

COMMISSION OF INQUIRY  
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 29, 2008

Appearances:

- Bernard Coffey, Q.C. . . . . . Commission Co-counsel
- Sandra Chaytor, Q.C. . . . . . 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
- Darlene Russell. . . . . Members of the Breast Cancer  
. . . . . Testing Class Action
- Mark Pike . . . . . NL Medical Association
- Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
- Blair Pritchett. . . . . Central, Western and Labrador-Grenfell  
. . . . . Regional Integrated Health Authorities

1 THE COMMISSIONER:  
 2 Q. Mr. Coffey.  
 3 DR. BEVERLEY CARTER, RESUMES STAND, EXAMINATION BY  
 4 BERNARD COFFEY, Q.C.  
 5 COFFEY, Q.C.:  
 6 Q. Good morning, Commissioner. Good morning, Dr.  
 7 Carter.  
 8 DR. CARTER:  
 9 A. Good morning.  
 10 COFFEY, Q.C.:  
 11 Q. If we could bring up, please, before we go  
 12 back to May of 2005, Doctor, and yesterday, a  
 13 number of times you said it would be helpful,  
 14 of course, to look at the documents, and I'm  
 15 going to take you through them. Before we do  
 16 that, Exhibit P-0046, please? This is Dr.  
 17 Banerjee's October 2005 report and we finished  
 18 off with that, or we were looking at that when  
 19 we finished yesterday. Doctor, just to  
 20 conclude my review of this with you, under the  
 21 heading "other system flaws observed" Dr.  
 22 Banerjee has noted "a lack of dedicated  
 23 immunohistochemistry technologists" and  
 24 "rotation system is used. This prevents the  
 25 technologists from gaining in-depth expertise

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- Certificate

1 and troubleshooting." I take it, Doctor, that  
 2 at the time, in the middle of 2005, in the  
 3 fall of '05, you would have agreed with that?  
 4 DR. CARTER:  
 5 A. Yes, I would.  
 6 COFFEY, Q.C.:  
 7 Q. And as well, to be fair here, the idea of  
 8 dedicating immunohistochemistry technologists,  
 9 had that, to your knowledge, been raised  
 10 before at times in the past?  
 11 DR. CARTER:  
 12 A. I think it had been raised at times in the  
 13 past that the technologists should  
 14 subspecialize, if you will, especially in more  
 15 difficult areas.  
 16 COFFEY, Q.C.:  
 17 Q. "A lack of an officially designated  
 18 pathologist as director of  
 19 immunohistochemistry service. Technologists  
 20 thus getting conflicting feedback from a large  
 21 number of pathologists. There is no  
 22 accountability for the quality of the  
 23 service." Dr. Carter, you, of course, knew  
 24 Dr. Ejeckam?  
 25 DR. CARTER:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. But you were not stationed at the General  
 4 Hospital, except for -  
 5 DR. CARTER:  
 6 A. During my locums, I was.  
 7 COFFEY, Q.C.:  
 8 Q. - your locums. Doctor, from your perspective,  
 9 at the time, can you tell us, please, whether  
 10 you would have seen Dr. Ejeckam, at the time,  
 11 as responsible for immunohistochemistry?  
 12 DR. CARTER:  
 13 A. I certainly would have seen him as the point  
 14 person for immunohistochemistry, the person  
 15 that you would go to for, you know, problems  
 16 with immunohistochemistry or even questions  
 17 about immunohistochemistry that we, as  
 18 pathologists, would have. Whether or not he  
 19 had responsibility for what went on in the  
 20 laboratory, I'm not certain.  
 21 COFFEY, Q.C.:  
 22 Q. And you, in fact, yourself, I take it, in July  
 23 of '05 when you got involved in your effort  
 24 that you described yesterday, you described  
 25 yesterday your concerns or challenges that you

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1 faced even when you were told that certain  
 2 technologists or administrative staff would be  
 3 yours to utilize.  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. In fact, that was problematic for you?  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. In that context. So as far as you knew, I  
 12 take it, he was the point person, but he would  
 13 not have been officially designated, at least  
 14 to your knowledge?  
 15 DR. CARTER:  
 16 A. Not to my knowledge.  
 17 COFFEY, Q.C.:  
 18 Q. And I'm asking you this because trying to get  
 19 some sense of staff pathologists who happen to  
 20 be in the other physical institution in the  
 21 City at the time, across town at St. Clare's,  
 22 that's all, so the Commissioner can get some  
 23 sense of what a practising pathologist at the  
 24 time thought. "A lack of standard operating  
 25 procedures for grossing, fixation, tissue

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1 processing, block selection, positive control  
 2 block selection, method optimization through  
 3 systematic titration, incubation time and  
 4 antigen retrieval time for each analyte."  
 5 When you checked at the time, Doctor, were  
 6 there any such standard operating procedures?  
 7 DR. CARTER:  
 8 A. I don't think that there were any. If they  
 9 were, I was not able to get access to them.  
 10 COFFEY, Q.C.:  
 11 Q. Number four, "lack of subspecialization among  
 12 pathologists, leading to the lack of in-depth  
 13 knowledge about IHC technical interpretation  
 14 details and pitfalls." Doctor, first of all,  
 15 in relation to this, "lack of  
 16 subspecialization among pathologists," at that  
 17 time, was there?  
 18 DR. CARTER:  
 19 A. In 2005?  
 20 COFFEY, Q.C.:  
 21 Q. Yes.  
 22 DR. CARTER:  
 23 A. Yes, there would have been some  
 24 subspecialization. I was working there. We  
 25 had a pediatric pathologist, forensic. Some

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1 people had a great interest in hemapath.  
 2 COFFEY, Q.C.:  
 3 Q. Jane Baron, I take it, was -  
 4 DR. CARTER:  
 5 A. Neuropathologist.  
 6 COFFEY, Q.C.:  
 7 Q. - neuropathologist. So there was some  
 8 subspecialization?  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. But there were other areas, I take it, in  
 13 which, for example, breast pathology, you  
 14 would have seen, described yourself as being  
 15 particularly interested in that?  
 16 DR. CARTER:  
 17 A. Yes, so I would have been a point person for  
 18 breast pathology.  
 19 COFFEY, Q.C.:  
 20 Q. Doctor, the reference to "a lack of in-depth  
 21 knowledge about IHC technical and  
 22 interpretation details and pitfalls," bearing  
 23 in mind, at least in respect of the review  
 24 that you conducted in the summer of '05, what  
 25 you saw on the original slides, that grouping

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1 of slides you looked at, your references  
 2 yesterday to lack of internal controls in some  
 3 instances or internal controls not staining,  
 4 from your perspective, did that reflect  
 5 anything about the level of knowledge  
 6 concerning that particular aspect of  
 7 pathology?  
 8 DR. CARTER:  
 9 A. I didn't assess the knowledge of them. I can  
 10 state that I saw that there were some problems  
 11 with interpretation.  
 12 COFFEY, Q.C.:  
 13 Q. Interpretation, and we'll deal with those  
 14 later on this morning. And then the reference  
 15 to "a disconnect between laboratory program  
 16 director, division manager, clinical site  
 17 chief and laboratory director in decision  
 18 making."  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. "The organizational charts indicate a complete  
 23 separation of reporting structures in the  
 24 technical and clinical streams with no  
 25 matrixed cross reporting between technical and

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1 medical leadership. This leads to frustration  
 2 and resentment on both sides, lack of  
 3 communication, lack of accountability and lack  
 4 of buy in. The division manager and program  
 5 director appear enthusiastic and keen on  
 6 modernizing the lab, but their efforts have  
 7 not been appreciated by the pathologists and  
 8 work flow changes have not been mapped out and  
 9 implemented. Example, the Sakura Express  
 10 implementation has failed due to lack of  
 11 planning work flow changes. Superior outcomes  
 12 could be achieved by ensuring better linkages  
 13 between technical, managerial and medical  
 14 leadership." Now there's a fair amount of  
 15 information in this.  
 16 DR. CARTER:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. Doctor, dealing with the issue of what's  
 20 described here as a disconnect, in effect,  
 21 between the clinical side of the lab and the  
 22 technological side of the lab, from your  
 23 perspective, was there, if not a disconnect,  
 24 certainly some gap?  
 25 DR. CARTER:

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1 A. Yes, in my experience with the--between the  
 2 pathologists and lab administration more so  
 3 than from pathologists and technologists.  
 4 COFFEY, Q.C.:  
 5 Q. And the reference here, Doctor, to "the  
 6 division manager and program director appear  
 7 enthusiastic and keen on modernizing the  
 8 laboratory," Doctor, and there's a reference  
 9 to "but their efforts have not been  
 10 appreciated by the pathologists." Can you  
 11 tell me, please, or tell us, please, from your  
 12 perspective, what your view was in terms of  
 13 modernizing the lab, your own view?  
 14 DR. CARTER:  
 15 A. I mean, I would be interested in keeping up  
 16 and modernizing the laboratory in a general  
 17 sense.  
 18 COFFEY, Q.C.:  
 19 Q. Your concern, and we'll deal with this a  
 20 little bit more later I expect this morning,  
 21 you referred yesterday to, in this August 1st  
 22 meeting, this reference to the DAKO machine  
 23 and the changeover to the Ventana, kind of  
 24 explaining the results changes.  
 25 DR. CARTER:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. And you have indicated to the Commissioner  
 4 that you didn't accept that. You knew that,  
 5 from your perspective, that was just not--that  
 6 was incorrect?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. Would you agree that the Ventana is a newer,  
 11 more modern version of an auto stainer?  
 12 DR. CARTER:  
 13 A. Than the DAKO semi-automatic, yes.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, and did you have anything against the  
 16 Ventana itself?  
 17 DR. CARTER:  
 18 A. No.  
 19 COFFEY, Q.C.:  
 20 Q. If it was--if it made people's -  
 21 DR. CARTER:  
 22 A. Lives easier, as long as it was correctly  
 23 optimized and used, no, I have no problem with  
 24 Ventana.  
 25 COFFEY, Q.C.:

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1 Q. And in order to correctly optimize and utilize  
 2 it, what, from your perspective, is required?  
 3 DR. CARTER:  
 4 A. I mean, there's a huge litany of things that  
 5 you need to do from basic equipment  
 6 maintenance and servicing. In terms of  
 7 estrogen receptor and progesterone receptor,  
 8 to use the fully automated, and I'm not an  
 9 expert in this, system you would need still to  
 10 validate your antibodies for your cases. You  
 11 would need to optimize things like antibody  
 12 concentration, buffer used, time of antibody  
 13 exposure, type of antigen retrieval or epitope  
 14 retrieval. So you would need to optimize  
 15 those for your system. With semi-auto--with  
 16 automated and some semi-automated platforms,  
 17 it would come with a list of manufacturer's  
 18 instructions as to how to use it, but you  
 19 can't just blindly follow those. You have to  
 20 optimize it for your locality.  
 21 COFFEY, Q.C.:  
 22 Q. And I take it, Doctor, in that regard, the  
 23 process of optimization requires knowledge?  
 24 DR. CARTER:  
 25 A. Yes.

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1 COFFEY, Q.C.:  
 2 Q. In-depth knowledge, in fact?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. And at times, can it be a tedious process?  
 7 DR. CARTER:  
 8 A. I've never done it, but I understand, yes,  
 9 that it can be.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor, the idea of "attendance by both  
 12 medical and technical staff at conferences  
 13 with a focus on new technology," or for that  
 14 matter, I take it, new techniques, you would  
 15 have been in favour of that?  
 16 DR. CARTER:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. He ends that paragraph six by saying  
 20 "consensus driven innovation should be the  
 21 goal." Doctor, at the time, in the middle of  
 22 2005, into the fall of '05, from your  
 23 perspective, who had the final decision making  
 24 authority in terms of equipment acquisition?  
 25 DR. CARTER:

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1 A. Mr. Gulliver.  
 2 COFFEY, Q.C.:  
 3 Q. And I take it that would be so even if the  
 4 equipment chosen and the manner in which it  
 5 was utilized could affect the pathologist's  
 6 work?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. And finally, seven, "the department needs  
 11 dedicated pathologist assistants to ensure  
 12 gross room consistency and tissue handling,  
 13 trimming and fixation," and you were in favour  
 14 of pathology assistants?  
 15 DR. CARTER:  
 16 A. Agree, yes.  
 17 COFFEY, Q.C.:  
 18 Q. Doctor, and we've heard that there are four or  
 19 five pathologists assistants.  
 20 DR. CARTER:  
 21 A. I think there are four.  
 22 COFFEY, Q.C.:  
 23 Q. Four now. Before the pathologists assistants  
 24 were put in place, at any one time, how many  
 25 pathologists, staff or residents, might be

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1 involved, different people might be involved  
 2 in grossing?  
 3 DR. CARTER:  
 4 A. On a particular day you mean?  
 5 COFFEY, Q.C.:  
 6 Q. No, over a period of time?  
 7 DR. CARTER:  
 8 A. I think there is 19 pathologists in St.  
 9 John's, and depending on what year you're  
 10 talking about, our residency program, since  
 11 I've been here, I think it's had a maximum of  
 12 eight residents.  
 13 COFFEY, Q.C.:  
 14 Q. So it could be upwards of 25-26 different  
 15 pathologists who would, for example, be called  
 16 upon in the run of a year to gross breast  
 17 tissue?  
 18 DR. CARTER:  
 19 A. Some of those wouldn't. The pediatric  
 20 pathologist and neuropathologist, but -  
 21 COFFEY, Q.C.:  
 22 Q. So down around 20.  
 23 DR. CARTER:  
 24 A. - I think there's 15 general.  
 25 COFFEY, Q.C.:

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1 Q. 15 general and about certainly five or so of  
 2 the residents, perhaps all of the residents?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. And from your perspective, what is the down  
 7 side in having 20 plus as opposed to four  
 8 people doing the grossing?  
 9 DR. CARTER:  
 10 A. I don't think there's a down side to the  
 11 number of people doing it, as long as  
 12 everybody's doing the same thing.  
 13 COFFEY, Q.C.:  
 14 Q. And that's what I was going to ask you about  
 15 then. What, in your experience, and you've  
 16 worked elsewhere, if there's no written  
 17 protocol or procedure for that within a  
 18 particular institution or region, what is your  
 19 experience in terms of whether or not all  
 20 pathologists and pathology residents gross  
 21 specimens in the same way, or is there  
 22 significant variation at times?  
 23 DR. CARTER:  
 24 A. I'm just trying to think back to when I was at  
 25 McMaster. I think all of us handled the

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1 specimens in basically the same way. I don't  
 2 recall there being any, you know, major  
 3 outliers when I was at McMaster, but I haven't  
 4 really thought about it until just right now.  
 5 COFFEY, Q.C.:  
 6 Q. How about in St. John's?  
 7 DR. CARTER:  
 8 A. In St. John's, was -  
 9 COFFEY, Q.C.:  
 10 Q. Were there differences, significant  
 11 differences sometimes?  
 12 DR. CARTER:  
 13 A. Things that I would have been aware of were  
 14 that some people would prefer to cut their  
 15 case on the day of, and other people would fix  
 16 it overnight, and you know, prepare it the  
 17 next day, but I think most people would fix it  
 18 overnight here.  
 19 COFFEY, Q.C.:  
 20 Q. What is the--what are the potential effects of  
 21 choosing one over the other?  
 22 DR. CARTER:  
 23 A. Well, there's a standardized fixation protocol  
 24 for large specimens, if we're talking about  
 25 lumpectomies and mastectomies, so you will

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1 want to make sure that the tissue is exposed  
 2 to formalin for a certain period of time,  
 3 usually we'll say eight to 24 hours. So you  
 4 would have to know what time your processor  
 5 was going on board. That's when the formalin  
 6 fixation would end. I should say, the only  
 7 pathologist I'm aware of that preferred to cut  
 8 his tissue that day, he would place it in  
 9 cassettes and then fix the cassettes  
 10 overnight. He didn't place it on the  
 11 processor. I'm not aware of anybody cutting  
 12 it and putting it through right away.  
 13 COFFEY, Q.C.:  
 14 Q. So would, from your perspective, would that  
 15 really make any difference, if you cut it and  
 16 then left it overnight to fix?  
 17 DR. CARTER:  
 18 A. Well, we've debated this. I think it can have  
 19 some subtle differences.  
 20 COFFEY, Q.C.:  
 21 Q. Potentially?  
 22 DR. CARTER:  
 23 A. Potentially, but I mean, you can have somebody  
 24 come up here and argue just the opposite.  
 25 COFFEY, Q.C.:

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1 Q. The idea of having everyone doing it in the  
 2 same manner, for example, yesterday you  
 3 referred to the idea that sometimes tissue  
 4 might not be sliced thin enough or small  
 5 enough to fit into the cassettes.  
 6 DR. CARTER:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. In the optimum manner?  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. And might some pathologists then, because  
 14 there's no one particular way of doing it, end  
 15 up with or tend to end up with specimens that  
 16 were a bit too thick?  
 17 DR. CARTER:  
 18 A. They would be a bit too thick but, I mean, the  
 19 cassettes themselves would limit because they  
 20 are small and they do close, so you couldn't  
 21 put in a five-centimetre piece of tissue. I  
 22 mean, you just couldn't do it. So you're  
 23 talking about differences between a two-  
 24 millimetre cut and a five-millimetre cut.  
 25 COFFEY, Q.C.:

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1 Q. But the--Dr. Banerjee here, elsewhere I  
 2 believe, earlier in his report, does refer to,  
 3 and I think you as well yesterday referred to  
 4 the idea that at times the tissue would--  
 5 perhaps was too thick for the particular  
 6 cassette?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. And with the potential negative consequence?  
 11 DR. CARTER:  
 12 A. Negative impact, yes.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, with respect to residents, just as an  
 15 aside here, who teaches a resident, for  
 16 example, the appropriate way to gross a breast  
 17 specimen?  
 18 DR. CARTER:  
 19 A. When they're first year residents, they would  
 20 be grossing under the supervision of a  
 21 pathologist, so just whoever they happen to be  
 22 working with that day in whatever rotation  
 23 they were on. So if they were at St. Clare's,  
 24 they would do it with myself or Dr. Elms, Dr.  
 25 Denic, Dr. Cook, and they would observe us and

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1 imitate us. For the most part, you see one,  
 2 you do one. There's also standard textbooks  
 3 of grossing tissues and also as part of their  
 4 academic half day, different pathologists  
 5 would be teaching in different topics in a  
 6 didactic form, giving lectures. So then areas  
 7 of grossing would be touched upon.  
 8 COFFEY, Q.C.:  
 9 Q. So I take it that it might then vary from  
 10 staff pathologist to staff pathologist,  
 11 depending upon his or her approach?  
 12 DR. CARTER:  
 13 A. Yes, there would be some variability.  
 14 COFFEY, Q.C.:  
 15 Q. Some variability?  
 16 DR. CARTER:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. The residents might be exposed, in respect of  
 20 a particular type of specimen, to just one,  
 21 that particular pathologist of the day, staff  
 22 pathologist's technique or if it was you one  
 23 day and another doctor, another staff  
 24 pathologist the next week, same sort of  
 25 specimen, they might be taught slightly

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1 different versions of--or different versions,  
 2 in fact?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. Doctor, I'm going to return now, if I could,  
 7 as I pointed out, to the exhibits themselves  
 8 and I'll allow you to, at times focus on and  
 9 perhaps elaborate on certain things in them.  
 10 Exhibit P-0067, please? Doctor, this is the  
 11 letter of May 24th, 2005 that Dr. Cook wrote  
 12 to Dr. Williams. Did Dr. Cook consult you  
 13 about the contents of this, do you recall?  
 14 DR. CARTER:  
 15 A. I don't--he never showed me the letter and  
 16 asked me did I agree with it, but I mean, we  
 17 would have been talking back and forth.  
 18 COFFEY, Q.C.:  
 19 Q. The second paragraph refers to--well, first of  
 20 all, go back a bit. He opens by referring to  
 21 a May 11, 2005 phone call from Dr. Joy  
 22 McCarthy.  
 23 DR. CARTER:  
 24 A. Um-hm.  
 25 COFFEY, Q.C.:

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1 Q. And you've indicated that sometime before May  
 2 17th, 2005, when you attended a meeting,  
 3 sometime before that, you had spoken to Dr.  
 4 Cook about Peggy Deane's case?  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Did you have any understanding at the time as  
 9 to when the retest of Ms. Deane's tissue  
 10 sample had occurred? You spoke to Dr. Cook.  
 11 Did you get any sense from him as to -  
 12 DR. CARTER:  
 13 A. I would have assumed it was around that time.  
 14 COFFEY, Q.C.:  
 15 Q. And your recollection is that it was about how  
 16 long before the meeting?  
 17 DR. CARTER:  
 18 A. Before the May 17th meeting?  
 19 COFFEY, Q.C.:  
 20 Q. Yes, that he spoke to you.  
 21 DR. CARTER:  
 22 A. I'm not sure. I wouldn't be able to say. I  
 23 would assume it was around that time.  
 24 COFFEY, Q.C.:  
 25 Q. At the time he spoke to you, other than asking

Page 25

1 you to look at the slides, and as you pointed  
 2 out, confirming from your perspective what he  
 3 already knew himself -  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. - at that point, were you--did you get any  
 8 sense that anything other than looking at the  
 9 slides was expected of you? Were you expected  
 10 to act upon this in any way at that point?  
 11 DR. CARTER:  
 12 A. No.  
 13 COFFEY, Q.C.:  
 14 Q. Other than to attend the May 17th, 2005  
 15 meeting, were you asked to do anything before  
 16 that?  
 17 DR. CARTER:  
 18 A. As I said yesterday, I think there was at  
 19 least one, I thought there were two other  
 20 patients that had been identified through the  
 21 medical oncologists, Dr. McCarthy and Dr.  
 22 Laing. There was probably, you know,  
 23 discussions amongst us all, you know, what's  
 24 going on and what does this mean.  
 25 COFFEY, Q.C.:

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1 Q. Identified, I take it, as one or two patients  
 2 other than Ms. Deane identified as invasive  
 3 lobular or with some particular type of cancer  
 4 that should be -  
 5 DR. CARTER:  
 6 A. Something about them that clinically had made  
 7 the oncologist think that maybe this case  
 8 would be like Ms. Deane's case.  
 9 COFFEY, Q.C.:  
 10 Q. And these cases, the oncologists were telling  
 11 you the original reports were negative?  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. And there was something about them and so at  
 16 that point, did they say anything else, do you  
 17 recall, about what they knew or understood  
 18 about this at the time?  
 19 DR. CARTER:  
 20 A. Who is they?  
 21 COFFEY, Q.C.:  
 22 Q. They, the oncologists, Drs. Laing and  
 23 McCarthy.  
 24 DR. CARTER:  
 25 A. That they were--you know, that they were

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1 worried that this might mean something bigger,  
 2 that they were thinking back, you know,  
 3 retrospectively about cases that they had had  
 4 that, you know, they wanted to have a look at  
 5 again.  
 6 COFFEY, Q.C.:  
 7 Q. So at that point, do you recall, was there any  
 8 discussion or were you told about Dr.  
 9 Ejeckam's intervention in '03?  
 10 DR. CARTER:  
 11 A. I would have been told about it somewhere  
 12 around this time, but I wouldn't be able to  
 13 pin it down for you, but this summer is when  
 14 I--spring, I guess, and summer, is when I  
 15 would have become aware of that.  
 16 COFFEY, Q.C.:  
 17 Q. The reference to the May 17th meeting, before  
 18 I get into that though, at the time you spoke  
 19 to Doctors Laing and McCarthy, did they, at  
 20 that point, identify to you or suggest to you  
 21 perhaps that there was a particular period  
 22 that they were concerned about?  
 23 DR. CARTER:  
 24 A. Not that I recall, a time period, no.  
 25 COFFEY, Q.C.:

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1 Q. And Doctor, in Peggy Deane's case, did you  
 2 have any understanding at that point as to who  
 3 the original pathologist had been?  
 4 DR. CARTER:  
 5 A. I don't think I had on the day that I was  
 6 shown them, you know. It was just sort of  
 7 casual.  
 8 COFFEY, Q.C.:  
 9 Q. How about afterwards?  
 10 DR. CARTER:  
 11 A. But very shortly afterward, because I think  
 12 the case was brought to that pathologist's  
 13 attention.  
 14 COFFEY, Q.C.:  
 15 Q. And did you speak to--it's Dr. Ford Elms.  
 16 He's going to be here.  
 17 DR. CARTER:  
 18 A. Okay.  
 19 COFFEY, Q.C.:  
 20 Q. Did you speak to Dr. Elms about that at the  
 21 time?  
 22 DR. CARTER:  
 23 A. I don't remember, you know, a particular  
 24 conversation, but I didn't not speak to him.  
 25 I mean, we were conversing freely, you know,

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1 about this issue in our department.  
 2 COFFEY, Q.C.:  
 3 Q. And in the course of talking about that, I  
 4 take it, so that would be Dr. Elms, Dr. Denic,  
 5 yourself, Dr. Cook, who else was?  
 6 DR. CARTER:  
 7 A. At the time, it would have been Dr. Naghibi  
 8 and Dr. Wadhwa.  
 9 COFFEY, Q.C.:  
 10 Q. At that stage, like in the spring of 2005,  
 11 what if anything was -- do you recall what was  
 12 said by the other pathologists about their  
 13 views as to what might have happened? Did  
 14 they have any -- did you get any sense at  
 15 time, because some of this would have predated  
 16 your time.  
 17 DR. CARTER:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. Some of it would and some of it wouldn't.  
 21 DR. CARTER:  
 22 A. I don't recall specific conversations directly  
 23 related to that. I know that Dr. Elms, you  
 24 know, looked at the slides and was quite  
 25 concerned and was trying to find those

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1 answers, but I don't recall a moment when we  
 2 all sat and talked about that.  
 3 COFFEY, Q.C.:  
 4 Q. Now the May 17th meeting, you went to the  
 5 meeting why, why were you asked to go?  
 6 DR. CARTER:  
 7 A. As a breast pathologist.  
 8 COFFEY, Q.C.:  
 9 Q. And you were there at the request of Dr. Cook?  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. And the purpose of the meeting from your  
 14 understanding was what?  
 15 DR. CARTER:  
 16 A. To discuss the issue that we had had three  
 17 conversions, what the oncologists thought  
 18 about that and the cases that they had  
 19 experienced. I guess my role would be to talk  
 20 about different things in the lab, including  
 21 technical and pathology that could be sources  
 22 of interest, and the purpose of the meeting  
 23 was to let all parties know where everybody  
 24 stood and to make a plan as to how we were  
 25 going to begin our discovery of this issue.

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1 COFFEY, Q.C.:  
 2 Q. Doctor, at the time, and we've heard from Mr.  
 3 Dyer as to what he recalled about what was --  
 4 some of what was said to him at the meeting.  
 5 At the time of that meeting, did you have  
 6 anything to say to Mr. Dyer yourself that you  
 7 recall?  
 8 DR. CARTER:  
 9 A. It was a general discussion of what the  
 10 problem was and what our plan was going to be  
 11 to look at it.  
 12 COFFEY, Q.C.:  
 13 Q. And he has indicated that at least one of the  
 14 oncologists made a very directly pointed  
 15 remark at him?  
 16 DR. CARTER:  
 17 A. No, I don't recall that happening.  
 18 COFFEY, Q.C.:  
 19 Q. You know the remark I'm talking about?  
 20 DR. CARTER:  
 21 A. Yes, that he was personally responsible for  
 22 what had happened.  
 23 COFFEY, Q.C.:  
 24 Q. Or it's his fault or his lab's fault.  
 25 DR. CARTER:

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1 A. I recall this as a working meeting. It was  
 2 pretty uneventful except for we came up with a  
 3 plan.  
 4 COFFEY, Q.C.:  
 5 Q. Doctor, if we could look, please, at page  
 6 three of the letter. As you pointed out,  
 7 there's a plan you came up with.  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. And this notes here at the top of the page,  
 12 "At the conclusion of the May 17th meeting, it  
 13 was decided to test all negative ER and PRs  
 14 for the year 2002 and possibly 2001", and Dr.  
 15 Cook writes, "I have no idea at this point in  
 16 time in knowing whether there are a few  
 17 isolated cases or whether we are dealing with  
 18 a much bigger issue. For now we've agreed  
 19 that if there's a receptor conversion that the  
 20 oncologist will inform the patient that we  
 21 have retested the ER/PR receptors under our  
 22 newer more sensitive technique. However, if  
 23 it is identified that we have a much more  
 24 significant conversion factor problem  
 25 involving many patients, we will need to seek



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1 advice and guidance from QI on how best to  
 2 disclose this information as this involves  
 3 breast cancer patients across the province".  
 4 So I take it, Doctor, even by that point in  
 5 time it was recognized that perhaps it wasn't  
 6 limited to St. John's potentially?  
 7 DR. CARTER:  
 8 A. Yes, because we tested for everybody across  
 9 the province.  
 10 COFFEY, Q.C.:  
 11 Q. At that point in time, Doctor, I take it from  
 12 your perspective, anyway, the retesting would  
 13 occur using the Ventana machine?  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Because the retest at that point, the one,  
 18 two, or three patients who had been retested  
 19 up to this point in time had been retested  
 20 using the Ventana?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Doctor, he does go on to say that, "In  
 25 closing, I would like to make the following

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1 recommendations for immunoperoxidase testing.  
 2 One is the immediate establishment of an  
 3 external proficiency testing and monitoring  
 4 program for immunoperoxidase testing", and  
 5 that suggests that there was not such external  
 6 proficiency testing and monitoring for  
 7 immunoperoxidase testing at that point.  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. There was not up to that point in time?  
 12 DR. CARTER:  
 13 A. I wouldn't have direct knowledge of that, but  
 14 I don't think so.  
 15 COFFEY, Q.C.:  
 16 Q. And coming out of that meeting, Doctor, what  
 17 was, from your perspective, expected of you,  
 18 yourself, if anything at that point?  
 19 DR. CARTER:  
 20 A. That I would begin to investigate the problem,  
 21 to try to outline, in fact, if we had a  
 22 problem. As I briefly said yesterday, you may  
 23 find out that this all occurred on one  
 24 Saturday.  
 25 COFFEY, Q.C.:

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1 Q. Sure.  
 2 DR. CARTER:  
 3 A. You know, something like that. So to try to  
 4 put together a descriptive sort of analysis of  
 5 starting with the NIDAS case and just moving  
 6 out from there to see if we had any issues --  
 7 COFFEY, Q.C.:  
 8 Q. Sorry, starting with the --  
 9 DR. CARTER:  
 10 A. The index case.  
 11 COFFEY, Q.C.:  
 12 Q. Index. I just didn't hear.  
 13 DR. CARTER:  
 14 A. NIDAS, I said, index, you know, to start at  
 15 NIDAS and to move out from it, and I think we  
 16 initially decided that we would do Eastern  
 17 Health because it was just physically easier,  
 18 and then possibly go into 2001 if we didn't  
 19 have enough numbers to draw any sort of  
 20 conclusions. I mean, at that point I would  
 21 have required an epidemiologist or somebody  
 22 familiar with statistics to help, but it was  
 23 just to start a descriptive.  
 24 COFFEY, Q.C.:  
 25 Q. And going away then -- so that was your

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1 understanding of your role?  
 2 DR. CARTER:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. It anticipates, the letter does, that  
 6 potentially there might be further  
 7 conversions, anticipates that?  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. If there's a receptor conversion, the  
 12 oncologist would inform the patient?  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. So I take it the understanding was that as any  
 17 retesting occurs, that the oncologist would be  
 18 told the results?  
 19 DR. CARTER:  
 20 A. Yes, we would tell the oncologist directly.  
 21 We have some form letters that we would send  
 22 over so that they would have advance notice.  
 23 Usually when you do an estrogen receptor, you  
 24 report it and then just upload it into  
 25 Meditec, and then the onus is sort of on the

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1 clinician to check their own work, but in this  
 2 case we would send the -- fax the results  
 3 directly to one of the oncologists so they  
 4 could pull all the retrospective cases and  
 5 then make appointments as needed with the  
 6 patients and inform them of what had happened.  
 7 COFFEY, Q.C.:  
 8 Q. And, Doctor, we will see letters here, there  
 9 are three of them where there's a large --  
 10 you're writing, yourself and Dr. Cook are  
 11 writing letters to Dr. McCarthy.  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. There are a large number of patients listed in  
 16 each letter.  
 17 DR. CARTER:  
 18 A. Twenty-five plus.  
 19 COFFEY, Q.C.:  
 20 Q. Yes, a large number in the sense of certainly  
 21 more than five or six at a time.  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. What I'm getting at here, Doctor, is this,

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1 that June 29th letter --  
 2 DR. CARTER:  
 3 A. Okay.  
 4 COFFEY, Q.C.:  
 5 Q. The 25 patients. Would Dr. McCarthy or the  
 6 attending oncologist, if it wasn't Dr.  
 7 McCarthy, already have been told those results  
 8 before that for many of those patients?  
 9 DR. CARTER:  
 10 A. For many of them, I think that she would. I  
 11 mean, I can't state it with any certainty, but  
 12 I know that we would be talking on the  
 13 telephone.  
 14 COFFEY, Q.C.:  
 15 Q. The point would be that you might very well  
 16 tell the doctor verbally, and you'd make a  
 17 note in Meditec at times the reference --  
 18 sometimes there'd be references to the fact  
 19 that --  
 20 DR. CARTER:  
 21 A. I would have to go back and look at each case  
 22 and examine it, but, yes, I think if they had  
 23 requested, you know, someone that they  
 24 expected, and I had gotten a report, I would  
 25 let them know. I may have reported it and

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1 then we made up a form letter.  
 2 COFFEY, Q.C.:  
 3 Q. So then what happened, Doctor? You start out.  
 4 You leave the May 24th meeting. You  
 5 understand what's required --  
 6 DR. CARTER:  
 7 A. May 17th.  
 8 COFFEY, Q.C.:  
 9 Q. May 17th, I apologize, May 17th meeting. What  
 10 happens then, what did you do?  
 11 DR. CARTER:  
 12 A. I talked to Mr. Dyer and asked that a search  
 13 be done for estrogen receptor negative  
 14 patients in 2002, and he gave me a list of  
 15 patients, and I began to request the slides,  
 16 blocks, reports from those patients, select  
 17 the blocks, send them to -- I think at that  
 18 time we were probably using Maria Mendes' lab  
 19 for -- but I would send them to Mount Sinai.  
 20 COFFEY, Q.C.:  
 21 Q. Initially?  
 22 DR. CARTER:  
 23 A. For retesting.  
 24 COFFEY, Q.C.:  
 25 Q. In the beginning?

