it all, that was at that point, at the  
 8 end of October.  
 9 DR. MULLEN:  
 10 A. Well, the issue was pointed out in one of the  
 11 previous e-mails was capacity. It wasn't--  
 12 well, part of it was my capacity to read them  
 13 because I was doing service and doing other  
 14 things, but the main was capacity on the  
 15 machines and when one went down, I think we  
 16 made a decision around--should say, Doctor  
 17 Pritzker and Ms. Mendes made a decision to  
 18 purchase a machine, that subsequently, I  
 19 believe, was mid November, it was installed  
 20 and then we had to go through the process of  
 21 validating. And that doubled our capacity  
 22 from 48, shouldn't say doubled, but when from  
 23 48 to 84. Instead of 48 slides, it had 84 and  
 24 if you do your math, which I'm trying to do  
 25 now, 28, theoretically 28 spots. Yes, that's

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1 correct. So, part of it was, the hold up was  
 2 the technical and then I must admit, part was  
 3 probably me not being available, but we tried  
 4 to as soon as they came out. And I honestly  
 5 cannot recall what I knew, where we were  
 6 going, whether--if you recall it was 50 to  
 7 100.  
 8 COFFEY, Q.C.:  
 9 Q. Yes, now -  
 10 DR. MULLEN:  
 11 A. Now, we're up to 547 -  
 12 COFFEY, Q.C.:  
 13 Q. And climbing?  
 14 DR. MULLEN:  
 15 A. - and climbing.  
 16 COFFEY, Q.C.:  
 17 Q. Doctor, in terms of that the and this is  
 18 really what--I take it though from your  
 19 perspective at the time, as your time was  
 20 available, I take it, you would read what was  
 21 available to you? That was as your time was  
 22 available.  
 23 DR. MULLEN:  
 24 A. I would clear a day within one or two days of  
 25 getting it, would sit down with Ms. Good, we

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1 would read what we could.  
 2 COFFEY, Q.C.:  
 3 Q. And here, and if I could -  
 4 DR. MULLEN:  
 5 A. Sorry, and then, as we hear, where results,  
 6 dash 9 (phonetic) some of these were, as we've  
 7 seen in two or three cases, you know, that  
 8 they had re-stained or done something separate  
 9 and they would go off and--but the majority of  
 10 those were fairly large batches.  
 11 COFFEY, Q.C.:  
 12 Q. And here the reference to, in the e-mail here,  
 13 to "the only other material I have to review  
 14 are the previous negatives, 0 or less than one  
 15 percent with no internal control". If you had  
 16 a block or were given, had been sent a block  
 17 and there was no internal control when you  
 18 looked at the slide, what as the practical  
 19 matter were you then faced with? If St.  
 20 John's had sent you a block that had no  
 21 internal control, tissue in it, what  
 22 practically were your choices?  
 23 DR. MULLEN:  
 24 A. I can ask them for another block; that's one  
 25 possibility. Well, first of all I would not

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1 see the case until it had been stained. So,  
 2 if I had--with the HNE, I'd make sure there  
 3 was tumor and then clarify whether there was  
 4 internal control or not. I'd look at the ER.  
 5 If the ER was positive, I would be comfortable  
 6 reporting it. If the PR was positive, I'd be  
 7 comfortable reporting it. The issue became if  
 8 they were negative, I couldn't be sure that it  
 9 was a true negative and not a false negative  
 10 because I didn't have a control that I could  
 11 be comfortable with. I had my external, as I  
 12 mentioned, it's not terribly relevant to how I  
 13 was interpreting this. I knew there was  
 14 stain, but I just wanted to make sure. So, I  
 15 left it up--I didn't request--the first, I  
 16 believe in the first 500 or so, we repeated  
 17 those cases. I believe I became comfortable  
 18 with the fact that they were true negatives  
 19 and didn't pursue it beyond that, didn't keep  
 20 repeating.  
 21 COFFEY, Q.C.:  
 22 Q. But initially, certainly for the first 500 and  
 23 some odd -  
 24 DR. MULLEN:  
 25 A. Yes.

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1 DR. MULLEN:  
 2 A. - that you, as you've indicated here, if--at  
 3 least on your first pass through it, the ER  
 4 was negative or the PR was negative or both  
 5 certainly, if both were negative, you were  
 6 looking for internal controls.  
 7 DR. MULLEN:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. If there was no internal control, you would  
 11 re-run it.  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. The alternative you would just simply--the  
 16 only alternative would be the ask St. John's  
 17 for another block in the same surgery, same  
 18 patient, same surgery.  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And one that might have an internal control  
 23 tissue in it, available.  
 24 DR. MULLEN:  
 25 A. Yes. And even based on if the tissue had been

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1 processed and fixed properly, it's not 100  
 2 percent that you have an internal control, as  
 3 I mentioned, pre-menopausal about 80 percent;  
 4 post-menopausal is 90 percent. So, it's not  
 5 an absolute, but it's better than nothing.  
 6 COFFEY, Q.C.:  
 7 Q. And just again to give one some sense, the  
 8 Commissioner, some sense at the time, page two  
 9 of this particular exhibit, P-1802. That  
 10 would be the results 9, as it turns out, I  
 11 believe there's about ten blocks being  
 12 reported there and results 9. You've  
 13 indicated sometimes the results were two or  
 14 three--the spreadsheet had two or three  
 15 entries and sometimes quite a number of  
 16 entries.  
 17 DR. MULLEN:  
 18 A. Yes.  
 19 THE COMMISSIONER:  
 20 Q. Mr. Coffey, wherever you can find a spot,  
 21 we'll break for lunch.  
 22 COFFEY, Q.C.:  
 23 Q. Thank you. If we could, please, Exhibit P-  
 24 1803. Here, and again, this is illustrative--  
 25 perhaps this e-mail at the bottom of the page

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1 here, October 28, 2005. It's 3:01 p.m. from  
 2 Doctor Cook to Nancy Good, subject is in bold  
 3 print, sorry, capital letters anyway, "URGENT  
 4 REQUEST FOR ER AND PR RESULT". He writes, "Hi  
 5 Nancy, we have a request for an urgent result  
 6 on" blank "a Grand Falls case. There are two  
 7 blocks sent up on her as part of the ER/PR  
 8 review. They are" and she specifies the  
 9 surgery number, Doctor Cook specifies the  
 10 surgical numbers. It would be appreciated if  
 11 these could be processed and interpreted as an  
 12 urgent case". And then Ms. Good, on the same  
 13 day, matter of minutes later, sends you an e-  
 14 mail saying "I'm going to look for these two  
 15 blocks today" and no RS number given, "yet,  
 16 I'll cut them on Monday and give them to  
 17 immuno on Tuesday, if that's okay with you",  
 18 she's asking you. So, I take it that would be  
 19 an example of one of those where it's kind of  
 20 pulled out of the -  
 21 DR. MULLEN:  
 22 A. Yes, and put through the routine lab, given  
 23 priority.  
 24 COFFEY, Q.C.:  
 25 Q. And it would be reported then as an individual

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1 report or a consult.  
 2 DR. MULLEN:  
 3 A. Yes, as opposed to the spreadsheet.  
 4 COFFEY, Q.C.:  
 5 Q. Commissioner, that would be great. Thank you  
 6 very much.  
 7 THE COMMISSIONER:  
 8 Q. All right. We'll take the luncheon break.  
 9 We'll meet again at ten after two.  
 10 (LUNCH BREAK)  
 11 THE COMMISSIONER:  
 12 Q. Please be seated. Mr. Coffey.  
 13 COFFEY, Q.C.:  
 14 Q. Thank you, Commissioner. If we could please,  
 15 just to carry on in the chronology, Doctor,  
 16 exhibit, Registrar, P-1804? Doctor, in this  
 17 particular exhibit, the e-mail toward the  
 18 bottom of the page we looked at before the  
 19 lunch break, it's one from yourself to Dr.  
 20 Cook on October 27th, 1:29 p.m., referring to-  
 21 -or saying this is the next set of results and  
 22 you are then referring to the "only other  
 23 material I have to review are the previous  
 24 negatives."  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. And then, Doctor, at 11:47 a.m. on October  
 4 30th, 2005, Maria Mendes sent an e-mail to you  
 5 saying, "Hi, Dr. Mullen. We shall be starting  
 6 to stain the next batches and will start  
 7 bringing them to you as they become ready for  
 8 reading. Also the RPT are ready for you, let  
 9 me know when you want me to bring them over."  
 10 Well first of all, what's RPT?  
 11 DR. MULLEN:  
 12 A. A repeat.  
 13 COFFEY, Q.C.:  
 14 Q. Repeats?  
 15 DR. MULLEN:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. And they would be those -  
 19 DR. MULLEN:  
 20 A. Those were the cases that I asked to be, the  
 21 ones that were either completely negative,  
 22 zero or had staining less than, what I  
 23 interpreted as one percent, with no internal  
 24 control, the internal control which stained  
 25 weakly or did not stain.

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1 COFFEY, Q.C.:

2 Q. As referred to in that earlier e-mail?

3 DR. MULLEN:

4 A. Yes, the one at 1:29 p.m.

5 COFFEY, Q.C.:

6 Q. Sure. And the idea that we'll be starting to

7 stain the next batches and will start bringing

8 them to you as they become ready for reading,

9 this is the end of October, 2005, I take it

10 then that as they--as we referred to earlier,

11 as they became available, they'd be brought to

12 you to, for your interpretation?

13 DR. MULLEN:

14 A. Yes, they'd be sent in batches, yes. Except

15 we made reference earlier to the ones that had

16 to be recover slipped, but this would be

17 substantial amounts, I believe.

18 COFFEY, Q.C.:

19 Q. Again, if we could please, exhibit P-1709?

20 Now, Doctor, here at the first of these in

21 time, is an e-mail of November 1st, 2005 from

22 Nancy Good to Dr. Cook. The subject is an

23 updated list of ER/PR and she writes, "This is

24 the updated list of all specimens we have

25 received so far, including the few received

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1 yesterday. The list also includes which

2 blocks have been reported, which have been

3 staining, which have been cut so far, the

4 specimens for 'blank' will be stained today"

5 and there are particular--the surgical number

6 is referred to there. And then, so I take it

7 then it would have been your understanding at

8 the beginning of November that Ms. Good was

9 keeping Dr. Cook apprised from time to time as

10 to what the status was?

11 DR. MULLEN:

12 A. Yes, he contacted with Ms. Mendes or Ms. Good

13 directly, because as I mentioned earlier, Ms.

14 Good was the point person on this project.

15 COFFEY, Q.C.:

16 Q. Now if we could please, exhibit P-1704? Now

17 here, Doctor, this is a series of e-mails on

18 November 2nd, 2005. The second page of the

19 exhibit there is an excerpt--well not an

20 excerpt, I'm sorry, it's a copy of a story

21 from the NTV News Headlines, I gather probably

22 taken from the internet, but maybe not. In

23 any case, it refers to NTV News Headlines,

24 "Eastern Health retests breast cancer

25 samples." It's a story file, October 13,

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1 2005, by Carolyn Stokes and just in the

2 beginning of it, it says "There was no

3 mistake, new sophisticated technology became

4 available and produced more accurate results,

5 that's basically Eastern Health's explanation

6 for why they are retesting 8 years work of

7 breast cancer samples taken from patients in

8 this province. It's called the

9 estrogen/progesterone receptor test and it

10 doesn't affect breast cancer diagnosis, but it

11 does influence treatment. The result is

12 either negative or positive but there were

13 some 'false' negatives discovered." And the

14 story goes on from there. Now here, this

15 accompanies an e-mail of October 17th, 2005 to

16 public relations, I gather this is, and then

17 there's an e-mail, the text is "It has come to

18 my attention that the same diagnostic machine

19 is used in"--blank, redacted--"and of course

20 is a woman that has a negative response to a

21 breast biopsy. I have great concerns, would

22 you please verify the NTV news headline from

23 the Province of Newfoundland and tell one, is

24 this indeed the same procedure that is used

25 in"--redacted--"if so, what is the hospital

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1 doing to ensure that false negatives are

2 caught before women"--and it just ends it with

3 a question mark. "Thank you." And then that

4 e-mail is forwarded on to Dr. O'Malley on

5 November 2nd, 2005 at 3:03 p.m. and the text

6 to Dr. O'Malley, he says, "Please see the

7 enclosed e-mail we have received from a

8 patient. I presume this is for ER and PR

9 tests which were done previously

10 biochemically. As per this patient, these

11 results are being repeated by Mount Sinai

12 Hospital. I would greatly appreciate

13 receiving some information regarding this

14 matter. Yours truly"--and the senders name is

15 there. And then Dr. O'Malley, the same day at

16 3:10 p.m. wrote an e-mail to yourself and Dr.

17 Pritzker. The subject is estrogen and

18 progesterone receptor test and she says "FYI",

19 for your information, "I haven't responded

20 yet, what's the party line?" Signed Frances.

21 And then we have here an e-mail at 10 p.m.

22 that evening from Dr. Pritzker to Dr. O'Malley

23 and yourself and Dr. Pritzker writes "As far

24 as we know, the Newfoundland problem is

25 special to Newfoundland." And then on

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1 November 2nd, 2005, at 11:16 p.m., you sent an  
 2 e-mail to Dr. Pritzker and Dr. O'Malley  
 3 saying, "I don't know if this is a machine or  
 4 lab specific problem in Newfoundland, so  
 5 cannot comment on relevance to"--redacted--  
 6 "Newfoundland and Labrador technical people  
 7 seem surprised at the concept of internal  
 8 controls, so I think it is a bit of both."  
 9 And it's your own e-mail. Now, Doctor, I take  
 10 it this was a concern raised by a patient and  
 11 brought to the attention of Mount Sinai about  
 12 whether or not Newfoundland's situation could  
 13 be at all relevant in your institution or an  
 14 institution in Ontario, anyway.  
 15 DR. MULLEN:  
 16 A. Can I go back to the letter to the patient--  
 17 letter from the patient to Public Relations?  
 18 That was interpreted by the next pathologist  
 19 when she talked about the, let's see "did the  
 20 same procedures as used in"--because they were  
 21 talking about a previous, I believe the  
 22 pathologist, Dr. Elavathil interpreted that as  
 23 ligand binding assay, rather than the DAKO  
 24 cytometry (phonetic), just to clarify that,  
 25 when we're talking biochemical, we're talking

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1 pre 1998, okay, so that was that. So then my  
 2 understanding, when we started this project  
 3 that it was an issue with the machinery. I  
 4 don't have a specific e-mail, whether it was  
 5 through conversations with Dr. O'Malley, Dr.  
 6 Pritzker or with Dr. Cook on the occasions I  
 7 did speak to him, that it was possibly a  
 8 machine specific, the DAKO autostainer, but  
 9 then sometime between we starting this project  
 10 and obviously November 2nd, we received a  
 11 telephone call, we, meaning the Mount Sinai  
 12 Hospital laboratory asking about the concept  
 13 of internal controls. I can't state  
 14 specifically who called, but they did speak to  
 15 someone in the laboratory who then passed the  
 16 message on to me, not through e-mail so we  
 17 don't have a papertrail, but spoke to me  
 18 directly and said they called about internal  
 19 controls and they weren't sure what we were  
 20 referring to and when did we start to report  
 21 them. Now, if you recall the surgical  
 22 pathology consult sheets that we have seen,  
 23 that were shown for the patients, states  
 24 specifically normal breast tissue was  
 25 available to assess the estrogen and

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1 progesterone--or reacted appropriately with  
 2 the estrogen and progesterone, so that was, I  
 3 think it's referring to that. So my response  
 4 to Dr. O'Malley and Dr. Pritzker was, possibly  
 5 machine based on what we gleaned from  
 6 conversations and then possibly the lab  
 7 specific problems because of the issue of  
 8 knowing about the concept of internal control.  
 9 COFFEY, Q.C.:  
 10 Q. Or relatively not knowing or apparently -  
 11 DR. MULLEN:  
 12 A. Yes, knowing about the concept, so--or not  
 13 knowing about the concept, well -  
 14 COFFEY, Q.C.:  
 15 Q. And, Doctor, in terms of this you've indicated  
 16 that Ms. Wegrynowski in your normal work day  
 17 you might run into her a number of times,  
 18 being in and out of the lab where she is.  
 19 DR. MULLEN:  
 20 A. Yes, I think she tries to restrict my access  
 21 every now and then.  
 22 COFFEY, Q.C.:  
 23 Q. Yes. Did you know she had actually prepared a  
 24 report in relation to what review she had done  
 25 in Newfoundland in September, 2005?