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1 DR. CARTER:  
 2 A. Oh, sorry, I would send -- do it on Ventana.  
 3 COFFEY, Q.C.:  
 4 Q. Ventana, okay, at that point.  
 5 DR. CARTER:  
 6 A. I need my exhibits.  
 7 COFFEY, Q.C.:  
 8 Q. And -- well, in terms of that, the actual --  
 9 and this is why I'm asking about this, what  
 10 happened in the beginning, because frankly the  
 11 Commission doesn't have a whole lot of  
 12 documents for the first month or two. We do  
 13 have a lot in July, Maria Mendes, and all  
 14 those from there, but I'm just trying to get  
 15 some sense of what went on in the first month.  
 16 DR. CARTER:  
 17 A. So between May and the end of June?  
 18 COFFEY, Q.C.:  
 19 Q. Yes, May and end of June.  
 20 DR. CARTER:  
 21 A. I mean, as I described -- that was my mistake  
 22 about sending them to Mount Sinai. We were  
 23 still using the Ventana system. I'm not sure  
 24 the date of when we turned it off, but it was  
 25 some time in July, I think.

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1 COFFEY, Q.C.:

2 Q. So in the beginning, I take it Mr. Dyer

3 provided you with a list for 2002 ER negative

4 cases?

5 DR. CARTER:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. Local cases, St. John's cases?

9 DR. CARTER:

10 A. Yes, and after a couple of weeks, I think Don

11 began to request them from outside of town for

12 2002.

13 COFFEY, Q.C.:

14 Q. Now what, if anything, had you learned by the

15 time Dr. Cook requested the out of town cases,

16 because that's June 14, Exhibit P-0492 -- this

17 is this June 14th, 2005 letter to the

18 laboratory directors throughout the province

19 from Dr. Cook looking for all the 2002 ER and

20 PR negatives, and at that point in time what

21 constitutes negative is not defined or set

22 out. Doctor, what had happened before that,

23 if anything, in terms of your investigation,

24 how far had you gotten?

25 DR. CARTER:

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1 A. Again, I mean, I wouldn't be able to give you

2 numbers, but as each day passed, we were

3 seeing a significant number of conversions

4 there, so as each day passed, we were becoming

5 more worried that this was a widespread thing.

6 I know by June 29th, we had 25, but --

7 COFFEY, Q.C.:

8 Q. Yes, there were 25 done and about 16 or so

9 conversions.

10 DR. CARTER:

11 A. Yes.

12 COFFEY, Q.C.:

13 Q. And, of course, they didn't all occur on June

14 27th, they occurred between May 17th --

15 DR. CARTER:

16 A. Some of them may have been before June 14th,

17 some after, but I can't clarify it any more

18 than that.

19 COFFEY, Q.C.:

20 Q. You were aware that Dr. Cook was looking for

21 the cases from outside St. John's? Were you

22 made aware that that was going to happen?

23 DR. CARTER:

24 A. Yes.

25 COFFEY, Q.C.:

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1 Q. And by that point, from your perspective, had

2 you thought or come to at least a tentative

3 conclusion that perhaps we do have a problem,

4 this is not isolated?

5 DR. CARTER:

6 A. That became, I think, clear for me fairly

7 early on in the process.

8 COFFEY, Q.C.:

9 Q. Exhibit P-0500, please. Doctor, this is the

10 June 29th, 2005 letter that was drafted and

11 sent to Dr. McCarthy. Your signature is there

12 and Dr. Cook has signed July -- effective July

13 13th, 2005. Was there discussion about the

14 form or format that should be used for this

15 letter?

16 DR. CARTER:

17 A. I think it was at the May 17th meeting or it

18 may have been in phone calls, you know, over

19 that month, we recognized that there as a

20 necessity to have the patients clearly put

21 through to a point person, if we're going to

22 continue to use that term, at the Cancer

23 Centre so that these patients would be dealt

24 with. Some patients from 1997 could have been

25 theoretically discharged from the Cancer

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1 Centre requiring no more oncology follow up,

2 physicians had moved out of town, some

3 physicians had died. I think that we had come

4 across one. So to simply upload it into the

5 Meditec chart, we wouldn't be at all certain

6 that patients would not be missed, so this was

7 sort of an official way, and we decided to

8 address it to Dr. McCarthy, just as a point

9 person, not that she would be responsible for

10 doing all that work.

11 COFFEY, Q.C.:

12 Q. And, Doctor, here the patients are identified

13 by name and MCP number, they're redacted and

14 surgical numbers, estrogen receptor status,

15 progesterone receptor status, I take it these

16 are the retest results?

17 DR. CARTER:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Now in determining whether or not to retest

21 people at all at this point -- as you had

22 indicated to the Commissioner now, you had

23 asked Mr. Dyer to identify estrogen receptor

24 negative. How is negative in that context

25 defined at this stage?

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1 DR. CARTER:  
 2 A. I would define negative at that stage as  
 3 anything that was below 10 percent or anything  
 4 -- surrogate markers.  
 5 COFFEY, Q.C.:  
 6 Q. Go ahead, perhaps you can --  
 7 DR. CARTER:  
 8 A. If you look at certain items in the patient  
 9 chart, such as infiltrating lobular or  
 10 mucinous, I mean, it's a key word, it's not a  
 11 definitive statement, but those are things  
 12 where you would think they would be high  
 13 expressers. So if I saw a low grade classic  
 14 mucinous in the report and the expresser was  
 15 10 percent or maybe 20 percent, then I would  
 16 think that that would be a case where you  
 17 would see that if there was a problem with the  
 18 process, that that would be a good case  
 19 because it was giving unexpected results.  
 20 There's two things going on. One, you're  
 21 trying to identify patients quickly and get  
 22 information out to them if there's going to be  
 23 any change in their treatment, but the second  
 24 thing that you're doing is trying to  
 25 scientifically examine a process, so, I mean,

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1 largely we concentrated on negatives, but  
 2 there would be other surrogate markers that I  
 3 would use to say, well, that test is not  
 4 performing the way that I would have thought.  
 5 COFFEY, Q.C.:  
 6 Q. Because there are some cases that were  
 7 retested in the early process that, in fact,  
 8 the original reports would have been 10, 15,  
 9 20 percent, but some of these did get retested  
 10 because you, in looking at the pathology  
 11 report, surrogate markers, thought that  
 12 perhaps potentially the result could be  
 13 expected -- originally should have been  
 14 perhaps higher?  
 15 DR. CARTER:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Might be expected to be.  
 19 DR. CARTER:  
 20 A. And I think there are only three or four of  
 21 those in the original grouping, and I think at  
 22 least one of those had been identified by the  
 23 clinicians and the other two would be picked  
 24 up in that way by myself.  
 25 COFFEY, Q.C.:

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1 Q. From the Commissioner's perspective in looking  
 2 at this overall in terms of if we come across  
 3 a case or a couple of cases that the original  
 4 result, in fact, doesn't kind of meet this  
 5 generally described here negative cut off  
 6 rate, the reason they're included is because  
 7 of the surrogate marker, and your kind of more  
 8 generalized approach to this in terms of  
 9 trying to figure out if there was a problem,  
 10 where it was?  
 11 DR. CARTER:  
 12 A. If I had selected the case, I mean, that would  
 13 be my reasoning behind selecting the case.  
 14 COMMISSIONER:  
 15 Q. Just to make sure I understand this now, if  
 16 you are looking at the results in a particular  
 17 case and because of something like diagnosis,  
 18 you would have expected positivity and high --  
 19 DR. CARTER:  
 20 A. High positivity. So if I saw an infiltrating  
 21 lobular, then I would expect the positivity to  
 22 be greater than 75 percent. So if it's an  
 23 infiltrating lobular and the positivity is  
 24 around 10 or 15 percent, I mean, there's two  
 25 things it could be: the pathologist who call

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1 it infiltrating lobular, it's not a classic  
 2 strictly defined infiltrating lobular, or  
 3 there's something with the testing.  
 4 COMMISSIONER:  
 5 Q. So while the result itself might be considered  
 6 positive on the strict percentage basis --  
 7 DR. CARTER:  
 8 A. In terms of clinical management of the  
 9 patient, yes.  
 10 COMMISSIONER:  
 11 Q. You would have wanted to look at that because  
 12 of that sort of inconsistency in what you  
 13 might expect and what you --  
 14 DR. CARTER:  
 15 A. Expected results and true results.  
 16 COMMISSIONER:  
 17 Q. Thank you.  
 18 COFFEY, Q.C.:  
 19 Q. Now, Doctor, the idea of utilizing surrogate  
 20 markers, you know, in pathology generally, I  
 21 mean, in the past, would you have utilized  
 22 them in, for example, evaluating ER/PR when  
 23 you're looking -- you look through a  
 24 microscope and see something and you do your  
 25 estimate for percentage or see no staining,

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1 and yet there's a particular type of cancer  
 2 surrogate marker, would that ever figure into  
 3 your approach to doing your job?  
 4 DR. CARTER:  
 5 A. Certainly that's what I was taught to do and  
 6 what I practised. I wouldn't say that it  
 7 happened every time.  
 8 COFFEY, Q.C.:  
 9 Q. Yes, but in terms of --  
 10 DR. CARTER:  
 11 A. It also is sort of a subconscious thing that  
 12 you do, so you wouldn't -- you just know that  
 13 when you look at lobulars, this is the way  
 14 they're supposed to behave.  
 15 COFFEY, Q.C.:  
 16 Q. I take it, Doctor, in terms of that very  
 17 point, the idea of surrogate markers or  
 18 surrogate factors, is that limited to breast  
 19 pathology or does that cut across pathology in  
 20 one form or another generally?  
 21 DR. CARTER:  
 22 A. There would be surrogate markers that you  
 23 would use in other instances -- I'm trying to  
 24 quickly go through, but, I mean, if you had a  
 25 melanoma, skin cancer, and it didn't express

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1 S100 or melanae (phonetic), I mean, you would  
 2 rethink your diagnosis. So there's expected  
 3 behaviour from certain tissues.  
 4 COFFEY, Q.C.:  
 5 Q. This -- the idea, as you say, subconsciously  
 6 perhaps or only semiconsciously kind of being  
 7 alert to sensing a certain way, bearing in  
 8 mind what I'm bringing to this in the way I do  
 9 it, or I expect to see, can that be influenced  
 10 by the frequency with which you do or don't do  
 11 something in the sense of if you're doing  
 12 breast pathology all the time is what I'm --  
 13 in your case, for example, would you be more  
 14 alert to potentially surrogate markers and  
 15 their potential significance from day to day  
 16 than if you only did a breast case once a week  
 17 or once a month?  
 18 DR. CARTER:  
 19 A. That actually hasn't been studied because  
 20 there's a lot of interest in that and whether  
 21 or not people subspecialize -- the last time I  
 22 looked, it had not been studied, but it's my  
 23 experience and many of my colleagues anecdotal  
 24 belief that, yes, the more cases you see, the  
 25 better you get at them, and some things are so

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1 subspecialized, not to do with this inquiry,  
 2 but somebody who's operating, say, on your  
 3 pancreas or your bile ducts, that that should  
 4 probably be restricted to, you know, people  
 5 who do it a fair amount.  
 6 COFFEY, Q.C.:  
 7 Q. And in this context, and I raise it now  
 8 because you've referred to it, we've heard  
 9 from some pathologists who have indicated that  
 10 they might see a breast case on average once a  
 11 month and ER/PR.  
 12 DR. CARTER:  
 13 A. Here in St. John's, yes --  
 14 COFFEY, Q.C.:  
 15 Q. Or particularly outside St. John's in some  
 16 instances, and they acknowledge, well, yes,  
 17 they would know invasive lobular should be  
 18 positive. That was what -- they understood  
 19 that from their training, but -- or ER  
 20 negative, PR positive, is relatively  
 21 infrequent.  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. But they would just attribute it to -- it

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1 wouldn't stand out at the time for them  
 2 because they just saw so few of them, and they  
 3 would just chalk it up to this happens to fall  
 4 into the 1 in 10 or 1 in 20 category, this  
 5 particular case.  
 6 DR. CARTER:  
 7 A. And I think that most people who are involved  
 8 in oncology, I mean, have a basic sort of  
 9 tenet that the statistics, you know, are to be  
 10 applied and to be recognized and utilized, but  
 11 that cancer is largely a process that often  
 12 does the unexpected and does what it wants.  
 13 So, I mean, if I saw something that was  
 14 negative, I wouldn't say an absolute statement  
 15 this should be positive.  
 16 COFFEY, Q.C.:  
 17 Q. Doctor, you've indicated that -- I think you  
 18 said several minutes ago that early on you  
 19 realized that in terms of your involvement  
 20 that perhaps this was a wider problem.  
 21 DR. CARTER:  
 22 A. Than 2002.  
 23 COFFEY, Q.C.:  
 24 Q. Yes. Doctor, what was it about what you were  
 25 seeing that caused you to think that?

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1 DR. CARTER:  
 2 A. We had some cases that were from 2003 and 2001  
 3 -- I think we might have had from 2005, I'm  
 4 not sure. So we were moving outside of the  
 5 point of interest. There also -- looking at  
 6 the slides, I could see things like internal  
 7 controls not staining over a wide variety of  
 8 those cases leading me to believe that it  
 9 wasn't an isolated incident, that that was  
 10 fairly common.  
 11 COFFEY, Q.C.:  
 12 Q. When we look down through this, we'll see in  
 13 this letter the majority of cases are 2002,  
 14 signified by the last two digits and the  
 15 surgical number, but even on the first page  
 16 there's a '99 case and then two '01s.  
 17 DR. CARTER:  
 18 A. I think these would have arisen at the request  
 19 of the oncologist.  
 20 COFFEY, Q.C.:  
 21 Q. The '99 and the '01s?  
 22 DR. CARTER:  
 23 A. Um.  
 24 COFFEY, Q.C.:  
 25 Q. And then the next page, all of those are '02

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1 cases, and the third page, there's a 2000  
 2 case, a 2005, as you pointed out, although it  
 3 may have originated in '03, Western Memorial  
 4 number, and a 2000, a 2001, and then a 2002  
 5 case out of Clarendville, but given an RI  
 6 number, and again an '03 case. Doctor, you  
 7 here uses generally either just positive or  
 8 negative as your descriptor of the status.  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. What was your practice in terms of would you  
 13 use positive, negative, use a percentage, or  
 14 might you vary?  
 15 DR. CARTER:  
 16 A. At that time, my practice would have been -- I  
 17 would say most of the time I probably would  
 18 have just said positive and negative and  
 19 sometimes I would have used a percentage point  
 20 with it.  
 21 COFFEY, Q.C.:  
 22 Q. And here, for example, at the beginning of the  
 23 second page there's a reference to positive  
 24 [10 percent moderate to strong positivity],  
 25 and then -- that's ER, and PR is positive,

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1 moderate to strong positivity in 10 percent of  
 2 cells. Why -- and we go down, for example, to  
 3 the fourth patient on this page is just  
 4 positive/positive, the two words simply. Why  
 5 would you add these descriptors here in  
 6 brackets for the first patient?  
 7 DR. CARTER:  
 8 A. I haven't gone back and looked at any of these  
 9 cases in any detail. Looking at them, I would  
 10 think that probably number seven was retested  
 11 for some reason at Mount Sinai, that sounds  
 12 like a Mount Sinai sign out, and number six, I  
 13 think we were talking about -sorry, number  
 14 ten.  
 15 COFFEY, Q.C.:  
 16 Q. Yes.  
 17 DR. CARTER:  
 18 A. That would have been signed out by myself. If  
 19 I signed out number seven, and as I said, I  
 20 don't know -- I don't have any reason for  
 21 saying that.  
 22 COFFEY, Q.C.:  
 23 Q. So what's inside the brackets here may be due  
 24 to this particular case having actually gone  
 25 to Mount Sinai?

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1 DR. CARTER:  
 2 A. Yes. I mean, if I signed it out, perhaps I  
 3 was reading a Mount Sinai report the minute  
 4 before I signed it out, and I did it, but  
 5 there was no strict way of reporting that I  
 6 did. My reporting will be variable.  
 7 COFFEY, Q.C.:  
 8 Q. The handwriting here on these, Doctor, whose  
 9 is that, do you know?  
 10 DR. CARTER:  
 11 A. I don't think so.  
 12 COFFEY, Q.C.:  
 13 Q. Okay, and as well the second last case in this  
 14 exhibit, there's again a descriptor inside  
 15 brackets [weak to moderate 30 percent  
 16 positive].  
 17 DR. CARTER:  
 18 A. That case is from Clarendville.  
 19 COFFEY, Q.C.:  
 20 Q. Yes.  
 21 DR. CARTER:  
 22 A. And I think that they had for a long time used  
 23 Mount Sinai as their testing, so that may be a  
 24 report from Mount Sinai as well.  
 25 COFFEY, Q.C.:

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1 Q. And here in the context the usage of positive  
 2 and negative, is positive 10 percent or more?  
 3 DR. CARTER:  
 4 A. Ten percent.  
 5 COFFEY, Q.C.:  
 6 Q. Or more?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. Doctor, what was the reaction around this  
 11 time, the end of June, beginning of July, from  
 12 the oncologists to this, 16 out of 25 of these  
 13 cases have converted?  
 14 DR. CARTER:  
 15 A. They were very concerned that -- for those 16  
 16 cases, but also that this was probably an  
 17 indication that there may be a lot more. They  
 18 wanted information on all of the patients  
 19 affected. They wanted it as quickly as we  
 20 could provide it to them, but I think there  
 21 was a great deal of concern that patients may  
 22 be harmed by all people that were involved in  
 23 the process.  
 24 COFFEY, Q.C.:  
 25 Q. Exhibit P-1698. Just before I leave it, if we

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1 could just go back to P-0500, please. That  
 2 second last case here the one that's referred  
 3 to as Clarendville.  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Where was that originally tested, do you  
 8 recall, Doctor?  
 9 DR. CARTER:  
 10 A. I haven't gone back and looked at these cases  
 11 as part of this in detail. My understanding  
 12 is that some time in the early 2000's  
 13 Clarendville had made the decision to switch  
 14 their estrogen receptor testing to Mount  
 15 Sinai.  
 16 COFFEY, Q.C.:  
 17 Q. And so do you recall how this case was  
 18 identified because it wouldn't have been  
 19 within the Health Science Centre system?  
 20 DR. CARTER:  
 21 A. No. Again I haven't gone back in detail.  
 22 COFFEY, Q.C.:  
 23 Q. Okay.  
 24 DR. CARTER:  
 25 A. Perhaps it was from one of the oncologists

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1 recognizing the patient.  
 2 COFFEY, Q.C.:  
 3 Q. Doctor, before you got involved in this in May  
 4 of 2005, had you been made aware of any  
 5 retests of ER and PR before that in which  
 6 there had been a conversion? I use the word  
 7 "conversion" in quotes.  
 8 DR. CARTER:  
 9 A. No. I mean, just a part of everyday practice  
 10 sometimes you would order a retest, but, no, I  
 11 don't remember it coming up as an issue.  
 12 COFFEY, Q.C.:  
 13 Q. And if you in that context of everyday  
 14 practice, reorder a test, had you been aware  
 15 of any that upon reordering it, the result was  
 16 different, and I mean in a clinically  
 17 significant manner, for example, like Peggy  
 18 Deane's was?  
 19 DR. CARTER:  
 20 A. Not that I recall, no.  
 21 COFFEY, Q.C.:  
 22 Q. Exhibit P-1698, please. Doctor, here -- this  
 23 is your letter of July 14th, 2005, to Dr.  
 24 Cook, and I'll refer to it as kind of a plan  
 25 of action letter.

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1 DR. CARTER:  
 2 A. Okay.  
 3 COFFEY, Q.C.:  
 4 Q. Because that's certainly what it appears to  
 5 outline. You outlined this yesterday to the  
 6 Commissioner, the steps here. Toward the  
 7 bottom of the first page, you write, "Ten  
 8 percent of cases should be randomly selected  
 9 for outside quality assurance consultation.  
 10 Dr. Frances O'Malley of Mount Sinai Hospital  
 11 has agreed to act in this capacity.  
 12 Problematic cases as defined by a multiplicity  
 13 of reasons should also be sent for outside  
 14 testing". Now the sentence, "Ten percent of  
 15 cases should be randomly selected for outside  
 16 quality assurance consultation", what were you  
 17 referring to there, Doctor?  
 18 DR. CARTER:  
 19 A. When we had patients who were diagnosed in,  
 20 say, 2001 as negative, those cases would have  
 21 been pulled and retested, and then  
 22 theoretically called positive, but then you  
 23 would have to have something in place to say,  
 24 well, the new test is the appropriate test, so  
 25 you would want to do quality control on your

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1 new testing procedure.  
 2 COFFEY, Q.C.:  
 3 Q. On your current testing of your old cases.  
 4 DR. CARTER:  
 5 A. If you just have them both standing, it's,  
 6 well, who's right, so you would want to have  
 7 some quality assurance. Ten percent is a  
 8 little high. It's usually less than that that  
 9 you would send for quality control.  
 10 COFFEY, Q.C.:  
 11 Q. I take it --  
 12 DR. CARTER:  
 13 A. We were being overly cautious at that time.  
 14 COFFEY, Q.C.:  
 15 Q. And you -- this indicates -- by saying that  
 16 Dr. Frances O'Malley had agreed to act in this  
 17 capacity, it suggests you had already spoken  
 18 to Dr. O'Malley about this?  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. So the idea would be that of those retested,  
 23 those originally negative cases that were  
 24 retested, 10 percent of the conversions would  
 25 be sent out or 10 percent of the total of

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1 retests?  
 2 DR. CARTER:  
 3 A. In proper quality control, it would be 10  
 4 percent of all the tests. I would assume  
 5 that's what I would have done. I would have  
 6 put in some negatives, some strong converters,  
 7 some that had ended up being weak positives on  
 8 retesting.  
 9 COFFEY, Q.C.:  
 10 Q. "Problematic cases as defined by a  
 11 multiplicity of reasons should also be sent  
 12 for outside testing". What was that about,  
 13 Doctor?  
 14 DR. CARTER:  
 15 A. Again referring to the surrogate marker  
 16 discussion that we just had. So if I saw a  
 17 case that I thought the percentage positivity  
 18 wasn't in agreement with the very bare facts  
 19 that I would have about the pathology from the  
 20 report, we would send them up. I guess other  
 21 problematic cases would be -- they wouldn't be  
 22 called problematic cases, you know, from the  
 23 oncologist, but that wouldn't be called  
 24 problematic.  
 25 COFFEY, Q.C.:

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1 Q. So at this point, the middle of July, you  
 2 envisaged for those sorts -- I'll just the  
 3 words you've got here, problematic cases, were  
 4 they going to be retested in-house too and  
 5 sent to Mount Sinai, or just sent outside to  
 6 start?  
 7 DR. CARTER:  
 8 A. No, they would be included in the large cohort  
 9 that was being retested in St. John's, and  
 10 then by random chance they would be included  
 11 in the cohort that would go to Mount Sinai for  
 12 quality control.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, why Mount Sinai, from your perspective  
 15 at the time?  
 16 DR. CARTER:  
 17 A. I knew of Mount Sinai Hospital because I was  
 18 working at McMaster and Dr. O'Malley and I had  
 19 done our residency training and fellowship  
 20 training in similar areas -- in the same area,  
 21 actually, and I had been doing some -- taken a  
 22 very minor role in some collaborative research  
 23 with her. She was not the only person that I  
 24 would have talked to. The protocol that they  
 25 had in place for their laboratory was a DAKO

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1 semi-automated platform. They had a protocol  
 2 that they were using with the antibody 6F11  
 3 that had been clinically validated. I mean,  
 4 if you start talking about antibodies and  
 5 things -- when you're measuring estrogen  
 6 receptor positivity, what you want to do is to  
 7 correlate it to clinical outcome. So the  
 8 people that you call positive, do they, in  
 9 fact, respond to hormonal manipulation. So  
 10 6F11 and the DAKO semi-automated protocol had  
 11 been validated by Dr. Craig Allred when he was  
 12 in Texas to clinical outcome. So that's a  
 13 very well studied and reliable protocol for  
 14 testing for estrogen receptor. Mount Sinai  
 15 Hospital also acts as a quality control for  
 16 people around Canada for a variety of  
 17 antibodies in immunohistochemistry. They also  
 18 take part in a number of external proficiency  
 19 testing. I think they were the first lab in  
 20 Canada to have College of American  
 21 Pathologists accreditation. So they were a  
 22 lab, that after we had talked to a few labs,  
 23 that stood out.  
 24 COFFEY, Q.C.:  
 25 Q. So, it wasn't just--you happen to know someone



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1 there and made a phone call. This was  
 2 actually thought through.  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.  
 6 Q. Doctor, go on to the next page of this, second  
 7 page, you say, you begin that here by saying,  
 8 "it will be necessary to have a computerized  
 9 data base for this project". And then you  
 10 spell out what the certain of the things that  
 11 it should included and you list them, in  
 12 effect, I take it, searchable and utilizable  
 13 spreadsheet.  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.  
 17 Q. That's what you were looking at.  
 18 DR. CARTER:  
 19 A. I mean, in the initial part, this is a very  
 20 basic approach to it. I mean, we're just  
 21 getting a descriptive analysis. I don't think  
 22 it would stand up to a lot of statistical  
 23 mining for research purposes, but it was just  
 24 to get a description, put it into some sort of  
 25 database where we could begin to manipulate it

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1 and see if something stood out.  
 2 COFFEY, Q.C.  
 3 Q. Now, Doctor, were you ever actually, in  
 4 practice then, offered the services of someone  
 5 who could build a computerized database?  
 6 DR. CARTER:  
 7 A. I don't think so, no.  
 8 COFFEY, Q.C.  
 9 Q. Okay. Yourself, do you have any facility or  
 10 skill with computerized databases?  
 11 DR. CARTER:  
 12 A. I can fill out an Excel spreadsheet and I can  
 13 manipulate it, but probably would have needed  
 14 something more sophisticated than that. And I  
 15 mean, it's just not a very good use of my  
 16 time.  
 17 COFFEY, Q.C.  
 18 Q. And so, what I'm getting at here is even at  
 19 this stage when you're embarking upon this,  
 20 you, yourself recognized that it would be  
 21 useful to have someone with that skill set  
 22 available.  
 23 DR. CARTER:  
 24 A. Yes.  
 25 COFFEY, Q.C.

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1 Q. And you requested it.  
 2 DR. CARTER:  
 3 A. Yes.  
 4 COFFEY, Q.C.  
 5 Q. And there was no one actually identified, no  
 6 individual that you can recall.  
 7 DR. CARTER:  
 8 A. Not that I can recall, no.  
 9 COFFEY, Q.C.  
 10 Q. Page three of this exhibit, Doctor, is a July  
 11 19th, 2005 letter from Dr. Cook to yourself.  
 12 He acknowledges receipt of your July 14th  
 13 letter. He states, "I certainly accept"--  
 14 "it's been stated in your letter and will  
 15 ensure that you obtain the necessary resources  
 16 to carry out your suggestions". And that's  
 17 copied to Dr. Williams.  
 18 Doctor, you described yesterday how that  
 19 turned out by the end of the month, beginning  
 20 of August in terms of what happened with  
 21 respect to that. Have you ever spoken to Dr.  
 22 Cook--did you speak to him at that time about  
 23 your frustrations?  
 24 DR. CARTER:  
 25 A. Yes, I did.

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1 COFFEY, Q.C.  
 2 Q. And what, if anything, did he tell you?  
 3 DR. CARTER:  
 4 A. The timelines, if you look at the memos and  
 5 things are kind of strict. This had been  
 6 going on from May 17, so it's not July 14th  
 7 this happened and then July 29th that  
 8 happened. But in the months of May and June  
 9 and July I was, as it became more formalized,  
 10 I was trying to become more rigorous in my  
 11 approach to it. And had been repeatedly  
 12 asking for specific entities that I talked  
 13 about yesterday and was having frustration  
 14 getting that. Also just having physical  
 15 people on the ground doing a lot of this work.  
 16 I talked to Dr. Cook about it, I mean, he  
 17 would sympathize with it and state his support  
 18 for it and say that he would talk to Dr.  
 19 Williams about it to see what could happen,  
 20 but he had no authority to tell people on the  
 21 technical half, I guess we're calling it, of  
 22 the laboratory, how the resources should be  
 23 allocated.  
 24 COFFEY, Q.C.  
 25 Q. In terms of--just so the Commissioner, again,

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1 can get some sense of, as you point out, July  
 2 14th just didn't happen and your letter begins  
 3 on July 14th as per discussions or many  
 4 discussions.  
 5 DR. CARTER:  
 6 A. So, we may have been doing it for three weeks.  
 7 And Dr. Cook may have said you got to get this  
 8 down on paper.  
 9 COFFEY, Q.C.  
 10 Q. Exhibit P-0508, please. Now, this is a July  
 11 18th, 2005 letter. It's from yourself and Dr.  
 12 Cook to Dr. McCarthy and this is the second of  
 13 the three reporting letters as it were. It  
 14 says, "as per our previous discussions, repeat  
 15 ER and PR has been performed on the following  
 16 patients initially identified as estrogen  
 17 receptor negative. The results are as  
 18 follows" and here sometimes there's, again,  
 19 positive and simply the words "positive" and  
 20 "negative" used sometimes, longer descriptors  
 21 such as for the first patient here, 100  
 22 percent strong nuclear positivity in both  
 23 instances for ER and PR. And then the fourth  
 24 patient, moderate nuclear staining and 60  
 25 percent strong nuclear staining and 80 percent

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1 for PR for that fourth patient on the first  
 2 page. And as we look through this, it varies.  
 3 Now, I take it Doctor, this is signed on the  
 4 fourth page by yourself and Dr. Cook.  
 5 DR. CARTER:  
 6 A. Um-hm.  
 7 COFFEY, Q.C.  
 8 Q. There are, I think, 33 patients, roughly,  
 9 here. We can count them up, but there's  
 10 approximately that.  
 11 DR. CARTER:  
 12 A. I think 19 had -  
 13 COFFEY, Q.C.  
 14 Q. Converted or so. And again, we can just kind  
 15 of look through it and calculate it, but I'm  
 16 getting at, in this context, Doctor, is this,  
 17 this is written July 18th, signed off. I take  
 18 it the actual work of doing the retesting had  
 19 occurred in the weeks before this.  
 20 DR. CARTER:  
 21 A. I would assume that it had been done between  
 22 June 29th which was the previous letter and  
 23 this date.  
 24 COFFEY, Q.C.  
 25 Q. Yes, and July 18th. So, Doctor, really by the

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1 time you wrote the July 14th letter  
 2 formalizing your request and your plan, would  
 3 it be safe for the Commissioner to accept  
 4 that, from your perspective, accept that most  
 5 of the July 18th patients listed in that  
 6 letter had already been retested by July 14th.  
 7 DR. CARTER:  
 8 A. Yes, I would agree with that most of them  
 9 would have -  
 10 COFFEY, Q.C.  
 11 Q. Had already occurred. Doctor, if we could  
 12 look again, to give the Commissioner some  
 13 sense of what was going on in that time frame,  
 14 Exhibit P-1697. Here, Doctor, this is another  
 15 letter of July 14th, 2005. It's from yourself  
 16 to Dr. O'Malley at Mount Sinai and you write,  
 17 "as per our telephone conversation of July  
 18 13th, 2005 could you please have ER/PR  
 19 staining done on the following and also  
 20 provide interpretation for same". I believe  
 21 there are 13 blocks, at least, anyway listed  
 22 there. Yes, there are nine on the first page  
 23 and four on the second. And you conclude by  
 24 saying "I would appreciate a return of the  
 25 blocks as soon as you have finished them".

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1 Could you bring up please, Exhibit P-  
 2 2189? Is this your handwriting, Doctor?  
 3 DR. CARTER:  
 4 A. Yes, it is.  
 5 COFFEY, Q.C.  
 6 Q. And you've written Mary Butler, pathology,  
 7 HSC, "Mary, send the following blocks to me"  
 8 and you list them. And if we check and  
 9 compare certainly the block numbers, in this  
 10 particular letter, we've redacted the middle  
 11 numbers in the surgical number, but they are,  
 12 in effect, generally the same blocks, aren't  
 13 they?  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.  
 17 Q. And Mary Butler has written to you, "still  
 18 looking for blocks that are circled" and there  
 19 are a couple of them there. Doctor, and  
 20 you've written here, I think, FOM, as per our  
 21 telephone discussion on this, it says July  
 22 16th, '05, "perform ER/PR staining and provide  
 23 interpretation and please return blocks". I  
 24 take it this was a draft of the text that ends  
 25 up in your letter?

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1 DR. CARTER:  
 2 A. Yes, that would be a note to Judy Thomas, the  
 3 secretary I spoke about yesterday, so she  
 4 would have canned text letters on her  
 5 computer. I would give her the basic facts  
 6 and then she would type it nicely. I'm not  
 7 sure with the 16 07, I'm not sure if that  
 8 refers to my discussion with Dr. O'Malley or  
 9 if that's the date that I requested the  
 10 blocks.  
 11 COFFEY, Q.C.  
 12 Q. Yes, because in your letter itself, you refer  
 13 to--which is dated July 14th, you refer to  
 14 your and her discussion of July 13th. If we  
 15 could go back please to Exhibit P-1--perhaps  
 16 I'll just stay on this one. What was going on  
 17 here, Doctor? Why were these blocks being  
 18 sent to Mount Sinai?  
 19 DR. CARTER:  
 20 A. So, this would be the quality control cases.  
 21 So, they were somewhat randomly selected  
 22 because if you look at one end you'll see the  
 23 tick marks. I think that's as the lab  
 24 assistant, Judy Quinlan or Mary Butler found  
 25 that they would tick it off. Next to that you

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1 can see, sometimes there's a minus sign, a  
 2 plus sign, 10 percent, 60, 80, that would be  
 3 the estrogen receptor and progesterone  
 4 receptor status. So, there's a mixture there  
 5 of high expressors, moderate expressors, low  
 6 expressors, negative cases. So, it's a  
 7 somewhat random selection, but it's not a true  
 8 random selection and these would be sent up  
 9 for quality control purposes.  
 10 COFFEY, Q.C.  
 11 Q. That was in furtherance or in furthering your  
 12 plan set out in your July 14th letter to Dr.  
 13 Cook, ten percent -  
 14 DR. CARTER:  
 15 A. Yes. I think it's probably more than ten  
 16 percent, but -  
 17 COFFEY, Q.C.  
 18 Q. You had also said, in your letter, problematic  
 19 cases should also be sent for testing as well.  
 20 DR. CARTER:  
 21 A. Not for the QC as I explained, the problematic  
 22 cases would be included in the large  
 23 retrospective cohort and if they randomly  
 24 ended up -  
 25 COFFEY, Q.C.

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1 Q. They would be sent.  
 2 DR. CARTER:  
 3 A. Yes.  
 4 COFFEY, Q.C.  
 5 Q. What happened with respect to these then,  
 6 Doctor, do you recall what the result of this  
 7 was?  
 8 DR. CARTER:  
 9 A. I'm going on memory here, but it was written  
 10 down somewhere, maybe you have it, I don't  
 11 know, but I haven't been able to find it.  
 12 When we sent these up to Mount Sinai there was  
 13 some disagreement between the Ventana system  
 14 at the St. John's site and the results that  
 15 came out of Mount Sinai. There was some  
 16 differences that would have been regarded as  
 17 clinically significant. So, things that we  
 18 had called negative, they would call positive  
 19 and vice versa, I think. And I think this is  
 20 the cohort where we thought that we had  
 21 probably identified that the Ventana may give  
 22 us some false positives.  
 23 COFFEY, Q.C.  
 24 Q. And that came out of Mount Sinai's reports of  
 25 their analysis of these cases, later that

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1 month.  
 2 DR. CARTER:  
 3 A. Yes.  
 4 COFFEY, Q.C.  
 5 Q. I haven't found the paperwork that hooks it  
 6 all together, but there was at least one case  
 7 that was called negative in St. John's back  
 8 before 2002 that was retested, called positive  
 9 and then sent to Mount Sinai and then it was  
 10 called negative.  
 11 COFFEY, Q.C.  
 12 Q. Exhibit P-2452, please. Doctor, this is a  
 13 letter, it's July 15th, 2005, it's addressed  
 14 to Dr. Cook. It's from Dr. McCarthy. It's  
 15 copied to yourself and it's "re: list of  
 16 patients ER positive status". Dr. McCarthy  
 17 writes, "I refer to your correspondence dated  
 18 June 29th, 2005 which lists a number of  
 19 patients identified as ER negative. I wish to  
 20 identify two names which appear on that list.  
 21 They are not patients of the Dr. H. Bliss  
 22 Murphy Cancer Centre" and they're two surgical  
 23 numbers here but the names are redacted.  
 24 "Please check your records on these two  
 25 patients to identify the referring physician.

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1 We cannot take responsibility for these  
 2 patients with regards to notifying them of  
 3 this new information." I take it, Doctor,  
 4 that this was kind of a formal response to  
 5 saying "well, we can identify or deal with all  
 6 but two."  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. And asking that those two be addressed?  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. By your and Dr. Cook's office. Exhibit P-  
 15 2360? This is an e-mail, Doctor, of July  
 16 25th, 2005 from yourself to Dr. Gallagher. It  
 17 reads "1997 to" it should be 2004, "ER  
 18 negative, don't care about PR. ER/PR slides  
 19 controls and H & E of that block report. I'm  
 20 looking at histologic type grade, internal  
 21 controls, external controls, date of testing."  
 22 Signed Beverley Clarke (sic.) and he had  
 23 written to you on July 24th saying, subject is  
 24 a question, "I just wanted to check again the  
 25 criteria on the breast cancers that they want

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1 us to send to St. John's. January 1997 to  
 2 December 2004, ER and PR negative, both  
 3 negative, block, H/E slide, ER/PR slides and  
 4 report?" Now, and of course, you responded in  
 5 the way you did on July 25. Do you recall how  
 6 it was you came to communicate with Dr.  
 7 Gallagher in Gander?  
 8 DR. CARTER:  
 9 A. I mean, I don't recall this in particular.  
 10 They would have phoned when they had--I think  
 11 my name was listed on many of the e-mails that  
 12 I would act as a consultant on this process,  
 13 if they wanted.  
 14 COFFEY, Q.C.:  
 15 Q. Do you recall any of the contacts you had with  
 16 the pathologists outside St. John's?  
 17 DR. CARTER:  
 18 A. I know that I had them, that if they  
 19 telephoned me or e-mailed me, in this case,  
 20 and asked me questions about the process, I  
 21 would have. In an official capacity, I think  
 22 there was a couple of memos that I was  
 23 cosigner on with Dr. Cook, but largely it  
 24 would be informal, I would think.  
 25 COFFEY, Q.C.:

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1 Q. Exhibit P-0492, please? Doctor, that June  
 2 14th 2005 memo from Dr. Cook. He had  
 3 concluded by saying, and this went to Dr.  
 4 Gallagher and others, "if you have any  
 5 questions"--concerns or questions, please feel  
 6 free to contact him or yourself?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. So right from the beginning, that was so.  
 11 Doctor, why the--if we could go back then to  
 12 P-2360? Doctor, why the focus on ER?  
 13 DR. CARTER:  
 14 A. As opposed to the PR?  
 15 COFFEY, Q.C.:  
 16 Q. Yes, because you say "ER negative, don't care  
 17 about PR."  
 18 DR. CARTER:  
 19 A. "Don't care about PR." I think the estrogen  
 20 receptor had come up as the most important  
 21 molecule, most important thing, protein that  
 22 we would be looking at, in terms of ER/PR.  
 23 There's been literature that changes over time  
 24 about the value of progesterone receptor  
 25 status in determining response to hormone

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1 therapy. Sometimes it's very important and  
 2 sometimes not at all, but from the scientific  
 3 point of view, I was looking at estrogen  
 4 receptor and seeing if there was a problem  
 5 with that testing and I think, from Barry's  
 6 point--sorry, Dr. Gallagher's point number  
 7 two, he says "both negative" and I was  
 8 interested in the ER negative, irrespective of  
 9 the status of PR.  
 10 COFFEY, Q.C.:  
 11 Q. And by--so Doctor, if you just took ER  
 12 negatives, without regard to the PR status,  
 13 from your perspective at the time, would that  
 14 then, assuming that all patients could be so  
 15 identified as ER negative, appropriately  
 16 identified, would that capture any one who  
 17 could be affected by this process?  
 18 DR. CARTER:  
 19 A. There's two different processes going on. One  
 20 is to identify patients who can be clinically  
 21 affected by this. The other one is a  
 22 scientific investigation of what had gone on  
 23 with the particular antibody in the lab. So  
 24 it depends what your question is about the  
 25 process.

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1 COFFEY, Q.C.:

2 Q. Why don't we deal with each of them in turn?

3 Clinically?

4 DR. CARTER:

5 A. So clinically, if you're looking at estrogen

6 receptor negative, almost all of the patients

7 who are estrogen receptor negative are

8 progesterone receptor negative. So you would

9 be talking about a very small number of

10 patients who would be ER negative, PR

11 positive, usually quoted somewhere around

12 three to five percent of all patients tested

13 there. In terms of the scientific assessment,

14 I guess at that time, I thought that my role

15 was to figure out what happened to estrogen

16 receptor, what, if anything, had happened to

17 estrogen receptor.

18 COFFEY, Q.C.:

19 Q. Doctor, at any point in the process, when you

20 were involved in it, did you ever come to any

21 views as to the past results having involved

22 more than expected number of ER negatives PR

23 positives?

24 DR. CARTER:

25 A. At that time?

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1 COFFEY, Q.C.:

2 Q. Yes, or any point thereafter.

3 DR. CARTER:

4 A. Yes, I mean, we saw a lot of ER negative PR

5 positives.

6 COFFEY, Q.C.:

7 Q. So when did that come--begin to come home to

8 you, that you were seeing a lot of--in the

9 original reports, ER negatives, PR positives?

10 DR. CARTER:

11 A. I think, again subconsciously, I may have

12 recognized that the--trying to think about it

13 now, I mean, the first time I remember sort of

14 seeing it was when we had the spreadsheets at

15 the tumour panel, when the large cohort had

16 come back. So you're just looking at, you

17 know, a large -

18 COFFEY, Q.C.:

19 Q. Listing.

20 DR. CARTER:

21 A. - list of numbers, so I mean the pattern

22 becomes available.

23 COFFEY, Q.C.:

24 Q. And that would have been--because there are

25 different groupings of returns. The largest

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1 return in numbers was in January of '06, but

2 there were fairly significant numbers of

3 returns back in September and October.

4 DR. CARTER:

5 A. And I'm not sure at which time it was, but,

6 you know, the image that I have is of seeing

7 it on a spreadsheet. There's a lot of ER

8 negative PR positive here.

9 COFFEY, Q.C.:

10 Q. And they would be, depending upon the study

11 one looks at, between three and five percent,

12 should be in that category?

13 DR. CARTER:

14 A. Yeah.

15 COFFEY, Q.C.:

16 Q. I think that's the figure you just used and

17 we've heard 3.8 here from other witnesses and

18 so on, but there's--it's five percent or so or

19 less?

20 DR. CARTER:

21 A. Yes.

22 COFFEY, Q.C.:

23 Q. Exhibit P-0529, please? Doctor, this is a

24 letter from--your name is not on it, but it's

25 a letter of July 27th, 2005, to Dr. Watters at

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1 McGill University. It's from Dr. Cook, copied

2 to Doctors Williams and Mr. Gulliver. He

3 writes "as discussed, we are in the process of

4 evaluating our ER and PR immunoperoxidase

5 stains. We will be forwarding two unstained

6 labelled slides to your lab. These slides

7 will be stained for estrogen and progesterone

8 receptors via immunoperoxidase technique.

9 Once the slides are stained, they can be

10 forwarded to my office. I anticipate that we

11 may be evaluating anywhere from 40 to 50

12 cases. Of course, we will be reimbursing you

13 for this service. I certainly appreciate your

14 help in this difficult situation."

15 Do you recall what the nature of--what

16 you knew about the nature of Dr. Watters and

17 McGill University's involvement?

18 DR. CARTER:

19 A. This would have occurred at or around the same

20 time that we began to suspect that there may

21 have been an issue with the Ventana staining,

22 and in the course of discussions with people

23 in labs across Canada, it was found that Dr.

24 Watters had a Ventana machine. I think it was

25 the exact same model as we had. So I mean, it

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1 would just be another quality control practice  
 2 that you would take our slides, send them to  
 3 their machine and see if we got the same sort  
 4 of results, and I think we were going to  
 5 report them, as opposed to when we sent the  
 6 note to Dr. O'Malley, we asked her to report  
 7 them, because then we wanted to do a QC  
 8 between pathologists' interpretation skills  
 9 and I think when we talked to Dr. Watters,  
 10 they felt that they were really quite busy and  
 11 that pathologists couldn't provide that  
 12 practice, but the lab could restrain slides for  
 13 us if that's what we wanted to do.  
 14 COFFEY, Q.C.:  
 15 Q. And was that done, do you know?  
 16 DR. CARTER:  
 17 A. Yes. I'm not sure about the 40 to 50 cases,  
 18 but we did send some cases up to Dr. Watters  
 19 for staining.  
 20 COFFEY, Q.C.:  
 21 Q. Do you recall what happened?  
 22 DR. CARTER:  
 23 A. The slides were returned to Dr. Cook, I think,  
 24 and we looked at them together. I'm not sure  
 25 if there was anyone else there besides myself

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1 and Dr. Cook, but the slides had a technical  
 2 problem with them. They were uninterpretable  
 3 for us and I'm not sure what happened after  
 4 that.  
 5 COFFEY, Q.C.:  
 6 Q. Exhibit P-0508? Doctor, this is this July  
 7 18th letter. Just on this, again there is a  
 8 variety of--well, variety, it's either  
 9 positive--the simple words positive and  
 10 negative are used, or again, in this case, a  
 11 descriptor using the words positive or  
 12 negative or positivity or negativity, but--  
 13 positivity, I'm sorry, and a percentage. Is  
 14 there any particular significance to utilizing  
 15 one format or another here?  
 16 DR. CARTER:  
 17 A. There is evidence, going back as far as 2001,  
 18 that patients who have one percent or greater  
 19 staining may show response to hormonal  
 20 manipulation, Tamoxifen or aromatase  
 21 inhibitors, and that paper largely came out of  
 22 people who, again, were using Dr. Allred's  
 23 system, not only of testing but also of  
 24 reporting and in the Allred score--I don't  
 25 know if you've gone through that already?

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1 COFFEY, Q.C.:  
 2 Q. We have, the Allred scoring, yes.  
 3 DR. CARTER:  
 4 A. So the Allred score, you would give a score  
 5 for intensity and also a score for quantity  
 6 and then you would put them together. So an  
 7 Allred score, that would be equivalent to one  
 8 percent would respond on some level to  
 9 hormonal manipulation. So the practice is to  
 10 give an intensity, which would be the strong,  
 11 the moderate, the weak that you see there, and  
 12 then a percentage.  
 13 COFFEY, Q.C.:  
 14 Q. And so that's where that reporting style or  
 15 format would be associated with that, and but  
 16 there are others that are just simply positive  
 17 or negative?  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. In terms of these particular patients, for  
 22 example, looking at the second page and the  
 23 third patient is just described as  
 24 negative/negative. Let me see if I can find  
 25 one here. Go back to the--yes, on the first

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1 page, the second patient is described simply  
 2 as positive/positive, as is the second last  
 3 patient on the first page. But in other  
 4 instances, the weak, moderate or strong is  
 5 used and an actual percentage. Was there any  
 6 significance to your--for example, the second  
 7 last patient using positive and positive, on  
 8 the first page, but then going to a modified  
 9 Allred description, why would you choose for  
 10 this patient to use positive/positive and then  
 11 an Allred approach in the second one?  
 12 DR. CARTER:  
 13 A. I'm not sure that that's what happened. I  
 14 would guess, and as I said, I haven't gone  
 15 back and looked at all these cases in detail,  
 16 but I would guess that the ones that just say  
 17 positive or negative were reported by me. The  
 18 ones that give a longer descriptor were either  
 19 reported by somebody from Mount Sinai and  
 20 perhaps me being influenced by reading a Mount  
 21 Sinai report immediately before.  
 22 COFFEY, Q.C.:  
 23 Q. Okay, and Doctor, here, on this July 18th  
 24 letter, all the patients on the first page are  
 25 2002 cases, at least have 2002 surgical

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1 numbers, all those on the second page, look  
 2 down through it, all those on the third page  
 3 and all those on the fourth. So at least the  
 4 reporting as of July 18th were all 2002 cases.  
 5 DR. CARTER:  
 6 A. So this would have been the retrospective  
 7 cases.  
 8 COFFEY, Q.C.:  
 9 Q. Doctor, while we're on the topic, Exhibit P-  
 10 0535. Here, Doctor, this is a letter of July  
 11 29th, 2005. It's again addressed to Dr.  
 12 McCarthy, and on the last page, there's a  
 13 place for yourself and Dr. Cook's signature.  
 14 Do you know if this letter was ever sent, the  
 15 July 29th one?  
 16 DR. CARTER:  
 17 A. I would assume so, but now that you're asking  
 18 the question.  
 19 COFFEY, Q.C.:  
 20 Q. Just because a signed copy versus the unsigned  
 21 copies, and it was around this time, and we'll  
 22 deal with it momentarily, there was a decision  
 23 made to kind of hold off and wait for the  
 24 Ventana situation to be clarified somewhat.  
 25 So I'm just wondering if at that point in

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1 time, if you recall actually sending--actually  
 2 signing and sending the July 29th letter.  
 3 DR. CARTER:  
 4 A. I don't have a specific memory of it. I would  
 5 assume that it went, but I don't know.  
 6 COFFEY, Q.C.:  
 7 Q. Now Doctor, here, these on the first page of  
 8 this letter, these are all 2002 cases listed  
 9 there. Second page are all 2002. On the  
 10 third page, there are--there's a mixture of  
 11 '02 and then you'll see an '05 case in the  
 12 third entry, a 2000 case, some '03 cases  
 13 toward the bottom of the page, all the way  
 14 down, and then going on to the next page, the  
 15 top of the page, three '03 cases and then five  
 16 '04 cases. So Doctor, by the end of July  
 17 then, what had happened in respect of what  
 18 sorts of cases were being retested?  
 19 DR. CARTER:  
 20 A. We were still doing the retrospective cases  
 21 and we were doing cases that would have been  
 22 identified by the oncologists for retesting.  
 23 COFFEY, Q.C.:  
 24 Q. If they fall into the '02, they would be there  
 25 anyway, but if they fall into these other

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1 years -  
 2 DR. CARTER:  
 3 A. I don't think we had moved out of the 2002  
 4 cohort at that time in a retrospective kind of  
 5 view.  
 6 COFFEY, Q.C.:  
 7 Q. So the '03, '04 and '05 and 2000 cases here  
 8 are probably the ones identified by  
 9 oncologists in particular for retesting?  
 10 DR. CARTER:  
 11 A. Or by other people. I mean, I'm trying to  
 12 think now if anybody else had telephoned us,  
 13 but these ones would have been requested to  
 14 the lab.  
 15 COFFEY, Q.C.:  
 16 Q. And I take it then that these would have been  
 17 done probably actually retested sometime  
 18 between July 18th and July 29th?  
 19 DR. CARTER:  
 20 A. That would be my assumption.  
 21 COFFEY, Q.C.:  
 22 Q. Doctor, here, there are--as these were ER,  
 23 generally I take it ER negative cases that  
 24 were being retested to start?  
 25 DR. CARTER:

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1 A. Yes, again, but there would have been  
 2 surrogate marker cases that would have arisen.  
 3 COFFEY, Q.C.:  
 4 Q. Was the conversion rate of these cases, again,  
 5 about 50 percent?  
 6 DR. CARTER:  
 7 A. I think so. Again, I don't have my numbers  
 8 with me.  
 9 COFFEY, Q.C.:  
 10 Q. We can actually--we can count them up, but in  
 11 effect, by the end of July, had you had  
 12 confirmed really what you had found in June  
 13 and the first part of July?  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Doctor, if we could, please, Exhibit P-1743?  
 18 Doctor, this is your--this is an e-mail from  
 19 Pat Wegrynowski of July 28th, 2005 to  
 20 yourself, and this is just confirming, I take  
 21 it, the arrangement that you referred to  
 22 yesterday that had been made with her to come  
 23 down and look at the lab.  
 24 DR. CARTER:  
 25 A. Um-hm.

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1 COFFEY, Q.C.:

2 Q. Doctor, you described yesterday what you

3 eventually learned about the amount of

4 documentation or lack thereof that the lab

5 had, the technologists, technology side of the

6 lab. As a pathologist, what--the time you

7 learned, as you learned more about it, what

8 was your reaction as a pathologist?

9 DR. CARTER:

10 A. To the fact that there was no documentation?

11 COFFEY, Q.C.:

12 Q. Yes.

13 DR. CARTER:

14 A. I mean, I wasn't happy that there was no

15 documentation. I mean, it's a basic sort of

16 tenet of laboratory life, actually

17 increasingly becoming more of all health care

18 that you document everything, but especially

19 when you're doing laboratory testing and I

20 don't just mean immunohistochemistry, but even

21 if you get your blood taken, all of those

22 machines, there's lots of documentation, lots

23 of quality control.

24 COFFEY, Q.C.:

25 Q. Had you had any sense before this process that

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1 that was the state of affairs?

2 DR. CARTER:

3 A. I would have thought, I think, coming in that

4 these things were basic laboratory practice.

5 COFFEY, Q.C.:

6 Q. So you had no inkling that this was the state

7 of affairs before the middle of 2005?

8 DR. CARTER:

9 A. No, I certainly thought that the antibodies

10 would have been validated before use.

11 Standard operating procedures for maintenance,

12 things like that. No, I would have thought

13 that they were in place.

14 COFFEY, Q.C.:

15 Q. Exhibit P-0076, please? Doctor, this is a

16 memo. It's styled to all pathologists,

17 pathology residents in Department of

18 Pathology, St. John's Hospitals, Eastern

19 Health. It's from Dr. Cook and yourself.

20 It's dated July 28th, 2005. It's re: optimal

21 assessment and reporting of hormone receptor

22 status in infiltrating carcinoma, and a space

23 for Dr. Cook and your signatures. This is

24 nine paragraphs, so numbered, and it begins by

25 saying "when ordering and reporting ER/PR

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1 status in infiltrating carcinoma of the

2 breast" and there is, in effect, a checklist,

3 as it were.

4 DR. CARTER:

5 A. Yes.

6 COFFEY, Q.C.:

7 Q. A how-to and a checklist relating to what to

8 do in relation to ER/PR status for breast

9 cancer. Doctor, why was this drafted?

10 DR. CARTER:

11 A. I think it's--can I see the date on it again,

12 please?

13 COFFEY, Q.C.:

14 Q. Yes, it's July 28th.

15 DR. CARTER:

16 A. July 28th. By that time, and again, this memo

17 was probably written or thought about a few

18 days before the date there. I think by that

19 time, we had looked at a significant number of

20 slides or I had looked at a significant number

21 of slides where I had identified that there

22 were issues with it. Also, when we were

23 sending it out, we were going to be over

24 inclusive and ask for everything in a report,

25 so if you go through them, you'll just see

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1 that we're giving sort of a step-by-step of

2 what people should do.

3 COFFEY, Q.C.:

4 Q. So I take it was this motivated by--the

5 drafting of this motivated by any concern that

6 perhaps not everyone knew everything that they

7 should know about it?

8 DR. CARTER:

9 A. I mean, I don't want to make definitive

10 statements about the spreadsheets, because

11 they haven't been rigorously studied and that

12 sort of thing, but these were trends that we

13 had seen, looking at those cases.

14 COFFEY, Q.C.:

15 Q. And I take it, if there was a lack or

16 potential lack of knowledge by certain

17 pathologists or pathology residents that this

18 was meant to -

19 DR. CARTER:

20 A. Educate.

21 COFFEY, Q.C.:

22 Q. - remediate that, correct it?

23 DR. CARTER:

24 A. Yes.

25 COFFEY, Q.C.:



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1 Q. Doctor, just go down through this briefly,  
 2 "select a block that contains infiltrating  
 3 carcinoma and normal and or benign breast  
 4 epithelium," which is, I take it, the internal  
 5 control issue?  
 6 DR. CARTER:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. "When reporting, always check internal and  
 10 external controls. The external positive  
 11 control should show some variability of  
 12 staining throughout the tissue selection."  
 13 Doctor, what is that meant to address?  
 14 DR. CARTER:  
 15 A. The external positive control?  
 16 COFFEY, Q.C.:  
 17 Q. Yes.  
 18 DR. CARTER:  
 19 A. Statement No. 3?  
 20 COFFEY, Q.C.:  
 21 Q. And the variability, yes.  
 22 DR. CARTER:  
 23 A. Immunohistochemistry largely is a--is it  
 24 present or is it absent type of testing, so if  
 25 you're looking at a melanoma, as I mentioned

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1 earlier, you look is S100 present or absent,  
 2 you're not looking at the amount of S100  
 3 that's present. With estrogen receptor,  
 4 progesterone receptor and a couple of other  
 5 immunohistochemistry stains, we do in a semi-  
 6 quantitative analysis, so you're looking at it  
 7 for its presence or absence, but also the  
 8 degree to which it's present. So when you  
 9 have a control tissue that you're essentially  
 10 comparing your test against, you want to make  
 11 sure that there was some variability  
 12 throughout your tissue, however you go about  
 13 picking your controls, so that patients on  
 14 either end of the spectrum, the very strongly  
 15 positive, which is not really a worry; that  
 16 those that are weakly positive and/or negative  
 17 will not be missed. So your control must show  
 18 some variability.  
 19 COFFEY, Q.C.:  
 20 Q. Must show character--involve all of those  
 21 characteristics in part of it weak positivity  
 22 and then part of it moderate perhaps and  
 23 strong.  
 24 DR. CARTER:  
 25 A. You would have a negative, a clearly positive

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1 and then you would have one that's somewhere  
 2 between the two, but you would like to move  
 3 down towards the 10 percent, but that's not  
 4 always possible.  
 5 COFFEY, Q.C.:  
 6 Q. And that's if you have, for example, three  
 7 separate controls. This relates to the  
 8 external positive control should show some  
 9 variability of staining throughout the tissue  
 10 section.  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. So this presupposes one external control.  
 15 DR. CARTER:  
 16 A. Yes, so you could use a, like we saw in some  
 17 of the previous ones, you could use a tumour  
 18 that expresses at 40 percent with a very  
 19 weakly staining, internal, native epithelium,  
 20 something like that. It's easier just to use  
 21 a sausage type, which is what you just  
 22 described with the three tissue sections.  
 23 COFFEY, Q.C.:  
 24 Q. Here the negative, "external negative control,  
 25 if made available should show no staining".

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1 Why would you say or did you say "if made  
 2 available"?.  
 3 DR. CARTER:  
 4 A. It was my practise prior to coming to St.  
 5 John's is that external negative controls were  
 6 read by the laboratory, they wouldn't come to  
 7 the attention of the pathologist.  
 8 COFFEY, Q.C.:  
 9 Q. In St. John's at that point, in July, 2005,  
 10 were there external negative controls being  
 11 run at all do you know, in this context?  
 12 DR. CARTER:  
 13 A. I don't think that they were run at all.  
 14 COFFEY, Q.C.:  
 15 Q. Paragraph five, "Internal negative control,  
 16 stroma, vascular, endothelium, should show no  
 17 staining." So I take it the idea of an  
 18 internal negative control with an ER/PR, there  
 19 should be -  
 20 DR. CARTER:  
 21 A. So if you have a breast cancer around that,  
 22 you'll have some supporting tissue, some blood  
 23 vessels that feed the cancer, so you'd just  
 24 have to make sure--those things are supposed  
 25 to be negative for estrogen, so you'd just

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1 have to make sure that they are negative as  
 2 well.  
 3 COFFEY, Q.C.:  
 4 Q. Paragraph six, "Internal breast epithelium  
 5 should show some positivity, but not diffuse."  
 6 What does that relate to?  
 7 DR. CARTER:  
 8 A. Again, if you're looking at benign or native  
 9 breast epithelium, you should see some  
 10 positivity in it. It's a very rare case where  
 11 you would find that the internal breast  
 12 epithelium would show a hundred percent  
 13 positivity. If it does, then again you'd  
 14 think about the degree of optimization of your  
 15 antibody.  
 16 COFFEY, Q.C.:  
 17 Q. And you think about it and potentially  
 18 question whether or not -  
 19 DR. CARTER:  
 20 A. Yes, potentially there would be a problem with  
 21 it.  
 22 COFFEY, Q.C.:  
 23 Q. And paragraph 7, "If the external positive  
 24 control is negative, the test is invalid." So  
 25 I take it if the external positive control

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1 doesn't stain, you'd have a problem?  
 2 DR. CARTER:  
 3 A. Yes. So that would be an absolute statement  
 4 there.  
 5 COFFEY, Q.C.:  
 6 Q. And you'd have to repeat it. "If the external  
 7 negative control is positive, the test is  
 8 invalid."  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Fair enough. In paragraph 9, Doctor, "If the  
 13 internal control shows aberrant staining, the  
 14 test may be invalid, please refer to Dr. Bev  
 15 Carter." So, Doctor, what in this, could you  
 16 elaborate please on paragraph 9?  
 17 DR. CARTER:  
 18 A. I had said earlier that the internal control  
 19 should show some variability, i.e. (not  
 20 diffuse), but you could have a case where  
 21 somebody was a very high expressor of  
 22 estrogen, either due to medication that  
 23 they're taking or their age or just their  
 24 estrogenic status, so it wouldn't necessarily,  
 25 because your internal control is diffusely

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1 positive, it wouldn't necessarily mean that  
 2 your test was invalid and conversely and more  
 3 controversial, you may have an internal  
 4 control that would be entirely negative.  
 5 COFFEY, Q.C.:  
 6 Q. Now what then, if you received such a phone  
 7 call or for example you received a phone call  
 8 or just yourself were analysing tissue, the  
 9 external control did work, positive and  
 10 negative controls if they were there did work,  
 11 Doctor, stain or not stained, as appropriate,  
 12 what would then be your approach with internal  
 13 controls? Perhaps you could just take the  
 14 Commissioner through that?  
 15 DR. CARTER:  
 16 A. Well if the internal control was negative, is  
 17 that what we're saying?  
 18 COFFEY, Q.C.:  
 19 Q. Well first of all, we'll assume it's positive,  
 20 it is working in the sense that the internal  
 21 control, you expected to stain -  
 22 DR. CARTER:  
 23 A. Show some variability and it does.  
 24 COFFEY, Q.C.:  
 25 Q. And it stains appropriately and the external

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1 controls are working, what do you then do?  
 2 DR. CARTER:  
 3 A. I would report the test, I'm not sure I  
 4 understand your question.  
 5 COFFEY, Q.C.:  
 6 Q. Okay, fair enough. So everything is working,  
 7 is fine. If the internal control does not  
 8 stain.  
 9 DR. CARTER:  
 10 A. So if the internal control is negative, then I  
 11 would look at other things surrounding that  
 12 idea, so -  
 13 COFFEY, Q.C.:  
 14 Q. What are the possible explanations?  
 15 DR. CARTER:  
 16 A. If you had a small portion of tissue that is  
 17 an internal control, like one gland or two  
 18 glands and it's negative, I mean just by  
 19 chance you may have hit the one or two glands  
 20 in that woman's breast that don't express any  
 21 estrogen.  
 22 COFFEY, Q.C.:  
 23 Q. Okay, that's one possibility, what are the  
 24 other possibilities? And what would you do if  
 25 you came across an internal control that

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1 wasn't staining?  
 2 DR. CARTER:  
 3 A. Well I would look at other aspects of the  
 4 testing process, so like you said, you'd look  
 5 at your external controls. I would look at the  
 6 tumour, so if my internal control was negative  
 7 and tumour was positive, I would be fine, you  
 8 know and if everything else had worked out. I  
 9 would look at how much internal control is  
 10 there, so if I have half a slide full of  
 11 native epithelium and it's all negative,  
 12 that's a problem. If I have one slide that's  
 13 negative, I mean, then that would bear looking  
 14 at.  
 15 COFFEY, Q.C.:  
 16 Q. Doctor, if the tumour stains negative and the  
 17 internal control is negative?  
 18 DR. CARTER:  
 19 A. So again you're narrowing down the  
 20 possibilities become, you know, more and more  
 21 to when you wouldn't accept that it would -  
 22 COFFEY, Q.C.:  
 23 Q. So what then would be your approach? What is,  
 24 from your perspective, the appropriate  
 25 approach then?

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1 DR. CARTER:  
 2 A. The same sort of thing, hopefully the same  
 3 sort of thing that you would look around and  
 4 see other indicators that tell you that the  
 5 test is good, you know, what was the run like,  
 6 is this a high grade cancer in a young female,  
 7 so you'd have other -  
 8 COFFEY, Q.C.:  
 9 Q. Look at the surrogate markers issue, examine  
 10 that. Might you re-run the test at times?  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. Now, Doctor, we have as well, we've seen  
 15 reference in some requisition forms, okay,  
 16 there's a couple of notes where there is  
 17 reference to external controls staining weakly  
 18 and this was in the days when there was just  
 19 one external control.  
 20 DR. CARTER:  
 21 A. Uh-hm.  
 22 COFFEY, Q.C.:  
 23 Q. What, if anything, would be the significance  
 24 of an external control staining weakly?  
 25 DR. CARTER:

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1 A. I would want to know what they meant by  
 2 staining weakly, but I would prefer a weakly  
 3 staining or moderately staining than a strong,  
 4 so I'm not sure what the question -  
 5 COFFEY, Q.C.:  
 6 Q. Well, at the time it was reported as noted ER  
 7 external control, weak, but okay to report or  
 8 words to that effect. What is the potential  
 9 implications of weakly staining external  
 10 control, one that was expected to be strongly  
 11 staining?  
 12 DR. CARTER:  
 13 A. Well then if you know that that is a strong  
 14 expressor and you've got weak staining on it,  
 15 then again, you're probably going to miss  
 16 people at the extremes of expression.  
 17 COFFEY, Q.C.:  
 18 Q. I take it people who are low expressors, they  
 19 might be missed by that particular run?  
 20 DR. CARTER:  
 21 A. I think so, but I would have to think about  
 22 negative, positives, that sort of thing.  
 23 THE COMMISSIONER:  
 24 Q. Mr. Coffey, wherever you can find a spot,  
 25 we'll take the morning Break.