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1 DR. MULLEN:  
 2 A. At this time?  
 3 COFFEY, Q.C.:  
 4 Q. Yes.  
 5 DR. MULLEN:  
 6 A. No, I did not know.  
 7 COFFEY, Q.C.:  
 8 Q. When did you first learn that?  
 9 DR. MULLEN:  
 10 A. When--I believe it would have been probably  
 11 2006 or--late 2006, early 2007, certainly  
 12 learned about the report when it hit the  
 13 papers, but we knew that she was in  
 14 Newfoundland, we didn't know what she was  
 15 doing in Newfoundland.  
 16 COFFEY, Q.C.:  
 17 Q. And have you ever actually seen a report sheet  
 18 prepared?  
 19 DR. MULLEN:  
 20 A. Yes, once it was posted on your website -  
 21 COFFEY, Q.C.:  
 22 Q. On the Commission's website.  
 23 DR. MULLEN:  
 24 A. Sorry, the Commission's website, yes.  
 25 COFFEY, Q.C.:

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1 Q. That's when you first saw it.  
 2 DR. MULLEN:  
 3 A. Yes, late 2006, early 2007, we knew there was  
 4 a report, we never asked her about the report,  
 5 she never told us about the report because of  
 6 the confidentiality issue. It was only once  
 7 it became public knowledge then, we took a  
 8 look at what type of a report she prepared.  
 9 COFFEY, Q.C.:  
 10 Q. So in terms of the matter of or the subject  
 11 matter of whether it was a machine or lab  
 12 specific problem--now lab specific problem  
 13 would mean what in this context?  
 14 DR. MULLEN:  
 15 A. Everything that--other than the machine  
 16 actually doing its job, moving the dispenser  
 17 across, dispensing the correct amount, was it  
 18 something to do with the preanalyt (phonetic),  
 19 was it something to do with the preparation of  
 20 the tissue, was it something to do with the--  
 21 so we're talking about the portion where we go  
 22 from the gross specimen to the block. Was it  
 23 something, the fixation processing or was it  
 24 once it had been cut and put on the machine,  
 25 were they giving--had they titrated the

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1 antibodies, had they used the right buffers,  
 2 had they used the right pH, all of those sorts  
 3 of things. So all the technical issues  
 4 specifically related to the process, but not  
 5 the fact the machine wasn't dispensing  
 6 properly, that's what I was separating from a  
 7 machine specific to a lab specific.  
 8 COFFEY, Q.C.:  
 9 Q. And in terms of events, so in saying you think  
 10 it was a bit of both, did you actually have  
 11 any actual evidence as to what it was at the  
 12 time?  
 13 DR. MULLEN:  
 14 A. None whatsoever, none whatsoever. Putting  
 15 together sort of, two conversations or two  
 16 recollections of conversations, one being the  
 17 machine, being told that this was why we were  
 18 getting it and then the concept of knowing  
 19 about internal controls, so trying to put the  
 20 two together.  
 21 COFFEY, Q.C.:  
 22 Q. Now, Dr. Diponkar Banerjee, do you know Dr.  
 23 Banerjee?  
 24 DR. MULLEN:  
 25 A. Yes, he's a pathologist in the BC Cancer

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1 Agency, he also used to be head of the  
 2 pathology department at the Princess Margaret  
 3 Hospital, Toronto.  
 4 COFFEY, Q.C.:  
 5 Q. And at that point in time, in November of  
 6 2005, did you have any knowledge that he had  
 7 been asked to come to St. John's in September  
 8 of 2005 to conduct a review?  
 9 DR. MULLEN:  
 10 A. None whatsoever, none whatsoever.  
 11 COFFEY, Q.C.:  
 12 Q. Now, Doctor, as of November 2, 2005, I take it  
 13 by this point in time you would have had an  
 14 opportunity at least to review a number of the  
 15 retest slides? The slides produced for  
 16 retesting of the -  
 17 DR. MULLEN:  
 18 A. Yes, the retrospective study, yes.  
 19 COFFEY, Q.C.:  
 20 Q. The retrospective study. And in some of the  
 21 e-mails we looked at involving particular  
 22 slides this morning, you referred to fixation  
 23 issues that were apparent on particular  
 24 slides.  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. By November of 2005, had you reached any  
 4 conclusions or drawn, at least tentatively  
 5 reach any conclusions about whether or not  
 6 fixation could have played a part in this?  
 7 Fixation issues?  
 8 DR. MULLEN:  
 9 A. Fixation/processing, we use fixation for both  
 10 parts, yes, a very major -  
 11 COFFEY, Q.C.:  
 12 Q. Even by this point in time?  
 13 DR. MULLEN:  
 14 A. Yes, oh yes, I mean -  
 15 COFFEY, Q.C.:  
 16 Q. And when I say fixation, I mean -  
 17 DR. MULLEN:  
 18 A. Before the block is prepared and sent to the  
 19 slide--sent to immunohistochemistry, yes, all  
 20 of that as a major, major player.  
 21 COFFEY, Q.C.:  
 22 Q. And by November, 2005, would you have had any  
 23 reason to believe that perhaps whatever caused  
 24 those problems, fixation/processing problems  
 25 that you were seeing in these slides that were

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1 now being produced in the retrospective study,  
 2 would you have thought that they might have  
 3 had anything to do with the problem in  
 4 Newfoundland or contributed to the problem in  
 5 Newfoundland, that aspect of it?  
 6 DR. MULLEN:  
 7 A. Yes, yes, that would fall under the lab  
 8 specific issue as well as the concept of  
 9 internal controls.  
 10 COFFEY, Q.C.:  
 11 Q. If we could, please, Registrar, Exhibit P-  
 12 1805? And, now here, Doctor, there's a series  
 13 of e-mails of November 2nd and 3rd, 2005. The  
 14 first is from yourself, November 2nd at 9: 24  
 15 a.m. to Dr. Cook. "Alternate for ERs and PRs"  
 16 and you say "we'll do a cc to you" and then  
 17 from Dr. Cook, the same day, 4:13 p.m. to  
 18 Heather Predham, "Alternate for ERs and PRs"  
 19 and then one on November 3rd, 2005 at 2: 34  
 20 p.m., the same subject matter "Alternate for  
 21 ERs and PRs" and she writes, "Upon Dr. Cook's  
 22 and Dr. Williams' request, I have reviewed  
 23 your list and highlighted in yellow all of  
 24 those individuals that are now deceased.  
 25 Although we do intend to have these

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1 individuals retested, it may be helpful at  
 2 this time to be able to leave those specimens  
 3 to a later date. If you have any questions,  
 4 please do not hesitate to contact me, thanks,  
 5 Heather Predham." And this e-mail had been  
 6 sent to Dr. Cook, Maria Mendes and yourself.  
 7 DR. MULLEN:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. Do you see that? So, Doctor, what was this  
 11 about at this point in time, in early  
 12 November?  
 13 DR. MULLEN:  
 14 A. I believe the alternate at the bottom was Dr.  
 15 Cook was going to be away and I was to send  
 16 the reports to Dr. Williams.  
 17 COFFEY, Q.C.:  
 18 Q. Yes.  
 19 DR. MULLEN:  
 20 A. And then that's -  
 21 COFFEY, Q.C.:  
 22 Q. And as well then, they're talking about the  
 23 deceased?  
 24 DR. MULLEN:  
 25 A. Yes. At that time there was a concern about

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1 the--well the delay or the time it was taking  
 2 me to report--well, me, the Mount Sinai  
 3 Hospital to report three cases to them. So  
 4 basically what they were doing was triaging--  
 5 my understanding was they were triaging the  
 6 specimens so that we would focus on the  
 7 patients who were alive and potentially could  
 8 have change in therapy, as opposed to the  
 9 patients who had died and therapy--a change in  
 10 therapy wouldn't be relevant and they could,  
 11 for statistical reasons and information to the  
 12 family, possibly be done later, it wasn't the  
 13 same priority.  
 14 COFFEY, Q.C.:  
 15 Q. If I could, please, look at Exhibit P-1807?  
 16 Now this is an e-mail from Dr. Cook,  
 17 Wednesday, November 16th, 2005 at 9:44 a.m. to  
 18 yourself, it's follow up on RS and the number  
 19 is redacted. He writes, "Hi Brendan, could  
 20 you and Bev Carter follow up on RS"--number  
 21 and he refers to the surgical number and block  
 22 A, "blank, reported as ER zero percent, PR  
 23 zero percent. She was also sent up as a  
 24 consult in late October and reported as ER 60  
 25 percent, PR 10 percent on block C." And the

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1 surgical number is there. "Bev may also want  
 2 to see the slides. I do hope Bev is treating  
 3 all of you well and using her people skills at  
 4 an optimal level. Many thanks, Don Cook." I  
 5 wanted to ask you about, because this seems to  
 6 indicate that Dr. Carter is in fact in  
 7 Toronto.  
 8 DR. MULLEN:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. Okay, could you tell the Commissioner about  
 12 that?  
 13 DR. MULLEN:  
 14 A. I'm trying to recall--Dr. Carter I believe was  
 15 in Toronto either--she was there for a week,  
 16 whether she wrote a chapter in a textbook that  
 17 Francis O'Malley published on breast  
 18 pathology, she may have been there for that,  
 19 but she was also in Toronto, I believe, for  
 20 social and spent some time with us, that was  
 21 the primary reason. And we took the  
 22 opportunity--I took the opportunity at that  
 23 time to sit down with her and discuss some of  
 24 the issues that I was having in, not the  
 25 retrospective, but the prospective cases.

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1 Again, the fixation processing issue, and how-  
 2 -there was one case in particular that I  
 3 wanted some explanation on. It was a woman  
 4 who had had breast surgery, bilateral breast  
 5 surgery on the same day and one specimen was  
 6 adequate for assessment and the other one, it  
 7 was beyond--basically almost beyond assessing  
 8 it. The two were as though they were--they  
 9 had come from different worlds. One I could--  
 10 was adequate and the other one was--it was as  
 11 though they had done something to it. I  
 12 didn't know what it was and I tried to get her  
 13 to explain to me why two specimens, same  
 14 patient, same day, would be diametrically  
 15 opposed in quality.  
 16 COFFEY, Q.C.:  
 17 Q. From one patient -  
 18 DR. MULLEN:  
 19 A. One breast and the other breast, yes, why one  
 20 side would be adequate and the other side was  
 21 totally inadequate.  
 22 COFFEY, Q.C.:  
 23 Q. Was there an explanation provided, do you  
 24 recall?  
 25 DR. MULLEN:

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1 A. She couldn't speak to the specific case.  
 2 COFFEY, Q.C.:  
 3 Q. And -  
 4 DR. MULLEN:  
 5 A. Well, it was more--okay, so I'm getting this,  
 6 I'm getting these sorts of issues all the  
 7 time. What--can you explain what or do  
 8 something to prevent it.  
 9 COFFEY, Q.C.:  
 10 Q. So in terms of the then prospective or current  
 11 cases, like current in the sense of people who  
 12 just had surgery, there were--you were still  
 13 noticing or you were seeing problems related  
 14 to possibly fixation or processing in relation  
 15 to them?  
 16 DR. MULLEN:  
 17 A. Yes, major, major issues.  
 18 COFFEY, Q.C.:  
 19 Q. And you communicated that, you believe, to Dr.  
 20 Carter. Did you tell anyone else, do you  
 21 know?  
 22 DR. MULLEN:  
 23 A. I believe there's an e-mail in one of the  
 24 later exhibits where I--I think at the very  
 25 end, I send the final results to Dr. Cook and

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1 I make reference to "I'd please like to  
 2 discuss the"--basically saying the same issues  
 3 that I saw in the retrospective are in the  
 4 prospective material, and -  
 5 COFFEY, Q.C.:  
 6 Q. I'll be talking to you about that.  
 7 DR. MULLEN:  
 8 A. Okay.  
 9 COFFEY, Q.C.:  
 10 Q. So that -  
 11 DR. MULLEN:  
 12 A. Now, I don't think I spoke to him directly  
 13 about it.  
 14 COFFEY, Q.C.:  
 15 Q. And we'll get to that. But at this point in  
 16 time when Dr. Carter was in Toronto in  
 17 November 2005, you recall at least broaching  
 18 the subject with her?  
 19 DR. MULLEN:  
 20 A. Yes. I took the opportunity, I can't tell you  
 21 the number of cases or the range of the cases,  
 22 but I took the opportunity to go over cases  
 23 with her, specifically the HER2 cases, telling  
 24 her that--or showing her, you know, the  
 25 difficulties we were having because of

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1 fixation that we had to reflex a large  
 2 proportion to the FISH because of the  
 3 disparity in the results and we attributed  
 4 that to a technical rather than a biological  
 5 variability, and the fact that we were  
 6 getting--then when we went to FISH, the  
 7 fluorescent in situ hybridization, we weren't  
 8 able to see much nuclear detail, which again  
 9 is a reflection of fixation and processing.  
 10 COFFEY, Q.C.:  
 11 Q. Problems?  
 12 DR. MULLEN:  
 13 A. Yes, yes. So it was--part of it was, you  
 14 could say, venting and part of it was "here,  
 15 can we do something?"  
 16 COFFEY, Q.C.:  
 17 Q. Exhibit P-1808? Now Doctor, I show you this  
 18 because perhaps it'll help the Commissioner  
 19 put some of this in a temporal context.  
 20 There's an e-mail from Dr. Cook, November 16th  
 21 2005 at 3:32 p.m. to Dr. Pritzker, Ken  
 22 Pritzker, the subject is ER/PRS, and he writes  
 23 "Hi, Ken. I would like to thank you and your  
 24 department for your ongoing efforts in helping  
 25 us deal with this very difficult situation.

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1 We are getting a lot of pressure for faster  
 2 reporting of the retro cases. 'In speaking to  
 3 the powers that be'" and he's got that in  
 4 quotes, "I repeated to them that Mount Sinai  
 5 is operating at full capacity and that  
 6 resources are limited. This appears to be the  
 7 general state of laboratory medicine today in  
 8 Canada, and that there" should be "there is  
 9 very little flexibility in the system,  
 10 especially when it comes to our pathology  
 11 manpower situation and the shortages we are  
 12 experiencing. If there is any way Mount Sinai  
 13 can speed up the reporting, I would certainly  
 14 appreciate it. In the meantime, the issue of  
 15 'national standards for immunohistochemistry  
 16 testing' will be on the agenda for our next  
 17 executive meeting of the Canadian Association  
 18 of Pathologists in late November. There may  
 19 be a good opportunity to make this a national  
 20 issue and to bring to the Federal Minister of  
 21 Health along with the need for additional  
 22 human and financial resources for our labs,  
 23 issues surrounding patient safety and national  
 24 standards for all aspects of laboratory  
 25 medicine. I will keep you posted on any

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1 developments. Many thanks, Don Cook."  
 2 And then Dr. Pritzker, on the same day,  
 3 at 5:24 p.m., responded to Dr. Cook, but he  
 4 copied yourself and Maria Mendes, saying "Don,  
 5 we have done 200 with 500 to go. As we were  
 6 capacity, we have just received a batch  
 7 stainer, which I'm told can go live next week.  
 8 Then the pressures will be on us for  
 9 interpretation. We'll try to get this stuff  
 10 out as soon as we can. Had a good chat with  
 11 Bev earlier in the afternoon. Cheers, Ken."  
 12 So Doctor, as of mid November 2005, would  
 13 that, from your recollection, generally  
 14 capture the state of affairs at the time?  
 15 DR. MULLEN:  
 16 A. Yes. I believe--let me just, the exact date,  
 17 I think it was November 14th, we installed the  
 18 stainer I mentioned that had 84 slots for  
 19 staining. The issue there, it had to be  
 20 validated. You can't just take a machine out  
 21 of a box, put it on the table and expect it to  
 22 run. You have to validate it. You have to  
 23 compare its runs with the established and it  
 24 was being--it was placed in a different room,  
 25 so there are all environmental issues that you

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1 have to think about. So we basically had to  
 2 duplicate the validation of what we'd done  
 3 initially for the ER/PR on the DAKO stainer on  
 4 this stainer and make sure that we had  
 5 concordance with the results that we were  
 6 getting on the DAKO, and that took, I believe,  
 7 two weeks.  
 8 COFFEY, Q.C.:  
 9 Q. Doctor -  
 10 DR. MULLEN:  
 11 A. So then, so we're now beginning of December,  
 12 and then I believe early -  
 13 COFFEY, Q.C.:  
 14 Q. I'll be showing you some e-mails now -  
 15 DR. MULLEN:  
 16 A. Okay.  
 17 COFFEY, Q.C.:  
 18 Q. - that are going to capture what I understand  
 19 probably happened there. If we could please  
 20 look, Registrar, at Exhibit P-1710, in  
 21 particular page two? Okay, and Doctor, this  
 22 is an e-mail from Dr. Pritzker, November 24th  
 23 2005, 11:55 a.m. to Dr. Cook and he's copied  
 24 one to himself, sent one to himself as well,  
 25 the same e-mail, and Dr. Robert Williams. He

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1 writes "Don, we are now completing validation  
 2 studies with the batch autostainer equipment.  
 3 If there is no hitch, then we can--then we  
 4 start in production mode for ER/PR for  
 5 Newfoundland on Monday." Signed, Ken. In the  
 6 context here, he was responding to an e-mail  
 7 of the same date from Dr. Cook who was--who  
 8 had explained to Dr. Pritzker that Dr.  
 9 Williams had asked Dr. Cook to contact Dr.  
 10 Pritzker for an update on the operational  
 11 status of the batch stainer. So by the end of  
 12 November -  
 13 DR. MULLEN:  
 14 A. Yes, I believe the validation started on the  
 15 14th and ended on the 30th. I gave the go  
 16 ahead to put it into production.  
 17 COFFEY, Q.C.:  
 18 Q. If we could, please, Exhibit P-1341? Now here  
 19 there's a series of e-mails, and I'll go to  
 20 the first in time. On page two of the  
 21 exhibit, there's one from Donald Cook,  
 22 December 19th, 2005 at 8:28 a.m. to Dr.  
 23 Pritzker and he says "Dr. Williams has asked  
 24 me to follow up with you on the status of ER  
 25 and PRs and the review process. I understand

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1 that we could push on this after Christmas  
 2 with a view to completion at the end of  
 3 January 2006. I am assuming this target is  
 4 still in place. I would appreciate your  
 5 comments," and then Dr. Pritzker asked for an  
 6 update, please, and then is told by Maria  
 7 Mendes, who sends an e-mail to Nancy Good on  
 8 December 19th at 8:31 a.m. She says "Hi,  
 9 Nancy, would you please let me know. Of the  
 10 total we have received, 864, how many have we  
 11 stained and how many have we reported?" And  
 12 then there's a message from Nancy Good on the  
 13 same day to Maria Mendes saying "here is the  
 14 breakdown of cases as of December 19th. 861  
 15 cases received (934 blocks)." So I take it  
 16 that that would indicate for some patients  
 17 more than one block?  
 18 DR. MULLEN:  
 19 A. Again, if you recall the case, we had 1D, 2  
 20 and 3, that--yes.  
 21 COFFEY, Q.C.:  
 22 Q. As of that point then, 12 cases went for  
 23 consult (HER2/neu) ER/PR equals 13 blocks.  
 24 That would be ones for which, in the  
 25 retrospective, there were at least 13 that

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1 were done that they asked for HER2/neu?  
 2 DR. MULLEN:  
 3 A. Yes, 12 cases. One case, I think, had two  
 4 blocks. So those, we pulled out and did as a  
 5 rush.  
 6 COFFEY, Q.C.:  
 7 Q. 225 cases reported by BM, which would be  
 8 Brendan Mullen?  
 9 DR. MULLEN:  
 10 A. Yes, that's correct.  
 11 COFFEY, Q.C.:  
 12 Q. Up to that point in time. 398 cases stained,  
 13 679 cases cut, and 182 cases to be cut. So  
 14 that would be kind of just before Christmas of  
 15 2005, that would be the -  
 16 DR. MULLEN:  
 17 A. Yes. Yes, that's correct. Seems like a -  
 18 COFFEY, Q.C.:  
 19 Q. And it would add up to more than 861 because  
 20 some of them would be over, presumably  
 21 overlapped.  
 22 DR. MULLEN:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. I believe, Doctor, if you add up 679 and 182,