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1 COFFEY, Q.C.:  
 2 Q. Commissioner, I'm going to come back and deal  
 3 with some of the work papers of Dr. Carter, so  
 4 now would be a good time.  
 5 THE COMMISSIONER:  
 6 Q. All right, we'll take fifteen minutes.  
 7 (RECESS)  
 8 THE COMMISSIONER:  
 9 Q. Please be seated. Mr. Coffey.  
 10 COFFEY, Q.C.:  
 11 Q. Thank you, Commissioner. Registrar, Exhibit  
 12 P-2476 please? Now, Doctor, these are, this  
 13 document is halfway redacted, but handwritten  
 14 at the top of the page there is a green, I  
 15 should point out here, it's obviously created  
 16 by a computer, the document is, the original  
 17 document, and then it has either a green or  
 18 yellow highlighting, depending upon which row  
 19 you're talking about. And at the top of the  
 20 first page it's noted in green, dark green  
 21 highlighter, "not on sheets" and then yellow  
 22 highlighting is "on sheet". And whose  
 23 handwriting is this, do you know?  
 24 DR. CARTER:  
 25 A. No, I don't know.

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1 COFFEY, Q.C.:

2 Q. Now, Doctor, do you know what these sheets

3 were?

4 DR. CARTER:

5 A. I don't know for certain, but I think that

6 these were the sheets that the lab assistants

7 and technologists were using to identify

8 cases.

9 COFFEY, Q.C.:

10 Q. Were you involved in these particular sheets

11 themselves?

12 DR. CARTER:

13 A. No.

14 COFFEY, Q.C.:

15 Q. And the handwriting itself, I take it, is not

16 yours?

17 DR. CARTER:

18 A. No.

19 COFFEY, Q.C.:

20 Q. Now, Doctor, I would ask you then to turn to--

21 and Registrar, to turn to P-2477. And,

22 Doctor, this is--do you recognize this

23 document first of all?

24 DR. CARTER:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And it's entitled "Breast Receptors" as we go

3 through these sheets. What is this document?

4 DR. CARTER:

5 A. This was a chart that I used, it's a

6 spreadsheet type format, but it wasn't an

7 electronic spreadsheet that I think, again,

8 Judy Thomas actually made the chart for me,

9 where I was entering patients as they were

10 being identified through the review or

11 identified from oncologists and then I was

12 filling in--do you want me to go through each

13 one of the columns?

14 COFFEY, Q.C.:

15 Q. Yes, I'll be taking you through them, Doctor.

16 Before I do, the handwriting here, "ER" just

17 crossed out and then there's "ER/PRR".

18 Doctor, just on that point because we

19 sometimes see rather than just PR, PRR, what's

20 that mean?

21 DR. CARTER:

22 A. I'm not certain but I think this is reference

23 to a completely different thing. We were

24 making up canned text, do you know of canned

25 text, for the computer, so if you were reading

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1 an estrogen receptor and progesterone receptor

2 case that was positive, you would tell the

3 secretary to call up ER/PRR and if it was

4 negative, you would ask them to call up, I

5 think that says ER/PR -

6 COFFEY, Q.C.:

7 Q. ER/PR is negative -

8 DR. CARTER:

9 A. I think it's completely unrelated to what the

10 spreadsheets are about, I think it's--Judy and

11 I were working on canned text.

12 COFFEY, Q.C.:

13 Q. And for what purpose at that point, canned

14 text?

15 DR. CARTER:

16 A. This would have been before we had decided to

17 suspend the testing, but as we had recognized

18 that there was a lot of variability in the

19 type of testing, so we wanted to develop a

20 stylized format or standardized report or

21 canned text that a pathologist would use,

22 because everybody is saying the same thing

23 over and over again, the secretary has just

24 entered it into the computer and can call it

25 up as a canned text so they don't have to type

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1 the same thing over and over again, it would

2 just come up. If you pressed ER/PR in a

3 particular field, it would come up with all

4 the common words there and they would just

5 fill in the percentages, things that were

6 subject to change.

7 COFFEY, Q.C.:

8 Q. And why I pursue that a bit more is this was

9 being pursued by yourself and Judy -

10 DR. CARTER:

11 A. Sorry, Ms. Thomas is a secretary, so she would

12 have been designing them.

13 COFFEY, Q.C.:

14 Q. Ms. Thomas, and this was in the summer of

15 2005, probably?

16 DR. CARTER:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. Before that then, such a canned text for these

20 purposes did not exist, to your knowledge.

21 DR. CARTER:

22 A. To my knowledge, no.

23 COFFEY, Q.C.:

24 Q. Okay. Doctor then, if you could take us then

25 across the column headings and describe what

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1 each of them relates to?

2 DR. CARTER:

3 A. Well the first three would be the patient's

4 name, the surgical number and the MCP number,

5 so they would just be unique identifiers for

6 the patients and then you would have three

7 there, so they're easy to cross-reference and

8 make sure you're talking about the same

9 patient. The next category would be tumour

10 type and as I've explained earlier, that may

11 be helpful as a surrogate marker to what you

12 would expect. The tumour grade, we do grading

13 of breast cancers according to Nottingham

14 Grading System, where we look at different

15 aspects of the tumour and it's been found

16 loosely to be correlated with prognosis, but

17 also it's been shown to be in association with

18 estrogen receptor testing on a very loose

19 basis, but lower grade tumours tend to be

20 positive more often than higher grade tumours.

21 COFFEY, Q.C.:

22 Q. And the grading runs from what to what,

23 Doctor?

24 DR. CARTER:

25 A. Just one, two or three. The block number then

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1 would be the block that the original test had

2 been performed on, the original report, the

3 estrogen receptor status and progesterone

4 receptor status off of the report, say in 2002

5 or in 1999, controls on the original, I think

6 here I was talking about external controls for

7 the purposes of this column, then the repeat

8 test and then a page--sorry, an area for

9 comments, just anything that had come up, as I

10 stated earlier, this was sort of a descriptive

11 document and I think eventually I added in the

12 date of the test and the name of the

13 pathologist, if you look over at page 9, for

14 example. So it was meant to be a fluid thing

15 that was subject to change.

16 COFFEY, Q.C.:

17 Q. Looking at page 9 and you pointed out that the

18 columns got added to, as time went on.

19 DR. CARTER:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. And you anticipated that really in the

23 beginning that that would probably happen.

24 DR. CARTER:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. Now, Doctor, the information, looking back at

3 page 1, the information to fill this in was

4 coming from where? I take it the patient's

5 name you would get from--where would you get

6 the patient's name from?

7 DR. CARTER:

8 A. As far as I can remember in the beginning, Mr.

9 Dyer and Mr. Gulliver were giving me the list

10 of the patient's names.

11 COFFEY, Q.C.:

12 Q. So it was just a list of names?

13 DR. CARTER:

14 A. No, they would give me the report.

15 COFFEY, Q.C.:

16 Q. Okay, that's what I was getting at. So you

17 have the pathology report -

18 DR. CARTER:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. - or reports, for that matter, for any one

22 patient.

23 DR. CARTER:

24 A. I think some of the patients have two, yes.

25 COFFEY, Q.C.:

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1 Q. Identified by Mr. Dyer and Mr. Gulliver.

2 DR. CARTER:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. Were, you, yourself, involved in doing any

6 searches of Meditec in relation to this?

7 DR. CARTER:

8 A. I would have asked for searches to be done,

9 but I wouldn't have performed them, I don't

10 think.

11 COFFEY, Q.C.:

12 Q. And the people in this context, your

13 understanding was--who was actually performing

14 the Meditec searches that you asked for?

15 DR. CARTER:

16 A. I think Mr. Dyer and Mr. Gulliver would be

17 performing.

18 COFFEY, Q.C.:

19 Q. So if a pathology report says the source of

20 information, usually.

21 DR. CARTER:

22 A. Yes.

23 COFFEY, Q.C.:

24 Q. We have the patient's name and their MCP

25 number would be on that report.

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1 DR. CARTER:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And a surgical number.  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Now here, looking at the surgical numbers,  
 9 you've listed SS's, SG, I believe.  
 10 DR. CARTER:  
 11 A. Yes, SG.  
 12 COFFEY, Q.C.:  
 13 Q. SU and--that's in the main, the first two  
 14 letters. What was the significance of those,  
 15 if any?  
 16 DR. CARTER:  
 17 A. SS, for the most part, would refer to St.  
 18 Clare's; SG would be the Grace; and SU would  
 19 be the General Hospital.  
 20 COFFEY, Q.C.:  
 21 Q. And I take it at that point you were only  
 22 looking at the St. John's cases?  
 23 DR. CARTER:  
 24 A. Yes, but I think there were some outside as  
 25 well here.

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1 COFFEY, Q.C.:  
 2 Q. Yes, and they may have a different beginning.  
 3 DR. CARTER:  
 4 A. Or the same, often it would be SS or SU, it  
 5 was quite common.  
 6 COFFEY, Q.C.:  
 7 Q. The MCP number, of course, would come off the  
 8 pathology report. Tumour type, where would  
 9 you get that from, Doctor?  
 10 DR. CARTER:  
 11 A. From the pathology report.  
 12 COFFEY, Q.C.:  
 13 Q. And so in the instance where, for example, in  
 14 this first page, the sixth and seventh  
 15 entries, four, five, sixth and seventh,  
 16 there's nothing filled in, why wouldn't it be  
 17 filled in? Would there be potentially nothing  
 18 written on the report about it?  
 19 DR. CARTER:  
 20 A. No, it's hard to--no, I don't think that would  
 21 be a possibility and again, I haven't looked  
 22 at these in, you know, fine detail.  
 23 COFFEY, Q.C.:  
 24 Q. You'd actually, in order to examine and  
 25 analyze this, you'd actually have to get out

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1 all the original pathology reports to do it.  
 2 DR. CARTER:  
 3 A. Perhaps they may have been metastases or  
 4 another specimen with breast, they may have  
 5 called it infiltrating carcinoma.  
 6 COFFEY, Q.C.:  
 7 Q. Without identifying it as ductal or lobular  
 8 for example?  
 9 DR. CARTER:  
 10 A. Yes, but infiltrating carcinoma, that bear  
 11 statement is interpreted as infiltrating  
 12 ductal.  
 13 COFFEY, Q.C.:  
 14 Q. Ductal, okay, but again, the information for  
 15 the tumour type, such as is listed here on  
 16 these pages, you would have just simply have  
 17 gleaned off the pathology report?  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. This is not your analysis of the original  
 22 slides?  
 23 DR. CARTER:  
 24 A. No.  
 25 COFFEY, Q.C.:

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1 Q. The tumour grade, again the information here  
 2 is from the pathology reports?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. The original reports. It's not you making a  
 7 determination.  
 8 DR. CARTER:  
 9 A. No.  
 10 COFFEY, Q.C.:  
 11 Q. Using the original slides yourself. The block  
 12 number?  
 13 DR. CARTER:  
 14 A. When people are doing the gross description of  
 15 the case, so sometimes they will say in it  
 16 Block A has been sent for estrogen receptor,  
 17 progesterone receptor testing. But often that  
 18 was not included in the report which was why  
 19 we eventually included it in our canned texts.  
 20 Also there are internal comments on reports  
 21 that are not available to the patient's chart,  
 22 so the technologists when they enter into the  
 23 computer what sort of procedure, so sometimes  
 24 on that you can see Block A has been sent to  
 25 Ken--Mr. Green for testing, so we picked it up

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1 that way.  
 2 COFFEY, Q.C.:  
 3 Q. That's what I'm getting at, how were you able  
 4 to identify that, if it wasn't on the  
 5 pathology reports?  
 6 DR. CARTER:  
 7 A. There's different kinds of pathology reports  
 8 that you can get, so I would assume I got the  
 9 type, I don't know what it's called, that  
 10 would include the patient, the stuff that goes  
 11 on the patient chart, all that information,  
 12 but as well, portions of internal comments,  
 13 lab kind of comments, when you can simply get  
 14 a report that is just a diagnosis, you can get  
 15 it--that doesn't include the diagnosis, so you  
 16 can manipulate the computer many ways.  
 17 COFFEY, Q.C.:  
 18 Q. Meditec to give you different types of  
 19 reports.  
 20 DR. CARTER:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. Any one of which might be called a pathology  
 24 report, but might relate to different aspects  
 25 of it.

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1 DR. CARTER:  
 2 A. Yes, I mean, we would call it the pathology  
 3 report.  
 4 COFFEY, Q.C.:  
 5 Q. And so your observation at the time in  
 6 reviewing the pathology report simpliciter,  
 7 okay, I'll call it that, that very often the  
 8 block numbers were not actually identified by  
 9 the pathologist.  
 10 DR. CARTER:  
 11 A. That's correct.  
 12 COFFEY, Q.C.:  
 13 Q. Occasionally they were, but very often they  
 14 weren't.  
 15 DR. CARTER:  
 16 A. No.  
 17 COFFEY, Q.C.:  
 18 Q. But there was a way, because of the type of  
 19 print-out that you got, of you looking at this  
 20 internal material.  
 21 DR. CARTER:  
 22 A. And sometimes it would be--I would suspect  
 23 that most of the time I got the block number  
 24 off of a slide when I got it.  
 25 COFFEY, Q.C.:

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1 Q. Okay.  
 2 DR. CARTER:  
 3 A. It wasn't a common practice for us to include  
 4 that.  
 5 COFFEY, Q.C.:  
 6 Q. And I was going to ask you, the other way you  
 7 could identify the block number was look at the  
 8 slides.  
 9 DR. CARTER:  
 10 A. Simply when I got the slides, yes.  
 11 COFFEY, Q.C.:  
 12 Q. So I take it on the slide itself it would be  
 13 identified by the surgical number and at  
 14 times, the block number as well?  
 15 DR. CARTER:  
 16 A. All slides have their surgical number and  
 17 their block number--well, they should, yes.  
 18 COFFEY, Q.C.:  
 19 Q. So in filling out the block number here, the  
 20 sources were the pathology reports,  
 21 simpliciter, the internal comments coming from  
 22 Meditec you understand related to the  
 23 technology end of the lab, and potentially  
 24 and/or the actual slides, the original slides  
 25 themselves. The original report, ER and PR

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1 columns, Doctor, where did the information for  
 2 these come from?  
 3 DR. CARTER:  
 4 A. Again, from the report.  
 5 COFFEY, Q.C.:  
 6 Q. Now, Doctor, here, just looking down through  
 7 this first page, in some instances, for  
 8 example here on the first one, there's a black  
 9 marker kind of squiggle through, there's a  
 10 dash, a dash and then I'll refer to it as a  
 11 squiggle, a wavy line through it. What would  
 12 that signify?  
 13 DR. CARTER:  
 14 A. The dash dash would be negative negative. The  
 15 blue line, I know we've discussed this and I  
 16 have gone back and looked at these in their  
 17 native form, I haven't gone back and looked in  
 18 the charts and co-ordinated anything, but I  
 19 have gone back and looked at the different  
 20 colours and things that are here and tried to  
 21 see if I could find a relationship. I think  
 22 the blue mark would be over the ER/PR, would  
 23 mean that that patient would be considered a  
 24 convertor. The black mark, I have no idea why  
 25 that was there, I think I started off with a

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1 black marker and then saw it would just cover  
 2 up everything else.  
 3 COFFEY, Q.C.:  
 4 Q. Okay, and then there are some references here,  
 5 we go down to more at the bottom of the page,  
 6 on the first page, the third and fourth last  
 7 entries under ER/PR are written in as "NEG",  
 8 do you see that?  
 9 DR. CARTER:  
 10 A. They would be the same as the dash dash, the  
 11 negative, negative.  
 12 COFFEY, Q.C.:  
 13 Q. Okay, so negative, negative and just a simple  
 14 dash--a simple dash means negative in your  
 15 world filling these out?  
 16 DR. CARTER:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. Now there are other entries here, I'll just,  
 20 the second row on this page, "WK" would be  
 21 weak, I take it or is it?  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. "NEG" circled, one percent and then "WK 1 dash

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1 two percent 'N' circled." Could you just  
 2 translate that for us, what that means?  
 3 DR. CARTER:  
 4 A. Weak one percent, which I would consider a  
 5 negative; weak one to two percent and I would  
 6 assume that the N with the circle around it  
 7 would mean negative again.  
 8 COFFEY, Q.C.:  
 9 Q. And then we go down a bit further, I take it  
 10 there's a, sixth row, "WK" would be weak,  
 11 slash less than 5 percent?  
 12 DR. CARTER:  
 13 A. Yes, I think so.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, if I could--too far, I'm just going to  
 16 go back. Page 2 of the exhibit, the third  
 17 last--I'm sorry, here Doctor, on page two  
 18 toward the bottom of the page, third last  
 19 entry under "Original report E/R" and there's  
 20 a positive sign, do you see that?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. So why would that have been--it's an '02 case,  
 25 why would that have been retested at that

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1 point, do you know or being looked at at the  
 2 time?  
 3 DR. CARTER:  
 4 A. It would have ended up in the, somehow in the  
 5 data sheets, I don't know why, I mean I'm  
 6 looking at, it was called infiltrating ductal  
 7 carcinoma, I'm not sure it was picked up in  
 8 the group.  
 9 COFFEY, Q.C.:  
 10 Q. Doctor, anywhere and just looking further up  
 11 the page here, the fourth entry under "PR"  
 12 there's a positive.  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. ER negative, PR positive. What would the  
 17 positive in this context, a positive sign  
 18 signify?  
 19 DR. CARTER:  
 20 A. Going by my usual practice, I would think it  
 21 would be greater than 10 percent.  
 22 COFFEY, Q.C.:  
 23 Q. We go over then to, I'll going to go back to  
 24 the first page, and again to give the  
 25 Commissioner some sense of this, in repeat

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1 receptors, which I take it is the results of  
 2 the Ventana retests at this point.  
 3 DR. CARTER:  
 4 A. It would have been a mixture, I think, of  
 5 Ventana and Mount Sinai, I don't have dates on  
 6 this.  
 7 COFFEY, Q.C.:  
 8 Q. And here, as we go down through the first  
 9 page, there's a positive. Is there any  
 10 significance to the circle?  
 11 DR. CARTER:  
 12 A. No.  
 13 COFFEY, Q.C.:  
 14 Q. And there's some positive signs and then the  
 15 third entry is negative negative here and if  
 16 you go down the sixth row, has S/80 percent P,  
 17 S/100 percent P, would that be strong positive  
 18 80 percent?  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. Now, Doctor, go down a bit--I apologize,  
 23 further down the first page, page 2, there we  
 24 are, page 1, the fourth last entry, fourth  
 25 last row, there's a negative and a negative



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1 under the ER and then a negative negative  
 2 under the PR, do you see that?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. What would that signify?  
 7 DR. CARTER:  
 8 A. I don't remember. If you look back in block  
 9 number, there's two blocks there, so I would  
 10 presume that we tested two blocks.  
 11 COFFEY, Q.C.:  
 12 Q. Two blocks, okay. And then under the column  
 13 section, just going to run down through some  
 14 of the columns and perhaps you can expand--I'm  
 15 sorry, some of the comments in the comment  
 16 section. First of all, I'll back up, where  
 17 you have no entry in the comment section,  
 18 what, if anything, did that mean?  
 19 DR. CARTER:  
 20 A. It would have meant at the time that nothing  
 21 really struck me as unique to that case or  
 22 something that struck me that was there on a  
 23 case I had already written it on another case.  
 24 COFFEY, Q.C.:  
 25 Q. And a third row on the first page, you've

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1 noted "good internal control".  
 2 DR. CARTER:  
 3 A. So there probably was, we're always searching  
 4 for nice controls to use in the  
 5 immunohistochemistry department.  
 6 COFFEY, Q.C.:  
 7 Q. Now here the original report had been negative  
 8 negative and then on repeat it was negative  
 9 negative.  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. So I take it this would not be a conversion?  
 14 DR. CARTER:  
 15 A. No.  
 16 COFFEY, Q.C.:  
 17 Q. So the blue may not then signify a conversion,  
 18 this blue highlight or whatever it did  
 19 signify. You would agree, would you?  
 20 THE COMMISSIONER:  
 21 Q. Were the repeats always on the same block?  
 22 DR. CARTER:  
 23 A. No, they weren't always on the same block,  
 24 they were if we could find that block easily,  
 25 but if it wasn't available for whatever

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1 reason, we would select another block.  
 2 THE COMMISSIONER:  
 3 Q. Okay, thank you.  
 4 COFFEY, Q.C.:  
 5 Q. And here then on the fourth row you've written  
 6 "review of original equals positive", what was  
 7 that, Doctor?  
 8 DR. CARTER:  
 9 A. If you look at the chart, it says "negative  
 10 negative".  
 11 COFFEY, Q.C.:  
 12 Q. Yes, for the original report, yes.  
 13 DR. CARTER:  
 14 A. And review of the original is that this case  
 15 is in fact positive and so it's probably an  
 16 error on my part, introducing the data into  
 17 the table, so I mean, I'm guessing again, but  
 18 maybe the surgical number was wrong or I read  
 19 the report incorrectly.  
 20 COFFEY, Q.C.:  
 21 Q. So this is not one that, from your  
 22 perspective, had been reported wrongly by the  
 23 pathologist?  
 24 DR. CARTER:  
 25 A. Again, I don't know because this is, you know,

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1 very preliminary data entered by me, not  
 2 rigorously controlled, not checked or  
 3 whatever, so I'm just going on memory, but I  
 4 would think because it hasn't been retested,  
 5 that there is a data entry error on my part.  
 6 COFFEY, Q.C.:  
 7 Q. Because you've noted here there is no  
 8 indication that it was actually retested.  
 9 DR. CARTER:  
 10 A. Yes, I'm just taking all these little facts  
 11 and trying to come up with a plausible  
 12 explanation.  
 13 COFFEY, Q.C.:  
 14 Q. And then here, Doctor, you've noted the next--  
 15 in the fifth row, you've written in "skin  
 16 specimen", why would you note that?  
 17 DR. CARTER:  
 18 A. There would probably be something on the slide  
 19 that either showed skin or was a skin specimen  
 20 or that I thought was interesting from an  
 21 educational point of view.  
 22 COFFEY, Q.C.:  
 23 Q. And here, Doctor, the fifth row says "HSC  
 24 SU7761-01" and you've got "XX" there and then  
 25 you've got "HSC SU9323-01". Now the SS meant

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1 here -  
 2 DR. CARTER:  
 3 A. St. Clare's.  
 4 COFFEY, Q.C.:  
 5 Q. St. Clare's and the HSC SU would be, I take it  
 6 the Health Sciences -  
 7 DR. CARTER:  
 8 A. Most likely, yes.  
 9 COFFEY, Q.C.:  
 10 Q. Surgical number, for the same surgical number,  
 11 the corresponding one, I take it, here.  
 12 DR. CARTER:  
 13 A. 7761 corresponds to SS1148-01, I believe. So  
 14 these probably would be two other specimens on  
 15 that same patient that I noted for some  
 16 reason.  
 17 COFFEY, Q.C.:  
 18 Q. And you've written, in the row below, "stain  
 19 dirty."  
 20 DR. CARTER:  
 21 A. That's usually a lot of background staining,  
 22 so often a lot of native things that can  
 23 interfere with the test, endogenous  
 24 peroxidases haven't been quenched off the  
 25 slide.

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1 COFFEY, Q.C.:  
 2 Q. Would this comment be in relation to the  
 3 retest slides or the original slides?  
 4 DR. CARTER:  
 5 A. I would think for the original slides. That's  
 6 what I was commenting on. I think for the  
 7 retest slides, I was just entering. But  
 8 again, not rigorously examined.  
 9 COFFEY, Q.C.:  
 10 Q. Now here, for the fifth, sixth and seventh  
 11 rows on this page, under controls on original,  
 12 you've got a question mark.  
 13 DR. CARTER:  
 14 A. Oh, okay. Sorry, yes.  
 15 COFFEY, Q.C.:  
 16 Q. See those? What does that mean?  
 17 DR. CARTER:  
 18 A. That means that there was no control slide--  
 19 there was no control tissue on the slides and  
 20 I was not a--because sometimes they did the  
 21 control on a separate slide and sometimes they  
 22 put the control tissue exactly on the slide.  
 23 COFFEY, Q.C.:  
 24 Q. On the patient slide?  
 25 DR. CARTER:

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1 A. On the patient slide, thank you, yes. So this  
 2 is I couldn't--there was no control slide and  
 3 I couldn't find the external control.  
 4 COFFEY, Q.C.:  
 5 Q. Now here, as well, while we're on this  
 6 particular row, I take it the first and second  
 7 and fourth entry, fourth rows, where you've  
 8 got a positive, controls on original, you've  
 9 got--the first of them, you've noted "positive  
 10 report only" positive meaning that there were  
 11 external controls?  
 12 DR. CARTER:  
 13 A. I would think that that's what it means.  
 14 COFFEY, Q.C.:  
 15 Q. And then positive would--but it was in the  
 16 report only. A positive without a reference  
 17 to the report only, would that suggest that,  
 18 in fact, you did see the external control  
 19 slide for that particular surgical number,  
 20 like these?  
 21 DR. CARTER:  
 22 A. I would think that the "report only" maybe  
 23 refers to the fact that I couldn't get the  
 24 original slides.  
 25 COFFEY, Q.C.:

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1 Q. And then a positive though, without any kind  
 2 of qualification, probably meant you might  
 3 have seen the -  
 4 DR. CARTER:  
 5 A. Probably.  
 6 COFFEY, Q.C.:  
 7 Q. Now there though, then we go down further,  
 8 past that series of three question marks,  
 9 you've written for the last five out of the  
 10 last six rows, you've written "no".  
 11 DR. CARTER:  
 12 A. So there would be no control tissue on the  
 13 patient slide.  
 14 COFFEY, Q.C.:  
 15 Q. And you didn't see the external control  
 16 slides?  
 17 DR. CARTER:  
 18 A. I didn't see--I don't think I saw any external  
 19 controls in this, for the purposes of this  
 20 investigation.  
 21 COFFEY, Q.C.:  
 22 Q. Doctor, if we could go back then to the  
 23 comments column, you've written under the row  
 24 "stain dirty" you've written in the next row,  
 25 "only"--is it "L lymph node with tumour"?

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1 DR. CARTER:  
 2 A. Yes, so this was not a breast case, but a  
 3 metastases from the breast, I would assume. So  
 4 there'd be no internal control with that  
 5 tissue, by definition.  
 6 COFFEY, Q.C.:  
 7 Q. And then the next two rows, you've written in  
 8 "internal control of ER negative." Is that a  
 9 slash?  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. PR positive?  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Same thing again, so what did that mean in  
 18 respect of these two surgical numbers?  
 19 DR. CARTER:  
 20 A. That when I looked at the original slides, at  
 21 the patient's sample slide, the patient's  
 22 report would have gone out as negative for  
 23 estrogen receptor and negative for  
 24 progesterone receptor and when I was looking  
 25 around the slide, internal control was

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1 present, but when I looked at the estrogen  
 2 receptor slide, the internal control was  
 3 negative and when I looked at the progesterone  
 4 receptor slide, the tumour was negative and  
 5 the internal control showed appropriate  
 6 staining.  
 7 COFFEY, Q.C.:  
 8 Q. So, just here, just on this point, the  
 9 Commissioner follow this, perhaps we'll just  
 10 deal with the ninth row one first, the first  
 11 of these two right here. The surgical number  
 12 here is SU647-02.  
 13 DR. CARTER:  
 14 A. Um-hm.  
 15 COFFEY, Q.C.:  
 16 Q. It's infiltrating ductal carcinoma, tumour  
 17 grade three, block number C. The original  
 18 report is negative. Dash, dash means  
 19 negative, negative, ER and PR. You did not--  
 20 there were no controls on the original, no  
 21 external control tissue, and on repeat  
 22 receptors, the ER and PR was negative in both  
 23 instances?  
 24 DR. CARTER:  
 25 A. Yes.

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1 COFFEY, Q.C.:  
 2 Q. Now here, Doctor, what, if anything, then  
 3 would be the significance of finding--because  
 4 on repeat, both that case and, in fact, the  
 5 one below it, which is SU4741-02, they are not  
 6 conversions?  
 7 DR. CARTER:  
 8 A. No, they're not.  
 9 COFFEY, Q.C.:  
 10 Q. At least at that time, they're both -  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. - originally negative and on repeats,  
 15 negatives. What, if anything, is the  
 16 significance of finding that the internal  
 17 control for ER was negative and PR was  
 18 positive?  
 19 DR. CARTER:  
 20 A. The significance for these cases?  
 21 COFFEY, Q.C.:  
 22 Q. Yes.  
 23 DR. CARTER:  
 24 A. I don't think there's a particular  
 25 significance for these two, but there's a

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1 significance -  
 2 COFFEY, Q.C.:  
 3 Q. Overall.  
 4 DR. CARTER:  
 5 A. - in general, that you would want your  
 6 internal controls to show some variable  
 7 positivity.  
 8 COFFEY, Q.C.:  
 9 Q. And in fact, the PRs, it had shown it?  
 10 DR. CARTER:  
 11 A. So the PR was good internal control, what we  
 12 would call good internal control, and the ER  
 13 was not.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, were these cases that were originally  
 16 examined, not only these but all of these, in  
 17 fact, throughout that June, July process, were  
 18 they ever retested in Mount Sinai overall, do  
 19 you know?  
 20 DR. CARTER:  
 21 A. The ones that were retested?  
 22 COFFEY, Q.C.:  
 23 Q. Yes.  
 24 DR. CARTER:  
 25 A. At the--on the Ventana system?

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1 COFFEY, Q.C.:

2 Q. Yes.

3 DR. CARTER:

4 A. I think so, but I'm not certain of that, but

5 yes, I think so.

6 COFFEY, Q.C.:

7 Q. Now the next entry is, in the comments column,

8 is "internal control adequate".

9 DR. CARTER:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. Here, repeat receptors is noted not done. Do

13 you know, at that point, why that hadn't been

14 done up to that point?

15 DR. CARTER:

16 A. No, I have no specific recollection of it.

17 I'm sure that it probably was going to be done

18 as a part of the retrospective.

19 COFFEY, Q.C.:

20 Q. And just hadn't been redone up to that point

21 on the Ventana?

22 DR. CARTER:

23 A. You know, and the other likelihood is that it

24 was a perfect slide that would have no need

25 for any kind of error or deficiency in it, but

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1 I don't know.

2 COFFEY, Q.C.:

3 Q. And you do note here, the internal controls--

4 saying "internal control adequate" I take it

5 that would be both controls in this context?

6 DR. CARTER:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. Internal control for ER negative PR weak, I

10 take it that would fall into a similar

11 category to these two above here, internal

12 control negative PR positive, except that the

13 PR is negative?

14 DR. CARTER:

15 A. It was faint, but it was there when you

16 looked. It was there.

17 COFFEY, Q.C.:

18 Q. Now Doctor, on the second page, of these--and

19 it is a form of a spreadsheet, the third row,

20 you've written "fixation terrible." What is--

21 it's negative and then positive on--are you

22 able to pick that out?

23 DR. CARTER:

24 A. RPT, I would assume I mean repeat.

25 COFFEY, Q.C.:

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1 Q. On repeat, okay. Now in saying "fixation

2 terrible" I take it you would be looking at

3 the original slides?

4 DR. CARTER:

5 A. Yes.

6 COFFEY, Q.C.:

7 Q. A particular--well, the slide made from Block

8 G I presume?

9 DR. CARTER:

10 A. Yes. Two blocks were tested, so maybe the

11 first time it was negative/negative, the

12 second time negative/positive in Block E, but

13 again, I'm not certain.

14 COFFEY, Q.C.:

15 Q. E and G, I take it G, the "fixation terrible"

16 you're referring to Block G?

17 DR. CARTER:

18 A. That's what it seems to be what I'm doing on

19 this.

20 COFFEY, Q.C.:

21 Q. Doctor, if we look down then through the

22 comments sections here, you got "internal

23 control negative." Now that would signify

24 that there was an internal control but it had

25 controls but they had stained negatively?

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1 DR. CARTER:

2 A. On my first look through, yes.

3 COFFEY, Q.C.:

4 Q. And ER weakly positive, would that be a

5 comment in relation to the control, internal

6 control tissue or overall ER?

7 DR. CARTER:

8 A. I think it would be comment on overall, if you

9 look under the original, ER, I've got down

10 weak.

11 COFFEY, Q.C.:

12 Q. Yes, and then you got "internal control

13 negative. ER/PR missing, reported negative."

14 DR. CARTER:

15 A. So I wouldn't have been able to have access to

16 the slides.

17 COFFEY, Q.C.:

18 Q. And then "internal controls negative."

19 Negative, now, and then there's a--the style

20 becomes negative sign circled, internal

21 control.

22 DR. CARTER:

23 A. Yes.

24 COFFEY, Q.C.:

25 Q. So I take it that means the internal control

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1 is there, it's negative, or there's -  
 2 DR. CARTER:  
 3 A. It could be either or actually.  
 4 COFFEY, Q.C.:  
 5 Q. Or no internal control?  
 6 DR. CARTER:  
 7 A. Yeah, it could be either or. Generally, I  
 8 think it would mean negative internal control.  
 9 COFFEY, Q.C.:  
 10 Q. I apologize, Doctor, just this is very  
 11 sensitive there now. Okay, the third row,  
 12 third last row on the second page, you've got  
 13 "invasive micropapillary"?  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Why would you note that, Doctor?  
 18 DR. CARTER:  
 19 A. It's a very rare, relatively rare type of  
 20 tumour. I was probably making a note there  
 21 that I would show it to the residents.  
 22 COFFEY, Q.C.:  
 23 Q. And then below that, there's a reference to  
 24 METS?

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1 DR. CARTER:  
 2 A. So it would be metastases. I don't know if  
 3 this was a metastases or the patient had  
 4 metastases.  
 5 COFFEY, Q.C.:  
 6 Q. Now Doctor, in the course of doing this work,  
 7 you were looking at the original slides, the  
 8 original pathology reports, you were noting  
 9 the repeat receptors results. You were  
 10 getting those results from where?  
 11 DR. CARTER:  
 12 A. From Ventana.  
 13 COFFEY, Q.C.:  
 14 Q. From the Ventana machine.  
 15 DR. CARTER:  
 16 A. And from Mount Sinai, depending on when it  
 17 happened, around when we shut off the machine.  
 18 COFFEY, Q.C.:  
 19 Q. So as they were coming--as the repeat testing  
 20 was being done on the Ventana machine and -  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. - became available, you would make a note of  
 25 it?

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1 DR. CARTER:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And some of the time, I take it that it would  
 5 be you actually doing the analysis yourself or  
 6 were you doing, in fact, at this point, all of  
 7 the analysis of the repeats on the Ventana?  
 8 DR. CARTER:  
 9 A. The actual reading of them?  
 10 COFFEY, Q.C.:  
 11 Q. Yes.  
 12 DR. CARTER:  
 13 A. Probably Dr. Cook and Dr. Naghibi, but largely  
 14 me.  
 15 COFFEY, Q.C.:  
 16 Q. Now here, on the third page, in the first row,  
 17 you've written "not working" and the ER and PR  
 18 is--there's a figure there, but it's scratched  
 19 out. Do you recall -  
 20 DR. CARTER:  
 21 A. I would assume that I'm referring to the  
 22 internal control not working. These would all  
 23 be done on different days, different times of  
 24 day. This was all being squeezed in with my  
 25 regular work. So sometimes I would say

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1 "internal control, dash" and sometimes I'd say  
 2 "dash, internal control."  
 3 COFFEY, Q.C.:  
 4 Q. And -  
 5 DR. CARTER:  
 6 A. I would presume that that's what I mean, that  
 7 it was not--the internal control was negative.  
 8 COFFEY, Q.C.:  
 9 Q. And then, there are a number of entries for  
 10 internal control negatives. Now, Doctor, here  
 11 where there is no entry, for example, the  
 12 second and third last rows on page three,  
 13 there's nothing under the comments section,  
 14 what, if anything, did that signify about the  
 15 internal controls on the original slides? Did  
 16 it signify anything?  
 17 DR. CARTER:  
 18 A. Again, this hasn't been, you know, rigorously  
 19 studied. I would assume that the internal  
 20 controls in fact showed some staining with  
 21 those, but I wouldn't state that as a  
 22 certainty.  
 23 COFFEY, Q.C.:  
 24 Q. Here Doctor, when we go on to the fourth page,  
 25 then looking at the comments column, you noted

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1 "done on MET, not done on original." I  
 2 believe that says "not done on original."  
 3 What is the second row entry?  
 4 DR. CARTER:  
 5 A. The second row entry?  
 6 COFFEY, Q.C.:  
 7 Q. Yes, this one here, page four.  
 8 DR. CARTER:  
 9 A. Oh, skin.  
 10 COFFEY, Q.C.:  
 11 Q. Skin, oh, I apologize. It's skin, okay. And  
 12 so the next entry in the comments column below  
 13 that, "ER internal controls not working."  
 14 DR. CARTER:  
 15 A. Correct.  
 16 COFFEY, Q.C.:  
 17 Q. Okay. Which is, in effect, the same as  
 18 negative?  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. So Doctor, go down through the fifth page,  
 23 there are a number of entries for internal  
 24 controls negative. So in a number of these  
 25 instances, I take it, Doctor, what you are

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1 seeing on the original slides was that there  
 2 was internal--there was normal tissue there  
 3 that could have been used as an internal  
 4 control. It just hadn't stained?  
 5 DR. CARTER:  
 6 A. For the most part, I would assume that that's  
 7 what I meant, yes.  
 8 COFFEY, Q.C.:  
 9 Q. And it hadn't stained though, from what you  
 10 could see?  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.:  
 14 Q. Occasionally, Doctor, we go on to the sixth  
 15 page, there's a reference, third last row, to  
 16 slides lost. So I take it occasionally then  
 17 the original slides were not available?  
 18 DR. CARTER:  
 19 A. That's correct.  
 20 COFFEY, Q.C.:  
 21 Q. Because above that, you've written, in the  
 22 fifth last row, "no slides." You've got a  
 23 question mark.  
 24 DR. CARTER:  
 25 A. And then Dr. Wadhwa's name is after it, her

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1 first name, and I'm not sure what I'm  
 2 referring to there.  
 3 COFFEY, Q.C.:  
 4 Q. We go on to the page seven, again there are a  
 5 number of entries for internal controls  
 6 negative, and then when you would write in,  
 7 for example, in these first two rows here, on  
 8 page seven, "internal control negative" and  
 9 you got a slash WK, weak, would that signify  
 10 that the ER was negative and the PR was weak?  
 11 Is that the sort of -  
 12 DR. CARTER:  
 13 A. That may be what it referred to or that it was  
 14 so weak that I would have called it negative,  
 15 so either or.  
 16 COFFEY, Q.C.:  
 17 Q. In the main here, Doctor, you are  
 18 concentrating of ER or PR or were you  
 19 concentrating on either, you're just making  
 20 observations on both, in this process?  
 21 DR. CARTER:  
 22 A. We were looking at both, but you know, I tend  
 23 to think of estrogen receptor status as the  
 24 most important, so more emphasis would  
 25 definitely be placed on that test.

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1 COFFEY, Q.C.:  
 2 Q. Page eight, there are a number of entries  
 3 again for negative control or negative  
 4 internal control, or you've got written in  
 5 INT, which I take it is internal control  
 6 negative?  
 7 DR. CARTER:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. Okay. Page ten, again some entries for  
 11 internal control negative, and then page 11,  
 12 again a number of entries. In the comments  
 13 column, you said "internal control negative"  
 14 or the mathematical sign, in fact, circle with  
 15 a slash through it.  
 16 DR. CARTER:  
 17 A. I would think that that would be my way of  
 18 saying that there was no internal control on  
 19 that slide.  
 20 COFFEY, Q.C.:  
 21 Q. No internal control, okay.  
 22 DR. CARTER:  
 23 A. But I can't be certain that some of the ones  
 24 that say negative internal control don't mean  
 25 that as well.

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1 COFFEY, Q.C.:

2 Q. Yes. This page is a good example of it.

3 You've got internal control negative a number

4 of times, written, internal control and a

5 negative sign with a circle around it, and

6 then a number of other instances, you've got

7 the symbol for it. In fact, it is no.

8 DR. CARTER:

9 A. Yes.

10 COFFEY, Q.C.:

11 Q. The mathematical symbol.

12 DR. CARTER:

13 A. So I would assume I used both things reliably

14 throughout, but I can't guarantee that.

15 COFFEY, Q.C.:

16 Q. And here, the second row is this mark, and by

17 that circle with a slash through it, you mean

18 no?

19 DR. CARTER:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. And so if indeed that's what you meant at the

23 time, there would be no internal control.

24 Same thing appears in the fifth row, the

25 seventh and eighth rows.

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1 DR. CARTER:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. And then, Doctor, we come to page 12 and where

5 there are names, surgical numbers and MCP

6 numbers, and of course, the names and MCP

7 numbers here are redacted, but and then they

8 go on, there's a page 13, page 14, page 15,

9 16, 17, and it ends on page 18 with two

10 entries and there's no data though other than

11 in those three columns, names, surgical number

12 and MCP number.

13 DR. CARTER:

14 A. Um-hm.

15 COFFEY, Q.C.:

16 Q. Do you recall why that was?

17 DR. CARTER:

18 A. I think these would be cases then that Judy

19 Quinlan was identifying through whatever

20 information she had been given, and placing

21 them at least initially into the--it's not

22 really a spreadsheet, but that's what we're

23 calling it, but it's not an electronic

24 spreadsheet, into the table for me because a

25 considerable amount of my time was being taken

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1 up with clerical sort of duties.

2 COFFEY, Q.C.:

3 Q. Now Doctor, these documents that we've just

4 looked at, what, if any, records did you make

5 during June and July of 2005 concerning your

6 work on your examination that you set out on?

7 Does this summarize your work?

8 DR. CARTER:

9 A. Yes, it does summarize my work, but I've tried

10 to make the point to the Commissioner that

11 this is my data entry and my writing and I

12 think you can take the general concepts that

13 I'm saying from it, but the specifics of it,

14 none of this has been--you know, the data

15 entry has not been verified by a second

16 person, things that you would do before you

17 presented something as being absolute fact.

18 But I think trends are fine to take from it.

19 COFFEY, Q.C.:

20 Q. And Doctor, your comment about--earlier to the

21 Commissioner about your observations about

22 either an absence of internal control tissue

23 on the original slides or internal control

24 tissue was there, it just wasn't stained

25 appropriately from your perspective?

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1 DR. CARTER:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. This is reflected here in this material, isn't

5 it?

6 DR. CARTER:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. Doctor, were there some patients for whom

10 there were, in fact, two surgical numbers?

11 Would there have been some patients, do you

12 think?

13 DR. CARTER:

14 A. Two or more, yes. Most people would undergo

15 several procedures as part of their treatment.

16 COFFEY, Q.C.:

17 Q. And a reference to--let's go to--just go back

18 a bit here. The first entry here on page

19 four, under comments, "done on MET, not done

20 on original." Why would that be, Doctor? I

21 take it that--I'd suggest that the ER/PR test

22 was done on the metastases, but had not been

23 done on the original?

24 DR. CARTER:

25 A. Or it may suggest that the repeat receptors

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1 were done on metastases, not on the original,  
 2 because we couldn't find the original blocks.  
 3 It may have been sent outside.  
 4 COFFEY, Q.C.:  
 5 Q. Doctor, as you were doing or going through  
 6 this process in June and July, you would have  
 7 finished this--first, I should ask you, this  
 8 process, you had finished this by when, what  
 9 we've seen here?  
 10 DR. CARTER:  
 11 A. I hadn't finished anything at all.  
 12 COFFEY, Q.C.:  
 13 Q. No, I appreciate that.  
 14 DR. CARTER:  
 15 A. I stopped this on August the 2nd  
 16 COFFEY, Q.C.:  
 17 Q. That's what I'm getting at. So August -  
 18 DR. CARTER:  
 19 A. I stopped this on August the 2nd.  
 20 COFFEY, Q.C.:  
 21 Q. - as of August 2, anything that we see  
 22 reflected here, any work, this is what I'm  
 23 trying to ask you, any work that we see  
 24 reflected here had occurred on or before  
 25 August 2?

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1 DR. CARTER:  
 2 A. I would say that that's true, yes.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, your observations and your thoughts at  
 5 the time, were you communicating them to  
 6 anyone?  
 7 DR. CARTER:  
 8 A. I would have been communicating them to Dr.  
 9 Cook.  
 10 COFFEY, Q.C.:  
 11 Q. And what you were seeing, were at times you  
 12 showing him the slides?  
 13 DR. CARTER:  
 14 A. I think that we did look at some slides  
 15 together.  
 16 COFFEY, Q.C.:  
 17 Q. Did you communicate your observations to  
 18 anyone else?  
 19 DR. CARTER:  
 20 A. Not in any official manner, but I don't think  
 21 either that, you know, we were keeping quiet  
 22 about it. So I think that we would -  
 23 COFFEY, Q.C.:  
 24 Q. Within the office certainly, around the  
 25 building, within the pathology office at St.

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1 Clare's, you wouldn't--you're saying, you  
 2 wouldn't say to the Commissioner that "I  
 3 didn't tell anybody. I might very well have  
 4 spoken to other doctors about it."  
 5 DR. CARTER:  
 6 A. Yeah, and I think everybody knew that there  
 7 was something going on, and everybody had  
 8 little pieces of information about it.  
 9 COFFEY, Q.C.:  
 10 Q. And if they asked you something about it, one  
 11 of your colleagues?  
 12 DR. CARTER:  
 13 A. I would answer.  
 14 COFFEY, Q.C.:  
 15 Q. Doctor, do you recall how many then cases you  
 16 looked at?  
 17 DR. CARTER:  
 18 A. I think I counted them up on the weekend. I  
 19 think there's 97, but I'm not sure. My  
 20 figures are at home.  
 21 COFFEY, Q.C.:  
 22 Q. And you used what to count? Was it this sheet  
 23 here, these sheets?  
 24 DR. CARTER:  
 25 A. Yes, I didn't use the patient name or

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1 anything. I used--did it on, I think, the  
 2 redacted sheets.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, were there--there would have been  
 5 then, I take it, patients for whom there'd be  
 6 more than one surgical number, and you've  
 7 referred to that.  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. There might be two or three in fact.  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Were there any patients you came across that  
 16 had had repeat ER/PR testing done before 2005?  
 17 DR. CARTER:  
 18 A. I think so, yes.  
 19 COFFEY, Q.C.:  
 20 Q. And do you recall--and repeat on the same  
 21 surgical number, is what I'm -  
 22 DR. CARTER:  
 23 A. Yes, so I would have seen cases, just say,  
 24 September 1st, 2002, a few cases, September  
 25 1st, 2002, and then repeated again on



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1 September 7th, 2002, something like that.  
 2 COFFEY, Q.C.:  
 3 Q. Would they have been reported on September 1st  
 4 and then reported again on September 7th, for  
 5 example?  
 6 DR. CARTER:  
 7 A. I saw things like that, yes.  
 8 COFFEY, Q.C.:  
 9 Q. Had the results changed in those instances?  
 10 DR. CARTER:  
 11 A. I think most of them had stayed the same, but  
 12 I think I do recall one that changed from  
 13 weakly positive to positive, but again, I'd  
 14 have to go back and look at them all.  
 15 COFFEY, Q.C.:  
 16 Q. Yes, and that would require, I take it,  
 17 actually just going through all--getting out  
 18 the 90 odd cases again, all the material, and  
 19 kind of going through it?  
 20 DR. CARTER:  
 21 A. Getting all the reports and the slides and the  
 22 blocks and the retests and those sorts of  
 23 things. You really can't go back and do it  
 24 now, because now we know so much compared to  
 25 what we knew then. It would never be as pure.

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1 COFFEY, Q.C.:  
 2 Q. Doctor, in relation to that, we have heard--in  
 3 fact, Mr. Dyer has told the Commissioner that  
 4 himself and Mr. Gulliver, when they were going  
 5 through the pathology reports, they noted or  
 6 noticed at least a couple of instances, one or  
 7 two instances or more, and he indicated it  
 8 would be relatively few, but there were  
 9 instances where a test had been done on a  
 10 surgical, particular surgical specimen,  
 11 reported and he had seen then another  
 12 pathology report, reading the same pathology  
 13 report or reference to a retest with a  
 14 different result.  
 15 DR. CARTER:  
 16 A. In my experience, that wouldn't be a common  
 17 finding, no.  
 18 COFFEY, Q.C.:  
 19 Q. No, it wasn't common. He didn't say it -  
 20 DR. CARTER:  
 21 A. Oh sorry, I thought you said commonly.  
 22 COFFEY, Q.C.:  
 23 Q. No, no, he said it was relatively uncommon,  
 24 but they had seen it in at least a couple of  
 25 instances. So is that what you're telling the

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1 Commissioner, in your review, you came across  
 2 one or two cases where that was so?  
 3 DR. CARTER:  
 4 A. You have to--I think I have a fair memory of  
 5 one case, and there's probably a few more, but  
 6 it's not a common finding.  
 7 COFFEY, Q.C.:  
 8 Q. Do you recall how much that case had changed  
 9 on retest?  
 10 DR. CARTER:  
 11 A. It was significant. I mean, I think it had  
 12 gone from weakly positive to positive, but I  
 13 feel uncomfortable commenting on it if I don't  
 14 have the case in front of me.  
 15 COFFEY, Q.C.:  
 16 Q. And in light of what happened in 2005, would  
 17 that have been considered, applying the 2005  
 18 process, would that have been considered a  
 19 conversion at the time?  
 20 DR. CARTER:  
 21 A. Again, I would have to see the case. If it  
 22 was -  
 23 COFFEY, Q.C.:  
 24 Q. If you went from five percent to -  
 25 DR. CARTER:

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1 A. To 80.  
 2 COFFEY, Q.C.:  
 3 Q. - to 80 percent.  
 4 DR. CARTER:  
 5 A. Yeah, then that would be conversion.  
 6 COFFEY, Q.C.:  
 7 Q. Conversion. So there may have been at least  
 8 one or two instances that you saw that,  
 9 looking back on it, from the vantage point of  
 10 2005, had converted in the earlier years, at  
 11 some point, on the DAKO, it had converted?  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Up to that point, had you ever heard that or  
 16 been--like within your, within Eastern Health,  
 17 while you were working there, that there had  
 18 been such cases in the past, rarely, but there  
 19 had been?  
 20 DR. CARTER:  
 21 A. As a specific, no.  
 22 COFFEY, Q.C.:  
 23 Q. Well, as a non-specific?  
 24 DR. CARTER:  
 25 A. Well, as I explained earlier, I think many of

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1 us have had experiences where we've ordered  
 2 retesting on a case, for a variety of reasons.  
 3 So I would have known that retesting was going  
 4 on, but I wouldn't have known that retesting  
 5 that was of significance to the clinical  
 6 management of the patient had gone on.  
 7 COFFEY, Q.C.:  
 8 Q. Your observation about that one -  
 9 THE COMMISSIONER:  
 10 Q. Mr. Coffey?  
 11 COFFEY, Q.C.:  
 12 Q. Sure, Commissioner.  
 13 THE COMMISSIONER:  
 14 Q. Is what you're talking about, retesting in  
 15 that sense, a kind of thing that I would think  
 16 of as the normal part of what a pathologist  
 17 does in the sense of when you get a slides,  
 18 you say to yourself "there's something about  
 19 this that I don't trust and want it done again  
 20 before I give an opinion"?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 THE COMMISSIONER:  
 24 Q. And are there other kinds of occasions when  
 25 you might want to go back and order a retest

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1 after you've given an opinion?  
 2 DR. CARTER:  
 3 A. Yes. If I gave an opinion on a case and the  
 4 clinician thought that that wasn't congruent  
 5 with what they thought about the patient, they  
 6 may request or discuss with you and you may  
 7 decide that you're going to request the  
 8 retest. You could bring it to your colleagues  
 9 and, you know, show it to them, sign it out  
 10 because, you know, you feel confident with  
 11 your diagnosis and then show it to your  
 12 colleagues and your colleagues say "no, I'm  
 13 not really happy with that. Just retest it."  
 14 THE COMMISSIONER:  
 15 Q. Okay, thank you.  
 16 COFFEY, Q.C.:  
 17 Q. Doctor, did you bring that -- at least one or  
 18 two instances that you did come across, did  
 19 you bring that to Dr. Cook's attention?  
 20 DR. CARTER:  
 21 A. I don't think so, no.  
 22 COFFEY, Q.C.:  
 23 Q. Can you tell the Commissioner did you bring it  
 24 to anyone else's attention?  
 25 DR. CARTER:

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1 A. I don't think so, no. I would have thought  
 2 that it was handled when it had happened.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, that sort of instance in terms of the  
 5 overall retesting that eventually occurred  
 6 through Mount Sinai, were those cases  
 7 retested?  
 8 DR. CARTER:  
 9 A. I'm sorry, I don't understand your question.  
 10 COFFEY, Q.C.:  
 11 Q. In the case of the one or two instances that  
 12 you came across that had been conversions that  
 13 you saw in the reports --  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. Using -- for example, using the DAKO, or  
 18 around the time of the Ventana switch over,  
 19 for example, again I don't know, but say the  
 20 DAKO, we'll just assume it was retested on the  
 21 DAKO years ago, and upon retest the result was  
 22 clinically different -- significantly  
 23 different, do you know if those particular  
 24 cases were retested at Mount Sinai?  
 25 DR. CARTER:

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1 A. I have no knowledge of how they selected cases  
 2 for retest outside of the cases that I was  
 3 involved in.  
 4 COFFEY, Q.C.:  
 5 Q. So the Mount Sinai --  
 6 DR. CARTER:  
 7 A. I don't know what they used for their  
 8 selection criteria for that.  
 9 COFFEY, Q.C.:  
 10 Q. Doctor, if we could, please, Exhibit P-0539.  
 11 Doctor, these are handwritten notes of the  
 12 meeting of August -- relating to the meeting  
 13 of August 1st, 2005, and the source of them is  
 14 VP Medical, which would be Dr. Williams. On  
 15 page three, and you won't see those actually  
 16 in the book there, Doctor, just a couple of --  
 17 you recounted your recollection of the meeting  
 18 itself yesterday, but in the typed version  
 19 he's noted here, August 1, 2005, and he  
 20 attributes comments or certain comments under  
 21 these bullets to certain individuals. Here  
 22 there's a reference from Dr. Cook, "Eleven  
 23 cases sent to Mount Sinai, negative and  
 24 variable positives. Some areas of  
 25 disagreement. One case, 10 percent positive

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1 came back negative. Some minor variations".  
 2 So I take it that would be that one instance  
 3 you referred to?  
 4 DR. CARTER:  
 5 A. As the false positive, but this is the first  
 6 time that I've seen this.  
 7 COFFEY, Q.C.:  
 8 Q. Oh, yes, these notes, yes, I appreciate that.  
 9 Would that have come up, do you think, during  
 10 the August 1st meeting, like, the fact that  
 11 there was a problem, potential problem with  
 12 the Ventana? Perhaps I'll just let you look  
 13 down through this first. There's certain  
 14 comments attributed to you.  
 15 DR. CARTER:  
 16 A. But this is not the August 1st meeting that I  
 17 talked about, the big meeting, I don't think.  
 18 I think this is an earlier meeting in the day.  
 19 COFFEY, Q.C.:  
 20 Q. Oh, okay, this is an earlier meeting in the  
 21 day. Okay, a smaller -- and so how many  
 22 meetings of August 1 do you recall attending?  
 23 DR. CARTER:  
 24 A. I mean, I would need to look at this again,  
 25 but I think this was just a small meeting in

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1 Dr. Williams office where we discussed the  
 2 cases, I think, that this is about that went  
 3 up for quality control, and then there was the  
 4 August 1st administrative meeting that was  
 5 later in the afternoon.  
 6 COFFEY, Q.C.:  
 7 Q. So a smaller group of, in fact, doctors had  
 8 met earlier in the day; yourself, Dr.  
 9 McCarthy, and Dr. Cook, and Dr. Williams, I  
 10 presume. These are his notes.  
 11 DR. CARTER:  
 12 A. And I would have to look at them.  
 13 COFFEY, Q.C.:  
 14 Q. But your recollection is that there were  
 15 separate meetings amongst a smaller group of  
 16 you outside of the administrative group?  
 17 DR. CARTER:  
 18 A. On August 1st?  
 19 COFFEY, Q.C.:  
 20 Q. Or before that?  
 21 DR. CARTER:  
 22 A. Yes, sometimes -- I mean, there would be  
 23 different meetings with lots of people.  
 24 COFFEY, Q.C.:  
 25 Q. So, Doctor, looking at this, amongst the

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1 smaller non-administrative group, these 11  
 2 cases that have been sent out to Mount Sinai  
 3 were discussed, the results, amongst the group  
 4 of you, according to this. Dr. Cook is  
 5 reported to have referred to 11 cases going to  
 6 Mount Sinai, negative and variable positives,  
 7 some areas of disagreement, one case 10  
 8 percent positive came back negative, which  
 9 would be a false positive in your world. "Dr.  
 10 McCarthy, positive is positive. Some  
 11 disagreements with the PRs. As long as one ER  
 12 or PR is positive, this is okay. Dr. Cook,  
 13 now have 11 cases we can use as controls.  
 14 Future correlation with Mount Sinai for next  
 15 two or three months. Mount Sinai is  
 16 accredited by IAP and participates in outside"  
 17 - it's probably CAP, it should be, "and  
 18 participates in outside review. Dr. McCarthy  
 19 very comfortable with future plan and Mount  
 20 Sinai", and then Dr. Carter, "There is been  
 21 known variability in the results over the  
 22 years". Now, Doctor, the idea of known  
 23 variability in the results over the years, is  
 24 that locally or generally in the profession?  
 25 DR. CARTER:

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1 A. I'm not sure what it is that I am referring to  
 2 there.  
 3 COFFEY, Q.C.:  
 4 Q. Was there known variability in the results  
 5 over the years locally?  
 6 DR. CARTER:  
 7 A. But in the results of what?  
 8 COFFEY, Q.C.:  
 9 Q. Well, presumably the ER/PR in this context?  
 10 DR. CARTER:  
 11 A. That there's variable results for ER/PR?  
 12 COFFEY, Q.C.:  
 13 Q. Known variability in the results over the  
 14 years?  
 15 DR. CARTER:  
 16 A. I'm not sure what that is in reference to.  
 17 People would know that ER shows variable  
 18 results from patient to patient, people would  
 19 know that there are false negatives, false  
 20 positives, built in. I'm not sure what that  
 21 sentence is about.  
 22 COFFEY, Q.C.:  
 23 Q. And then there's a remark attributed to you,  
 24 "Tumour Board discussion, talked about issue  
 25 which has been found". Do you recall what

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1 that was about?

2 DR. CARTER:

3 A. No, I don't.

4 COFFEY, Q.C.:

5 Q. And, "The memory of this case back when the

6 patient was lobular cancer carcinoma tested

7 negative", I take it that would be a reference

8 at least indirectly to Peggy Deane?

9 DR. CARTER:

10 A. I would think so.

11 COFFEY, Q.C.:

12 Q. And "June to November, 2002, follow up that

13 year and no positive reports", what was that

14 about, Doctor?

15 DR. CARTER:

16 A. Again I'm not sure what the context of this

17 is, but when I have been looking at stacks of

18 papers that had come to me, eventually I was

19 getting stacks of positive and negative -- you

20 know, all of the ER/PR cases, not just the

21 negatives, it had switched to getting those,

22 and I was looking through them to try to find

23 the negatives and I came across a period where

24 there had been no positive results come out of

25 one of the hospital sites in St. John's for a

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1 period of time. I guess it was June to

2 November.

3 COFFEY, Q.C.:

4 Q. Do you recall which hospital site that was?

5 DR. CARTER:

6 A. Health Science Centre, and this is again a

7 very quick review. This is not to be taken as

8 fact, this is myself searching quickly through

9 a pile of papers.

10 COFFEY, Q.C.:

11 Q. I take it this was an observation of yours at

12 the time and you were querying it?

13 DR. CARTER:

14 A. Yes, that there was a significant period of

15 time where everything seemed to be negative.

16 COFFEY, Q.C.:

17 Q. Doctor, just so the Commissioner can get some

18 sense of this, as between the General Hospital

19 and St. Clare's, who was doing the bulk of the

20 breast surgery?

21 DR. CARTER:

22 A. In 2005?

23 COFFEY, Q.C.:

24 Q. Yes.

25 DR. CARTER:

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1 A. St. Clare's.

2 COFFEY, Q.C.:

3 Q. And bearing in mind that while you did examine

4 the 2001 ones, for example, we know that, who

5 had been doing the bulk of it in 2002?

6 DR. CARTER:

7 A. I think it was more equal, but I didn't look

8 at that, but I think over time people have

9 switched to St. Clare's -- surgeons have

10 switched to St. Clare's because the

11 mammographic facilities, things that they may

12 require during surgery are located there, and

13 probably just through attrition of surgeons.

14 COFFEY, Q.C.:

15 Q. And when you arrived your first year, the

16 summer of '03 at St. Clare's, approximately

17 how many breast surgeries was St. Clare's

18 doing annually, do you know?

19 DR. CARTER:

20 A. In '03, I was at the Health Science Centre.

21 COFFEY, Q.C.:

22 Q. Yes, I apologize, yes, because you showed up

23 in August of '03.

24 DR. CARTER:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. In August of '04?

3 DR. CARTER:

4 A. I can give you sort of the statistics that I

5 give out to everybody. I mean, there's about

6 300 cases of breast -- there's 300 patients

7 with breast cancer diagnosed in Newfoundland

8 every year based on population statistics.

9 About 200 of those 300 would be seen in the

10 St. John's area, and probably about two-third

11 to three-quarters of those would be seen at

12 St. Clare's.

13 COFFEY, Q.C.:

14 Q. Those statistics reflect what time frame, what

15 particular year or years?

16 DR. CARTER:

17 A. I mean, when I came here, I asked because

18 there was some question of what site I was

19 going to work at. So I would have asked people

20 at the Cancer Centre, that's a ball park of

21 what's going on.

22 COFFEY, Q.C.:

23 Q. I take it then that that at least somewhat had

24 some influence on you arrival at St. Clare's?

25 DR. CARTER:

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1 A. I mean, it was largely determined by where the  
 2 vacancy existed, but, you know, I'm sure I  
 3 could have managed to switch from one site to  
 4 the other if I thought it was needed.  
 5 COFFEY, Q.C.:  
 6 Q. Doctor, here it goes on to say or note that  
 7 you reported here or said here, "The 16 of 25  
 8 conversions have been reported", which is  
 9 consistent with that June 29th letter. "Dr.  
 10 Kwan notified, Dr. Boone notified". Why would  
 11 there be a reference to them here?  
 12 DR. CARTER:  
 13 A. Again I don't know -- I don't know -- it's the  
 14 first time I've seen this. Maybe the two --  
 15 remember that Dr. McCarthy had sent back two  
 16 cases and said that we don't know who these  
 17 are, so maybe we tracked them down and those  
 18 surgeons were at least the person who  
 19 performed the initial surgery. So it may have  
 20 some contact, but -- I'm doing a little bit of  
 21 guessing here.  
 22 COFFEY, Q.C.:  
 23 Q. And, "Ten have been notified by NCTR", that's  
 24 ten of what?  
 25 DR. CARTER:

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1 A. I think that's NCTRF, probably the old name  
 2 for the Cancer Centre.  
 3 COFFEY, Q.C.:  
 4 Q. "Ten have been notified".  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Notified of the what, change in results?  
 9 DR. CARTER:  
 10 A. I would assume so, but again I'm guessing.  
 11 COFFEY, Q.C.:  
 12 Q. And, "Four already on appropriate treatment".  
 13 The fact that ten have been notified and four  
 14 were already on appropriate treatment, if you  
 15 did indeed report that --  
 16 DR. CARTER:  
 17 A. I don't know how I would have known that.  
 18 COFFEY, Q.C.:  
 19 Q. The only place you'd find that out from is  
 20 from --  
 21 DR. CARTER:  
 22 A. From an oncologist.  
 23 COFFEY, Q.C.:  
 24 Q. Oncologist. So if indeed it came from you,  
 25 then, in fact, it was only --

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1 DR. CARTER:  
 2 A. Hearsay.  
 3 COFFEY, Q.C.:  
 4 Q. Hearsay from Dr. McCarthy, and it may have  
 5 even been, in fact, Dr. McCarthy's comments  
 6 for all we know here because she's at this  
 7 meeting too.  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor -- bring up, please, Exhibit P-0079.  
 12 I'm going to ask you about a comment here. On  
 13 the second page, you conclude by saying, "I  
 14 regret not being able to participate fully in  
 15 this process, but I'm very uncomfortable  
 16 placing my professional licensure in the  
 17 forefront of this operation and risking my  
 18 reputation, etc, as an expert in breast  
 19 pathology". Doctor, at the time, you know,  
 20 coming out of that August 1st meeting and  
 21 going into August 2nd, what was your concern  
 22 overall about the direction this was taking  
 23 and who was in -- who was in control?  
 24 DR. CARTER:  
 25 A. I think my largest concern was with the

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1 management structure that we had in the lab,  
 2 that this was, I mean, a fairly serious issue,  
 3 and a lot of the decisions that were being  
 4 made were being made by the management team in  
 5 the lab, which I felt at that meeting had  
 6 demonstrated that they didn't have a lot of in  
 7 depth knowledge of the issues that were at  
 8 hand, and I thought that this investigation  
 9 could go down some wrong paths.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor, had there been anything said at the  
 12 August 1st meeting in relation to this,  
 13 attributing the reasons for the conversion  
 14 from DAKO to the Ventana switch over? You  
 15 recall you told the Commissioner about that  
 16 yesterday that the press release or --  
 17 DR. CARTER:  
 18 A. The big meeting?  
 19 COFFEY, Q.C.:  
 20 Q. The big meeting.  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. The written document, whether it was a memo or  
 25 a press release or whatever, that the --

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1 DR. CARTER:  
 2 A. I think it was some sort of release because  
 3 there was some discussion about they were, you  
 4 know -- this was ready to go.  
 5 COFFEY, Q.C.:  
 6 Q. Was there anything said at the meeting that  
 7 led you to believe or conclude or understand  
 8 that that was, in fact, the way that they  
 9 intended to go, despite your observations that  
 10 you couldn't attribute this to just a change  
 11 from one piece of machinery to the other?  
 12 DR. CARTER:  
 13 A. After I left the meeting that they were going  
 14 to continue to --  
 15 COFFEY, Q.C.:  
 16 Q. No, by the time you left the meeting?  
 17 DR. CARTER:  
 18 A. I would have thought that they were going to  
 19 abandon that idea.  
 20 COFFEY, Q.C.:  
 21 Q. Okay, that was your --  
 22 DR. CARTER:  
 23 A. That was my understanding.  
 24 COFFEY, Q.C.:  
 25 Q. Based upon what?