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1 you'll get roughly 861 in total.  
 2 DR. MULLEN:  
 3 A. Okay, because of the cases. I was trying to  
 4 do cut and stain, so it's actually--okay.  
 5 COFFEY, Q.C.:  
 6 Q. And there would be some -  
 7 DR. MULLEN:  
 8 A. Yes, 225, 3--the relevant numbers are 225, 398  
 9 and 182, I think.  
 10 COFFEY, Q.C.:  
 11 Q. Yes.  
 12 DR. MULLEN:  
 13 A. Okay.  
 14 COFFEY, Q.C.:  
 15 Q. Then at the top of the page here in the  
 16 exhibit, Nancy Good notes "a correction,  
 17 Maria. It looks like 530 slides have been  
 18 stained." So Doctor, coming then into the  
 19 holiday season in 2005, Christmas holidays,  
 20 what then happened?  
 21 DR. MULLEN:  
 22 A. I took a short break. I was away from Boxing  
 23 Day to, I believe, the 2nd or 3rd after--2nd  
 24 or 3rd of January. They continued to do the  
 25 staining, cutting and staining, and I believe

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1 on January 10th, if I'm not mistaken, January  
 2 10th was the last day anything was stained,  
 3 and basically upon my return until--you'll  
 4 have the exact date, basically towards the end  
 5 of January, non-stop reporting of these cases.  
 6 COFFEY, Q.C.:  
 7 Q. If we could, please, Exhibit P-1342? Doctor,  
 8 this is--at the top of the page, there is a  
 9 response from Dr. Pritzker to Dr. Cook on  
 10 December 20th 2005 at 5:00 p.m. He copies it  
 11 to a number of individuals including yourself.  
 12 He says "Don, as of today, everything is  
 13 tracking towards successful completion at the  
 14 end of January 2006. All the best for the  
 15 holidays and the new year." Signed Ken.  
 16 So by, I take it, five or so days before  
 17 Christmas in 2005, I take it some calculation  
 18 had been done roughly as to when you might  
 19 finally get this done?  
 20 DR. MULLEN:  
 21 A. Yes. Part of it was the technical. Again, as  
 22 I mentioned on November 30th, the validation  
 23 of the new machine, so the capacity was  
 24 increased and the staff was going to work  
 25 through the holidays to--and then upon my

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1 return, I'd basically sit down and, when I  
 2 wasn't on service, and sign these out or  
 3 report them rather.  
 4 COFFEY, Q.C.:  
 5 Q. Exhibit P-1809? This, Doctor, is a series of  
 6 e-mails. The first of them in time is January  
 7 4th, 2006, now in the New Year, at 3:05 p.m.  
 8 from Dr. Cook to Dr. Pritzker. He says "Dr.  
 9 Williams is asking for an update on ER and PRs  
 10 in regard to the progress in staining and how  
 11 soon we can expect to receive further results  
 12 in the review process. Looking forward to  
 13 hearing from you. All the best for the New  
 14 Year," signed Don Cook.  
 15 And then Dr. Pritzker sent that on to  
 16 Maria Mendes and yourself, and then you,  
 17 January 5th, at 2:45 p.m., responded saying  
 18 "update on ER/PRs" and you indicated here "by  
 19 the end of next week." So I take it that -  
 20 DR. MULLEN:  
 21 A. I'm trying -  
 22 COFFEY, Q.C.:  
 23 Q. Pardon?  
 24 DR. MULLEN:  
 25 A. I'm just trying to see--let's see. So we're

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1 on the 4th, the 5th. So we thought we would  
 2 be--the end of next week was referring to the  
 3 staining. So we would complete the staining,  
 4 which I believe we did on January 10th, and  
 5 then the reporting--I'm not sure if I was  
 6 doing reporting that week or would start when  
 7 everything was ready.  
 8 COFFEY, Q.C.:  
 9 Q. If we could, Exhibit, please, 1075? Here,  
 10 Doctor, the first of the e-mails in this  
 11 exhibits is January 9th at 2:55 p.m. from Dr.  
 12 Cook to yourself and he says "Hi, Brendan.  
 13 Dr. Williams is wondering when we can expect  
 14 to receive further results on the review/retro  
 15 cases. It is our impression that all of these  
 16 will be completed at the end of January 2006.  
 17 I am assuming this target is still in place?"  
 18 and that's a question mark.  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. "Regards, Donald Cook," and then on the same  
 23 day, at 4:30 p.m., you responded to him  
 24 writing "yes, they will all be reported by the  
 25 end of January. When do you plan to re-

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1 institute the ER/PR/HER2 assessment for the  
 2 current cases?" So I take it you're saying  
 3 "look, we will have it done by the end of  
 4 January." The reference to "when do you plan  
 5 to re-institute the ER/PR/HER2 assessment for  
 6 the current cases?" okay, what are you asking  
 7 about there and why?  
 8 DR. MULLEN:  
 9 A. Well, if you remember my earlier testimony, I  
 10 basically agreed to 50 to 100 cases, and we're  
 11 now up to, you have the final number, 9 or  
 12 1100 cases.  
 13 COFFEY, Q.C.:  
 14 Q. It ends up being 11. It's about 850 or 60 at  
 15 that point.  
 16 DR. MULLEN:  
 17 A. Yes. So I'm reviewing those. I'm also doing  
 18 all of the prospective ER/PR/HER2 from  
 19 Newfoundland that I'm aware of and basically I  
 20 was asking "when is your laboratory going to  
 21 be up to speed to repatriate this?" It was an  
 22 awful lot of work and it was getting sort of  
 23 overwhelming at that time because of the push.  
 24 I forget how many cases, we had 400 or so  
 25 cases I had to look at that month, plus the

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1 current, and I couldn't tell you off the top  
 2 of my head, but it would be ten, maybe ten  
 3 cases a week on top of that and so plus the  
 4 routine service I was doing. It was just sort  
 5 of when--you've had, what, six months now, at  
 6 least six months. We could get a--in the back  
 7 of my mind, we could get a machine up and  
 8 validated in two weeks. You've had six  
 9 months. So basically my little nudge to  
 10 please repatriate this.  
 11 COFFEY, Q.C.:  
 12 Q. Now Doctor, did you, by that point in time,  
 13 did you have any understanding as to what the  
 14 nature of the actual problem was, or problems  
 15 had been?  
 16 DR. MULLEN:  
 17 A. No, not other than the machine and the  
 18 technical. That was still the working  
 19 hypothesis.  
 20 COFFEY, Q.C.:  
 21 Q. I take it no one from Newfoundland had  
 22 contacted you to let you know what the basic  
 23 reason for the delay in repatriation, as you  
 24 put it, was?  
 25 DR. MULLEN:

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1 A. No, no. There'll be some e-mails further  
 2 about they plan on repatriating.  
 3 COFFEY, Q.C.:  
 4 Q. Exhibit P-1076? This an e-mail of January  
 5 9th, 2006, at 5:28 p.m. to yourself from Dr.  
 6 Cook. The subject is re-institution date for  
 7 ER/PR/HER2, and Dr. Cook writes "Hi, Brendan.  
 8 In regards to the start-up date for resumption  
 9 of testing on our current cases, we are  
 10 looking at around March 31, 2006. We will, of  
 11 course, will try for an earlier start-up date  
 12 depending on the implementation on the various  
 13 recommendations. Regards, Don Cook." So this  
 14 is the response to your question.  
 15 DR. MULLEN:  
 16 A. To pacify me.  
 17 COFFEY, Q.C.:  
 18 Q. And you're being told, at least as of that  
 19 time, that it'll be about three months time.  
 20 I gather it ended up being quite a bit longer.  
 21 DR. MULLEN:  
 22 A. 15 months, if not mistaken. I believe March  
 23 of '07 is the final date.  
 24 COFFEY, Q.C.:  
 25 Q. If we could, please, Exhibit P-1810? This is

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1 several e-mails of January 17th, 2006. The  
 2 first of them is at 9:28 a.m. from Barry Dyer  
 3 to Vince D'Mello?  
 4 DR. MULLEN:  
 5 A. D'Mello, yes, that's correct.  
 6 COFFEY, Q.C.:  
 7 Q. Who is Vince D'Mello?  
 8 DR. MULLEN:  
 9 A. He's the laboratory manager. He's in charge  
 10 of all technical services in the department.  
 11 COFFEY, Q.C.:  
 12 Q. And he says, Mr. Dyer writes "Hi, Vince. How  
 13 are things? Would it be possible for your lab  
 14 to review some ER/PR slides for us? They come  
 15 from a grid of procedures and require a grade  
 16 for our in-house purpose only, not for  
 17 diagnostic purposes. We would be glad to pay  
 18 for this service. If you can, Mary brought  
 19 them with her. If not, please let her know.  
 20 Thanks, Barry." And then the same day, Mr.  
 21 D'Mello forwards that to yourself, that e-  
 22 mail. "This is a request from our friends in  
 23 Newfoundland. Can you help? Charges  
 24 involved?" and that's a question mark. "No  
 25 idea how many slides involved." Signed Vince.

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1 And then you responded to Mr. D'Mello saying  
 2 "before responding, I need to know numbers and  
 3 time lines."  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. So I take it that you wanted to have some idea  
 8 of how much might--how much work might be  
 9 involved here?  
 10 DR. MULLEN:  
 11 A. Yes, yes, because if you recall, January 17th,  
 12 I was at the final push for the retros and I  
 13 also had the current prospectives.  
 14 COFFEY, Q.C.:  
 15 Q. And that'll be apparent in the next exhibit,  
 16 Exhibit P-1348. And Doctor, this is two e-  
 17 mails of January 19th, 2006, one from Dr.  
 18 Cook, the first of them from Dr. Cook at 11:12  
 19 a.m. to Dr. Pritzker. It's copied to Dr.  
 20 Williams and yourself. He writes "Hi, Ken.  
 21 Dr. Williams has to give a report to our Board  
 22 of Directors at Eastern Health early next  
 23 week. As to the status of ERs and PRs, we  
 24 know that these cases will be completed by the  
 25 end of January 2006. However, Dr. Williams

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1 would like an updated report as to the  
 2 progress of staining and interpretation,  
 3 etcetera. This information would be greatly  
 4 appreciated. Thanks, Don Cook." And then the  
 5 same day at 12:45 p.m. you responded to Dr.  
 6 Cook saying, "We are currently reviewing and  
 7 entering the technical repeats. The completed  
 8 spreadsheet will be sent to you on Monday."  
 9 And what is a technical repeat here, do you  
 10 recall?  
 11 DR. MULLEN:  
 12 A. I think it was probably--I don't recall. If  
 13 we had the spreadsheet, I might look at it.  
 14 But I think it was again the same issues, the  
 15 internal controls absent, the negatives with  
 16 internal control absent, that group of cases,  
 17 but I'm not 100 percent sure.  
 18 COFFEY, Q.C.:  
 19 Q. If we could, please, Exhibit P-1811? Now,  
 20 here, Doctor, is an e-mail from yourself,  
 21 Friday, January 20th, 2006 at 8:20 a.m. to Dr.  
 22 Cook, copied to Dr. Pritzker, Maria Mendes and  
 23 Nancy Good. The subject is ER/PR data. The  
 24 attachments are labelled "ER/PR code," I'm  
 25 sorry, "complete ER/PR XLS" that should be a

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1 spreadsheet. "Revised ER/PR XLS." And three  
 2 attachments. And you write, "Attached please  
 3 find ER/PR results for the Newfoundland and  
 4 Labrador retrospective review. The initial  
 5 report of the ER/PR results is being reviewed  
 6 for seven cases due to restraining of the  
 7 material when the initial specimen was  
 8 negative and the internal controls were either  
 9 negative or absent. The cases are" and  
 10 they're spelled out there, they're redacted  
 11 here. "When you have had an opportunity to  
 12 review the results, I would like to discuss  
 13 some of the technical difficulties we  
 14 encountered with processing and staining the  
 15 specimens. Some of the same issues are  
 16 present in the current Newfoundland and  
 17 Labrador material." And that's, I take it,  
 18 the reference that you -  
 19 DR. MULLEN:  
 20 A. In the first -  
 21 COFFEY, Q.C.:  
 22 Q. - referred to earlier?  
 23 DR. MULLEN:  
 24 A. Yes. The first paragraph refers to what I had  
 25 spelled out in the previous e-mails, negative

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1 with absent internal control or internal  
 2 control, internal control didn't stain or  
 3 stained weakly.  
 4 COFFEY, Q.C.:  
 5 Q. And the -  
 6 DR. MULLEN:  
 7 A. And then the second paragraph was basically a  
 8 reiteration of what I'd said to Bev, that now  
 9 we're into the end of January, we'd gone from  
 10 November to January, we were still having the  
 11 same issues.  
 12 COFFEY, Q.C.:  
 13 Q. And that would be on your current cases, I  
 14 take it?  
 15 DR. MULLEN:  
 16 A. Yes. This was the, the second paragraph is  
 17 the prospective of, yes, some of the  
 18 technicals we encountered with the  
 19 prospective--okay. Some of the same issues  
 20 are present in the current NL material. So  
 21 that was the prospective. The issues I had  
 22 with the retro were still present in the  
 23 prospective and I wanted to draw it to his  
 24 attention. I had drawn it to Bev's attention.  
 25 COFFEY, Q.C.:

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1 Q. Did you ever hear from Dr. Cook about that?  
 2 DR. MULLEN:  
 3 A. No, no, I didn't.  
 4 COFFEY, Q.C.:  
 5 Q. Did you ever hear from anybody about it,  
 6 anybody in Newfoundland and Labrador that you  
 7 can recall?  
 8 DR. MULLEN:  
 9 A. Other than my conversation with Bev, no, no.  
 10 COFFEY, Q.C.:  
 11 Q. Which had been back in November?  
 12 DR. MULLEN:  
 13 A. Back in November, no.  
 14 COFFEY, Q.C.:  
 15 Q. But other than that -  
 16 DR. MULLEN:  
 17 A. No.  
 18 COFFEY, Q.C.:  
 19 Q. - up to this day, up until as we are here now,  
 20 has anyone ever, to your knowledge, attempted  
 21 to speak to you or communicate with you from  
 22 Eastern Health about such things as technical  
 23 difficulties that we, Mount Sinai,  
 24 encountered?  
 25 DR. MULLEN:

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1 A. No, no, other than, as I said, my conversation  
 2 with Bev, that was it. And that's Dr. Carter.  
 3 COFFEY, Q.C.:  
 4 Q. Yes.  
 5 DR. MULLEN:  
 6 A. Sorry, Dr. Carter.  
 7 COFFEY, Q.C.:  
 8 Q. So here, Doctor, if we could, I'm just going  
 9 to--I take it then this really is, and I  
 10 appreciate, and I understand that there were  
 11 some subsequent cases involving St. Anthony?  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Another batch of cases that came in. And I  
 16 understand that in 2007, I'll be asking about  
 17 this, you were asked to review or do a  
 18 retrospective review for deceased patients,  
 19 some deceased patients?  
 20 DR. MULLEN:  
 21 A. Yes. I wasn't--I'm not sure if I knew that  
 22 they were deceased at the time.  
 23 COFFEY, Q.C.:  
 24 Q. Okay.  
 25 DR. MULLEN:

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1 A. But that -  
 2 COFFEY, Q.C.:  
 3 Q. That comes up -  
 4 DR. MULLEN:  
 5 A. I'm not sure if that, the e-mail that, from is  
 6 it Ms. Predham?  
 7 COFFEY, Q.C.:  
 8 Q. Yes.  
 9 DR. MULLEN:  
 10 A. I don't know if that's, she was--that's what  
 11 she was referring to or if when I completed  
 12 everything, they were also, that group of  
 13 patients was included in the initial, I'm not  
 14 sure the details there.  
 15 COFFEY, Q.C.:  
 16 Q. But I take it, though, other than the deceased  
 17 patients who, I gather, in 2007 you -  
 18 DR. MULLEN:  
 19 A. That separate batch, yes.  
 20 COFFEY, Q.C.:  
 21 Q. - separate group and St. Anthony cases, in the  
 22 main by January 20th, 2006 was this  
 23 spreadsheet the results of your retrospective  
 24 review?  
 25 DR. MULLEN:

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1 A. Yes, yes, I believe so.  
 2 COFFEY, Q.C.:  
 3 Q. If we could, please, now page 2 of the exhibit  
 4 is the code, and you say "The code I used is  
 5 as follows."  
 6 DR. MULLEN:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. And first five entries are the same as the one  
 10 we looked earlier this morning. But then by  
 11 now you've got tumor type, my tumor type was D  
 12 ductal, DL ductal, lobular features, DT ductal  
 13 with tubular features, L for lobular, PAP,  
 14 papillary, DCIS and ductal carcinoma in situ,  
 15 DCIS/M, ductal carcinoma in situ with micro  
 16 invasion, less than one millimetre. C for  
 17 colloid, am I correct?  
 18 DR. MULLEN:  
 19 A. Yes, that's correct.  
 20 COFFEY, Q.C.:  
 21 Q. T for tubular. MCA for metastatic cancer,  
 22 EPAP for encysted?  
 23 DR. MULLEN:  
 24 A. Encysted papillary.  
 25 COFFEY, Q.C.:

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1 Q. Encysted, I apologize.  
 2 DR. MULLEN:  
 3 A. Sorry.  
 4 COFFEY, Q.C.:  
 5 Q. Papillary in situ carcinoma, DA for ductal  
 6 carcinoma with -  
 7 DR. MULLEN:  
 8 A. Epicrine features.  
 9 COFFEY, Q.C.:  
 10 Q. Epicrine features. "EIC, extensive, DCIS  
 11 (greater than 25 percent)." M for metaplastic  
 12 carcinoma, AC for, and perhaps you can?  
 13 DR. MULLEN:  
 14 A. Adenoid cystic carcinoma.  
 15 COFFEY, Q.C.:  
 16 Q. CANOS for unclassified carcinoma, and PU for  
 17 pick up with tumor adherent to tissue and NT  
 18 for no tumor?  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. So I take it the class, various possible  
 23 classifications of what you'd seen for these  
 24 tumors had grown?  
 25 DR. MULLEN:

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1 A. Yes. If you--I think in the first e-mail it  
 2 was two lines or the first--it's grown. And  
 3 the majority of these as when I was talking  
 4 earlier, the majority of these are ductal.  
 5 And these are very rare birds, sorry, very  
 6 rare cases. In the, I think the no tumor with  
 7 the--sorry, I just check what I--no tumor  
 8 there are 21 blocks, two were pick up, and  
 9 then metastatic CA there were 26 of them and  
 10 ductal carcinoma in situ there were 60. And  
 11 then the other 997 out of my--the blocks were  
 12 invasive tumor. And the majority would be the  
 13 ductal, the smaller proportion would be the  
 14 other types.  
 15 COFFEY, Q.C.:  
 16 Q. And here looking at page 3 of the exhibit,  
 17 here there's a--well, the box number, there's-  
 18 -see that?  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. The box number of one. And then the first  
 23 column. And then we get partway down there,  
 24 we got two.  
 25 DR. MULLEN:

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1 A. Box two, yes.  
 2 COFFEY, Q.C.:  
 3 Q. And then it goes on then, three, four, we can  
 4 look on through. What does that -  
 5 DR. MULLEN:  
 6 A. Now, just before we go.  
 7 COFFEY, Q.C.:  
 8 Q. Sure.  
 9 DR. MULLEN:  
 10 A. Okay. The box one, these are slide transport  
 11 boxes that we were shipping things back to.  
 12 So when Newfoundland received them, they would  
 13 know block one would contain these cases. It  
 14 wasn't a hunt and search process.  
 15 COFFEY, Q.C.:  
 16 Q. Box one would -  
 17 DR. MULLEN:  
 18 A. Box one, box two would then--now, if you look  
 19 in the specimen number, if you recall--oh,  
 20 there's our favourite case. Box two, S--  
 21 99SU7806 1D, two and three, there's the two  
 22 ditto marks underneath. So each block was  
 23 reported separately, if you recall. So if you  
 24 go across, SUID two and three, they're all  
 25 lobular, 90, 90, 70, 20, 30, 10, you can see

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1 the variability there. I'm just--so -  
 2 COFFEY, Q.C.:  
 3 Q. The variability is 90, 20 for ER/PR?  
 4 DR. MULLEN:  
 5 A. Sorry, 90, 90 and then it drops to 70 in one  
 6 block.  
 7 COFFEY, Q.C.:  
 8 Q. Yes.  
 9 DR. MULLEN:  
 10 A. PR is 20, 30, 10.  
 11 COFFEY, Q.C.:  
 12 Q. Yes.  
 13 DR. MULLEN:  
 14 A. And then--so and then the processing was  
 15 fairly stable.  
 16 COFFEY, Q.C.:  
 17 Q. So just again I'm going to take you then, if I  
 18 could, across the top of the page here, the  
 19 box number is there. The results, the RS  
 20 number?  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. I take it would be the number assigned by  
 25 Mount Sinai?

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1 DR. MULLEN:  
 2 A. Yes, that's our research service number.  
 3 COFFEY, Q.C.:  
 4 Q. The specimen number would be the number  
 5 utilized -  
 6 DR. MULLEN:  
 7 A. By whichever hospital had referred the case to  
 8 us.  
 9 COFFEY, Q.C.:  
 10 Q. There'd be a listing of patients names were  
 11 are all redacted here?  
 12 DR. MULLEN:  
 13 A. Um.  
 14 COFFEY, Q.C.:  
 15 Q. The blocks column would be -  
 16 DR. MULLEN:  
 17 A. That was the block number, so that would--the  
 18 first case we look at that it was a specimen  
 19 from year 2000. The initiating hospital SS, I  
 20 think, would probably be St. Clare's. 5977,  
 21 block three. The next case would be 5710  
 22 would have been block five. And you notice  
 23 some hospitals use numerical, others use alpha  
 24 and others use alpha numerical.  
 25 COFFEY, Q.C.:

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1 Q. And then under "Comments/site" I take it this  
 2 is -  
 3 DR. MULLEN:  
 4 A. Which, who was the initiating -  
 5 COFFEY, Q.C.:  
 6 Q. Institution?  
 7 DR. MULLEN:  
 8 A. If you go to page 5, you can see that we now  
 9 go where the comments are beside, most were  
 10 St. John's. And if I keep--sorry, if I just  
 11 scroll down.  
 12 COFFEY, Q.C.:  
 13 Q. Sure.  
 14 DR. MULLEN:  
 15 A. Okay. St. John's, we're now on page 9, we  
 16 move to Carbonear, Gander, Gander, Carbonear.  
 17 So we tried to--it was from the site.  
 18 COFFEY, Q.C.:  
 19 Q. And then as we go on through Gander and we go  
 20 down further onto page 10, we're into Grand  
 21 Falls, some of them are indicated to be, some  
 22 are James Paton.  
 23 DR. MULLEN:  
 24 A. Yes. We ran into a couple of difficulties, we  
 25 weren't sure what the name of the hospital--

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1 there were, I forget, one or two places we had  
 2 no idea where they were.  
 3 COFFEY, Q.C.:  
 4 Q. And then we get into page, for example, page  
 5 15. Let's go. We have the beginning of a  
 6 large group of Western Memorial.  
 7 DR. MULLEN:  
 8 A. Oh, yes, that was it. Western Memorial path  
 9 report says Sir, it's not here but there was  
 10 the name of another hospital.  
 11 MR. BROWNE:  
 12 Q. Thomas Roddick.  
 13 DR. MULLEN:  
 14 A. Yes, thank you.  
 15 COFFEY, Q.C.:  
 16 Q. Thank you, sir, Mr. Browne. So and then  
 17 looking again at the headings here, I'm just  
 18 on, for the record, Commissioner, page 15.  
 19 You again got a heading, or a column entitled  
 20 "Tumor".  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Which I take it is that listing of whatever  
 25 type of tumor you classified?

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1 DR. MULLEN:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. It as. This particular one at page 15, "NT"  
 5 means no tumor?  
 6 DR. MULLEN:  
 7 A. No tumor.  
 8 COFFEY, Q.C.:  
 9 Q. In that block. And for that situation then  
 10 the ER/PR, the internal control and the  
 11 indication of status of fixation -  
 12 DR. MULLEN:  
 13 A. I didn't complete it because it wasn't  
 14 terribly relevant.  
 15 COFFEY, Q.C.:  
 16 Q. Fixation processing. So it wouldn't be  
 17 relevant to a no tumor situation?  
 18 DR. MULLEN:  
 19 A. No.  
 20 COFFEY, Q.C.:  
 21 Q. And then for the next entry here just on page  
 22 15, the second row, it's the first item in box  
 23 21, apparently, it's indicated to be from St.  
 24 John's. The tumor is a D for ductal?  
 25 DR. MULLEN:

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1 A. Um-hm.  
 2 COFFEY, Q.C.:  
 3 Q. And here under the column "ER" there's the  
 4 number zero, which would signify what?  
 5 DR. MULLEN:  
 6 A. I didn't see any positive cells.  
 7 COFFEY, Q.C.:  
 8 Q. In the tumor itself?  
 9 DR. MULLEN:  
 10 A. In the tumor, in the tumor, yes.  
 11 COFFEY, Q.C.:  
 12 Q. And -  
 13 DR. MULLEN:  
 14 A. Sorry, the ER and PR refer to the malignant  
 15 cells in the invasive component.  
 16 COFFEY, Q.C.:  
 17 Q. And the PR is indicated for this particular  
 18 block to b zero. And if we can go on further  
 19 down, the next particular block, the entries  
 20 are for ER 50, which would be 50 percent?  
 21 DR. MULLEN:  
 22 A. Yes, that's correct.  
 23 COFFEY, Q.C.:  
 24 Q. And PR is 70 percent and so on and so forth?  
 25 DR. MULLEN:

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1 A. Yes. And the -  
 2 COFFEY, Q.C.:  
 3 Q. Well, when you look at this, I'm going to take  
 4 you down to a couple of others, see, partway  
 5 down the page here, there's another entry  
 6 toward, it's about nine up from the bottom,  
 7 Western Memorial, an NT, which would be no  
 8 tumor again?  
 9 DR. MULLEN:  
 10 A. That's correct.  
 11 COFFEY, Q.C.:  
 12 Q. No entries in the subsequent columns. But and  
 13 there's one here, see, I count it up, about  
 14 six rows above that for Western Memorial,  
 15 DCIS?  
 16 DR. MULLEN:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. And here as we look out through the columns  
 20 there are no entries?  
 21 DR. MULLEN:  
 22 A. Yes, that's correct.  
 23 COFFEY, Q.C.:  
 24 Q. And why is that?  
 25 DR. MULLEN:

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1 A. I believe I mentioned this morning that it's  
 2 not our policy to report ductal carcinoma in--  
 3 the ER and PR results for ductal carcinoma in  
 4 situ. We will do it if specifically asked by  
 5 the clinician. We are not sure, we meaning  
 6 the Mount Sinai or myself and Dr. O'Malley, of  
 7 the biological significance and the cut points  
 8 that are appropriate for reporting. So when  
 9 we do report it, we will just say that there  
 10 was 60 percent were positive or 30 percent  
 11 were positive. We will make no interpretation  
 12 of the biological behaviour, the significance  
 13 of it.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, I'm just going to go back and if we  
 16 could, Commissioner, to page 3 of the exhibit,  
 17 just because I want to be able to go back and  
 18 forth to page 2, which is the code. For the  
 19 columns now, column entitled or head "IC",  
 20 that would be the internal control?  
 21 DR. MULLEN:  
 22 A. Um-hm.  
 23 COFFEY, Q.C.:  
 24 Q. And that would be your observation of the  
 25 internal control tissue that you were seeing

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1 on the slide produced at Mount Sinai?  
 2 DR. MULLEN:  
 3 A. Yes, that's correct.  
 4 COFFEY, Q.C.:  
 5 Q. Okay. Now, here there are various possible--  
 6 if we look back at the code, you have here for  
 7 IC, internal controls, the various possible  
 8 entries listed here are P for present, but not  
 9 stained; PS for present and stained; PSW for  
 10 present and stained weakly; and A for absent?  
 11 DR. MULLEN:  
 12 A. Um-hm.  
 13 COFFEY, Q.C.:  
 14 Q. So I take it the best possible scenario is PS,  
 15 present and stained?  
 16 DR. MULLEN:  
 17 A. That's correct.  
 18 COFFEY, Q.C.:  
 19 Q. So if we could just go back then to that  
 20 column entitled "IC" we see, I think, the  
 21 first five entries are "PS," present and  
 22 stained?  
 23 DR. MULLEN:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. Then there's an "A", absent?  
 2 DR. MULLEN:  
 3 A. Um-hm.  
 4 COFFEY, Q.C.:  
 5 Q. Which would mean on that block there was no  
 6 internal control tissue?  
 7 DR. MULLEN:  
 8 A. That's correct.  
 9 COFFEY, Q.C.:  
 10 Q. And then we get some more, a number of PSs and  
 11 then we come across, encounter another block  
 12 which is indicated to be A for absent?  
 13 DR. MULLEN:  
 14 A. Um-hm.  
 15 COFFEY, Q.C.:  
 16 Q. And they're either, on that page their all  
 17 either PS, present, stained, or A for absent?  
 18 DR. MULLEN:  
 19 A. Um-hm.  
 20 COFFEY, Q.C.:  
 21 Q. If we could, just, I'm going, yes, to the next  
 22 page, Doctor, page 4.  
 23 DR. MULLEN:  
 24 A. Um-hm.  
 25 COFFEY, Q.C.:

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1 Q. And I'm just going to pick one here coming  
 2 down that column.  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. The first entry that contains the letters  
 7 "PSW" which would be, I take it, present,  
 8 stained weakly?  
 9 DR. MULLEN:  
 10 A. Stained weakly, yes.  
 11 COFFEY, Q.C.:  
 12 Q. And the entries for ER and PR are less than  
 13 one and less than one?  
 14 DR. MULLEN:  
 15 A. Um-hm.  
 16 COFFEY, Q.C.:  
 17 Q. So would that be the sort of case you were  
 18 talking about?  
 19 DR. MULLEN:  
 20 A. Yes, that would be the type of case.  
 21 COFFEY, Q.C.:  
 22 Q. That would be -  
 23 DR. MULLEN:  
 24 A. Yes, yes.  
 25 COFFEY, Q.C.:

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1 Q. - had been repeated?  
 2 DR. MULLEN:  
 3 A. Um-hm. And then just for clarification, if  
 4 you move down to the next--oh, no, sorry. The  
 5 next, not the one two below, but the next case  
 6 that says "A", estrogen receptor ductal, it's  
 7 zero 2SS2504, C block, St. John's, ductal 10,  
 8 less than one, A and poor. That case I would  
 9 not repeat because estrogen receptor was  
 10 positive. So it was only in those cases where  
 11 either--where ER was less--was zero or less  
 12 than one, the internal control was absent or  
 13 present stained weakly. So those are the ones  
 14 that I reflex to repeat.  
 15 COFFEY, Q.C.:  
 16 Q. And in repeating them, how often did you then  
 17 report them if you repeated, what would you  
 18 report when you repeated it?  
 19 DR. MULLEN:  
 20 A. I would, I believe in the last e-mail I had  
 21 that there were seven and two changed. I've  
 22 forgotten. I would change the spreadsheet and  
 23 tell them that I changed it.  
 24 COFFEY, Q.C.:  
 25 Q. And, Doctor, and I'm not going to take the

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1 Commissioner through, you know, each of those  
 2 pages as it goes on indefinitely.  
 3 DR. MULLEN:  
 4 A. I'd be more than happy -  
 5 COFFEY, Q.C.:  
 6 Q. At least for the -  
 7 DR. MULLEN:  
 8 A. - to sit down with the slides if you'd like to  
 9 look at them with me if you have a year.  
 10 COMMISSIONER:  
 11 Q. I don't have a year.  
 12 COFFEY, Q.C.:  
 13 Q. The column entitled--and just while I'm on  
 14 that, before I leave the IC column, Doctor,  
 15 bearing in mind that that's a particular  
 16 block, whatever the block is, a particular  
 17 surgical number and block, is there any way if  
 18 there's no internal control tissue, is there  
 19 any way of you putting any there? I mean, I  
 20 take it if it's not there, it's not there?  
 21 DR. MULLEN:  
 22 A. No. No, no, no, no. The only thing you can  
 23 do--you can't put benign breast epithelium in  
 24 a section. The only thing you can do is  
 25 check--try another block.

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1 COFFEY, Q.C.:  
 2 Q. Yes. And we talked about that earlier.  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. From the same surgical specimen?  
 7 DR. MULLEN:  
 8 A. Going forward for my in-house cases, as I  
 9 mentioned, I may have mentioned or--I try to  
 10 choose, I endeavour to choose a block that has  
 11 benign ductal epithelium to use as an internal  
 12 control. You can only deal with what's given  
 13 to you from the outside, somebody else has  
 14 selected, so you're at--you can't manipulate  
 15 what's there, which block you choose.  
 16 COFFEY, Q.C.:  
 17 Q. Now, Doctor, what sort of situation--I'll just  
 18 bring up one, page 7, please? Thank you,  
 19 Registrar. Because one of the possible codes  
 20 is a P, in the third entry -  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. I'm sorry, the second entry here is -  
 25 DR. MULLEN:

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1 A. That's the internal control was present but it  
 2 did not stain.  
 3 COFFEY, Q.C.:  
 4 Q. Okay. And here it's indicated ER zero and PR  
 5 zero. What would be done in that sort of  
 6 situation when you encounter -  
 7 DR. MULLEN:  
 8 A. That I would repeat. Again, that fit the  
 9 criteria zero or less than one, internal  
 10 control that was present didn't stain or  
 11 present stained weakly.  
 12 COFFEY, Q.C.:  
 13 Q. And in -  
 14 DR. MULLEN:  
 15 A. While in the one below, zero, zero present and  
 16 stain, I would not repeat, wouldn't repeat.  
 17 Although I had the same results, it was  
 18 because of the presence or absence of the  
 19 internal control, that dictated whether I  
 20 would repeat it or not.  
 21 COFFEY, Q.C.:  
 22 Q. And if the internal control was present and  
 23 stained and the result was zero and zero, you  
 24 would be satisfied -  
 25 DR. MULLEN:

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1 A. Because--that's right -  
 2 COFFEY, Q.C.:  
 3 Q. - because the internal control stained -  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. I can rely upon the zero and zero as is?  
 8 DR. MULLEN:  
 9 A. Yes, yes.  
 10 COFFEY, Q.C.:  
 11 Q. But where the internal control was present and  
 12 did not stain -  
 13 DR. MULLEN:  
 14 A. That would reflex -  
 15 COFFEY, Q.C.:  
 16 Q. Reflex -  
 17 DR. MULLEN:  
 18 A. - and if you go down, you keep going down,  
 19 there's another--let's see, it's 1D, if you go  
 20 down the block, it's 1D? there's zero, zero  
 21 present, that would have been reflexed. But  
 22 the one--the two below, zero, zero PS, zero,  
 23 zero PS would not be reflexed.  
 24 COFFEY, Q.C.:  
 25 Q. Yes. It's down in this area here?