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1 DR. CARTER:  
 2 A. Well, after the large argument, I thought that  
 3 the agreement was between the people in the  
 4 lab that, no, that this was not a machinery  
 5 issue.  
 6 COFFEY, Q.C.:  
 7 Q. And, Doctor, have you ever come to a  
 8 conclusion about the reasons for, I think,  
 9 test failure, to utilize Dr. Banerjee's  
 10 phrase, yourself? Had you ever come to any  
 11 conclusions about that or -- I won't say  
 12 definitive conclusions, but conclusions.  
 13 DR. CARTER:  
 14 A. You mean opinion?  
 15 COFFEY, Q.C.:  
 16 Q. Yes, opinion, professional opinion.  
 17 DR. CARTER:  
 18 A. As to what went on -- I mean, I think that the  
 19 strongest evidence that we have is that the  
 20 retesting, retrospective retesting, was, in  
 21 fact, successful and Dr. Mullen was quite  
 22 satisfied to report on all of these. So I  
 23 think pre-analytic variables such as fixation,  
 24 that's been given a lot of talk, would have  
 25 less importance, and you would have to think

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1 that it's the testing procedure itself, and  
 2 just going on statistics really, the testing  
 3 procedure itself would probably have something  
 4 to do with antigen retrieval, and I think Dr.  
 5 Mullen compared post-analytic variables  
 6 himself as well in terms of disagreement with  
 7 pathologists interpretation, and that was fine  
 8 as well.  
 9 COFFEY, Q.C.:  
 10 Q. And, I take it, it's your understanding that  
 11 Dr. Mullen generally agreed -- in terms of the  
 12 call of percentages, his general view was is  
 13 if somebody earlier said 10, he might have  
 14 said 15, but he didn't differ significantly?  
 15 DR. CARTER:  
 16 A. That is my general understanding, just from  
 17 reading his evidence.  
 18 COFFEY, Q.C.:  
 19 Q. And in terms of your own analysis at the time  
 20 back in June/July of '05, we just saw a  
 21 summary of it here, how had your calling of  
 22 the percentages compared to the original  
 23 pathologist's calling of the percentages on  
 24 the original slides?  
 25 DR. CARTER:

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1 A. There was a high degree of agreement. There  
 2 was one case that I can think of that was  
 3 called positive that I felt was negative, but  
 4 other than that, I don't recall it standing  
 5 out as a large issue.  
 6 COFFEY, Q.C.:  
 7 Q. And you attributed that particular case to  
 8 what, the difference in view?  
 9 DR. CARTER:  
 10 A. There was a lot of background staining on that  
 11 case that was interpreted --  
 12 COFFEY, Q.C.:  
 13 Q. It was interpreted as nuclear staining, and in  
 14 your view it wasn't nuclear staining, it was  
 15 simply background?  
 16 DR. CARTER:  
 17 A. Non-specific cytoplasmic staining.  
 18 COFFEY, Q.C.:  
 19 Q. Doctor, what about the internal controls issue  
 20 in terms of your observations of those slides,  
 21 the original slides? Did you think any of  
 22 them should have been reported at all in 2002?  
 23 I mean, looking at those 90 odd, we just  
 24 looked at them now, should they have been  
 25 reported, bearing in mind the total number of

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1 them that there were either no internal  
 2 controls or internal controls did not stain?  
 3 DR. CARTER:  
 4 A. That's a very difficult question to answer.  
 5 If you saw one slide in the condition that  
 6 we've discussed with no internal control or  
 7 negative internal controls, poor fixation,  
 8 within 200 other slides that were, you know,  
 9 quite adequate -- if I had seen them all in a  
 10 row, as I did this time, then it's very easy  
 11 to spot trends.  
 12 COFFEY, Q.C.:  
 13 Q. And to say, no, it shouldn't have been  
 14 reported?  
 15 DR. CARTER:  
 16 A. Yes, then you wouldn't report it, but if I had  
 17 seen that in isolated case, and I'm sure that  
 18 I have because i think that I'm in that group  
 19 -- I'm not sure specifics of my case, but,  
 20 yes, I think I would have reported it as an  
 21 isolated event, but not if I had seen it over  
 22 and over, you know, in time.  
 23 COFFEY, Q.C.:  
 24 Q. And, Doctor, harking back to, Doctor, the  
 25 September 1st, 2004 minutes of a meeting where

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1 Dr. Fontaine is reported to have said that he  
 2 understood that you wanted to look at all the  
 3 ER/PR HER2/neu slides in St. John's --  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. If someone, not yourself because you weren't  
 8 here at the time, but if someone had done that  
 9 back in 2000 or 2001, and all the slides were  
 10 going through one or two individuals?  
 11 DR. CARTER:  
 12 A. It would have been more likely that they would  
 13 have seen that.  
 14 COFFEY, Q.C.:  
 15 Q. If they were aware to look for internal  
 16 controls?  
 17 DR. CARTER:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. And to see that they were stained  
 21 appropriately, they would have been aware that  
 22 the internal controls are not staining --  
 23 DR. CARTER:  
 24 A. Yes, in my opinion.  
 25 COFFEY, Q.C.:

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1 Q. At times they were not staining more  
 2 frequently than should be accepted?  
 3 DR. CARTER:  
 4 A. In my opinion, yes, they probably would have.  
 5 COFFEY, Q.C.:  
 6 Q. Doctor, the -- when you arrived in St. John's,  
 7 I want to ask you about external controls  
 8 first, your understanding. Were you seeing  
 9 external control slides?  
 10 DR. CARTER:  
 11 A. When I first arrived as a locum at the Health  
 12 Sciences Centre, I think at that point they  
 13 were still doing external controls that were  
 14 being reported separately, and I wouldn't have  
 15 seen those, I wouldn't have been included in  
 16 the roster of people who would --  
 17 COFFEY, Q.C.:  
 18 Q. Examine them.  
 19 DR. CARTER:  
 20 A. Examine them, because my presence was  
 21 unreliable, I was in and out, covering people  
 22 for vacation. I think when I started work in  
 23 August of -- sorry, yes, August of 2004, I  
 24 think that they were on the slide by that  
 25 point. I think the transition had been made.

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1 COFFEY, Q.C.:  
 2 Q. And in the earlier time when you were kind of  
 3 substituting for people doing the locums --  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. If you reported an ER/PR case at the time,  
 8 would you have asked to see the external  
 9 control slide?  
 10 DR. CARTER:  
 11 A. No, we would have -- I would have assumed that  
 12 the process had been followed and that the  
 13 controls were appropriate.  
 14 COFFEY, Q.C.:  
 15 Q. Being read by another pathologist?  
 16 DR. CARTER:  
 17 A. Yes, and appropriately reported.  
 18 COFFEY, Q.C.:  
 19 Q. And that would -- so your understanding when  
 20 you arrived to do locums in August of '03,  
 21 even though you were at the Health Sciences  
 22 Centre because that's where you went  
 23 initially, was that the external control  
 24 slides for ER/PR were being read by some other  
 25 pathologist and reported as being

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1 appropriately stained?  
 2 DR. CARTER:  
 3 A. Yes, and it switched somewhere in that first  
 4 year to having the slide -- control slide on  
 5 the patient slide.  
 6 COFFEY, Q.C.:  
 7 Q. But when you first arrived, your understanding  
 8 is you wouldn't go looking for the external  
 9 control slide, even in August, 2003?  
 10 DR. CARTER:  
 11 A. No, if I wasn't provided with it, then the  
 12 assumption was that it was being read.  
 13 COFFEY, Q.C.:  
 14 Q. And that was, for yourself, even being at the  
 15 Health Sciences Centre?  
 16 DR. CARTER:  
 17 A. Yes. If you had --  
 18 COMMISSIONER:  
 19 Q. Mr. Coffey, when it's convenient -- sorry, I  
 20 didn't mean to interrupt you, Dr. Carter.  
 21 Carry on.  
 22 DR. CARTER:  
 23 A. That's okay. I mean, if you had difficulty  
 24 with your case or questions, you could ask for  
 25 the external control, but I don't recall doing

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1 that.  
 2 COFFEY, Q.C.:  
 3 Q. Commissioner. Thank you.  
 4 COMMISSIONER:  
 5 Q. Ten after two.  
 6 (LUNCH BREAK)  
 7 COMMISSIONER:  
 8 Q. Mr. Coffey.  
 9 COFFEY, Q.C.:  
 10 Q. Thank you, Commissioner. Exhibit P-0071,  
 11 please, registrar, page nine, please. Now,  
 12 Doctor, this particular exhibit is a series of  
 13 draft documents that the Commission received.  
 14 The source was Deborah Thomas-Pennell, who  
 15 worked with Ms. Bonnell. In particular, page  
 16 nine, this is a draft media release for  
 17 immediate release, retesting due to improved  
 18 technology. It's styled, "July XX, 2005, St.  
 19 John's, Newfoundland and Labrador", and it  
 20 reads, "Some former and current breast cancer  
 21 patients will have some existing breast tissue  
 22 specimens re-examined on new technology to  
 23 ensure accuracy, Eastern Health announced  
 24 today. The decision to retest some specimens  
 25 comes after a second test of a tissue sample

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1 obtained in 2002 on an older piece of  
 2 technology yielded a different result on a  
 3 newer system installed last year", and it goes  
 4 on from there. Doctor, I appreciate that this  
 5 is some number of years ago now. The draft  
 6 release that you saw at that August 1st  
 7 meeting, that administrative meeting, was it  
 8 possibly this or something like it?  
 9 DR. CARTER:  
 10 A. Possibly, yes, but this is the first time that  
 11 I've seen this. That would be the gist of  
 12 what was being discussed at the meeting.  
 13 COFFEY, Q.C.:  
 14 Q. At the meeting, the draft of whatever they  
 15 had, was it passed out or was it just read  
 16 out, do you recall?  
 17 DR. CARTER:  
 18 A. I don't recall it being passed around. I  
 19 think somebody read it, or they may have read  
 20 parts of it.  
 21 COFFEY, Q.C.:  
 22 Q. And your recollection is the people in  
 23 question were the people associated with  
 24 public relations, whomever they --  
 25 DR. CARTER:

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1 A. And QI, and I'm not sure who was from what  
 2 area.  
 3 COFFEY, Q.C.:  
 4 Q. Doctor, on another note to assist you --  
 5 perhaps before I leave this, I did want to ask  
 6 you something. You had a concern about this  
 7 purported press release or whatever it was,  
 8 whatever one would wanted to term it, being  
 9 utilized. Did anyone else express any  
 10 concerns about it being utilized that you  
 11 recall at the meeting? I take it, you weren't  
 12 concerned about the idea of a press release,  
 13 you were concerned about the content?  
 14 DR. CARTER:  
 15 A. The contents -- that's what you're asking me,  
 16 what anyone else said about the contents?  
 17 COFFEY, Q.C.:  
 18 Q. Yes.  
 19 DR. CARTER:  
 20 A. I don't -- I don't think so.  
 21 COFFEY, Q.C.:  
 22 Q. And I'm not suggesting they did. I'm just  
 23 kind of asking --  
 24 DR. CARTER:  
 25 A. I don't think so.



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1 COFFEY, Q.C.:

2 Q. Support on your side, as it were, that's what

3 I'm --

4 DR. CARTER:

5 A. No, I think as the discussion ensued, then,

6 you know, people were expressing concerns, but

7 I think I was the person who expressed it

8 initially.

9 COFFEY, Q.C.:

10 Q. And as you explained your approach and your

11 reservations, others took part in the

12 discussion then?

13 DR. CARTER:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. And by the end of it, your understanding was

17 that they had accepted your view in that

18 regard?

19 DR. CARTER:

20 A. That was my understanding.

21 COFFEY, Q.C.:

22 Q. Doctor, did anyone, do you recall, express any

23 reservations that you recall at that meeting

24 to the idea of informing the public at large,

25 not as to what they would be informed, but

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1 informing them about the problem?

2 DR. CARTER:

3 A. The discussion that I remember that went

4 around that because that's when I was involved

5 in that sort of thing, was I don't think there

6 was a reluctance to inform the patients. I'm

7 not sure about the public, but there was not

8 reluctance to disclose to them, but to know

9 your facts before you disclose. That was kind

10 of the thing.

11 COFFEY, Q.C.:

12 Q. Who was expressing that?

13 DR. CARTER:

14 A. I was expressing that before they disclose to

15 people, they should know what it is that they

16 are disclosing. Other people in the room

17 would have had other opinions.

18 COFFEY, Q.C.:

19 Q. Do you recall who expressed them and what?

20 DR. CARTER:

21 A. I don't remember it being a big part of the

22 conversation.

23 COFFEY, Q.C.:

24 Q. Okay.

25 DR. CARTER:

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1 A. That we were there, but I know that Mr. Tilley

2 was saying that he wanted some info and he

3 wanted it in a timely fashion, or hurry up and

4 get some ideas, and I remember that was one of

5 my comments.

6 COFFEY, Q.C.:

7 Q. And what do they need to know?

8 DR. CARTER:

9 A. Well, they need to know that it's not

10 technology that's causing the problem. That

11 was my issue, that they didn't know what it

12 was that they were going to release, so to

13 stand up and say that we have a problem, you

14 need to have a little bit more information

15 than that before you start to tell people.

16 COFFEY, Q.C.:

17 Q. How much more did you think was necessary?

18 DR. CARTER:

19 A. I've never really thought about it.

20 COFFEY, Q.C.:

21 Q. For example, like, from the patient's

22 perspective, you know, if a patient's tissue

23 sample was being retested or it was going to

24 be retested -- I appreciate if it had been

25 retested, you understood that they should be

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1 told the result.

2 DR. CARTER:

3 A. Yes, they should be told the result.

4 COFFEY, Q.C.:

5 Q. How about being told that they were being

6 retested?

7 DR. CARTER:

8 A. I mean, this is not my area of expertise,

9 disclosure ethics, those sorts of things. If

10 a decision -- if a sound scientific decision

11 had been made that, yes, there was an issue

12 here and we were going to retest.

13 COFFEY, Q.C.:

14 Q. And I take it by August 1st, that decision had

15 been made, we are going to retest?

16 DR. CARTER:

17 A. Not that we were going to retest everyone

18 retrospectively. I mean, we were certainly

19 heading in that direction, but we were still,

20 I think, working on a subset of patients to

21 see if we could outline the problem a little

22 more clearly.

23 COFFEY, Q.C.:

24 Q. So up to the time that you left or resigned on

25 August 2nd --

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1 DR. CARTER:  
 2 A. Yes, I think shortly after that they decided  
 3 to do just a large retrospective analysis of  
 4 everybody, but we were certainly heading in  
 5 that direction.  
 6 COFFEY, Q.C.:  
 7 Q. Doctor, your understanding of that August 1st  
 8 larger meeting, the administrative meeting,  
 9 I'll call it --  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Was what, what was the purpose of the meeting?  
 14 DR. CARTER:  
 15 A. I understood it to be a routine meeting of  
 16 senior administration and other people who  
 17 were involved with the issue. I thought that  
 18 it was a routine briefing meeting, I guess you  
 19 would call it.  
 20 COFFEY, Q.C.:  
 21 Q. And you spoke of this yesterday, but I just  
 22 want to be certain I understand it. You asked  
 23 to go to the meeting or were asked?  
 24 DR. CARTER:  
 25 A. I asked.

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1 COFFEY, Q.C.:  
 2 Q. And why was it you wanted to be there?  
 3 DR. CARTER:  
 4 A. Because I wanted to talk to Dr. Williams and  
 5 Mr. Tilley about the frustrations that I was  
 6 having obtaining some of the information that  
 7 I needed.  
 8 COFFEY, Q.C.:  
 9 Q. The resourcing issue?  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Exhibit P-1993. I'm going to show you now  
 14 several exhibits, Doctor, that deal with this  
 15 11 patients, 11 surgical tissue samples being  
 16 retested. This is dated July 29th, 2005.  
 17 It's written here, "Compare results from Mount  
 18 Sinai, 447-02", and then there's an agree,  
 19 which is six; a maybe, which is three, and I  
 20 take it these are probably surgical numbers  
 21 here, and there's a disagree is two. Two out  
 22 of 11 disagree, six out of 11, correct; three  
 23 out of 11, I presume that fall under the  
 24 category of maybe. Five out of 11, 40 percent  
 25 disagreement --

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1 DR. CARTER:  
 2 A. Of which --  
 3 COFFEY, Q.C.:  
 4 Q. "Of which 20 percent serious". Serious  
 5 disagreement, I take it, and approximately 60  
 6 percent agreement, "PR is problematic". Do  
 7 you recognize the handwriting, Doctor?  
 8 DR. CARTER:  
 9 A. Most of it is my handwriting, some of it is  
 10 not.  
 11 COFFEY, Q.C.:  
 12 Q. This is probably Dr. Cook's?  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. And the date --  
 17 DR. CARTER:  
 18 A. That's Dr. Cook's as well.  
 19 COFFEY, Q.C.:  
 20 Q. But the body of the text is yours?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. So would that -- to assist you, Doctor, what  
 25 was going on here at the time?

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1 DR. CARTER:  
 2 A. Again this is the first time that I've seen  
 3 this in a --  
 4 COFFEY, Q.C.:  
 5 Q. In a while, I take it.  
 6 DR. CARTER:  
 7 A. In a while. I wrote it, I saw it then, but I  
 8 think this is the -- I talked this morning  
 9 about the quality control that we were doing  
 10 with Mount Sinai, so I think this is the  
 11 results that we had from those cases, and it's  
 12 listing the amount of agreement that we had,  
 13 and disagreement that we had. I think I would  
 14 have categorized a serious disagreement as  
 15 something being clinically significant, but I  
 16 don't know -- I'd like to go back and look at  
 17 the numbers again, and I think that we found  
 18 in that that the progesterone was more  
 19 problematic than the estrogen, there was more  
 20 agreement with the estrogens than there was  
 21 with the progesterones, but I'd have to see it  
 22 all again.  
 23 COFFEY, Q.C.:  
 24 Q. Sure. This was an agreement between your  
 25 Ventana retest results, August 11th --

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1 DR. CARTER:  
 2 A. Yes, and --  
 3 COFFEY, Q.C.:  
 4 Q. And Mount Sinai's.  
 5 DR. CARTER:  
 6 A. And Mount Sinai's --  
 7 COFFEY, Q.C.:  
 8 Q. Test results for those 11.  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. Exhibit P-1990. Now here, Doctor, do you  
 13 recognize any of this?  
 14 DR. CARTER:  
 15 A. Again I wrote it. Some of it is Dr. Cook's.  
 16 COFFEY, Q.C.:  
 17 Q. With the exception of, "Received July 29th,  
 18 2005", would be Dr. Cook's.  
 19 DR. CARTER:  
 20 A. And, "So many cases from Mount Sinai, and  
 21 notified on the original report are --  
 22 COFFEY, Q.C.:  
 23 Q. "Notified ten" on the original report?  
 24 DR. CARTER:  
 25 A. Yes, I didn't write that or -- can I control

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1 the mouse?  
 2 COFFEY, Q.C.:  
 3 Q. Yes, you go right ahead.  
 4 DR. CARTER:  
 5 A. I didn't write this.  
 6 COFFEY, Q.C.:  
 7 Q. "Eleven cases from Mount Sinai", you didn't  
 8 write. What then --  
 9 DR. CARTER:  
 10 A. And this down here is not my writing as well.  
 11 COFFEY, Q.C.:  
 12 Q. The body of it here, this portion -- I'm  
 13 sorry, go ahead.  
 14 DR. CARTER:  
 15 A. No, that's fine.  
 16 COFFEY, Q.C.:  
 17 Q. The middle portion right there, I take it, is  
 18 yours?  
 19 DR. CARTER:  
 20 A. Yes, it is.  
 21 COFFEY, Q.C.:  
 22 Q. And it started out with, "ER/PR us/them". Us  
 23 would be --  
 24 DR. CARTER:  
 25 A. St. John's Eastern Health.

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1 COFFEY, Q.C.:  
 2 Q. Ventana?  
 3 DR. CARTER:  
 4 A. Yes, and "them" would be Mount Sinai. Again  
 5 this is the first time that I've seen this --  
 6 COFFEY, Q.C.:  
 7 Q. In years?  
 8 DR. CARTER:  
 9 A. In years. Thank you.  
 10 COFFEY, Q.C.:  
 11 Q. And "us", I take it -- ER would be faint, 10;  
 12 faint, 10 -- F10, F5, would be faint 5?  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. And then would be "negative", and then 2  
 17 percent, 2 percent, and so on all the way  
 18 down.  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And then the PR, similar sort of analysis?  
 23 DR. CARTER:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. And it's the numbers here and the comparison  
 2 of those numbers which is, in effect, I take  
 3 it, summarized in the page we just looked at  
 4 in terms of the --  
 5 DR. CARTER:  
 6 A. I would think so, but again this is the first  
 7 time I've seen these two pieces of paper in a  
 8 while, so I will need to look at them in  
 9 detail and correlate them.  
 10 COFFEY, Q.C.:  
 11 Q. And here -- in fact, if we count them up,  
 12 there are 11 rows, 11 of them?  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. Doctor, another document I want to ask you  
 17 about, Exhibit P-1938. Now this is a document  
 18 dated Wednesday, August 10th, 2005. It's from  
 19 McGill University. It's addressed to Dr.  
 20 Cook, and he says, "As discussed with Dr.  
 21 Watters, please find enclosed ER/PR stain  
 22 slide you requested on the following cases".  
 23 Do you recognize any of the handwriting there?  
 24 DR. CARTER:  
 25 A. That's my handwriting.

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1 COFFEY, Q.C.:

2 Q. And I take it this is ER/PR and then there's

3 some results?

4 DR. CARTER:

5 A. Uh-hm.

6 COFFEY, Q.C.:

7 Q. So I take it this is your interpretation,

8 looking at the stain slides that came back?

9 DR. CARTER:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. And then there's "edge artifact". Now could

13 you describe -- tell the Commissioner what

14 that means because it's referred to twice

15 here?

16 DR. CARTER:

17 A. I think it actually was a finding throughout

18 all of the slides, but I would like to look at

19 them. We sent some cases up to Dr. Watters at

20 McGill who had a Ventana machine which was

21 similar or identical to the one that we had,

22 and when we received the slides, a lot of the

23 staining was uninterpretable. They had a

24 technical problem with their Ventana at the

25 time.

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1 COFFEY, Q.C.:

2 Q. Now do you know -- did they actually use the

3 Ventana there or did they end up using the

4 DAKO because the Ventana wasn't available?

5 DR. CARTER:

6 A. There may have been a second run to them.

7 COFFEY, Q.C.:

8 Q. Okay, because we've heard something about that

9 from some witnesses.

10 DR. CARTER:

11 A. Yes. The first time that we sent it up, I

12 thought that this was it, but there may have

13 been a second run.

14 COFFEY, Q.C.:

15 Q. So there was certainly one returned group of

16 slides from McGill that you remember, that you

17 had a problem interpreting because of some

18 technical problem with the production of them?

19 DR. CARTER:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. Page two of this exhibit, do you recognize any

23 of this handwriting?

24 DR. CARTER:

25 A. It's Dr. Don Cook.

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1 COFFEY, Q.C.:

2 Q. And while we're at it, page three?

3 DR. CARTER:

4 A. Dr. Cook.

5 COFFEY, Q.C.:

6 Q. So it's Dr. Cook's handwriting. Here, Doctor,

7 on page two of the exhibit, it says, "Received

8 July 29th, 2005", and it's numbered 1 to 11,

9 2002 cases, and presented to August 13005

10 meeting with steering group. DAKO, and

11 original is crossed out, Ventana, and Mount

12 Sinai Hospital, MSH. Did you ever see this

13 before, do you know?

14 DR. CARTER:

15 A. It doesn't look familiar to me.

16 COFFEY, Q.C.:

17 Q. Okay. The idea of presenting the information

18 contained in this, if this is indeed those 11

19 cases that were sent to Mount Sinai for slide

20 production and reporting, if indeed this is

21 the 11, do you ever recall that being

22 presented at the August 1st meeting, either of

23 the August 1st --

24 DR. CARTER:

25 A. At the large meeting?

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1 COFFEY, Q.C.:

2 Q. Yes.

3 DR. CARTER:

4 A. I don't think it was presented at the large

5 meeting, you know, in this format. The

6 synopsis of it might have been mentioned

7 there. In the smaller meeting that you showed

8 me the minutes to, or Dr. Williams notes from

9 prior to the lunch break, we were talking

10 about false positives, but again these are all

11 new documents for me. I mean, I would have to

12 put them together. I know this is probably

13 some of the material that we used to make the

14 decision not to use the Ventana any more.

15 COFFEY, Q.C.:

16 Q. At that point in time?

17 DR. CARTER:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Doctor, in relation to that, that particular

21 aspect of the matter, what, if anything, do

22 you know about what happened then with respect

23 to the Ventana and ER/PR locally, what was

24 done?

25 DR. CARTER:

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1 A. We decided to send our cases on a go forward  
 2 basis to Mount Sinai for testing. We started  
 3 a plan where prior to sending the case up to  
 4 Mount Sinai, they would cut some slides here,  
 5 they would supposedly stain the slides here,  
 6 and then it went through a bunch of  
 7 permutations. It started off that all of the  
 8 pathologists would read the slides, make their  
 9 opinion, and then the slides would be sent to  
 10 myself and I would read the slides, make my  
 11 opinion, so we would be comparing  
 12 pathologists, comparing technologies, and  
 13 making sure that our technology was equivalent  
 14 to their technology. Then I think we decided  
 15 to forego the step of comparing pathologists,  
 16 and eventually we just stopped doing any sort  
 17 of parallel testing. I don't even think that  
 18 we did very much parallel testing at all at  
 19 that time.  
 20 COFFEY, Q.C.:  
 21 Q. Of course, testing eventually did resume in  
 22 2007?  
 23 DR. CARTER:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. Locally.  
 2 DR. CARTER:  
 3 A. Yes.  
 4 COFFEY, Q.C.:  
 5 Q. What, if any, changes were made, do you know?  
 6 DR. CARTER:  
 7 A. In the lab?  
 8 COFFEY, Q.C.:  
 9 Q. Yes, in the lab.  
 10 DR. CARTER:  
 11 A. We had dedicated staff, we had proper  
 12 validation, optimization, standard operating  
 13 procedures. I'm not sure if the physical move  
 14 of the histochemistry lab was done before or  
 15 after 2005, but --  
 16 COFFEY, Q.C.:  
 17 Q. The optimization process, who was the  
 18 pathologist directly involved in that?  
 19 DR. CARTER:  
 20 A. I think it would have been Dr. Elms. Dr.  
 21 Fontaine, he was involved for a while, Dr.  
 22 Makarla, and myself.  
 23 COFFEY, Q.C.:  
 24 Q. And what was your role?  
 25 DR. CARTER:

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1 A. I think I worked with them on optimizing the  
 2 larger aspect of the recipe, if you will, for  
 3 performing, so Mr. Green, Mr. Simms, and I,  
 4 looked at antibody exposure time, so how long  
 5 you let it sort of bake together, As well as  
 6 antigen retrieval timing. So we compared  
 7 various protocols and picked out a few that we  
 8 thought were showing, you know, very good  
 9 results, which would be one step of the whole  
 10 process. I would look at slides for the group  
 11 or answer questions about it.  
 12 COFFEY, Q.C.:  
 13 Q. If we could -- while I'm on that, at this  
 14 point in time, you're aware that Mr. Dyer has  
 15 testified about a couple of voice messages  
 16 that you left for him.  
 17 DR. CARTER:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. Do you -- have you looked at the transcripts  
 21 of those, have you reviewed the transcripts,  
 22 do you know?  
 23 DR. CARTER:  
 24 A. I have looked at the handwritten -- the  
 25 typewritten transcript.

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1 COFFEY, Q.C.:  
 2 Q. I'll bring it up -- have the registrar bring  
 3 it up, please, Exhibit P-2361, please.  
 4 DR. CARTER:  
 5 A. And I've read portions of his testimony. Is  
 6 that what you mean?  
 7 COFFEY, Q.C.:  
 8 Q. Sure.  
 9 DR. CARTER:  
 10 A. I've read portions of it, but I don't know if  
 11 I specifically read all around that, but I  
 12 have the general gist of what was said.  
 13 COFFEY, Q.C.:  
 14 Q. Now he's indicated these were voice messages  
 15 left by yourself for him in August 2005. What  
 16 was the point in you leaving these messages,  
 17 Doctor?  
 18 DR. CARTER:  
 19 A. I think the main point--I mean, I think there  
 20 were two points, and one, we had come out of a  
 21 very heated meeting where I thought that some  
 22 things had been settled and that we were  
 23 moving forward, and they had essentially spent  
 24 the time since that meeting trying to prove  
 25 things that I had said during the meeting were

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1 untrue, and the way that I heard it was at the  
 2 request of Dr. Williams that they were doing  
 3 this. I felt it would have been more  
 4 appropriate for someone to telephone me and  
 5 ask me to substantiate or not what I had said  
 6 during the meeting, and I also felt that they  
 7 were wasting a lot of time doing this, that  
 8 this was unnecessary work. That we had an  
 9 issue and that we should move forward.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor, just looking at message number two  
 12 first, you note that or stated "I'm sure that  
 13 Don" that would be Don Cook had told Mr. Dyer  
 14 that you had withdrawn from the project after  
 15 the meeting on Monday, which would be August  
 16 1, due to the fact--"due to what I felt was  
 17 incorrect handling of the validation and just  
 18 lack of cooperation between pathologists and  
 19 administrative technical staff here. So I  
 20 won't be involved any more," and you go on to  
 21 say "you guys are the ones that are going to  
 22 be identifying the true negatives, so you  
 23 don't really need to discredit me. You can  
 24 put your effort into that."  
 25 Doctor, the concern about validation,

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1 incorrect handling of the validation, this  
 2 would be the validation of what?  
 3 DR. CARTER:  
 4 A. The validation on the new Ventana that had  
 5 been introduced 2004.  
 6 COFFEY, Q.C.:  
 7 Q. Yes, validation of what, what -  
 8 DR. CARTER:  
 9 A. Oh sorry, estrogen receptor and progesterone  
 10 receptor, but it had arisen out of a  
 11 generalized discussion at the long meeting on  
 12 August 2nd, if that's how we're going to refer  
 13 to it.  
 14 COFFEY, Q.C.:  
 15 Q. That would be August 1st, actually.  
 16 DR. CARTER:  
 17 A. August 1st, sorry. Where we had been  
 18 discussing the advantages of the fully  
 19 automated Ventana versus the semi-automated  
 20 DAKO, and there was statements made that, you  
 21 know, it's just sort of a load and go. You  
 22 just put the slides in, that there's no need  
 23 for local optimization and validation.  
 24 COFFEY, Q.C.:  
 25 Q. And I take it you disagree with that sort of

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1 an assertion?  
 2 DR. CARTER:  
 3 A. Yes, I do.  
 4 COFFEY, Q.C.:  
 5 Q. Doctor, I'm going to look at message number  
 6 one.  
 7 DR. CARTER:  
 8 A. These messages actually were sent at the same  
 9 time. There was just a cut off.  
 10 COFFEY, Q.C.:  
 11 Q. And you've indicated that, here, I understand,  
 12 "instead of identifying and finding the cases  
 13 and blocks on the greater than 200 women who  
 14 are identified as negative" and I take it by  
 15 that point in time, you knew or understood  
 16 that at least locally there'd be about 200  
 17 negatives?  
 18 DR. CARTER:  
 19 A. Yes, we had a series that we had retested and  
 20 I think Dr. Cook had gone back and looked  
 21 through a certain period, just on the  
 22 computer.  
 23 COFFEY, Q.C.:  
 24 Q. And this, "trying to prove things that I said  
 25 were wrong" I take it is in relation to this,

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1 what you had described this morning as and  
 2 referred to in one of the notes of a meeting  
 3 that perhaps, or there were no negatives  
 4 between point A and point B in 2002?  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. Over a several month period?  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. You've indicated from a particular hospital.  
 13 Doctor, do you know, in that regard, whether  
 14 or not there has ever been an analysis done as  
 15 to which hospital the conversions arose in,  
 16 which particular hospital, one as opposed to  
 17 the other, or were they equally distributed  
 18 between the two, or has there ever been an  
 19 analysis done of that?  
 20 DR. CARTER:  
 21 A. I don't think there's been an analysis done of  
 22 that.  
 23 COFFEY, Q.C.:  
 24 Q. And I say between the two, actually to include  
 25 the Grace even before 2000.

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1 DR. CARTER:  
 2 A. And everybody outside of St. John's as well.  
 3 COFFEY, Q.C.:  
 4 Q. Yes. So you go on to say "in the original 58  
 5 cases that were retested, there may have been  
 6 some weak positives. In that case, there are  
 7 several people that are around one percent or  
 8 whatever, but there were other issues with  
 9 them and I think that the thing that came out  
 10 of that was that our Ventana system certainly  
 11 was quite different than what we were having  
 12 on our original DAKO." I take it that  
 13 statement that they were quite different, you  
 14 still stand by that?  
 15 DR. CARTER:  
 16 A. Yes, there were conversions.  
 17 COFFEY, Q.C.:  
 18 Q. This reference to that "there may have been  
 19 weak positives" who was--what was that about?  
 20 DR. CARTER:  
 21 A. At the big meeting of August the 1st, we had  
 22 been giving an update to the group as part of  
 23 the discussions and said that there was 58  
 24 cases of which, I think, there's 30 something  
 25 conversions in it, and were presenting that to

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1 the group to tell them, you know, what the  
 2 strength of the problem was or the scope of  
 3 the problem was, and I guess one of the things  
 4 that Mr. Gulliver had told Dr. Williams, I  
 5 have heard, I did not have privy to that  
 6 conversation, was that I included a lot of  
 7 weak positives in that so that the conversion  
 8 rate -  
 9 COFFEY, Q.C.:  
 10 Q. Went up because you included as a -  
 11 DR. CARTER:  
 12 A. Because I included positives in it.  
 13 COFFEY, Q.C.:  
 14 Q. Weak positives, as part of the positives.  
 15 DR. CARTER:  
 16 A. But even if you accept that weak positives,  
 17 there are still only three in it, so there  
 18 would be three--I think there's 34 of the 58,  
 19 so three of them would be weak positives, but  
 20 as I explained earlier, they would be  
 21 percentages that I wouldn't have expected,  
 22 given the type of tumour that the patient had.  
 23 COFFEY, Q.C.:  
 24 Q. And Doctor, on this point, okay, just the  
 25 figure of 25 plus 33, which is those two

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1 letters, June 29th and July 18th -  
 2 DR. CARTER:  
 3 A. Okay, I'll accept your mathematics. I don't  
 4 have it here.  
 5 COFFEY, Q.C.:  
 6 Q. - they would add up to well, 33, 43, 53 and 5  
 7 is 58, that would be your 58 cases, probably.  
 8 DR. CARTER:  
 9 A. Yes, probably.  
 10 COFFEY, Q.C.:  
 11 Q. And out of those, you'd had 16 and 19, so  
 12 somewhere in the mid 30s, 34, 35 or so had  
 13 converted.  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. And you're telling the Commissioner that out  
 18 of those 34-35, maybe three of them were weak  
 19 positives?  
 20 DR. CARTER:  
 21 A. That's the best of my recollection of the  
 22 figures.  
 23 COFFEY, Q.C.:  
 24 Q. Then you went on to refer to "concerns about  
 25 the Ventana system arose. The 11 cases that

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1 we sent up to Mount Sinai which showed cases  
 2 that were negative by the original pathologist  
 3 were positive on Ventana and then were  
 4 negative up in Mount Sinai, and this is  
 5 especially true for the progesterone and less  
 6 true for the estrogen, both of which, in that  
 7 meeting, were decided were important." So  
 8 what was that about, Doctor?  
 9 DR. CARTER:  
 10 A. These were the variability of results between  
 11 the results on retesting on the Ventana and  
 12 the results on the Mount Sinai retesting, if  
 13 you will, so those handwritten charts that you  
 14 just showed.  
 15 COFFEY, Q.C.:  
 16 Q. In fact, if we could, Exhibit P-1990?  
 17 Actually, I have that as--oh yes, there it is.  
 18 This would be the chart, I take it?  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. Yes, and perhaps you could just, just running  
 23 down through the numbers here, just perhaps  
 24 using the cursor, explain to the Commissioner  
 25 what you're talking about here?