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1 DR. MULLEN:  
 2 A. Yes. Sorry, it's--yeah, it, yeah.  
 3 COFFEY, Q.C.:  
 4 Q. Okay. Now, Doctor, the final column here,  
 5 the--just go back to, apologize, page 2,  
 6 looking at our code, is the F/P which is  
 7 fixation and processing. And the possibly  
 8 entries there were adequate or poor, A for  
 9 adequate or P for poor. I'm just going to go  
 10 now to that particular column on page 3. And  
 11 here what does "A" for adequate signify and  
 12 what does "P" for poor signify as you use them  
 13 here?  
 14 DR. MULLEN:  
 15 A. If you recall at the beginning I mentioned I  
 16 looked at the specimens twice to get the range  
 17 of what I was to expect, you know, basically  
 18 the first ten cases I looked at, sat down and  
 19 looked at them again trying to establish  
 20 criteria. In the end "A" basically meant if  
 21 I had some tumor on the slide, it was an A. I  
 22 mean, if I felt that I was comfortable  
 23 interpreting that there was tumor and there  
 24 was some there, that was A. It was the lowest  
 25 of the low standards for an adequate. "P" it

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1 was basically there was nothing left. I mean,  
 2 there were a few cells or it was just so  
 3 poorly fixed that I couldn't make anything out  
 4 of it.  
 5 COFFEY, Q.C.:  
 6 Q. Okay.  
 7 DR. MULLEN:  
 8 A. I didn't feel comfortable making anything out  
 9 of it.  
 10 COFFEY, Q.C.:  
 11 Q. Now here, for example, here, Doctor, on that  
 12 point, go down to about the--let's see, at  
 13 page 3, I believe -  
 14 DR. MULLEN:  
 15 A. Yes, I can see that one.  
 16 COFFEY, Q.C.:  
 17 Q. About ten -  
 18 DR. MULLEN:  
 19 A. Yeah, ten less than one, PSP.  
 20 COFFEY, Q.C.:  
 21 Q. Yes. So I take it the internal control was  
 22 present and stained?  
 23 DR. MULLEN:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. You reported it as ER 10 and PR less than one?  
 2 DR. MULLEN:  
 3 A. Um-hm.  
 4 COFFEY, Q.C.:  
 5 Q. And you classified the fixation/processing as  
 6 P?  
 7 DR. MULLEN:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. So here you did report this?  
 11 DR. MULLEN:  
 12 A. Oh, yes. No, I--it was reported but with a  
 13 caveat. There wasn't--I mean, in no case did  
 14 I not report what was there. I mean, I'm  
 15 talking about--I can't speak to the specific  
 16 slide because I don't have it. But--and when  
 17 I go through my little show and tell, I'll  
 18 show you the, what basically the issue is that  
 19 it's either crumpled, it's fallen off, but  
 20 there are some cells that you can make a  
 21 interpretation of, but I didn't want them--  
 22 didn't want to leave the impression that these  
 23 were fabulous slides. There was an issue  
 24 here.  
 25 COFFEY, Q.C.:

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1 Q. Yeah. And I take it that there was, from your  
 2 perspective looking at this and looking at--or  
 3 looking at these slides, did you have any  
 4 understanding as to whether or not Mount Sinai  
 5 could really produce, bearing in mind what  
 6 they were given in the block, could they do  
 7 anything better or any more with it, for you?  
 8 DR. MULLEN:  
 9 A. Well, some of the--I think some of the ones  
 10 that kept falling off we repeated. We  
 11 repeated and we--some of them up to three  
 12 times to try to get something. I mean, you  
 13 can't make an adequate slide out of material  
 14 that's either raw, not fixed or just not  
 15 processed properly. You're asking an  
 16 impossibility.  
 17 COFFEY, Q.C.:  
 18 Q. So in respect, this is all, all these comments  
 19 are certainly here at this point in respect of  
 20 the retrospective study?  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. The retests going back, we understand, covers  
 25 about a seven-year period. So, Doctor, can I

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1 draw from what you just told us then that you  
 2 were doing what you could to give an  
 3 interpretation based upon what was available  
 4 to you?  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. And with all of the -  
 9 DR. MULLEN:  
 10 A. I mean, I have to make a--this is all we had.  
 11 You cannot go back and there's no fresh tumor,  
 12 it hasn't just been removed from the patient.  
 13 We didn't have any fresh samples that we could  
 14 process properly. You cannot reprocess tissue  
 15 that's been in a--you can, but you have no  
 16 idea what it's going to do to the antigens or  
 17 to the proteins, so it's--that would add a  
 18 whole other level of complexity. This is what  
 19 we had, these were the drawbacks to what we  
 20 did, these are the criteria that we used, and  
 21 this is how we reported it. If this were  
 22 coming--we're talking -  
 23 COFFEY, Q.C.:  
 24 Q. Okay.  
 25 COMMISSIONER:

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1 Q. Okay.  
 2 DR. MULLEN:  
 3 A. If this were material that was presenting in  
 4 the Mount Sinai laboratory in patients  
 5 undergoing operations in the Mount Sinai  
 6 laboratory, I might tolerate--if we go back to  
 7 the first page, I might tolerate the first  
 8 one. The second one, get very, very--and the  
 9 third one all, sorry, expression, all hell  
 10 would break loose. This is not acceptable.  
 11 That -  
 12 COFFEY, Q.C.:  
 13 Q. This sort of fixation processing would not -  
 14 DR. MULLEN:  
 15 A. Yes. We have to revisit all our processes.  
 16 COFFEY, Q.C.:  
 17 Q. From that perspective by the second or third  
 18 you're realize there's something going wrong?  
 19 DR. MULLEN:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. Further out in the lab or upstairs somewhere  
 23 or wherever the ORs are?  
 24 DR. MULLEN:  
 25 A. Yes, yes. From the time the specimen is

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1 removed to the time it hits the lab to the  
 2 time basically a section is made, there's  
 3 something going--there's something seriously  
 4 wrong with the process. So that then we would  
 5 have to sit down and go through, revisit all  
 6 our processes, see what's, you know, were  
 7 these aberrant cases or were they--is this the  
 8 norm. And the other thing to remember is that  
 9 what's affecting breast tissue is also  
 10 affecting all the other specimens that are  
 11 being received, so this is not something that  
 12 you would see in isolation.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, do you--can you think of any reason  
 15 why, because apparently you can even look at  
 16 the surgical numbers, you can tell it covers  
 17 quite a number of years?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. Covers quite a number of institutions?  
 22 DR. MULLEN:  
 23 A. Um-hm.  
 24 COFFEY, Q.C.:  
 25 Q. Okay. Are you able to think of or offer any

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1 possible explanation as to why it had gone on  
 2 so long, this sort of problem, because it is  
 3 apparent to you there were problems with  
 4 fixation and processing now looking at this?  
 5 DR. MULLEN:  
 6 A. Yes. There are very few pathologists who've  
 7 had the opportunity to review the number of  
 8 cases I've reviewed, both prospective,  
 9 retrospective and so what is inherently  
 10 obvious to me, if you're looking at it for the  
 11 first time or you see one case a month, it may  
 12 not be obvious. It's sort of the cumulation  
 13 or the--the total amount of material that I  
 14 was seeing and I could pick out issues because  
 15 I was seeing them repeatedly, not only day  
 16 after day but within the same day, so you're  
 17 much more attune to what the issues are. But  
 18 if I were seeing one case, if I were on  
 19 routine service and I was seeing one breast  
 20 case a month, I may not pick up the issue.  
 21 COFFEY, Q.C.:  
 22 Q. And if we could, please, Exhibit P-1812? Yes.  
 23 And, Doctor, this is two e-mails of January  
 24 23rd, 2006, the first from Dr. Cook at 9:09  
 25 a.m. to yourself. He asks, "Can you recheck"

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1 a particular RS number and a particular block.  
 2 "The spreadsheet I received in early October  
 3 reported an ER of five percent. The  
 4 spreadsheet received on January 20th reports  
 5 an ER of 65 percent on the same block.  
 6 Thanks, Donald Cook." And then on the same  
 7 day at 10:53 a.m. you responded saying, "This  
 8 was a restrain because of absent internal  
 9 controls. The repeat was stronger so I  
 10 reported the second stronger in the final  
 11 spreadsheet." And that's an example, I take  
 12 it, of -  
 13 DR. MULLEN:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. - of one of those that -  
 17 DR. MULLEN:  
 18 A. That was, yes.  
 19 COFFEY, Q.C.:  
 20 Q. If we could, please, Exhibit P-1813? This is,  
 21 well, it's two e-mails, but the one in  
 22 particular involving yourself of February  
 23 14th, 2006, you e-mail, 11:26 a.m. e-mail Dr.  
 24 Cook. The subject is "St. Anthony's results"  
 25 and you write here, "The last, hopefully, of

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1 the retrospective study." And signed, "Dr.  
 2 Brendan Mullen." And there's attached here  
 3 and Excel spreadsheet, and it's entitled  
 4 "ER/PR received from St. Anthony site, January  
 5 24th, '06." And there are a number of  
 6 surgical numbers, block numbers, patient names  
 7 are redacted. They're all comments from St.  
 8 Anthony. There are columns here for tumor,  
 9 ER/PR results, IC, internal controls and -  
 10 DR. MULLEN:  
 11 A. The same.  
 12 COFFEY, Q.C.:  
 13 Q. - fixation/processing, the same sort of  
 14 format. So I take it, then, Doctor, that  
 15 Mount Sinai then on or about January 24th, '06  
 16 received some cases involving St. Anthony,  
 17 Newfoundland?  
 18 DR. MULLEN:  
 19 A. Yes. Based on -  
 20 COFFEY, Q.C.:  
 21 Q. Apparently?  
 22 DR. MULLEN:  
 23 A. Based on the spreadsheet, yes.  
 24 COFFEY, Q.C.:  
 25 Q. And you were asked to -

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1 DR. MULLEN:  
 2 A. Do the same.  
 3 COFFEY, Q.C.:  
 4 Q. Review those. And this would be the results?  
 5 DR. MULLEN:  
 6 A. And reported, yes, the 14th.  
 7 COFFEY, Q.C.:  
 8 Q. That would be the?  
 9 DR. MULLEN:  
 10 A. Of February.  
 11 COFFEY, Q.C.:  
 12 Q. February. Exhibit P-1814? Again, there are  
 13 two e-mails here, one of February 20th, 2006,  
 14 7:54 a.m., it's from Dr. Cook to yourself  
 15 regarding a particular RS number. And he  
 16 writes, "Brendan, our tumor board committee  
 17 reviewing the ER/PR cases wishes you to  
 18 reconfirm that the ER result initially  
 19 reported in October, 2005" on a particular  
 20 patient, block number and so on, "as ER five  
 21 percent is revised to ER 65 percent on the  
 22 same block. The committee wants to know if  
 23 the second result is the one to go by." And  
 24 then the same day at 9:55 a.m. you responded,  
 25 "Yes, to the best of my recollection." You

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1 say then, "The slides were sent to St. John's  
 2 on January 30th so I am not able to recheck.  
 3 Hope that helps." Signed, "Dr. Mullen." Can  
 4 you tell us, please, about the--so these  
 5 slides would be which slides?  
 6 DR. MULLEN:  
 7 A. These were our restains. Now, if you recall,  
 8 the large spreadsheet where it had box one and  
 9 the results, those when we finished, we put  
 10 the slides into those boxes in consecutive  
 11 order and then we shipped everything to St.  
 12 John's where they--I mean, I it was my--I  
 13 would have expected they would have reviewed  
 14 the cases that I--and confirmed what I had  
 15 said. I'd hope they would.  
 16 COFFEY, Q.C.:  
 17 Q. Now, on that point, Doctor, confirm what you  
 18 said in this individual case of confirmed  
 19 overall, could you tell the Commissioner about  
 20 that? What was your expectation at the time,  
 21 Doctor, as to what happened?  
 22 DR. MULLEN:  
 23 A. I would have--well, I would have reviewed,  
 24 before I issued a report over my name -  
 25 COFFEY, Q.C.:

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1 Q. That would be in St. John's, I take it, if you  
 2 were in St. John's?  
 3 DR. MULLEN:  
 4 A. Or in the Sinai, I mean, if I--I mean, I send  
 5 out cases or cases we have, there are certain  
 6 areas of pathology, lots of areas of pathology  
 7 that I'm not an expert in and there are  
 8 experts in the city or in the province. I  
 9 send out, I get their opinion, then I look at  
 10 the case again when they send it back and  
 11 before I issue the report that so and so had  
 12 said such, I'd look at it and I agree or I  
 13 disagree, whatever, however you want to  
 14 express it. But if I'm outsourcing or not  
 15 outsourcing, having somebody restrain and  
 16 interpret who they've never met, they've  
 17 never, we've sat down other than Bev very  
 18 quickly, before I issue a report, I would like  
 19 to look at, if I'm changing anything, I would  
 20 like to, was he right, was he wrong, was his  
 21 interpretation correct. Those are the sorts,  
 22 you know, the--I feel very uncomfortable, I  
 23 would feel very uncomfortable just taking the  
 24 spreadsheet and acting on it without actually  
 25 looking at the report. And I'm not sure what

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1 the arrangement was, whether we were going to  
 2 keep everything or they wanted us to keep  
 3 everything to the end rather than sending it  
 4 to them -  
 5 COFFEY, Q.C.:  
 6 Q. Piecemeal, I take it?  
 7 DR. MULLEN:  
 8 A. Yes. And the other--I mean, when we first  
 9 started this, I thought, well, we can stain  
 10 them and let them interpret them, but they  
 11 didn't seem to want to do that, they wanted us  
 12 to do it. That was another -  
 13 COFFEY, Q.C.:  
 14 Q. That was another what?  
 15 DR. MULLEN:  
 16 A. Well, it could have saved me a lot of work,  
 17 but that was another--that had never been  
 18 clarified.  
 19 COMMISSIONER:  
 20 Q. Mr. Coffey, when you can find a space, we'll  
 21 take the afternoon break.  
 22 COFFEY, Q.C.:  
 23 Q. Thank you. That'll be great, actually,  
 24 Commissioner, because I'm going to go on now  
 25 to the--get into later on 2006 and '07.

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1 COMMISSIONER:  
 2 Q. Afternoon break, then.  
 3 (RECESS)  
 4 COMMISSIONER:  
 5 Q. Please be seated. Mr. Coffey.  
 6 COFFEY, Q.C.:  
 7 Q. Thank you, Commissioner. Exhibit P-1815,  
 8 please, Registrar? Here, Doctor, there's,  
 9 well, there are two e-mails, but one from  
 10 yourself April 5th, 2006 at 11:20 a.m. to Dr.  
 11 Cook and the subject is "Last six results."  
 12 And I take and the attachment was labelled  
 13 just that, "Last six.XLS." And here on page 2  
 14 of the exhibit there are six such results, the  
 15 redacted results, but there, nevertheless.  
 16 So, Doctor, I take it then by the beginning  
 17 of, at least as of April 5th that was, you  
 18 thought, it?  
 19 DR. MULLEN:  
 20 A. Yes, yes. And I can't speak to these cases,  
 21 whether they were add ons or something we  
 22 missed. I have--I cannot speak to that. I  
 23 thought that was--but, mind you, I said "last"  
 24 a few times.  
 25 COFFEY, Q.C.:

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1 Q. Yes. If we could, Exhibit P-1816? This is an  
 2 e-mail--the e-mail we just looked at was April  
 3 5th. This is an e-mail from Dr. Cook, April  
 4 7th, 2006, 9:17 a.m. to Maria Mendes, copied  
 5 to yourself and Ms. Good. Dr. Cook writes,  
 6 "Hi Maria, We are rechecking our master list  
 7 and have come across some patients that did  
 8 not come up on the initial computer screen.  
 9 There may be 15 to 20 such cases. We are  
 10 sending up six of these within the next few  
 11 days. These can be entered as retro cases and  
 12 given RS numbers. I am also sending up cases  
 13 that require another block. These are the  
 14 NT," which would be no tumor cases, "that  
 15 could not be reported. We will be sending  
 16 these up over the next week." So I take it  
 17 then that at the end of the first week of  
 18 April of 2006 Dr. Cook was advising you that  
 19 in terms of -  
 20 DR. MULLEN:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. - there'd be 15 to 20, at least 15 to 20 other  
 24 cases coming along as retro cases?  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. That's what he wanted them described as?  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Exhibit P-1818? These are two e-mails, one,  
 8 the first in time, May 1st, 2006, 5:56 p.m.  
 9 from Dr. Cook to yourself. He writes,  
 10 "Brendan, can you forward me the ER result on"  
 11 and the information there is redacted.  
 12 "Thanks, Don Cook." And then the next day at  
 13 8:48 a.m. you send an e-mail to Dr. Cook  
 14 saying, "ER equals zero. I will send an  
 15 updated spreadsheet when we have completed the  
 16 stragglers." So I take that by this point in  
 17 time, early in May you're trying to -  
 18 DR. MULLEN:  
 19 A. Whatever the residual cases were.  
 20 COFFEY, Q.C.:  
 21 Q. - finish them. Exhibit P-1819. I apologize.  
 22 I can accomplish the same thing, 1820, I  
 23 apologize. Here, Dr. Donald Cook on May 4,  
 24 2006 at 1:37 p.m. e-mailed you saying  
 25 "Brendan, could you repeat the staining on

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1 RS," that's redacted, a particular surgical  
 2 number and block, "A for PR only" and he goes  
 3 on to refer to another surgical number and a  
 4 different block "for PR only as we are  
 5 observing significant nuclear staining on our  
 6 original slides." Signed, "Don Cook." And  
 7 then you responded on May 16th, 2006 at 3:03  
 8 p.m. to him indicating "Re: repeat staining  
 9 on" two different RS numbers. And for the  
 10 first of them, the PR repeat was five percent  
 11 and the second the PR repeat is 60 percent.  
 12 So do you recall what this was about or just -  
 13 DR. MULLEN:  
 14 A. No, I -  
 15 COFFEY, Q.C.:  
 16 Q. - a request he asked and you did?  
 17 DR. MULLEN:  
 18 A. I'd have to check the original spreadsheet to  
 19 see what I had reported them at, and without  
 20 the slides, I really can't comment on this.  
 21 COFFEY, Q.C.:  
 22 Q. And I refer to it just simply because you're  
 23 still somewhat involved in a --  
 24 DR. MULLEN:  
 25 A. I think they were doing what I would like them

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1 to have done, to go through everything, make  
 2 sure that it fit and then -- it's interesting  
 3 that he didn't look at the original slides and  
 4 make his own interpretation of it.  
 5 COFFEY, Q.C.:  
 6 Q. Did you have any sense of whether or not a  
 7 pathologist in St. John's before sending the  
 8 blocks to Mount Sinai had offered the  
 9 retrospective study, had ever looked at the  
 10 original slides? Were you ever told whether  
 11 they had looked at the original slides or not,  
 12 the original St. John's slides?  
 13 DR. MULLEN:  
 14 A. The case would have been reported, so a  
 15 pathologist would, yes. It would have been  
 16 reported then, I believe, through conversation  
 17 with Dr. Carter. I can't state specifically  
 18 when I had that conversation that she had  
 19 started a review of a select set of cases. I  
 20 don't know the extent, don't know the time,  
 21 and don't know the results of that.  
 22 COFFEY, Q.C.:  
 23 Q. And in terms of the approximately 1,000  
 24 retrospective cases that -- or blocks that you  
 25 looked at, thousand or so blocks --