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1 DR. CARTER:  
 2 A. So in the first case, under the estrogen  
 3 receptor column, under us, it's F10. I would  
 4 assume that that means faint and ten, which  
 5 case the patient would meet criterion for  
 6 being considered positive, and when we sent it  
 7 up to Mount Sinai, they called it negative.  
 8 COFFEY, Q.C.:  
 9 Q. In their world, that was zero or less than  
 10 one?  
 11 DR. CARTER:  
 12 A. That was less than one percent.  
 13 COFFEY, Q.C.:  
 14 Q. Yes.  
 15 DR. CARTER:  
 16 A. So number two, would be a faint ten changed to  
 17 a two percent, so on Mount Sinai's one percent  
 18 cut off, that would be a positive. Clinical  
 19 practice in our group and in many centres  
 20 across Canada, that would be considered  
 21 positive and considered negative. Sorry, the  
 22 first one, F10 would be considered positive, I  
 23 would think. I'm not an oncologist. And the  
 24 two would be considered a negative. Faint  
 25 five and the two, clinically there would be no

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1 difference, and from a machine calibration  
 2 point of view, I don't think that would be  
 3 significant. The 100 to 70, sorry, the next  
 4 one is negative, negative, so no real need to  
 5 discuss that. The next line is strong at 100,  
 6 and they had 70 percent. So it just gives you  
 7 an idea that maybe our machine is staining  
 8 things a little bit too strongly. But again,  
 9 not clinically significant. The next line  
 10 would be negative/negative, so no change. The  
 11 next one would be negative/negative, no  
 12 change. The next one would be strong 100 when  
 13 tested in St. John's and 60 percent when  
 14 tested at Mount Sinai. So again, no clinical  
 15 significance to that change, but if you're  
 16 looking at it from a -  
 17 COFFEY, Q.C.:  
 18 Q. Optimization.  
 19 DR. CARTER:  
 20 A. - is our machine optimally working, again,  
 21 it's showing a little bit too much brightness.  
 22 The next one would be the same thing, going  
 23 from 80 percent to 20 percent. The next one  
 24 would be no change. The next one would be no  
 25 change. In the PR column, the first one is

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1 changed to moderate 55 percent, which would be  
 2 a good positive for us, and a negative in  
 3 Mount Sinai. So that would be a significant  
 4 change, recognizing that progesterone is not  
 5 as clinically important as the estrogen is,  
 6 but from an optimization point of view, this  
 7 would be an important change in values. The  
 8 next one is strong five percent, I think, and  
 9 negative would not really be of any  
 10 significance. Moderate ten percent, two  
 11 percent. Again, you're on that cusp where in  
 12 one instance the patient would be considered  
 13 positive and in one instance be considered  
 14 negative. The next one is moderate five  
 15 percent and negative in Mount Sinai. Again,  
 16 that would be of some significance, but not in  
 17 the routine clinical practice in our Cancer  
 18 Centre. The next one is 100 percent to five  
 19 percent. Again, maybe our progesterone is  
 20 staining a little bit too bright. That's a  
 21 significant change between the 100 percent and  
 22 the five percent. The next two are both  
 23 negative for us and them. Wouldn't be of any  
 24 significance. The 100 and 90, the same thing.  
 25 Then we had a moderate 60 percent, which was a

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1 five, which again is a change. That would be  
 2 considered significant. The next one was  
 3 negative/negative. The next case again was  
 4 100 percent as tested by us and negative by  
 5 them. And again, I mean, I would just stress  
 6 that these are handwritten notes and the data  
 7 hasn't been verified and -  
 8 COFFEY, Q.C.:  
 9 Q. But in terms of the -  
 10 DR. CARTER:  
 11 A. - we could take general ideas from them.  
 12 COFFEY, Q.C.:  
 13 Q. And again, just to--why I'm exploring it with  
 14 you is other than for its informational  
 15 content, is to give the Commissioner some  
 16 sense of what, you know, your thought process  
 17 in explaining the interaction with others and  
 18 things that are written here. So that's why  
 19 I'm reviewing it.  
 20 DR. CARTER:  
 21 A. But I did think, on the -  
 22 COFFEY, Q.C.:  
 23 Q. The overall result then of these 11, in terms  
 24 of the overall process, what was your overall  
 25 view of it at the time?



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1 DR. CARTER:  
 2 A. That our estrogen receptor staining was maybe  
 3 a little too strong, was always showing up  
 4 positive, you know. We were getting too many  
 5 positives in the assessment, and the  
 6 progesterone was a little harder to figure out  
 7 because it seemed--the estrogen seemed to show  
 8 a more consistent pattern of always being  
 9 stronger than you expected, but I thought in  
 10 the progesterone we had some instances where  
 11 it actually was a little bit weaker or, you  
 12 know, you would show great variability, 100  
 13 percent to negative, that sort of thing.  
 14 COFFEY, Q.C.:  
 15 Q. Looking down the column of progesterone, I  
 16 mean, it goes the first one, 55 and zero, or  
 17 55 and less than one, 100 and five, and then  
 18 60 and five and then 100 and less than one.  
 19 So in relation to those four -  
 20 DR. CARTER:  
 21 A. I don't have a less than one column. Are we  
 22 looking at -  
 23 COFFEY, Q.C.:  
 24 Q. It's not less than one. I'm saying they got  
 25 the negative so we--Dr. Mullen and Dr.

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1 O'Malley indicated that negative in their  
 2 world was either zero or less than one.  
 3 DR. CARTER:  
 4 A. Less than one, okay.  
 5 COFFEY, Q.C.:  
 6 Q. So there's at least four where you've  
 7 described in the progesterone instance that  
 8 there was, from your perspective, a  
 9 significant difference here?  
 10 DR. CARTER:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. Between Mount Sinai and the Ventana locally.  
 14 THE COMMISSIONER:  
 15 Q. Dr. Carter, you indicated that in the course  
 16 of one of these meetings, I believe you said  
 17 Mr. Gulliver had indicated that the Ventana  
 18 could be a load and go kind of -  
 19 DR. CARTER:  
 20 A. I'm not sure if it was Mr. Gulliver or Mr.  
 21 Dyer.  
 22 THE COMMISSIONER:  
 23 Q. Okay.  
 24 DR. CARTER:  
 25 A. But there was statements that it was a load

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1 and go.  
 2 THE COMMISSIONER:  
 3 Q. Did you have any reason to believe that there  
 4 had not been any validation process when the  
 5 Ventana use was commenced? You didn't connect  
 6 the two, did you?  
 7 DR. CARTER:  
 8 A. After that meeting?  
 9 THE COMMISSIONER:  
 10 Q. Yes.  
 11 DR. CARTER:  
 12 A. I would have asked about the validation  
 13 process for it.  
 14 THE COMMISSIONER:  
 15 Q. Okay, but did--do you--it may be a question  
 16 that you don't know anything about, but did  
 17 you know or have any reason to believe that  
 18 when the Ventana came into use, a validation  
 19 exercise was undertaken by those in the lab?  
 20 DR. CARTER:  
 21 A. I would have assumed that that had happened.  
 22 It's basic lab practice.  
 23 THE COMMISSIONER:  
 24 Q. So you proceeded on the understanding that  
 25 that would have occurred?

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1 DR. CARTER:  
 2 A. Yes.  
 3 THE COMMISSIONER:  
 4 Q. Okay, thank you.  
 5 THE COMMISSIONER:  
 6 Q. Doctor, you go on--if we could go back,  
 7 please, to 2361? Doctor, you've also--here,  
 8 the transcript indicates that you stated "as  
 9 for the cases that were identified between  
 10 June 29th-November 1st, that was not a  
 11 statement of fact. That was a statement that  
 12 was made during the meeting to explain to  
 13 people that it is not only a technical issue,  
 14 but also a fault of pathologists and a fault  
 15 of oncologists that in a certain period of  
 16 time, which I couldn't remember, virtually  
 17 every case that went out had a negative result  
 18 and nobody noticed it." Doctor, at the time,  
 19 going into the August 1st meeting and during  
 20 it, this statement here suggests that--seems  
 21 to suggest that, from your perspective, at the  
 22 time, bearing in mind what you reviewed in  
 23 June and July, that--I won't say you were  
 24 attributing fault or blame, but certainly were  
 25 noting that the pathologist and the

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1 oncologists, as best you could tell, had not  
 2 noticed this lack of positive results?  
 3 DR. CARTER:  
 4 A. But I mean, that's partially true. I think  
 5 the statements that I made there were again, I  
 6 have been told that they had had a meeting  
 7 where they said that they didn't want me  
 8 involved in the process. They'd prefer to  
 9 have another pathologist there. That I was  
 10 trying to find evidence and possibly  
 11 manufacturing evidence to make them look bad,  
 12 so they would prefer to work with another  
 13 pathologist.  
 14 COFFEY, Q.C.:  
 15 Q. Who's them?  
 16 DR. CARTER:  
 17 A. Oh, sorry, Mr. Dyer and Mr. Gulliver.  
 18 COFFEY, Q.C.:  
 19 Q. Okay.  
 20 DR. CARTER:  
 21 A. So I mean, that was sort of the background to  
 22 the telephone call.  
 23 COFFEY, Q.C.:  
 24 Q. Okay.  
 25 DR. CARTER:

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1 A. And what I was trying to say there was "how  
 2 can you think that I am trying to make you  
 3 guys look bad when we were talking about  
 4 trends in it, I was explaining that this could  
 5 very well be pathologists. This could very  
 6 well be oncologists. In this period of time,  
 7 a certain number went out and nobody noticed."  
 8 That was what I was trying to say there. I  
 9 mean, I can't comment on the voracity of this  
 10 transcription. I assume it's proper, but -  
 11 COFFEY, Q.C.:  
 12 Q. But in terms of yourself at the time, that was  
 13 how this came up? You're telling the  
 14 Commissioner this has to be read in the  
 15 context of what was said on August 1st?  
 16 DR. CARTER:  
 17 A. And I think at that time, and on August 1st,  
 18 and I think this is probably a day later or  
 19 two days later, I was still firm in the belief  
 20 that we didn't know what went on. So people  
 21 were making all of these statements, we're  
 22 going to this way, but it hadn't yet been  
 23 investigated properly, where you could look at  
 24 in an objective kind of sense and see.  
 25 COFFEY, Q.C.:

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1 Q. And Doctor, have you ever been--witness any  
 2 exchange between pathologists and oncologists  
 3 about this, about who should or shouldn't have  
 4 noticed this?  
 5 DR. CARTER:  
 6 A. Oh yes, it would come up at many meetings, I  
 7 think.  
 8 COFFEY, Q.C.:  
 9 Q. Between, involving the oncologists and  
 10 pathologists, exchanges between them.  
 11 DR. CARTER:  
 12 A. I can remember being at a meeting where Don  
 13 brought it up that trends, you know, were  
 14 present, usually in the context of the turn  
 15 over of staff that had occurred, so the trends  
 16 could not be expected to be recognized in  
 17 pathology because of the number of  
 18 pathologists that were looking at these cases  
 19 and in oncology as well, the same thing would  
 20 apply, I think to a lesser degree, but I'm not  
 21 sure. They had fewer turnovers, but they  
 22 still had a larger group of oncologists seeing  
 23 these results.  
 24 COFFEY, Q.C.:  
 25 Q. More consistently, I take it?

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1 DR. CARTER:  
 2 A. Pardon me?  
 3 COFFEY, Q.C.:  
 4 Q. More consistently, the oncologists would have  
 5 been--was Don raising this is the context of  
 6 they were in a better position, perhaps,  
 7 because they had fewer turnovers and there  
 8 were fewer -  
 9 DR. CARTER:  
 10 A. I don't think there was any sort of accusatory  
 11 thing, I think it was a supportive thing. We  
 12 didn't see the trends because there was so  
 13 many of us and you guys didn't see the trends  
 14 because there was so many of you.  
 15 COFFEY, Q.C.:  
 16 Q. Now, Doctor, if I could have you look at,  
 17 please, Exhibit P-0546? This is an e-mail you  
 18 sent, I gather to--on August 3rd, 2005, to  
 19 Heather Predham?  
 20 DR. CARTER:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. And you would have just met her.  
 24 DR. CARTER:  
 25 A. Yes, she was at the meeting and I think

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1 someone higher up in her organization was also  
 2 there.  
 3 COFFEY, Q.C.:  
 4 Q. And what was the purpose in sending--your  
 5 purpose in sending her this e-mail?  
 6 DR. CARTER:  
 7 A. To offer her references and a consultative  
 8 opinion if she felt that she required one.  
 9 She was at the meeting, I thought that she was  
 10 well spoken, she had taken it upon herself to  
 11 go through the scientific literature and had  
 12 brought a bunch of articles for people to look  
 13 at, so I was just offering her my consultative  
 14 opinion.  
 15 COFFEY, Q.C.:  
 16 Q. And how much interaction did you have with her  
 17 then afterward?  
 18 DR. CARTER:  
 19 A. Informally I would see her in the hallways and  
 20 talk with her and we were together on the  
 21 tumour panel. I think there were several  
 22 other large meetings of people involved in the  
 23 issue that I would have been on the same  
 24 committee meetings with her.  
 25 COFFEY, Q.C.:

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1 Q. Exhibit P-0925 please? Doctor, these are the  
 2 typed version of Dr. Cook's notes and there  
 3 are just a couple of them I am going to refer  
 4 you to, a couple of particular parts. On page  
 5 4, there's a note for July 15th, 2005, you are  
 6 not in attendance, but the fifth bullet says,  
 7 "Dr. Carter to check with Mount Sinai to see  
 8 if change in sensitivity over time with  
 9 testing they used." Do you know what that is  
 10 about? This is in the middle of July.  
 11 DR. CARTER:  
 12 A. No. Do you have any more context for it?  
 13 COFFEY, Q.C.:  
 14 Q. Well this is just to point out they had  
 15 reviewed an earlier meeting, Dr. Cook was to  
 16 contact pathologists in other centres to get  
 17 cases submitted. Terry is advising ever  
 18 patient slide was processed along a control  
 19 slide. Control slides are read, no reporting  
 20 done until control read is positive and then  
 21 Dr. Carter, someone has noted that Dr. Carter  
 22 is to check with Mount Sinai to see if the  
 23 change in sensitivity over time with the  
 24 testing they used. Were you ever asked to  
 25 approach Mount Sinai about whether they

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1 noticed any changes?  
 2 DR. CARTER:  
 3 A. I don't recall it specifically.  
 4 COFFEY, Q.C.:  
 5 Q. Okay, and again, you're not at the meeting,  
 6 noted to be there, so--page 6 of this exhibit  
 7 is a note of a meeting of July 21st, 2005 at  
 8 10:30 a.m. You are in attendance, noted to be  
 9 here at this, yourself, Dr. Cook and Dr.  
 10 Williams and here it says "In past, it didn't  
 11 seem to be a clear picture. Sentinel case,  
 12 reviewed old slides, program would not always  
 13 run a control. Clear test didn't work. Dr.  
 14 Carter feels there was a problem in 2002.  
 15 Some runs on retrospect were not normal.  
 16 Inconsistency from one batch to another.  
 17 Current Ventana is picking up to much. Have  
 18 sent out a"--that's probably "a sampling"--  
 19 something--"results and sent to Mount Sinai.  
 20 Dr. Carter also doing some work on quality  
 21 control and use them as controls. Important  
 22 for Dr. Carter to have all reports for ER/PR  
 23 for each year. Techs may need to be trained  
 24 on immunoperoxidase and need controlled access  
 25 to the room. Training of techs in

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1 immunohistochemistry, need separate service,  
 2 need QA and proficiency testing. Need to have  
 3 an external consultant to come to the lab and  
 4 do QA." Doctor, in relation to this, these  
 5 notes and they are Dr. Williams' notes, the  
 6 assertion or the attribution to you of Dr.  
 7 Carter feels there was a problem in 2002, and  
 8 this is the middle of, well July 21st, can you  
 9 recall having by that point reached that  
 10 conclusion and it's clear that the test didn't  
 11 work?  
 12 DR. CARTER:  
 13 A. By that time we would have had two of our  
 14 batches back.  
 15 COFFEY, Q.C.:  
 16 Q. Yes, two results. You've had the 58.  
 17 DR. CARTER:  
 18 A. There was some problem. I'm not sure that I  
 19 thought it was confined to 2002 at that point,  
 20 but we were still investigating 2002.  
 21 COFFEY, Q.C.:  
 22 Q. The reference to "inconsistency from one batch  
 23 to another" what does that refer to? And  
 24 "some runs on retrospect were not normal"?  
 25 DR. CARTER:

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1 A. I'm not sure what they mean by runs and  
 2 batches, I don't know if he's talking about  
 3 groups that we looked at.  
 4 COFFEY, Q.C.:  
 5 Q. See, that's what I was asking about, did you  
 6 ever get an opportunity to analyze these  
 7 earlier results in relation to whether or not  
 8 they were run on particular days or particular  
 9 weeks.  
 10 DR. CARTER:  
 11 A. I don't think I ever had that information, I  
 12 mean, that was information I was interested  
 13 in.  
 14 COFFEY, Q.C.:  
 15 Q. Because some runs, the idea of identifying  
 16 particular runs, were you ever able to  
 17 identify particular runs?  
 18 DR. CARTER:  
 19 A. No.  
 20 COFFEY, Q.C.:  
 21 Q. For example, in order to identify runs, I take  
 22 it you would need the worksheets?  
 23 DR. CARTER:  
 24 A. I wouldn't have to know what date each case  
 25 was tested on, which was one of my parameters

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1 I was looking at, but I couldn't get results  
 2 on.  
 3 COFFEY, Q.C.:  
 4 Q. If we could, I just bring up one, Exhibit P-  
 5 2190? Can we go to page 9, please? Doctor,  
 6 there has been evidence here that this is a  
 7 worksheet, you'll see it's labelled one to  
 8 forty-eight when you look down through it,  
 9 sort of worksheets that would have been used  
 10 on the DAKO autostainer. In the course of  
 11 your review in June and July of 2005, did you  
 12 ever have access to these sorts of sheets?  
 13 DR. CARTER:  
 14 A. I don't recognize these sheets, no.  
 15 COFFEY, Q.C.:  
 16 Q. Okay. You can see here the antibody is  
 17 referred to and a surgical number, you'd be  
 18 able to tell, presumably then if on a  
 19 particular day, a particular run occurred?  
 20 Well, a particular run, a particular set of  
 21 slides was from a particular surgical block  
 22 was run that day, you didn't see any such -  
 23 DR. CARTER:  
 24 A. No. And you would want to see more  
 25 information than this, you would want to see a

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1 tie in with the machine.  
 2 COFFEY, Q.C.:  
 3 Q. Oh yes.  
 4 DR. CARTER:  
 5 A. So there's usually some computer, you know,  
 6 the computer makes some note internally that  
 7 they have done that run that day and this is  
 8 just a handwritten -  
 9 COFFEY, Q.C.:  
 10 Q. Doctor, the computer, I take it that the DAKO  
 11 uses a computer or did use a computer.  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Did you ever ask--I appreciate by the time you  
 16 got involved in the review, the DAKO was gone,  
 17 the DAKO machine?  
 18 DR. CARTER:  
 19 A. It went in March of 2004, so I would have been  
 20 here doing some locums.  
 21 COFFEY, Q.C.:  
 22 Q. Pardon me?  
 23 DR. CARTER:  
 24 A. I would have been here doing some locums.  
 25 COFFEY, Q.C.:

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1 Q. Oh no, by the time '05, it was long gone.  
 2 DR. CARTER:  
 3 A. Yes, it wasn't in use, I don't know where it  
 4 was, I assume it was gone.  
 5 COFFEY, Q.C.:  
 6 Q. Did you ever make any inquiries about where  
 7 the computer was?  
 8 DR. CARTER:  
 9 A. No.  
 10 COFFEY, Q.C.:  
 11 Q. But from your perspective, you had understood  
 12 that perhaps there would be computer records  
 13 somehow from which -  
 14 DR. CARTER:  
 15 A. Yes, usually you can, I mean, I'm not a  
 16 computer expert, but usually you can ask the  
 17 computer to tell you this sort of thing and it  
 18 can tell you what the run was, what--any  
 19 issues that had arisen during the run, what  
 20 cases were run at that time.  
 21 COFFEY, Q.C.:  
 22 Q. Exhibit P-0925 please? Page 7, Doctor. This  
 23 is, here, although you're not in attendance,  
 24 this is the meeting that afternoon, apparently  
 25 they agreed to get Dr. Carter the information

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1 she needs. "Dr. Carter to do only this  
 2 service. Mary Butler to report and take  
 3 direction from Dr. Carter. Judy Quinlan to  
 4 report to Dr. Carter. Will arrange someone  
 5 from QA to be assigned." Now while you were  
 6 involved, was there anybody from QA assigned?  
 7 DR. CARTER:  
 8 A. I don't think he means assigned to me, maybe  
 9 to the project, so I think that would be maybe  
 10 Heather Predham, maybe.  
 11 COFFEY, Q.C.:  
 12 Q. The first four would be your -  
 13 DR. CARTER:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. Now, Exhibit P-0081 please? Doctor, this is a  
 17 letter to Dr. Williams and Dr. Cook. I take  
 18 it this is your handwriting, August 8th, 2005?  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.:  
 22 Q. And you signed it at the bottom. What was--  
 23 how did you come to write this letter?  
 24 DR. CARTER:  
 25 A. We looked at the handwritten notes a little

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1 earlier where I had the "Us" "Them" columns,  
 2 so I had just derived those for Dr. Cook  
 3 because a lot of this is being done in between  
 4 all your regular work, so I had just jotted  
 5 down the numbers for him and gave them to him.  
 6 And we had decided at or around this time to  
 7 shut down the Ventana system and Dr. Williams  
 8 and Dr. Cook wanted some formal numbers  
 9 written down as to why I thought that the  
 10 Ventana system needed to be evaluated as well,  
 11 and these are my numbers.  
 12 COFFEY, Q.C.:  
 13 Q. Doctor, did you ever receive any response from  
 14 anyone in relation to the evaluation of or  
 15 examination of the Ventana system in relation  
 16 to ER/PR? Did you ever receive any response?  
 17 You made the assertion that it should be  
 18 investigated further, the Ventana, did you  
 19 ever get any response?  
 20 DR. CARTER:  
 21 A. I'm not sure that I was expecting one, I think  
 22 I probably was expecting that we would be  
 23 doing this and Don and I were just moving  
 24 forward with the parallel testing, the  
 25 pathologist verses pathologist comparisons,

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1 those sorts of things.  
 2 COFFEY, Q.C.:  
 3 Q. Here, Doctor, just looking down through this  
 4 then, your second paragraph and you're, of  
 5 course, dealing only for cases seen at the  
 6 Health Sciences Centre in 2002, this relates  
 7 to.  
 8 DR. CARTER:  
 9 A. Health Care Corporation, so it would have been  
 10 at both sites.  
 11 COFFEY, Q.C.:  
 12 Q. Yes. "Have patients identified as ER negative  
 13 using a ten percent cut-off point or other  
 14 surrogate markers, such as male gender and/or  
 15 favourable histologic subtype of a low  
 16 positivity, 87." The ten percent cut-off,  
 17 readily apparent, I hope.  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. "The other surrogate markers, such as male  
 22 gender and/or favourable histologic subtype  
 23 with a low positivity" what are you referring  
 24 to there?  
 25 DR. CARTER:

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1 A. It used to be thought, but actually it's no  
 2 longer true, that virtually all men with  
 3 breast cancer are estrogen receptor positive.  
 4 I think now it's agreed that they probably  
 5 reflect the female population as well, so they  
 6 would be down around 75, 80 percent, maybe at  
 7 the upper end of that. But at that time, I  
 8 was trying to pick out any male breast cancers  
 9 that had unusual staining patters and then the  
 10 favourable histologic subtypes would be the  
 11 mucinous cases that would have something  
 12 around a 10 or 20 or 30 percent where I would  
 13 be expecting a higher percent positivity.  
 14 COFFEY, Q.C.:  
 15 Q. And totally them, that is the 10 percent cut-  
 16 off and those other surrogate markers, you  
 17 would come up with--identified 87 cases?  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. Number of patients undergoing ER testing  
 22 during that time period at the Health Care  
 23 Corporation, 189, based upon Mr. Gulliver's  
 24 figures.  
 25 DR. CARTER:

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. Then 87 over 189, 46 percent negative rate,

4 that, I take it, is just simply the arithmetic

5 itself?

6 DR. CARTER:

7 A. Yes, I mean there were cases that they gave me

8 that they said these are 87 cases that are ER

9 negative, say for example from January 1st to

10 June 30th, and then in that time, they told me

11 that there was 189 cases of estrogen receptor

12 done, so we had a 46 percent negative rate.

13 COFFEY, Q.C.:

14 Q. And of the 87 cases, 18 are not being

15 retested, so you have a balance of 69

16 retested, 43 have converted and read by both

17 yourself and Dr. Cook, using the Ventana. So

18 at that point, a 62 percent conversion rate.

19 DR. CARTER:

20 A. In this subset.

21 COFFEY, Q.C.:

22 Q. In that subset. Now assuming a 62 percent

23 conversion rate of all 87 negatives, you'd

24 have 54 positives and 33 true negatives, which

25 is 17.5 percent true negative rate using the

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1 Ventana.

2 DR. CARTER:

3 A. Which is now too low.

4 COFFEY, Q.C.:

5 Q. Now your assertion below that, you say, "I

6 believe that the idea that the DAKO system,

7 both its performance and interpretation

8 greatly under-estimated the number of women

9 who would benefit from hormonal manipulation

10 of their breast cancer and should be

11 investigated." Now just based upon those

12 figures and the conversions, you thought that

13 -

14 DR. CARTER:

15 A. There is a 46 percent negative rate.

16 COFFEY, Q.C.

17 Q. Which is far too high.

18 DR. CARTER:

19 A. Which is too high, yes.

20 COFFEY, Q.C.

21 Q. And from these numbers, it would also appear

22 that the Ventana system is overestimating the

23 number of patients who are ER positive. What

24 kind of percentage would you have expected to

25 be ER positive, if the test was optimized and

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1 optimally carried out.

2 DR. CARTER:

3 A. It should be around 75 to 80 percent, most

4 people would agree 75 percent is where you

5 would start to look at your population.

6 COFFEY, Q.C.

7 Q. And you go on to---"couple this finding with

8 the recent 60 percent disagreement with Mount

9 Sinai Hospital on crude progesterone status

10 (positive versus negative and not percentile

11 staining) and it appears that we have another

12 system that needs investigating". I take it

13 that 60 percent disagreement is those figures

14 that -

15 DR. CARTER:

16 A. Those hand written little tables that we just

17 looked at. But again, here I was trying to

18 emphasis that this is something that you're

19 doing in between doing everything else. This

20 is very preliminary and very raw numbered.

21 COFFEY, Q.C.

22 Q. Exhibit P-0562. Doctor, this is an e-mail of

23 August 9th, 2005 from Debbie Parsons to a

24 number of individuals, not including yourself,

25 but the subject is Dr. Carter's retesting

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1 results. She says, "I have Dr. Carter's

2 retesting results entered in the database and

3 have summarized the results as attached. And

4 I think I may be able to get the Tamoxifen

5 prescribed by MCP number from pharmacy". Do

6 you recall giving Ms. Parsons your retesting

7 results?

8 DR. CARTER:

9 A. No, I'm not sure, who is Ms. Parsons?

10 COFFEY, Q.C.

11 Q. Debbie Parsons and again, she is -

12 DR. CARTER:

13 A. I don't know.

14 COFFEY, Q.C.

15 Q. - I'm trying to remember. Mr.?

16 MR. BROWNE:

17 Q. Dr. Williams' assistant.

18 COFFEY, Q.C.

19 Q. Dr. Williams, that was it, I was trying to

20 remember whose assistant she was. She was Dr.

21 Williams' assistant. So, in terms of the

22 retesting results, the actual numbers -

23 MR. BROWNE:

24 Q. (Inaudible).

25 COFFEY, Q.C.

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1 Q. Thanks, Mr. Browne. The question again, is do  
 2 you recall giving or compiling the retesting  
 3 results in any format other than what we've  
 4 looked at already.  
 5 DR. CARTER:  
 6 A. I don't recall.  
 7 COFFEY, Q.C.  
 8 Q. If we look at the second page of this, she  
 9 says "see attached. Definition of positivity,  
 10 either ER or PR are positive with a value of  
 11 10 percent or greater" and then there's a  
 12 series of numbers, DAKO positive, Ventana  
 13 positive, 19. Number confirmed at Mount  
 14 Sinai, one confirmed as positive. DAKO  
 15 negative, Ventana positive, 39, three  
 16 confirmed Ventana results as positive, two  
 17 confirmed DAKO results as negative. And then  
 18 DAKO negative/Ventana negative, 34, five  
 19 confirmed as negative. And then DAKO  
 20 positive, Ventana negative one and DAKO  
 21 positive, other positive 94, 11 retested. Did  
 22 you prepare this?  
 23 DR. CARTER:  
 24 A. No, I didn't.  
 25 COFFEY, Q.C.

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1 Q. Okay. Now, Exhibit P-0585. Now, this is a  
 2 letter of August 24th, 2005 from Dr. Cook.  
 3 It's copied to Dr. Williams, to yourself  
 4 acknowledging receipt of your letter of August  
 5 2. So, did you and Dr. Cook discuss this  
 6 after the August 2nd letter, between August  
 7 2nd and 24th, your resignation letter and his  
 8 response to it here?  
 9 DR. CARTER:  
 10 A. We would have been discussing it every day.  
 11 I'm not sure what it is you're asking me.  
 12 Discussing just the ER issue or my  
 13 resignation?  
 14 COFFEY, Q.C.  
 15 Q. ER/PR, your resignation from the effort, but  
 16 your offer to still stay involved to a certain  
 17 extent.  
 18 DR. CARTER:  
 19 A. I would have been still offering consultative  
 20 advice and doing go forward things, but there  
 21 was no discussion of whether or not I would  
 22 come back into the fold, I think that was  
 23 pretty understood.  
 24 COFFEY, Q.C.  
 25 Q. That's what I'm getting -

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1 DR. CARTER:  
 2 A. No, I don't think Dr. Cook and I--he might  
 3 have, the first day or two, but no, I think I  
 4 was pretty firm and he was accepting of that.  
 5 COFFEY, Q.C.  
 6 Q. Doctor, did you ever refuse to do anything for  
 7 anyone?  
 8 DR. CARTER:  
 9 A. In my life, I'm sure -  
 10 COFFEY, Q.C.  
 11 Q. No, in this context. I appreciate the  
 12 comment, perhaps you have. Doctor, have you  
 13 ever--August 2nd, I appreciate you withdrew  
 14 and you indicated why and what you were  
 15 withdrawing from, but for the Commissioner's  
 16 benefit, after that, I mean, in terms of  
 17 anyone ask you for advice or input, did you  
 18 ever refuse to provide it, that you can  
 19 recall, in relation to this ER/PR -  
 20 DR. CARTER:  
 21 A. Not that I can recall. I mean, if somebody  
 22 asked me to do something and I was busy, I  
 23 mean, I would just -  
 24 COFFEY, Q.C.  
 25 Q. Oh, I -

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1 DR. CARTER:  
 2 A. - or whatever, but again, context, -  
 3 COFFEY, Q.C.  
 4 Q. But what I'm getting at is this, if you were--  
 5 as time went on, because your name does appear  
 6 a number of other times throughout this whole  
 7 matter including the tumour panel.  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.  
 11 Q. So, in terms of, in the normal course, if you  
 12 were asked to do something, if you were  
 13 available to do it or able to do it, did you  
 14 do so?  
 15 DR. CARTER:  
 16 A. I think so, yes.  
 17 COFFEY, Q.C.  
 18 Q. Exhibit P-2172, please. Now, Doctor, I'm  
 19 going to ask you, do you recognize the  
 20 handwriting on this?  
 21 DR. CARTER:  
 22 A. No, I don't. This my writing, yes, sorry, I  
 23 thought you meant the first one.  
 24 COFFEY, Q.C.  
 25 Q. Okay, the first one, yes, that's whose

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1 handwriting? Yours?  
 2 DR. CARTER:  
 3 A. No, that's not my handwriting.  
 4 COFFEY, Q.C.  
 5 Q. That's not yours, okay.  
 6 DR. CARTER:  
 7 A. I don't recognize it.  
 8 COFFEY, Q.C.  
 9 Q. And then it says, "a little bit rushed, but  
 10 you get the idea, Bev, I'm on holiday Friday,  
 11 vacation". This sort of form, slide ID,  
 12 staining antibody, antigen retrieval, antibody  
 13 time block, A block or B, previous result/new  
 14 result. Do you recognize any of this  
 15 material?  
 16 DR. CARTER:  
 17 A. Yes, these would be the optimizations that I  
 18 referred to earlier.  
 19 COFFEY, Q.C.  
 20 Q. And the hand writing in this context is whose?  
 21 DR. CARTER:  
 22 A. It's not mine. I would assume having seen  
 23 that I'm writing to Ken, it would Mr. Green or  
 24 Mr. Simms, that's who I was working with on  
 25 the issue.