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1 DR. MULLEN:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. Fall within the retrospective study or review.  
 5 In terms of whether or not when those blocks  
 6 were being selected, located, selected, and  
 7 then being, you know, packaged to be sent to  
 8 Mount Sinai, whether or not at that point just  
 9 before they came to Mount Sinai, any  
 10 pathologist had actually looked at the  
 11 original slides in the sense of the original  
 12 ER/PR slides?  
 13 DR. MULLEN:  
 14 A. I have no knowledge of that.  
 15 COFFEY, Q.C.:  
 16 Q. No knowledge of that?  
 17 DR. MULLEN:  
 18 A. No knowledge whatsoever.  
 19 COFFEY, Q.C.:  
 20 Q. If we could, please Exhibit P-01821. Here,  
 21 Doctor, the first e-mail here at the bottom of  
 22 the exhibit, it's one from yourself to Dr.  
 23 Cook, Tuesday, May 16, 2006, at 3:09 p.m. The  
 24 subject is "Complete and updated ER/PR file",  
 25 and you write here, "This is everything we

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1 have to date", and the attachment you can see  
 2 above is labelled NL May 16.XLS. I take it  
 3 you were then sending out an --  
 4 DR. MULLEN:  
 5 A. That was everything that I knew about in the  
 6 retro study.  
 7 COFFEY, Q.C.:  
 8 Q. Exhibit P-01822. Now had you ever met Dr.  
 9 Cook?  
 10 DR. MULLEN:  
 11 A. No.  
 12 COFFEY, Q.C.:  
 13 Q. Have you ever met him?  
 14 DR. MULLEN:  
 15 A. I beg your pardon?  
 16 COFFEY, Q.C.:  
 17 Q. Have you ever met him?  
 18 DR. MULLEN:  
 19 A. I've never met Dr. Cook.  
 20 COFFEY, Q.C.:  
 21 Q. Now here is again two e-mails. The first of  
 22 them at the bottom of the page here is from --  
 23 well, I refer to him as Dr. Nash Denic,  
 24 because he goes by the name Nash.  
 25 DR. MULLEN:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. Friday, May 19, 2006, 11:21, to yourself. The  
 4 subject is "Re; Testing ER/PR", and he writes,  
 5 "Hi Dr. Mullen, I am a new clinician chief of  
 6 the laboratory medicine program, Eastern  
 7 Health. Recently Dr. Cook stepped down from  
 8 this position. I will be taking over some of  
 9 the issues related to ER and PR. I would like  
 10 to thank you for your efforts and all the work  
 11 that you've put in regards to ER/PR. We are  
 12 expecting to resolve all the issues very soon.  
 13 However, I still have to ask you for another  
 14 favour (probably the last one) if you can  
 15 retest the group of seven patients who turned  
 16 out to be retro converted. We would like  
 17 first to deal with this group of patients  
 18 since the therapy might not be appropriate.  
 19 The list of the patients is enclosed", and  
 20 then there is down below here a retro  
 21 list.XLS. "I would appreciate it if you can  
 22 provide us with the requested test as soon as  
 23 possible. Sincerely, Nash Denic".  
 24 DR. MULLEN:  
 25 A. I send off the --

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1 COFFEY, Q.C.:  
 2 Q. Yes, and you then on the same day at 11:40  
 3 forwarded that e-mail to Nancy Good, and you  
 4 write succinctly "more work". When we look  
 5 then at the redacted Excel spreadsheet  
 6 attached on page two, it would be, I take it,  
 7 probably the -- we understand the retro  
 8 converters list that was sent here.  
 9 DR. MULLEN:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Or retro list sent here. Exhibit P-01130.  
 13 Here you did something other than forward the  
 14 list to Nancy Good because on the same day --  
 15 you see at the bottom of the page here,  
 16 Doctor, that's Dr. Denic's e-mail of May 19th  
 17 to you. On the same day at 1:09 p.m. you  
 18 responded to him saying, "I will have our  
 19 technologist stain the cases next week. My  
 20 question about repatriation of the work is an  
 21 issue of scheduling for us. I currently  
 22 segregate the Newfoundland and Labrador  
 23 material from our routine ER/PR HER2 service,  
 24 and with summer holidays upon us, I would like  
 25 to finalize our reporting protocol for these

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1 cases. If you have a time frame for me to  
 2 work with, that would be very helpful.  
 3 Thanks, Brendan Mullen". I take it then,  
 4 Doctor, you were attempting here to kind of  
 5 plan your --  
 6 DR. MULLEN:  
 7 A. The -- we, as the e-mail says, segregated the  
 8 ER/PR and HER2 from Newfoundland. Basically I  
 9 did the retros and I did the prospective and  
 10 the QAs, and we'll hear tomorrow the review,  
 11 and I occasionally take holidays, so I wanted  
 12 to -- especially in the summer, I try to take  
 13 two weeks at a time, and the person who was  
 14 going to take over signing them out if we did  
 15 have to sign them out, you know, that we were  
 16 still going to continue -- hopefully through  
 17 this e-mail I was trying to say please hurry  
 18 up and take it back, but then we set up on our  
 19 schedule about who would fax the reports to  
 20 the appropriate -- there's sort of a minor  
 21 hand off of the material just to make sure  
 22 that they were reported timely and they were  
 23 faxed to the appropriate person. It was more  
 24 logistics with the undertone or the under  
 25 "please take this back".

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1 COFFEY, Q.C.:  
 2 Q. Take it back in the sense of resume the  
 3 testing in St. John's?  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Repatriated.  
 8 DR. MULLEN:  
 9 A. Because if you recall, you showed me an e-mail  
 10 that it was going to be done by the end of  
 11 March 31st, 2006, and we're now into May.  
 12 That's probably seven/eight -- 10 weeks.  
 13 COFFEY, Q.C.:  
 14 Q. If we could, please, Exhibit P-01825. Now  
 15 this is an e-mail, Doctor, from yourself, June  
 16 1st, 2006, to Dr. Cook. The subject is  
 17 "repeats", and the attachment is "Repeat.XLS",  
 18 and you note here there was a change in  
 19 [blank] results or redacted results for the ER  
 20 changing from less than 1 to 2, and the PR  
 21 changing from 5 to 30, and then there is a  
 22 spreadsheet attached with some handwriting on  
 23 it.  
 24 DR. MULLEN:  
 25 A. I'm just trying to think -- from less than 1

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1 to 2. Okay, that would have -- guessing, that  
 2 would have been the Gander case where there  
 3 was no -- internal control was present, so it  
 4 would have been restrained. I think that would  
 5 be one --  
 6 COFFEY, Q.C.:  
 7 Q. It's present and not stained here, I take it.  
 8 DR. MULLEN:  
 9 A. Yes, present and not stained. So that's why  
 10 it would have gone through my protocol to --  
 11 and less than 1, so it would have been  
 12 repeated. So on the repeat, more than 1  
 13 percent, if it's 2 percent basically. So  
 14 that's -- I mean, that was always the concern.  
 15 I would report the -- I think they knew that I  
 16 would -- of all those cases, I'd reflex, and  
 17 not to delay the results, that there may be a  
 18 slight change every now and then.  
 19 COFFEY, Q.C.:  
 20 Q. Now, Doctor, in terms of that, and I'll just  
 21 use this -- Mount Sinai itself was, to your  
 22 understanding, using what sort of number --  
 23 what percentage would fall into the positive  
 24 category, weak positive or positive category?  
 25 DR. MULLEN:

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1 A. Anything greater than 1 percent. One percent  
 2 to 10 percent was our low positive. Anything  
 3 above 10 percent was -- I shouldn't say strong  
 4 positive, but positive.  
 5 COFFEY, Q.C.:  
 6 Q. Did you ever become aware of whether or not  
 7 St. John's was utilizing 10 percent at that  
 8 point, still utilizing 10 percent?  
 9 DR. MULLEN:  
 10 A. No, no. The only -- I was aware of their cut  
 11 points when I did the review of the original  
 12 material.  
 13 COFFEY, Q.C.:  
 14 Q. In 2008?  
 15 DR. MULLEN:  
 16 A. In 2008, and I looked at the reports to try to  
 17 see.  
 18 COFFEY, Q.C.:  
 19 Q. But that's in '08?  
 20 DR. MULLEN:  
 21 A. Yes, '08.  
 22 COFFEY, Q.C.:  
 23 Q. I'll be talking to you about that, and I'll  
 24 have you explain that to the Commissioner, but  
 25 back at this time in '05/'06 --

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1 DR. MULLEN:  
 2 A. No.  
 3 COFFEY, Q.C.:  
 4 Q. The idea that they had been utilizing -- what  
 5 cut off point they were still utilizing in St.  
 6 John's in '06?  
 7 DR. MULLEN:  
 8 A. I didn't know, but some of the e-mails --  
 9 there was one e-mail, I believe, where I said,  
 10 you know, if you read between the lines, well,  
 11 they were both positive, one was slightly more  
 12 than the other, but in our hands in our  
 13 institution, greater than 1 percent is  
 14 considered positive, and based on studies we  
 15 can think about or Frances may have spoken  
 16 about, what constitutes positive -- or Dr.  
 17 O'Malley rather.  
 18 COFFEY, Q.C.:  
 19 Q. Just one moment, Commissioner. If we could,  
 20 please, Exhibit P-01796. Now this is an  
 21 exchange of e-mails on October 9th and 11th,  
 22 2005, between yourself and Dr. Cook. I take  
 23 it that's what you just had in mind then when  
 24 you were referring to e-mails and --  
 25 DR. MULLEN:

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1 A. Yes, but there was one specifically where I  
 2 gave numbers.  
 3 COFFEY, Q.C.:  
 4 Q. Okay.  
 5 DR. MULLEN:  
 6 A. This may be the one. Oh, yes, here it is,  
 7 down on the bottom, sorry. He told me what I  
 8 reported, yes. This is what I'm referring to.  
 9 COFFEY, Q.C.:  
 10 Q. Here he had written on October 9th to you --  
 11 that's Dr. Cook had.  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. He wanted you to follow up and comment on a  
 16 particular case, and he said this case was  
 17 sent up as a consult patient in mid August '05  
 18 and reported as ER, 1 to 5 percent, and PR,  
 19 less than 1 percent on block 2E and there's a  
 20 report number.  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. "On the retro master list, she is reported as  
 25 ER, 20 percent; PR, 2 percent, Block 2F. She

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1 has been told that she is not converted on  
 2 repeat testing based on the results of  
 3 SF0512331", which would be the earlier report  
 4 of --  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. ER, 1 to 5 percent; PR, less than 1 percent.  
 9 DR. MULLEN:  
 10 A. That would have been probably  
 11 November/December on our prospective, yes.  
 12 COFFEY, Q.C.:  
 13 Q. And then what happened is that on October 11th  
 14 you responded and referenced first of all  
 15 SP0512331, and you described there, I've taken  
 16 you through it earlier, the observations you  
 17 made about poor fixation --  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. Processed in the centre of the slide, and what  
 22 you -- you explained the ER/PR result.  
 23 DR. MULLEN:  
 24 A. This e-mail, it twigged me that they weren't  
 25 using the same cut off points.

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1 COFFEY, Q.C.:  
 2 Q. Yes, because here you conclude by saying,  
 3 "Both slides are positive for ER and RS, in  
 4 particular, slide is positive for PR".  
 5 DR. MULLEN:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. So --  
 9 DR. MULLEN:  
 10 A. Yes, and if you -- I mean, do you remember one  
 11 of the WordPerfect -- or all the WordPerfects  
 12 with the codes. There is a line that we  
 13 consider greater than 1 percent positive.  
 14 COFFEY, Q.C.:  
 15 Q. Yes.  
 16 DR. MULLEN:  
 17 A. So that was always in my code.  
 18 COFFEY, Q.C.:  
 19 Q. And here then -- in effect, I take it, as of  
 20 October 9th, Dr. Cook, to your understanding,  
 21 was conveying to you, look, this patient was  
 22 told sometime in the late summer as a result  
 23 of a consult that she had not converted on  
 24 repeat testing as a consult, and now you've  
 25 sent us along a spreadsheet and reported it on

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1 block 2F, and you're telling us she's ER, 20  
 2 percent; PR, 2 percent?  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. And, in effect, did you understand that here  
 7 he was asking you which is it, Dr. Cook --  
 8 DR. MULLEN:  
 9 A. Yes, and I explained what it was, and I also  
 10 essentially said it didn't matter as both were  
 11 positive.  
 12 COFFEY, Q.C.:  
 13 Q. Yes.  
 14 DR. MULLEN:  
 15 A. That's basically -- in my hands, those were  
 16 both reported as positive. I'm not trying to  
 17 minimize the fact that there were differences  
 18 in the values. I explained the differences in  
 19 the values based on the material that was  
 20 provided, but the interpretation in Mount  
 21 Sinai hands would have been positive in both  
 22 cases.  
 23 COFFEY, Q.C.:  
 24 Q. And --  
 25 DR. MULLEN:

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1 A. Low positive in the first, but the other --  
 2 and positive in the second.  
 3 COFFEY, Q.C.:  
 4 Q. Well, in terms of PR, it would be no positive.  
 5 DR. MULLEN:  
 6 A. No.  
 7 COFFEY, Q.C.:  
 8 Q. Not positive in one, but positive in the other  
 9 for PR?  
 10 DR. MULLEN:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. ER being positive in both?  
 14 DR. MULLEN:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Different values, and these are different  
 18 blocks?  
 19 DR. MULLEN:  
 20 A. Yes, again different blocks. The quality of  
 21 the blocks, one was -- let me see, what did I  
 22 say. ER/PR, the periphery, the donut  
 23 (phonetic) effect. The other one was slightly  
 24 better with more going through.  
 25 COFFEY, Q.C.:

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1 Q. And we'll be looking at that shortly. If we  
 2 could, please, look at Exhibit P-01829.  
 3 DR. MULLEN:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. Here, Doctor, the first e-mail here is June  
 7 13th, 2006, at 10:45 a.m. It's from Dr. Cook  
 8 to yourself and the subject is -- it's a  
 9 particular block or surgical number, it's  
 10 redacted, and he writes, "Hi, Brendan; Could  
 11 you review", and it's redacted, "Western  
 12 Memorial Slide IX reported as DCIS. Both  
 13 myself and Bev Carter reviewed the slide this  
 14 morning and it looks like an infiltrating  
 15 ductal carcinoma with LIV", which is?  
 16 DR. MULLEN:  
 17 A. Lympho vascular invasion.  
 18 COFFEY, Q.C.:  
 19 Q. Okay. "If there is infiltration, could you  
 20 repeat the ER and PGR. If not, we will have  
 21 to send up another block. Signed, Don Cook",  
 22 and then you responded on June 19th to him  
 23 saying, "I reviewed the case with P63/SMMS  
 24 stains. There is LIV, but the invasive  
 25 component is not present in this block. I

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1 would prefer to report the invasive component  
 2 as I am unsure of the relationship of the  
 3 ER/PR response of the LIV component to the  
 4 invasive component". So what was this about,  
 5 doctor?  
 6 DR. MULLEN:  
 7 A. We are going to the minutia of pathology.  
 8 This is a case in which the slide -- there was  
 9 tumor present in the slide, but it was present  
 10 in vessels, and I'm not sure if there's -- I  
 11 remember the case now. I can't remember if  
 12 there's also co-existent ductal carcinoma in  
 13 situ. There was no classic invasive  
 14 carcinoma, the type that was present in all of  
 15 the other invasive tumor blocks. So the  
 16 question in my mind was, was this a carry  
 17 over, was this a ductal carcinoma in situ that  
 18 had popped out of the duct and ended up, which  
 19 is not unknown in a vessel, or was this the  
 20 true thing. Then the next question became if  
 21 I did an ER/PR, how valid those cells were to  
 22 the tumor. So I really wanted to see the  
 23 invasive component to do the ER/PR on invasive  
 24 component. We're into minutia here.  
 25 COFFEY, Q.C.:

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1 Q. Yes. Doctor, I -- in fact, in terms of that,  
 2 and I don't want -- I don't from my  
 3 perspective find it necessary to actually  
 4 delve into particular cases.

5 DR. MULLEN:  
 6 A. Yes.

7 COFFEY, Q.C.:  
 8 Q. What I'm getting at in terms of this is to  
 9 have you -- this is why I brought it up. At  
 10 times if you were asked to delve into  
 11 particular cases and respond to this, this is  
 12 an example of one such case?

13 DR. MULLEN:  
 14 A. This is an example, and the stains -- the P63.  
 15 Yes, now the P63 SMS stain -- okay, I -- I  
 16 wish I had my original spreadsheet. I think  
 17 this case of DCIS, ductal carcinoma in situ,  
 18 it had tumor in vessels in didn't see in  
 19 invasive components. So the issue was, was it  
 20 DCIS as they were cutting it, which is not  
 21 unknown, popped out of that area and ended up  
 22 in the vessel. You have to be a pathologist  
 23 to understand the subtleties of this, but --  
 24 so that was my issue and I wasn't going to  
 25 report the tumor that was present in the

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1 vessel in the absence of an invasive  
 2 component, but every time I -- just a broader  
 3 review, any time I was asked to review a case  
 4 and explain it, we certainly did it. If they  
 5 asked us to restrain, we restrained. There was  
 6 no hesitation whatsoever.

7 COFFEY, Q.C.:  
 8 Q. If we could, please, Registrar, Exhibit P-  
 9 01830. Doctor, before we get into this, in  
 10 2006, and that particular e-mail we've been  
 11 just looking at, the initial communication to  
 12 you is about you reported it as a DCIS?

13 DR. MULLEN:  
 14 A. Yes.

15 COFFEY, Q.C.:  
 16 Q. I take it then, if we look back at the  
 17 January, for example, January 20th, 2006  
 18 spreadsheet, there are a number of DCIS cases?

19 DR. MULLEN:  
 20 A. Yes.

21 COFFEY, Q.C.:  
 22 Q. That you reported in your spreadsheet. What,  
 23 if any, involvement did you then have in the  
 24 whole DCIS matter? You'd reported what you'd  
 25 seen, and I take it that's one example here

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1 where you've delving into a particular case.  
 2 In terms of the overall matter involving DCIS,  
 3 were you involved further?

4 DR. MULLEN:  
 5 A. There was one -- there were two cases. I  
 6 reported the DCIS, and I think I've tried to  
 7 explain that they may have had invasive tumor  
 8 elsewhere. I didn't have it in that block, or  
 9 it may have been in that block, but the  
 10 sections that I had did not have it. Then  
 11 there were two cases. One was from Western  
 12 Memorial, I believe. There were three blocks.  
 13 Two blocks -- I don't think it's our famous  
 14 1D, 2 and 3, but two blocks had ductal  
 15 carcinoma in situ, and a third block I  
 16 reported as invasive carcinoma, and last  
 17 December, Dr. Denic asked -- they had reviewed  
 18 the case, they were split in the Department  
 19 whether it was or wasn't invasive, so they  
 20 sent it to me and asked me to review it. I  
 21 did the special stains -- because when I had  
 22 first gone around, yes, fine, it's invasive,  
 23 done. I did the special stains, showed it to  
 24 colleagues, do you agree, disagree, what do  
 25 you think this is; we all agreed it was

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1 invasive based on -- they basically supported  
 2 my diagnosis and went. There was another case  
 3 of what I call DCIS. Now basically when I was  
 4 going through, this was not a review of the  
 5 preneoplastic abnormalities. If it was  
 6 atypical -- sorry, if it was completely  
 7 benign, it was basically no tumor. If there  
 8 was severe enough atypia, just classified as  
 9 DCIS and went on. I was asked to review a  
 10 case -- I think there were four blocks they  
 11 sent up, and it was what we call atypical  
 12 ductal hyperplasia, but it was -- you know, my  
 13 classification was just generally it went into  
 14 that, they weren't to act on what I call the  
 15 DCIS. That was the sort of the classification  
 16 when we reviewed that. The other cases, if  
 17 they reviewed the blocks or reviewed the case,  
 18 were comfortable that there was invasive  
 19 component, they'd send me another block. If  
 20 they reviewed the case and comfortable it was  
 21 just DCIS, it went no further.

22 THE COMMISSIONER:  
 23 Q. Just to make sure I understand this, as I  
 24 understand it when you -- what you're saying  
 25 is that when you returned your work, if you

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1 listed something as DCIS, they would then pull  
 2 the --  
 3 DR. MULLEN:  
 4 A. If it was -- I think if it was discrepant with  
 5 what their initial diagnosis was. If they had  
 6 a diagnosis of invasive carcinoma, they would  
 7 pull, but if it was ductal carcinoma in situ,  
 8 and I agreed, they wouldn't.  
 9 THE COMMISSIONER:  
 10 Q. So, in effect, if your view that it was DCIS  
 11 varied with theirs, they would pull.  
 12 DR. MULLEN:  
 13 A. Yes.  
 14 THE COMMISSIONER:  
 15 Q. And then you between you would try to resolve  
 16 what it was by their sending something back.  
 17 DR. MULLEN:  
 18 A. Well, if they weren't convinced that -- if  
 19 they thought I had overcalled something, they  
 20 would send it back to me, and that was the one  
 21 case from Western Memorial.  
 22 THE COMMISSIONER:  
 23 Q. Uh-hm.  
 24 DR. MULLEN:  
 25 A. The other cases -- it wasn't that I was having

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1 a back and forth with them. They would on  
 2 their own, I think, decide it was another  
 3 block that had invasive tumor and would send  
 4 it to me.  
 5 THE COMMISSIONER:  
 6 Q. Okay, all right, for your opinion on the other  
 7 block?  
 8 DR. MULLEN:  
 9 A. To do the ER/PR on the other block, yes, to  
 10 give them results.  
 11 COFFEY, Q.C.:  
 12 Q. With the invasive component?  
 13 DR. MULLEN:  
 14 A. Yes. I mean, also any of the prospectives that  
 15 were called DCIS, I basically said it was DCIS  
 16 and didn't do the ER/PR on those.  
 17 COFFEY, Q.C.:  
 18 Q. And if -- in terms of the prospective cases,  
 19 if then St. John's wanted to send you another  
 20 block, a different block, they could request  
 21 that, and I think you've told the Commissioner  
 22 that even if on a DCIS case, if the requested  
 23 it --  
 24 DR. MULLEN:  
 25 A. I would do it.

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1 COFFEY, Q.C.:  
 2 Q. You would do the ER/PR anyway?  
 3 DR. MULLEN:  
 4 A. Yes. I don't believe there were any for them.  
 5 In the four or five years we've been doing --  
 6 I mean, in the masses, I've had two requests  
 7 in-house and one request from a peripheral  
 8 hospital in Ontario to do it. It's extremely  
 9 rare that they ask this. It's one of the sort  
 10 of -- a specific clinician may want it, either  
 11 for a trial or they've read somewhere that it  
 12 might be useful, but it's not widely accepted.  
 13 COFFEY, Q.C.:  
 14 Q. If we could, please, Exhibit P-1830. Now  
 15 we're up to -- this is an e-mail from Maria  
 16 Mendes, April 20th, 2007, to yourself and  
 17 others, and there are certain attachments I  
 18 want to take you through, but, Doctor, as we  
 19 are now up to the spring of 2007 -- we've been  
 20 looking at a series of e-mails that took us up  
 21 to June of '06, do you recall that?  
 22 DR. MULLEN:  
 23 A. So we skipped a year -- yeah, sorry.  
 24 COFFEY, Q.C.:  
 25 Q. So what had happened in the meantime then?

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1 From June of '06 really onward, do you recall  
 2 anything stand out in relation to this, and I  
 3 appreciate you were doing the current cases?  
 4 DR. MULLEN:  
 5 A. Okay, the current cases were continuing. We  
 6 instituted quality assurance which would be  
 7 two to three to four slides a month or so, and  
 8 I don't -- we've done 39 to date, so -- I  
 9 don't know if that would have overlapped with  
 10 that period. I'm trying to think '07. There  
 11 was another batch of 120. I can't remember  
 12 when they came, but they have --  
 13 COFFEY, Q.C.:  
 14 Q. Okay, well, in terms of that, if I can assist  
 15 you, you've indicated already this morning  
 16 that St. John's began at least to do the St.  
 17 John's cases, I believe, in March of '07.  
 18 DR. MULLEN:  
 19 A. Yes, all right. So March 13th was the last  
 20 case we received from St. John's for ER/PR, so  
 21 we continued to do HER2 for them. We were  
 22 doing ER/PR and HER2 for the rest of the  
 23 province or the people who were sending to us,  
 24 I can't say that we did everything, and then  
 25 March of '08, March 7th of '08, we started to

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1 receive cases again from St. John's for ER/PR.  
 2 COFFEY, Q.C.:  
 3 Q. I'll come to that in a moment if I could.  
 4 DR. MULLEN:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. So as we get into the late winter of '07 -- we  
 8 passed through '06 and we're into '07.  
 9 DR. MULLEN:  
 10 A. Okay.  
 11 COFFEY, Q.C.:  
 12 Q. Other than reporting the prospective cases,  
 13 after we get into the fall of '06, you just  
 14 continued to report and you've indicated at  
 15 some point there were some QA cases.  
 16 DR. MULLEN:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. Two or three a month would come up to be  
 20 looked at.  
 21 DR. MULLEN:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Or to be processed and --  
 25 DR. MULLEN:

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1 A. And there were also a few that were lumped --  
 2 a few cases that we lumped -- I believe we  
 3 lumped them as retrospective. They were, I  
 4 believe, patients who had previously been  
 5 reported as positive in St. John's, and they  
 6 had the option of having it repeated. There  
 7 weren't a large number of those, and I can't  
 8 give you the exact number, but I do have the  
 9 spreadsheet, I can get it this evening --  
 10 there weren't a large number, but they were  
 11 lumped under the retro category. So there  
 12 were those patients.  
 13 COFFEY, Q.C.:  
 14 Q. And in March of 2007 with respect to the last  
 15 case sent, I believe you've indicated, March  
 16 13th, 2007, the last case from St. John's for  
 17 this period of time, last ER/PR case, were you  
 18 advised that they were repatriating? Were you  
 19 being actually advised, Dr. Mullen, we are  
 20 repatriating, or did they just stop sending  
 21 them or what do you recall?  
 22 DR. MULLEN:  
 23 A. If you look at the e-mail sequences, I'm  
 24 usually the last to hear. So it's usually Dr.  
 25 Pritzker, Ms. Mendes, and so, no, I--no.

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1 COFFEY, Q.C.:  
 2 Q. Okay, just--you've checked since, and that's  
 3 the last time -  
 4 DR. MULLEN:  
 5 A. Yes, yes. I went through and then it started  
 6 again March 7th of '08.  
 7 COFFEY, Q.C.:  
 8 Q. Now with respect to the periods, the months  
 9 after March of '07, St. John's stops sending  
 10 their blocks looking for ER/PR tests, the rest  
 11 of Newfoundland and Labrador, and certainly  
 12 you understood you were doing them for at  
 13 least some other centres in Newfoundland, but  
 14 did you ever make any inquiries of these other  
 15 centres as to what their future plans were?  
 16 Like Corner Brook and Grand Falls and Gander.  
 17 DR. MULLEN:  
 18 A. No. I was acting under the assumption that  
 19 once St. John's resumed that if they were  
 20 mandated to or they could continue to send to  
 21 us. It really--they were not a significant  
 22 burden on us, and so it was--you know, it was  
 23 very happy--I shouldn't say very happy to do,  
 24 but there was no issue in capacity for us to  
 25 do their work.

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1 COFFEY, Q.C.:  
 2 Q. And that is on the current, the prospective  
 3 cases?  
 4 DR. MULLEN:  
 5 A. Yes, and if they were happy with our service  
 6 and wanted to continue, more than happy to do  
 7 it.  
 8 COFFEY, Q.C.:  
 9 Q. Now looking at this exhibit of April 20th, Ms.  
 10 Mendes writes "Hi, Dr. Mullen. This is the  
 11 information I had sent Newfoundland on a  
 12 previous occasion. Gordana will add the clone  
 13 number to the SOP. I have also attached the  
 14 Excel sheet showing all your results as well  
 15 as which instrument was used and which  
 16 dilutions, since there were some adjustments  
 17 made when we changed instruments. Let me know  
 18 if this looks okay. I will send it to the  
 19 person requesting the information." Signed  
 20 Maria.  
 21 DR. MULLEN:  
 22 A. Um-hm.  
 23 COFFEY, Q.C.:  
 24 Q. And then this then -  
 25 DR. MULLEN:

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1 A. Go through everything.  
 2 COFFEY, Q.C.:  
 3 Q. - is ER/PR IHC standard operating procedure,  
 4 and there's a table of contents, a flow chart,  
 5 and so on. So what is this, do you recall?  
 6 DR. MULLEN:  
 7 A. Every time we undertake a project, there's a--  
 8 if I could just go back to the title of this.  
 9 COFFEY, Q.C.:  
 10 Q. Sure, go right ahead.  
 11 DR. MULLEN:  
 12 A. There's basically a standard operating  
 13 procedure. When we were doing the--initially  
 14 when we were doing the ER and PR in the main  
 15 laboratory in Ms. Wegrynowski's area, we would  
 16 have used their standard operating procedure.  
 17 But when we moved the system to research  
 18 services area and especially after we  
 19 instituted the LabVision autostainer and  
 20 validated it, etcetera, the standard operating  
 21 procedure, which basically is the cookbook,  
 22 had to be rewritten. So on this machine, we  
 23 do this, this and this. On this machine, we  
 24 do this, this and this. Although they may be  
 25 the same machine, functionally there are

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1 differences, and you have to optimize the  
 2 procedure for the machine and that's what was  
 3 done in November, the 14th to the 30th, I  
 4 believe of '05, and then this reflects what  
 5 was--basically what we did and how to do it.  
 6 The idea is that if you are familiar with a  
 7 laboratory, you can walk in, read the manual  
 8 and do the test.  
 9 COFFEY, Q.C.:  
 10 Q. Now -  
 11 THE COMMISSIONER:  
 12 Q. Well, as long as you do it on that machine?  
 13 DR. MULLEN:  
 14 A. Yes, on the--it's on that machine. So each  
 15 machine has the--or each area of the  
 16 laboratory has standard operating procedure.  
 17 So it's laboratory specific and, so if I move  
 18 from the Mount Sinai across the street to the  
 19 Hospital for Sick Children, although the  
 20 standard operating procedures may be, in  
 21 general, the same, they have to be rewritten  
 22 for that department. So because there are  
 23 site variations in the buffers and all of  
 24 those sorts of things. Everything--all of  
 25 these procedures are optimized for the

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1 institution and the machine and in the area  
 2 where it's operating.  
 3 COFFEY, Q.C.:  
 4 Q. Did you have any understanding of why St.  
 5 John's wanted these or why it had been sent?  
 6 Because she indicates here "this is the  
 7 information I had sent Newfoundland"--I'm  
 8 sorry, I'll just go back to -  
 9 DR. MULLEN:  
 10 A. In '0--let's see, we're talking -  
 11 COFFEY, Q.C.:  
 12 Q. This is '07.  
 13 DR. MULLEN:  
 14 A. It may have been just to complete the circle,  
 15 that we've given you the results, now here's  
 16 how we proceeded, the protocols. I mean, it's  
 17 good for our--it's good PR on our part to  
 18 provide all of this information, as well as  
 19 it's necessary for them if they're trying to  
 20 report it.  
 21 COFFEY, Q.C.:  
 22 Q. And if we could, please, Exhibit P-1831? This  
 23 is an e-mail of April 30th, 2007 from Ms.  
 24 Mendes to Barry Dyer. It's copied to Dr.  
 25 Pritzker and yourself and Vince D'Mello. The

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1 subject is ER/PR SOPs and there are  
 2 attachments. She writes "Hi, Barry. Vince  
 3 let me know that you required the SOPs that  
 4 were used for the ER/PR cases. Attached is  
 5 the information. Please let me know if you  
 6 will be requiring any further information" and  
 7 then there are a number of attachments.  
 8 DR. MULLEN:  
 9 A. So these basically refer to what we had done  
 10 in the previous exhibit? Yeah.  
 11 COFFEY, Q.C.:  
 12 Q. And there's an SOP for ER/PR retrospective  
 13 study. There's, if I could, at page six of  
 14 the exhibit, there's ER/PR IHC standard  
 15 operating procedure and this particular one is  
 16 special histology hard tissue procedure  
 17 manual, project specific protocol, version  
 18 number two. And then if you go to page 13,  
 19 there's an ER/PR SOP for ER/PR retrospective  
 20 study, special histology hard tissue procedure  
 21 manual, project specific protocol, and there's  
 22 no--there's not a version two here. This is  
 23 just without version two label on it.  
 24 DR. MULLEN:  
 25 A. Yes. Can I just -

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1 COFFEY, Q.C.:

2 Q. Yes, you go right ahead, sir.

3 DR. MULLEN:

4 A. I'm trying to figure--okay. Okay, and I'm

5 trying to think if the--okay, so this is a

6 retrospective study. I think the SOP would--

7 okay, so this is specific for the

8 retrospective. So if you go to the specimen

9 receiving, while the other one would have been

10 for any ER/PR coming in new, this was specific

11 to the Newfoundland situation, because it's

12 "specimens were accessioned, given an RS

13 number indicating the research"--so basically

14 explains exactly how we did it.

15 COFFEY, Q.C.:

16 Q. Yes.

17 DR. MULLEN:

18 A. The specimens did not require processing, wax

19 bolster received. So it is the operating

20 procedure specific to the Newfoundland. So

21 all of the--so rather than having how we

22 processed things, the blocks were received,

23 etcetera, that sort of thing, and if I go back

24 to the other one.

25 COFFEY, Q.C.:

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1 Q. Sure.

2 DR. MULLEN:

3 A. Let me just--sorry, quickly, it's a generic.

4 It's for the IHC process itself. So once you

5 have the slides, how it goes forward, and then

6 that's on the LabVision 720. The SOP for the

7 DAKO autostainer would be different.

8 COFFEY, Q.C.:

9 Q. Doctor, Exhibit P-1832, please, Registrar?

10 DR. MULLEN:

11 A. Okay.

12 COFFEY, Q.C.:

13 Q. Now Doctor, here there's an e-mail of--it's

14 actually two e-mails, one of June 5th 2007 at

15 8:03 a.m. from Dr. Cook to Maria Mendes. The

16 subject is ER/PRs for QA. And she says "Hi,

17 Maria. Since April, we have sent up ER/PRs

18 for QA purposes. We have not yet received the

19 results. Could you advise me of the status of

20 these? Thanks, Dr. Cook." And then she

21 responded on June 21st, 2007 to Dr. Cook

22 saying "I have called and left you a message

23 regarding these samples. I apologize for the

24 late reply on our part. What had occurred is

25 that we have a general QA program, but your

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1 samples are not really part of this QA

2 program. Your samples have gone through and

3 Dr. Mullen will be looking at them. On a go-

4 forward basis, you can keep sending the

5 samples to me and I will forward them as

6 research samples." Signed Maria. So this is

7 around in the spring of '07, after St. John's

8 had re-instituted ER/PR itself for itself?

9 DR. MULLEN:

10 A. Yes, I believe Dr. Pritzker had mentioned that

11 they wanted to be part of our QA program, so

12 if they ended in March, the first month,

13 applicable month would be April and our QA

14 program is, I think--I shouldn't--I'm not sure

15 of how they run it in the accessioning area,

16 but obviously there was a delay, and these,

17 most of the QAs that I do are the QAs for

18 HER2's and they're part of a provincial or

19 voluntary program from other provinces and we

20 issue a report. Newfoundland didn't want

21 that. They wanted the same mechanism of the

22 spreadsheet. So that may have been part of

23 the issue.

24 COFFEY, Q.C.:

25 Q. If we could, please, Exhibit P-1833? This is

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1 a series of e-mails, the first on July 3rd

2 2007 from Dr. Cook to Ms. Mendes, ER/PR for

3 QA. He says "Hi, Maria, can you update me on

4 the results of the ER/PR that we sent up for

5 QA? Dr. Mullen reports that he gave back the

6 results to you" and then she, on July 4th

7 2007, sent an e-mail to Dr. Cook, copied it to

8 yourself and Ms. Reid with an attachment which

9 is labelled ER/PR request and results, June

10 30th 2007.xls. She writes "Dr. Cook, attached

11 is a report from Dr. Mullen on the cases sent

12 in June '07. As per our phone conversation,

13 on a go-forward basis, if further testing is

14 required" and she spells out what's to be

15 done.

16 DR. MULLEN:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. Five steps. "I apologize for the delay in

20 getting these results out to you." Signed

21 Maria, and she then, if we look at page two in

22 the exhibits, this is a spreadsheet style

23 reporting.

24 DR. MULLEN:

25 A. Basically, I continued with the same format

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1 that I had used for the retro.  
 2 COFFEY, Q.C.:  
 3 Q. Okay. Now Doctor, while we're on it, here  
 4 when one compares the surgical numbers,  
 5 they're the same, slightly different order,  
 6 but they're the same. Here, there's a per  
 7 case amount and a dollar figure. See that?  
 8 DR. MULLEN:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. So the subject did come up, I believe, earlier  
 12 in the week. How much was the charge for  
 13 doing an ER and a PR and the interpretation,  
 14 do you know? It's here under label. It's  
 15 costs and is it per case?  
 16 DR. MULLEN:  
 17 A. The costs and the charge?  
 18 COFFEY, Q.C.:  
 19 Q. Yes. Did you know, are you involved in that  
 20 really at all?  
 21 DR. MULLEN:  
 22 A. No.  
 23 COFFEY, Q.C.:  
 24 Q. Okay, well -  
 25 DR. MULLEN:

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1 A. I mean, I can justify the--not say justify, I  
 2 can--that -  
 3 COFFEY, Q.C.:  
 4 Q. You can explain kind of how it's arrived at?  
 5 DR. MULLEN:  
 6 A. I can explain how it is arrived at, but I  
 7 can't -  
 8 COFFEY, Q.C.:  
 9 Q. But in terms of the amounts and so on, in  
 10 terms of setting the amount, that's not your -  
 11 DR. MULLEN:  
 12 A. That's Dr. Pritzker.  
 13 COFFEY, Q.C.:  
 14 Q. Dr. Pritzker's concern. Here, this is an e-  
 15 mail and just looking at this, because this  
 16 particular sheet just has the patients -  
 17 DR. MULLEN:  
 18 A. Oh, that would be the front sheet.  
 19 COFFEY, Q.C.:  
 20 Q. Yes.  
 21 DR. MULLEN:  
 22 A. That's basically justifying the number of--  
 23 sorry, if you go back one, go back to the  
 24 original. Okay. As we cross, everything is  
 25 the same, first name, last name, etcetera.

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1 Number of blocks, one, if we have to repeat  
 2 them. It's more to explain the technical  
 3 issues. The SMMS P63, if I had to  
 4 differentiate--if I did a special stain to  
 5 differentiate in situ from invasive, D2, it  
 6 should be D240 not D24. It's a marker for  
 7 lymphovascular invasion, to see if I see some  
 8 tissue and I'm not sure whether it's--it's  
 9 just more for completeness sake, and those  
 10 are--if those would be additional and OHIP--I  
 11 think these costs are billed, are based on the  
 12 OHIP technical and professional fees, what the  
 13 interpretation costs were. There's no  
 14 additional--I don't think there's any  
 15 additional charge for the professional, but  
 16 it's all the technical fees. I think they're  
 17 in the range of--special stains are about--the  
 18 immunohistochemistry stains are in the range  
 19 of 30--let me see, I did write it down.  
 20 They're 38.78 per stain.  
 21 COFFEY, Q.C.:  
 22 Q. And here, Doctor, this spreadsheet at page  
 23 two, I take it, with the ER and PR results -  
 24 DR. MULLEN:  
 25 A. Yes.

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1 COFFEY, Q.C.:  
 2 Q. - for each of these blocks, the internal  
 3 control reference, the fixation/processing  
 4 column, and so on. I take it, and the stainer  
 5 used, the ER dilution, the PR dilution and the  
 6 negative controls.  
 7 DR. MULLEN:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. I take it this is all material--certainly, and  
 11 the ER/PR, this would be all your information?  
 12 DR. MULLEN:  
 13 A. The only information that I would be entering  
 14 would be the tumor ER/PR ICNF. The others are  
 15 basically standard.  
 16 COFFEY, Q.C.:  
 17 Q. And that's here in these five columns?  
 18 DR. MULLEN:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. And this e-mail is from Maria Mendes to Dr.  
 22 Cook on July 4th, so the figures, for example,  
 23 the \$200 figures here per case -  
 24 DR. MULLEN:  
 25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. - that I take it is the financial

3 administrative end of it that she's taking

4 care of with Dr. Cook?

5 DR. MULLEN:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. Okay. Now if we could, please, Doctor, if we

9 could look, please, at Exhibit P-1835?

10 DR. MULLEN:

11 A. Okay, all right.

12 COFFEY, Q.C.:

13 Q. Now here there's a series of e-mails, June 20-

14 -I'm sorry, August 27th and 28th, 2007, and

15 the first of them, in point of time, is August

16 27th, 2007, 4:25 p.m. from yourself to Mona

17 Reid. Who's Ms. Reid?

18 DR. MULLEN:

19 A. She replaced Ms. Good. She's a technologist

20 who is in the research services area. She, at

21 the moment, is looking after the ER/PR or the

22 HER2 QA and other projects. So she would also

23 look after the ER/PR.

24 COFFEY, Q.C.:

25 Q. And here, you've written to her "do you have a

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1 spreadsheet for the new cases? The lab gave

2 me two today."

3 DR. MULLEN:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. And then she responds or responded the next

7 day, next morning saying "sorry about that. I

8 didn't realize you would be getting the cases

9 already. The entry you are needing is under

10 the heading" and she refers to a particular

11 heading, signed Mona. And then you went back

12 to her saying "please separate QA from review

13 cases."

14 DR. MULLEN:

15 A. Um-hm.

16 COFFEY, Q.C.:

17 Q. And then she, at 1:55 p.m. on August 28th said

18 to you, "I have divided the sheets. Give me a

19 call and we can incorporate his results into

20 the divided Excel files to send back to the

21 site" and I said she had responded to you. In

22 fact, she had responded to--Maria Mendes had

23 sent an e-mail to Mona Reid.

24 DR. MULLEN:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And this is for ER/PR requests and results,

3 August 22nd, 2007, revised.

4 DR. MULLEN:

5 A. Yes.

6 COFFEY, Q.C.:

7 Q. Doctor, looking at that, I'm going to take you

8 to page 3 of the exhibit and page 4, and we'll

9 go back to page 3 there, page 3 and 3 are

10 spreadsheets, and here there are--there's a

11 heading on the left-hand side, "Cases done as

12 of June, 2007"?

13 DR. MULLEN:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. And there's--there's a MSSSH07 121 number and

17 the cases done as of July, 2007 and cases done

18 as of August 1, 2007 and there's many more

19 entries here -

20 DR. MULLEN:

21 A. Yes.

22 COFFEY, Q.C.:

23 Q. Under that. What was this about, Doctor, and

24 it continues on to the next page? This long

25 list of cases here, what were these about, do

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1 you recall how it came about that you were now

2 going to deal -

3 DR. MULLEN:

4 A. At the time I didn't know, after a

5 conversation with you in December, I believe

6 these are the cases of the patients who had

7 died.

8 COFFEY, Q.C.:

9 Q. Okay.

10 DR. MULLEN:

11 A. Correct me if I'm wrong.

12 COFFEY, Q.C.:

13 Q. So from your perspective, Doctor, I take it

14 did you have--what, if anything, were you told

15 about this new group of cases in 2007?

16 DR. MULLEN:

17 A. Probably as much as I had been told before,

18 very little, I mean, as I said, we started off

19 with 50 and we're now up to 1100, so -

20 COFFEY, Q.C.:

21 Q. So here you were just simply, the cases to

22 your knowledge anyway, came into Mount Sinai

23 and you were being asked to read them.

24 DR. MULLEN:

25 A. Yes, that's correct.

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1 COFFEY, Q.C.:

2 Q. Read the results.

3 DR. MULLEN:

4 A. Yes, and if the e-mail, if I remember

5 correctly, if I can go back to the original e-

6 mail.

7 COFFEY, Q.C.:

8 Q. Yes.

9 DR. MULLEN:

10 A. I didn't want to confuse the QA from the

11 retrospective and I'm not sure if I, in this

12 e-mail I was referring to this retrospective

13 or if I was referring to the retrospective of

14 the patients who were requesting, I just

15 wanted the QA's separate from the review,

16 either initiated by St. John's or initiated by

17 the patient.

18 COFFEY, Q.C.:

19 Q. Now, exhibit, please, P-1836? Now, Doctor, in

20 terms of--I apologize, I'll just go back, I

21 apologize Registrar, if we could go back,

22 please to Exhibit P-1835 and just page 3?

23 Thank you. All of these cases here, cases

24 done as of August 1, 2007 and there's a whole

25 lot of blank space here, of course, to the

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1 right-hand side in these columns to, I suppose

2 for data entry.

3 DR. MULLEN:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. Were these cases eventually reported by

7 yourself?

8 DR. MULLEN:

9 A. Oh yes, oh yes, everything--we reported

10 everything. I'm just trying to think -

11 COFFEY, Q.C.:

12 Q. Now if I could just then return then to

13 Exhibit P-1836? And, Doctor, this is the

14 first e-mail here is one of November 6th, 207

15 from Barry Dyer, Eastern Health to Maria

16 Mendes, copied to Nash Denic. The subject is

17 "Retrospective Study verses Consultation". He

18 writes, "Hi Maria, how are things? We did not

19 receive any of the ER/PR stains, slides on

20 patients performed at Mount Sinai Hospital on

21 consultation requests, but we did receive the

22 ER/PR stain slides from the retrospective

23 study. We have been asked by our lawyers to

24 obtain these slides for review, as well we

25 have patients requesting their original ER/PR

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1 stain slides and the ER/PR stain slides

2 performed by Mount Sinai Hospital. We require

3 the slides as soon as possible." And he

4 concludes with "Let me know your position,

5 please respond to Dr. Denic as well, both of

6 us should be in the loop. Thanks, Barry."

7 And then on the same day at 2:35 p.m., Ms.

8 Mendes writes to Barry Dyer, copies it to Dr.

9 Denic and Dr. Pritzker, saying, "Hi Barry and

10 Dr. Denic. Dr. Denic I mentioned in my phone

11 conversation that I would give you a timeline

12 for the retrospective samples we have, we have

13 a total of 96 cases. Of these we have

14 stained, as of Thursday, 22 cases and Dr.

15 Maung is going to get started on reading these

16 cases. These cases are the STAT cases you had

17 sent me. This leaves a total of 74 cases

18 which I am hoping we can do about 10 cases per

19 week. Hopefully this will give you what you

20 need in terms of timelines. If not, give me a

21 call and I can see what else we can do on our

22 end. In regards to Barry's question, the

23 reason why you are not getting the slides from

24 the consults is that it is not our general

25 process to send the stain consults slides back

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1 to the client, we only send the blocks. In

2 the case of the retrospective study, we sent

3 the slides and blocks back as this was a

4 special case. I am therefore copying Dr.

5 Pritzker on this e-mail in order for him to

6 okay this deviation from our consult protocol.

7 Hope this answers all of your questions.

8 Signed Maria." So I take it that in terms of

9 what should be done with the slides for the

10 consults or for the retrospective, was to be

11 decided at whose level?

12 DR. MULLEN:

13 A. Well, our standard procedure, the

14 retrospective was "a research project", so it

15 was the client's expressed wish that they get

16 the blocks and slides back. For medical legal

17 reasons, material that is referred to us for

18 consultation, I have to keep a copy--I have to

19 keep the slides. I can issue--I issue the

20 report, I'll send the block back, but in our

21 files we keep the slides. I need them to

22 support any requests. They're our material,

23 they're in our possession and they're not

24 released unless we get an order to release

25 them. And that's our policy across the board,

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1 it's not specific to ER/PR, it's our policy  
 2 across the board.  
 3 COFFEY, Q.C.:  
 4 Q. Okay.  
 5 DR. MULLEN:  
 6 A. We do not release original slides, we do not  
 7 release material that's been processed at  
 8 Mount Sinai Hospital, we do not release the  
 9 block, we will cut slides and just to keep all  
 10 of the material.  
 11 COFFEY, Q.C.:  
 12 Q. Now, Doctor, if I could please, Registrar,  
 13 Exhibit P-1840. Doctor, this is a letter  
 14 dated April 14th, 2008 and it's addressed to  
 15 myself, Commission Co-counsel, Commission of  
 16 Inquiry on Hormone Receptor Testing and I  
 17 believe it's here, it's a letter/report from  
 18 yourself. Commissioner, before--because I'm  
 19 going to spend some time or have the Doctor go  
 20 through this and have him show some slides and  
 21 so on and explain slides and perhaps put some  
 22 of his earlier testimony in perspective in  
 23 looking at the slides. So I know it's a bit  
 24 early, it's five minutes early.  
 25 THE COMMISSIONER:

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1 Q. It was late to start in the sense that we  
 2 would normally break in about five or ten  
 3 minutes, so if you prefer to break at this  
 4 point and do this in the morning -  
 5 DR. MULLEN:  
 6 A. May I clarify one of the exhibits?  
 7 THE COMMISSIONER:  
 8 Q. You may indeed, yes.  
 9 DR. MULLEN:  
 10 A. In your retroconverters, I'm not sure which  
 11 one it was, there was a column--I just wanted  
 12 to, this may take -  
 13 THE COMMISSIONER:  
 14 Q. No, take your time.  
 15 COFFEY, Q.C.:  
 16 Q. You take your time, we've got the time.  
 17 THE COMMISSIONER:  
 18 Q. Whatever it is you need.  
 19 DR. MULLEN:  
 20 A. I'm trying to figure out which one would be  
 21 the retroconverters. Sorry -  
 22 COFFEY, Q.C.:  
 23 Q. Just a moment, Doctor, I'll probably be able  
 24 to go right to it.  
 25 DR. MULLEN:

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1 A. It's a short--there were the seven cases,  
 2 there was a column that gave results, I just  
 3 wanted to point out that those were the  
 4 initial results from -  
 5 MR. BROWNE:  
 6 Q. P-1822.  
 7 COFFEY, Q.C.:  
 8 Q. Yes, it's around there.  
 9 DR. MULLEN:  
 10 A. 1822, there it is.  
 11 THE COMMISSIONER:  
 12 Q. Thank you once again, Mr. Browne.  
 13 DR. MULLEN:  
 14 A. The original ER/PR, those were the results  
 15 that were reported in Newfoundland. Those are  
 16 not Mount Sinai results.  
 17 THE COMMISSIONER:  
 18 Q. Oh, okay.  
 19 DR. MULLEN:  
 20 A. And I think, either they filled in that form  
 21 or we found it on one of their forms and put  
 22 it in.  
 23 COFFEY, Q.C.:  
 24 Q. So here, just looking at this, there's a RS  
 25 number, page 2 of the exhibit, specimen

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1 number, names are redacted, there's a block  
 2 number, the region, which would be presumably  
 3 the location of origin. There's an original  
 4 ER, so the entries there would be -  
 5 DR. MULLEN:  
 6 A. I'm not sure if they provided those results or  
 7 we found them on a report, but as you looked  
 8 at all of my--I've never reported anything 25  
 9 to 30 or 50 to 60, that type of thing, so  
 10 those are Newfoundland results, and negative--  
 11 my issue we'll discuss tomorrow, I don't know  
 12 what negative means, is it less than one, less  
 13 than ten or less than 30? So I'm not sure  
 14 what those are.  
 15 COFFEY, Q.C.:  
 16 Q. And then there's an original PR in which the  
 17 same thing would apply?  
 18 DR. MULLEN:  
 19 A. Same issue, yes.  
 20 COFFEY, Q.C.:  
 21 Q. Same issue. The MSER, which would be Mount  
 22 Sinai ER, that would be your figures.  
 23 DR. MULLEN:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

1 Q. The MSPR would be your figure.  
 2 DR. MULLEN:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. And the MS tumor would be Mount Sinai tumor,  
 6 your classification.  
 7 DR. MULLEN:  
 8 A. Yes, and then the other two being the same--  
 9 it's just I wanted to point out those are not--  
 10 -it's not that we changed our diagnosis, those  
 11 were the originals and this was what we had  
 12 stained. And that's, I think everything else  
 13 is -  
 14 THE COMMISSIONER:  
 15 Q. All right, well thank you. So we're in a  
 16 position to adjourn then until tomorrow  
 17 morning at 9:30. Mr. Eaton, would you please  
 18 convey to Ms. O'Dea our very best. As I  
 19 understand it, a baby girl was born this  
 20 morning.  
 21 EATON, Q.C.:  
 22 Q. She said she might be in tomorrow.  
 23 THE COMMISSIONER:  
 24 Q. I'm just sitting her wondering if that baby  
 25 girl is going to decide to become a

1 CERTIFICATE  
 2 I, Judy Moss, hereby certify that the foregoing is  
 3 a true and correct transcript in the matter of the  
 4 Commission of Inquiry on Hormone Receptor Testing,  
 5 heard on the 26th day of June, A.D., 2008 before  
 6 the Honourable Justice Margaret A. Cameron,  
 7 Commissioner, at the Commission of Inquiry, St.  
 8 John's, Newfoundland and Labrador and was  
 9 transcribed by me to the best of my ability by  
 10 means of a sound apparatus.  
 11 Dated at St. John's, Newfoundland and Labrador  
 12 this 26th day of June, A.D., 2008  
 13 Judy Moss

1 pathologist on the basis of all the  
 2 information she has heard up this point. But  
 3 do give her and the family our best regards.  
 4 Thank you very much. 9:30 in the morning  
 5 Upon conclusion at 4:47 p.m.

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