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1 COFFEY, Q.C.  
 2 Q. Okay. And then starting at page five of this  
 3 exhibit, what sort of a form is this, do you  
 4 know?  
 5 DR. CARTER:  
 6 A. This is the computer generated run form.  
 7 COFFEY, Q.C.  
 8 Q. I take it then as we go through these, these  
 9 would reflect an effort to optimize various  
 10 stains.  
 11 DR. CARTER:  
 12 A. Yes.  
 13 COFFEY, Q.C.  
 14 Q. And do you recall when this occurred, this  
 15 process?  
 16 DR. CARTER:  
 17 A. Not exactly.  
 18 COFFEY, Q.C.  
 19 Q. Were you asked to assist though, at times, the  
 20 technologist in doing so?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.  
 24 Q. You did, yes.  
 25 MR. BROWNE:

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1 Q. (Inaudible) dates on some -  
 2 COFFEY, Q.C.  
 3 Q. Yes, on some of them, some do have some dates.  
 4 Yes, on the computer runs themselves, they're  
 5 August 25. I just go back. Thank you. It  
 6 seems I seen that before. Sorry, I'm gone  
 7 well beyond, page five and the run start/run  
 8 completed, that's August 25, 2005 and 25 again  
 9 on page six. So, the same thing on page  
 10 seven. So, if this occurred at that time, you  
 11 were probably involved at the end of August  
 12 trying to assist the technologists at that  
 13 time -  
 14 DR. CARTER:  
 15 A. As you were flicking through that, my writing  
 16 shows up at the end when I'm talking about  
 17 very dirty stains, things like that, if you  
 18 keep on going. There, that's my writing, so  
 19 that was the beginning of my return to Mr.  
 20 Simms or Mr. Green.  
 21 COFFEY, Q.C.  
 22 Q. Beginning at page 14 of the exhibit, page 15.  
 23 The purpose in you producing this material  
 24 would be to given them advice as to your views  
 25 on whether this particular run or particular

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1 block, sorry, slide was well done or not.  
 2 DR. CARTER:  
 3 A. Well, the protocol number would be on one edge  
 4 of the chart. So, on this page that we're  
 5 looking now, PRA 316 KE, that would mean  
 6 something to the technologists as progesterone  
 7 and then run number 316. So, it would say in  
 8 it that they had used a certain antibody  
 9 concentration, that they had exposed the  
 10 ingredients for a certain period of time and  
 11 that they had used antigen retrieval and other  
 12 things and then I would comment on what each  
 13 one of the runs would look like to me. And  
 14 then from my comments to them and sometimes  
 15 you would look at the slides together. We  
 16 would pick out which protocol numbers we  
 17 thought were more appropriate.  
 18 COFFEY, Q.C.  
 19 Q. And on that particular page, back to page 14,  
 20 as we get down through the page, I think  
 21 you'll see ER begins.  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.  
 25 Q. These are the ERs and then some PRs and so on.



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1 I take it these continue on through page,  
 2 we're at page 19 now, 20, 21 -  
 3 DR. CARTER:  
 4 A. There are a lot of them, yes.  
 5 COFFEY, Q.C.  
 6 Q. - 22, all the way up through page 24 of the  
 7 exhibit. If we could look at Exhibit P-1738.  
 8 Doctor, these are notes, Dr. Cook's notes of a  
 9 meeting. He says, "spoke to Trish and Dr. Bev  
 10 Carter, September 21st, 2005". Do you know if  
 11 and I think you referred to this yesterday, I  
 12 asked you about whether you were  
 13 there when Trish had her exit interview.  
 14 DR. CARTER:  
 15 A. Her exit? I don't think I was there for her  
 16 exit. I was there when she was in the St.  
 17 Clare's site. I thought her exit interview  
 18 was just with Dr. Williams.  
 19 COFFEY, Q.C.  
 20 Q. Only Dr. Williams, okay. And the time when  
 21 you met with her at the time, did she discuss  
 22 any observations she had made up to that  
 23 point? This seem to be Dr. Cook's account of,  
 24 at least, certain things that Ms. Wegrynowski  
 25 is telling him. I'm not suggesting you were

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1 there.  
 2 DR. CARTER:  
 3 A. I don't recall Trish explaining specific  
 4 aspects of her report. Actually I remember  
 5 Trish telling me that she couldn't, that this  
 6 was peer review and we went--my friend and I  
 7 took her to dinner and movie and I sort of  
 8 asked, how's it going? And she said, I'm not  
 9 telling you, this is peer review. So, I don't  
 10 think I was at any meeting where she discussed  
 11 that.  
 12 COFFEY, Q.C.  
 13 Q. Exhibit P-1953, page two, please. This the  
 14 minutes of an anatomical pathology, October  
 15 4th, 2005 meeting. Doctor, an update on ER/PR  
 16 status and the note here, this is a meeting at  
 17 the General Hospital site. If you look back,  
 18 you'll see the people listed there.  
 19 DR. CARTER:  
 20 A. Yes.  
 21 COFFEY, Q.C.  
 22 Q. From that site.  
 23 DR. CARTER:  
 24 A. Yes, I've looked at this before.  
 25 COFFEY, Q.C.

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1 Q. Okay. And it says, "we are still in the  
 2 process"--"the media has gotten a hold of the  
 3 issue"--"we are still in the process of  
 4 determining how extensive this problem is. In  
 5 view of this discussion with Dr. Cook, he's  
 6 appointed Dr. Beverley Carter as the point  
 7 person for HER2/neu testing. With this in  
 8 mind, there is some sentiment from the  
 9 pathologists that Dr. Carter should review all  
 10 breast cases with a back-up person to cover in  
 11 her absence. A letter to this effect will be  
 12 sent to Dr. Cook stating opinion of the  
 13 pathologists at this site and this will be  
 14 discussed with Dr. Carter as well". What do  
 15 you recall about that, Doctor?  
 16 DR. CARTER:  
 17 A. Actually, I'm not familiar with this at all.  
 18 COFFEY, Q.C.  
 19 Q. The subject matter here of this.  
 20 DR. CARTER:  
 21 A. I'm not sure what he's talking about for a  
 22 point person for HER2 testing. I found out  
 23 that there had been a meeting of the  
 24 pathologists over at the General site where  
 25 they had expressed this concern, that they

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1 would like all cases to be transferred over to  
 2 St. Clare's, but I found that out on the day  
 3 that it began. So, there was no letter or  
 4 discussion with me.  
 5 COFFEY, Q.C.  
 6 Q. And when did that happen, in fact?  
 7 DR. CARTER:  
 8 A. Probably some time in late 2005. I had no  
 9 issue with it. I mean, that was my, sort of,  
 10 ongoing theme. I welcome all the breast  
 11 cases.  
 12 COFFEY, Q.C.  
 13 Q. And Doctor, but who was it discussed--because  
 14 it appears to have been in early October, you  
 15 didn't learn about this sentiment at the  
 16 General until, in fact, it had happened.  
 17 DR. CARTER:  
 18 A. Yes, it was happening that day, yes.  
 19 THE COMMISSIONER:  
 20 Q. Mr. Coffey, wherever you find a spot, we'll  
 21 take the afternoon break.  
 22 COFFEY, Q.C.  
 23 Q. Okay, thank you. I'm going to go to the next  
 24 exhibit P-0634. Doctor, this is a letter, a  
 25 memo of October 12th, 2005. It's from Dr.

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1 Williams to yourself. It's concerning the  
 2 panel ER/PR results and he writes, "Dr.  
 3 Carter, Dr. Cook has just informed me you've  
 4 agreed to sit on this panel, Don will be on it  
 5 in ex officio capacity to ensure that all  
 6 information is available from the laboratory  
 7 medicine program. You'll be there as an  
 8 expert in the area of breast pathology and  
 9 help with the deliberations of the panel". He  
 10 thanks you for your help. Doctor, how was it  
 11 that you came to be on the panel?  
 12 DR. CARTER:  
 13 A. Dr. Cook and I think, Dr. Williams were  
 14 telling me about the panel and asked me if I  
 15 was interested in serving on it.  
 16 COFFEY, Q.C.  
 17 Q. So, they approached you.  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.  
 21 Q. Exhibit P-2457. Now these, Doctor, I take it  
 22 are--I think this is minutes of the first  
 23 meeting of October 13, 2005, your name is  
 24 there to the top right. And I take it then,  
 25 Doctor, when you could or were available then

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1 from that point on, you attended these panel  
 2 meetings?  
 3 DR. CARTER:  
 4 A. Yes.  
 5 COFFEY, Q.C.  
 6 Q. Okay. I'll then come back and ask you some  
 7 questions about that after the break. Thank  
 8 you, Commissioner.  
 9 (BREAK)  
 10 THE COMMISSIONER:  
 11 Q. Please be seated. Mr. Coffey.  
 12 COFFEY, Q.C.  
 13 Q. Thank you, Commissioner. Registrar, Exhibit P-  
 14 1305, please. Doctor, these are the minutes  
 15 of the physician panel meeting number two,  
 16 October 20th, 2005. You're present right  
 17 here, noted to be present.  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.  
 21 Q. Form for taking minutes. Dr. Laing  
 22 distributed a form that could be used by the  
 23 secretary to assist when taking minutes at  
 24 meetings and the form consisted of, and it  
 25 lists a number of things. "After a review of

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1 form by group, it was agreed to add a line for  
 2 pathology specimen number, site, date of  
 3 pathology diagnosis to read date of pathology  
 4 and follow up, be changed to follow-up  
 5 physician. And then in bold, italics "the  
 6 minutes of the October 13th meeting will be  
 7 revised to include the extra information on  
 8 each patient, ie. OPUS number and pathology  
 9 specimen number/site" and then there's a note  
 10 that "patients who are deceased will be  
 11 addressed following the review of all the  
 12 patients who are currently alive." Now  
 13 Doctor, just in terms of that, if we could  
 14 look, please, at Exhibit P-1368? Actually, I  
 15 apologize, P-2457 first of all, 2457. Doctor,  
 16 this is the first draft of the October 13th,  
 17 2005 minutes. You'll note yourself here. I  
 18 say it's first draft because here, when we  
 19 look at the action plan, there's columns,  
 20 patient information, DAKO ER/PR, MS would be  
 21 Mount Sinai ER/PR and then follow up, with the  
 22 recommendation, whatever it was, and then the  
 23 follow up column and a doctor's name, and here  
 24 then, I want you to just bear that in mind, in  
 25 the left-hand column, there's just the

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1 patient's name and the MCP number, which of  
 2 course, here are redacted.  
 3 If we could look now at Exhibit P-1368?  
 4 This is the same minutes, October 13th, 2005.  
 5 The major change is reflective of the October  
 6 20th minutes. Here, on the left-hand side,  
 7 under patient information, there's space for  
 8 the name and MCP number. There's an entry for  
 9 OPUS number as well, and then the date of  
 10 pathology is noted, particular date by day,  
 11 month and year. Pathology specimen  
 12 number/site and then the surgical number would  
 13 have been there, and site being whether it's  
 14 the right or left breast noted here.  
 15 DR. CARTER:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Doctor, why was this changed? Why was this  
 19 information, the OPUS number, date of  
 20 pathology specimen number and site added?  
 21 DR. CARTER:  
 22 A. I think the OPUS number was added so that you  
 23 could have access to the Cancer Centre chart.  
 24 There's a different charting system. I can't  
 25 really speak intelligently about it. The

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1 other one, because many patients would have  
 2 more than one surgery performed and in some  
 3 rare instances, you may have bilateral disease  
 4 sites as well, so I think it was added just to  
 5 clarify exactly what we were talking about and  
 6 to provide more access to the computer charts.  
 7 COFFEY, Q.C.:  
 8 Q. Doctor, the date of pathology means what in  
 9 this context?  
 10 DR. CARTER:  
 11 A. I would assume the date that the original--  
 12 usually the date that we have is the date that  
 13 the original specimen was received in the  
 14 laboratory.  
 15 COFFEY, Q.C.:  
 16 Q. Okay, then that appears on the pathology  
 17 reports then, the date received?  
 18 DR. CARTER:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. That wouldn't necessarily mean the date that  
 22 ER/PR was reported?  
 23 DR. CARTER:  
 24 A. No. I don't think we had a way to know that.  
 25 We had difficulty finding that out.

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1 COFFEY, Q.C.:  
 2 Q. Doctor, on that very point, there are a number  
 3 of cases that, I believe in some C exhibits we  
 4 saw when Ms. Butler, if I recall correctly,  
 5 was here, at times the specimen would be  
 6 received, say on--I'll just pick a date,  
 7 September 1st, or in that particular instance,  
 8 perhaps late in '02, December '02, January '03  
 9 and wasn't reported until May of '03. Now I  
 10 understand Dr. Ejeckam had stopped testing for  
 11 a while, but I take it that you were not able  
 12 actually to tell generally when actual retest-  
 13 -not retest, I'm sorry, the original test  
 14 occurred?  
 15 DR. CARTER:  
 16 A. You could tell when it was reported. That  
 17 would be on the pathology report, but that  
 18 didn't necessarily correlate with when it was  
 19 performed. Some people reported, you know,  
 20 the next day, as soon as they get the slides,  
 21 and for some people, it would be on their desk  
 22 while they're waiting for other aspects of the  
 23 case or waiting for their own personal  
 24 schedule to clear.  
 25 COFFEY, Q.C.:

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1 Q. So there was no way, based upon the record, of  
 2 actually ascertaining, that you could tell,  
 3 when exactly the test was done?  
 4 DR. CARTER:  
 5 A. Not that I know of.  
 6 COFFEY, Q.C.:  
 7 Q. And even then, even if you could go to the  
 8 computer and find out when a test was run,  
 9 using computer data, you'd still have to go  
 10 and try and ascertain when the doctor actually  
 11 interpreted it?  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Which might be different than the day it was  
 16 entered on Meditec?  
 17 DR. CARTER:  
 18 A. Yes.  
 19 COFFEY, Q.C.:  
 20 Q. And signed off on Meditec might be a different  
 21 day again?  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. Doctor, when you were conducting your

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1 investigation in June and July of '05, did you  
 2 make any effort to record who the reporting,  
 3 original reporting pathologist had been?  
 4 DR. CARTER:  
 5 A. At some point the spreadsheets, the tables  
 6 changed, and I'm not sure what the date is,  
 7 but the first few tables, they don't have that  
 8 column and then I added in date of testing,  
 9 the pathologist and we started to look at  
 10 that.  
 11 COFFEY, Q.C.:  
 12 Q. And I take it that would be for the same  
 13 reason that you'd want to know whether the  
 14 problem was centred on a particular  
 15 pathologist or -  
 16 DR. CARTER:  
 17 A. Yes.  
 18 COFFEY, Q.C.:  
 19 Q. - particular days of the week or whatever, if  
 20 you could?  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. Doctor, while we're on the subject of  
 25 pathologists and who did the tests and

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1 reviews, were you ever made aware of any  
 2 concerns expressed by a pathologist at the  
 3 General Hospital in early August 2005 about  
 4 the nature of the review?  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. What do you recall about that?  
 9 DR. CARTER:  
 10 A. Well, since then, I've read -  
 11 COFFEY, Q.C.:  
 12 Q. Sure.  
 13 DR. CARTER:  
 14 A. - there's a document in exhibit, so it's hard  
 15 to separate one from the other, but at the  
 16 time, I think the pathologists at the General  
 17 site, and I'm not sure it was restricted to  
 18 the General site, they were very reluctant  
 19 with having another pathologist come in and  
 20 review their work.  
 21 COFFEY, Q.C.:  
 22 Q. In the context of this ER/PR review that you  
 23 had embarked upon.  
 24 DR. CARTER:  
 25 A. Yes.

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1 COFFEY, Q.C.:  
 2 Q. Exhibit P-1994? Doctor, that's some notes, a  
 3 typed account too that Dr. Cook provided to  
 4 the Commission of August 5, 2005, a meeting  
 5 with a number of pathologists.  
 6 DR. CARTER:  
 7 A. Yes, this is what was I was referring to.  
 8 COFFEY, Q.C.:  
 9 Q. So when you were told that they had concerns,  
 10 what, if anything--who were you told by, and  
 11 what, if anything, was your response?  
 12 DR. CARTER:  
 13 A. I was told by Dr. Cook that they had concerns.  
 14 My response was something along the lines of  
 15 that this was a process that was, you know,  
 16 sanctioned by administration, so you know, it  
 17 would go on and Don would need to facilitate  
 18 the smoothing of that. I mean, a lot of  
 19 people were very upset and frightened and, you  
 20 know, didn't know what was going on. I didn't  
 21 view it as a major barrier.  
 22 COFFEY, Q.C.:  
 23 Q. When did you first become aware of this  
 24 concern?  
 25 DR. CARTER:

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1 A. Is it August the 5th is the date there?  
 2 COFFEY, Q.C.:  
 3 Q. Well, that is August 5. Now by then, you had  
 4 already withdrawn, in effect, yourself.  
 5 DR. CARTER:  
 6 A. Oh, yeah, that's right. No, it was before  
 7 that.  
 8 COFFEY, Q.C.:  
 9 Q. It was before, you were aware of that.  
 10 DR. CARTER:  
 11 A. We were trying to get together a lot of  
 12 processes about parallel testing and canned  
 13 text, those sorts of things.  
 14 COFFEY, Q.C.:  
 15 Q. So sometime before August 1st, you would have  
 16 been made aware of the concern, but when  
 17 exactly, you can't recall?  
 18 DR. CARTER:  
 19 A. On or around, because this is talking about  
 20 the parallel process that I described, not the  
 21 retrospective process. This is the parallel  
 22 process.  
 23 COFFEY, Q.C.:  
 24 Q. Okay, the parallel process.  
 25 DR. CARTER:

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1 A. I think.  
 2 COFFEY, Q.C.:  
 3 Q. Okay. So it's "we should ensure that no bias  
 4 is introduced into the ongoing study." Now  
 5 which parallel process are you referring to?  
 6 DR. CARTER:  
 7 A. We put up an exhibit a little earlier, or you  
 8 put up an exhibit a little earlier where we  
 9 talked about after the DAKO had been shut off  
 10 and the Ventana was being used, and we had  
 11 some problem with the Ventana. Dr. Cook wrote  
 12 a memo that said from now on we would be  
 13 testing at Mount Sinai.  
 14 COFFEY, Q.C.:  
 15 Q. Yes.  
 16 DR. CARTER:  
 17 A. And I think bullets three through six are  
 18 about send the block to the technologist  
 19 first, have them cut it, they will send it--  
 20 they will stain it and send it to you. You  
 21 read it. You make your reading and you send -  
 22 COFFEY, Q.C.:  
 23 Q. You, individual pathologist A, B, C, whoever  
 24 they are?  
 25 DR. CARTER:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. And you make your determination?  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. And send that along to Dr. Carter?  
 8 DR. CARTER:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. Okay, and it was then Dr. Carter's review -  
 12 DR. CARTER:  
 13 A. I think this is what they're--the study that  
 14 they're referring to there, that they didn't  
 15 feel that their work should be audited.  
 16 COFFEY, Q.C.:  
 17 Q. Because you had understood that at the time,  
 18 at least, some of them felt that what you  
 19 would be doing in reviewing their  
 20 determination of the slides would be, in  
 21 effect, an audit?  
 22 DR. CARTER:  
 23 A. Yes.  
 24 COFFEY, Q.C.:  
 25 Q. Exhibit -

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1 THE COMMISSIONER:  
 2 Q. Sorry, before we go on, Dr. Carter, does not  
 3 the present system allow for a, in effect, a  
 4 reading by another pathologist of a percentage  
 5 of your work in any event, as sort of a QA  
 6 effort?  
 7 DR. CARTER:  
 8 A. A quality management program would include  
 9 that random review of specimens. This was a  
 10 concept, I think, that was not well known by  
 11 the group here.  
 12 THE COMMISSIONER:  
 13 Q. At the time.  
 14 DR. CARTER:  
 15 A. At the time, so this is in August 2005 and we  
 16 were setting up a parallel process.  
 17 THE COMMISSIONER:  
 18 Q. Okay. It was just because my reaction to this  
 19 frankly had been so what's the difference  
 20 between although you're reading more of their  
 21 slides, but it would seem to be not that much  
 22 different than doing a QA process whereby a  
 23 selective number of one pathologist's work  
 24 would be read by another pathologist.  
 25 DR. CARTER:

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1 A. Yeah, there's not a lot of difference to it.  
 2 I think here, it would be me reading everybody  
 3 else's work whereas in a random QA it would be  
 4 all of us reading everybody else's work. So  
 5 there may have been that sort of element, the  
 6 breast pathologist is looking at their work.  
 7 COMMISSIONER:  
 8 Q. But as far as you know, is this the first  
 9 introduction locally to the idea of reading  
 10 each other's work as opposed to somebody  
 11 working in an office and saying can I have  
 12 your opinion?  
 13 DR. CARTER:  
 14 A. I think so. To the best of my knowledge, it  
 15 would be.  
 16 COMMISSIONER:  
 17 Q. Okay, thank you.  
 18 COFFEY, Q.C.:  
 19 Q. Here, Doctor, just looking at this -- I  
 20 appreciate you were not at this meeting. In  
 21 fact, by this point you had withdrawn from  
 22 that kind of -- at least the retrospective  
 23 work.  
 24 DR. CARTER:  
 25 A. Yes, I think this was more about the

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1 prospective work.  
 2 COFFEY, Q.C.:  
 3 Q. Prospective.  
 4 DR. CARTER:  
 5 A. But, I mean, it's best to talk to the people  
 6 involved. I think that's what it's about.  
 7 COFFEY, Q.C.:  
 8 Q. And it does say in the second paragraph, "We  
 9 should ensure no bias is introduced into the  
 10 ongoing study. If the purpose is to compare  
 11 methods, then the following are important  
 12 features". Assuming that the pathologist  
 13 reported the original test correctly, then  
 14 only the report needs to be compared to the  
 15 result of the current accepted method. Send  
 16 an addendum if there is, in fact, a change in  
 17 the result. Persons conducting the study do  
 18 not need to know which pathologist signed the  
 19 report originally. Anything else is an audit  
 20 of individual pathologists, and if that is the  
 21 aim, this is not the proper procedure for the  
 22 audit of pathologist's performance". So that  
 23 would seem to suggest that, in fact, there  
 24 might be even retesting here going on and  
 25 addendums issued. So is it - again I

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1 appreciate you were not at this meeting and  
 2 it's possible, I take it, that these actual  
 3 concerns might be in relation to the retest  
 4 issue?  
 5 DR. CARTER:  
 6 A. Yes, when it was expressed with me --  
 7 COFFEY, Q.C.:  
 8 Q. When it was raised with you, though --  
 9 DR. CARTER:  
 10 A. It was talking about the parallel testing,  
 11 that they didn't want to report their work and  
 12 then have me to compare it.  
 13 COFFEY, Q.C.:  
 14 Q. Exhibit P-2458. Doctor, here this is a fax  
 15 transmission. It's 15 pages, including the  
 16 cover sheet, October 19th, 2005, to yourself  
 17 from Dr. Williams. He writes, "Bev, this is  
 18 the article I was referencing", signed, Bob,  
 19 and then there's an article by Dr. Neil Love,  
 20 and you can see here it's printed off the  
 21 internet, dating September 30th, 2005, and  
 22 then there are -- on the next page is a  
 23 reference to ER testing inter-laboratory  
 24 variability, and it comes from a publication  
 25 in 2004 by Lippincott Williams and Wilkins,

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1 and goes on for two pages, that does, and then  
 2 there's other material involving an abstract,  
 3 I take it, from Biotech Histochem, 1992, and  
 4 there's other material here.  
 5 DR. CARTER:  
 6 A. Uh-hm.  
 7 COFFEY, Q.C.:  
 8 Q. Do you recall how - the larger article, if I  
 9 could, at page eight is a publication entitled  
 10 "Assessment of tissue estrogen and  
 11 progesterone receptor levels, a survey of  
 12 current practice, techniques, and quantisation  
 13 methods" by Layfield, et al, and this is a  
 14 2000 publication. Doctor, do you recall why  
 15 it was or how it was that Dr. Williams came to  
 16 send this to you?  
 17 DR. CARTER:  
 18 A. It would have been a part of many discussions  
 19 that we had had about the estrogen receptor  
 20 issue. I think the first paper by Dr. Love,  
 21 the second last paragraph, they're talking  
 22 about a lot of the variability from site to  
 23 site, but that seems to be the theme of most  
 24 of them, what are some areas that could be  
 25 possibilities. I don't recall the specific

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1 context of the question -- of the discussion,  
 2 but it would have just been an exchange of  
 3 articles.  
 4 COFFEY, Q.C.:  
 5 Q. I take it, did you at times provide him with  
 6 material, Dr. Williams, do you recall?  
 7 DR. CARTER:  
 8 A. Yes, I think so.  
 9 COFFEY, Q.C.:  
 10 Q. Exhibit P-1807. Doctor, this is an e-mail,  
 11 November 16th, 2005, from Dr. Cook to Dr.  
 12 Mullen, and he writes, "Hi Brendan, could you  
 13 and Bev Carter follow up on particular  
 14 surgical specimen reported as ER zero percent,  
 15 PR zero percent", and he cross-references it.  
 16 "Bev may also want to see the slides. I do  
 17 hope Bev is treating all of you well and using  
 18 her people skills at an optimal level. Many  
 19 thanks, Don Cook". Dr. Carter, I take it you  
 20 were at Mount Sinai at the time?  
 21 DR. CARTER:  
 22 A. Yes, I was.  
 23 COFFEY, Q.C.:  
 24 Q. Why were you there at that point?  
 25 DR. CARTER:

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1 A. I had booked conference leave. It was in -- I  
 2 think it was in November in New Orleans, and  
 3 actually Hurricane Katrina happened, so I  
 4 still had the time booked off and I talked  
 5 with Dr. O'Malley and Dr. Mullen, and I was  
 6 still working on some of my textbook chapters  
 7 -- Dr. O'Malley is the editor of that  
 8 textbook, and I went up there, I think for a  
 9 week, and just looked at some  
 10 estrogen/progesterone cases with Dr. Mullen,  
 11 looked at some consults with Dr. O'Malley, and  
 12 worked on the textbook.  
 13 COFFEY, Q.C.:  
 14 Q. Okay. Exhibit P-0101. Doctor, this is that  
 15 December 7th, 2005 letter from yourself to Dr.  
 16 Williams. Doctor, here just looking through  
 17 the letter, other than the opening, beginning  
 18 at the bottom of the first page, the  
 19 paragraph, "the most important of these is  
 20 organization" -- well, in the paragraph above,  
 21 you note that there are multiple major issues  
 22 that must be addressed prior to any breast  
 23 testing being reported locally, and then, "The  
 24 most important of these is the organization of  
 25 the immunohistochemistry laboratory", and you

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1 go on to speak about that, and education of  
 2 technologists. You continue on to the top of  
 3 the next page, "The need for technologists to  
 4 document the optimization and validation of  
 5 every antibody" is referenced, the need to  
 6 define standard operating procedures is there  
 7 in the middle of that paragraph, the need for  
 8 all antibody specification sheets to be  
 9 available in readily available format, and  
 10 appropriate organizational chart be prepared  
 11 and designed, and some system be put in place  
 12 to address individual pathologist's complaints  
 13 and concerns about IHC. Now, Doctor, I take  
 14 it those in the main would refer to  
 15 technologist activities?  
 16 DR. CARTER:  
 17 A. Yes, so far.  
 18 COFFEY, Q.C.:  
 19 Q. So far, and I want to ask you about here,  
 20 "appropriate positive and negative controls  
 21 must be selected for ER/PR and HER2/neu", and  
 22 then you go on to talk about IHC technologists  
 23 need to be trained in the basic of  
 24 interpretation of them so that appropriately  
 25 stained slides only leave the laboratory.

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1 From your perspective, who should be reading  
 2 the control slides?  
 3 DR. CARTER:  
 4 A. Negative controls, I think, should be read by  
 5 technologists. I think that positive controls  
 6 for the most part can be read by  
 7 technologists.  
 8 COFFEY, Q.C.:  
 9 Q. I take it, the external ones?  
 10 DR. CARTER:  
 11 A. Sorry, external ones, yes, external controls.  
 12 COFFEY, Q.C.:  
 13 Q. And the selection of appropriate positive and  
 14 negative controls, in your experience who  
 15 actually does the selection?  
 16 DR. CARTER:  
 17 A. Well, here in St. John's, we do, the  
 18 pathologists do so far. I think at McMaster,  
 19 they were produced by the technologists.  
 20 COFFEY, Q.C.:  
 21 Q. And you go on then and talk about a microscope  
 22 is necessary for the use of the technologists,  
 23 and then on the next page, the first full  
 24 paragraph beginning, "The pathologists must  
 25 standardize their approach". I take it then

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1 what's spelled out here in this paragraph  
 2 relates to changes involving practice by  
 3 pathologist locally you felt were necessary?  
 4 DR. CARTER:  
 5 A. Yes, I think there was some more about  
 6 education somewhere, but --  
 7 COFFEY, Q.C.:  
 8 Q. Yes.  
 9 DR. CARTER:  
 10 A. Essentially, yes.  
 11 COFFEY, Q.C.:  
 12 Q. Actually here in the third line.  
 13 DR. CARTER:  
 14 A. Oh, okay.  
 15 COFFEY, Q.C.:  
 16 Q. "Should be educated about block selection in  
 17 breast cancer cases, should be taught basic  
 18 information about the reporting of predictive  
 19 factors in breast cancer, including aspects of  
 20 internal control, surrogate markers, and  
 21 handling of discordant results, and serious  
 22 consideration should be given to limited  
 23 number of pathologists reporting these often  
 24 difficult diagnosis. Standardized reporting  
 25 should be used", which includes certain

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1 information. Doctor, as of December 7th,  
 2 2005, I take it that you were telling Dr.  
 3 Williams that from your perspective changes  
 4 were needed by both the technologists and in  
 5 relation to the pathologists, as a group -- as  
 6 groups?  
 7 DR. CARTER:  
 8 A. Yes, and I think the biggest thing that I was  
 9 asking for in this case was some sort of  
 10 document that had said that these things were  
 11 being looked at. I know that many of these  
 12 things were actually in place, were being  
 13 worked on, but I wanted it written down that  
 14 we have taken this seriously and we have gone  
 15 through it and looked at it all.  
 16 COFFEY, Q.C.:  
 17 Q. Exhibit P-0694? This, I take it, Doctor, is  
 18 Dr. Williams' acknowledgement on December  
 19 14th, 2005 of your December 7th letter and he  
 20 writes, "I've asked Dr. Don Cook and Terry  
 21 Gulliver to review all the recommendations  
 22 made by Dr. Banerjee and Ms. Wegrynowski and  
 23 provide me with the spreadsheet of these  
 24 recommendations indicating our progress and  
 25 status with respect to implementation. Dr.

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1 Banerjee has agreed to participate in a  
 2 conference call, if required." And he goes on  
 3 to say once there is a full review of the  
 4 recommendations that were made and we achieve  
 5 consensus, a decision will be made about  
 6 timeframes and so on, about re-instituting the  
 7 service. Doctor, this list and a spreadsheet  
 8 of the recommendations, did you see those?  
 9 DR. CARTER:  
 10 A. I have seen them on a number of occasions.  
 11 COFFEY, Q.C.:  
 12 Q. Did you see them fairly early on after they  
 13 were initially--we understand they were  
 14 initially produced in mid December, 2005.  
 15 DR. CARTER:  
 16 A. I'm not sure when I first saw them, I'm not  
 17 sure.  
 18 COFFEY, Q.C.:  
 19 Q. Now in terms, Doctor, because you had written  
 20 on December 7th that Dr. Banerjee and Ms.  
 21 Wegrynowski had stated there were multiple  
 22 major issues that must be addressed. How did  
 23 you know that?  
 24 DR. CARTER:  
 25 A. I had seen the list of recommendations from

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1 Ms. Wegrynowski's report, but not her report.  
 2 COFFEY, Q.C.:  
 3 Q. How would you do that? We've seen the report  
 4 and it's kind of listed--her recommendations  
 5 are listed at various points in it.  
 6 DR. CARTER:  
 7 A. I mean, I received a sheet of papers, it was  
 8 probably about 16 or 17 of them there. Dr.  
 9 Banerjee's report I hadn't seen, I had spoken  
 10 to him, I had an idea of what may have been  
 11 going on and things that you would see in the  
 12 hallway, you know.  
 13 COFFEY, Q.C.:  
 14 Q. Changes that you were observing, I take it.  
 15 DR. CARTER:  
 16 A. Yes, I mean, Trish leaves and--sorry, Ms.  
 17 Wegrynowski leaves and then the next day,  
 18 you're buying a fridge, so it's not hard to  
 19 put two and two together.  
 20 COFFEY, Q.C.:  
 21 Q. Doctor, Exhibit P-0047 please?  
 22 THE COMMISSIONER:  
 23 Q. The Registrar is prepared this time.  
 24 COFFEY, Q.C.:  
 25 Q. Thank you, very much. Doctor, this is Ms.

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1 Wegrynowski's report of November 9th or dated  
 2 November 9th, 2005, just if you go to page,  
 3 for example, page 5 of it, you'll see under  
 4 paragraph 2.1, there are recommendations one  
 5 through three. Then paragraph 2.2,  
 6 "Processing" and then there are  
 7 recommendations four, five, six, seven and  
 8 eight. In paragraph three, 3.1, there's text  
 9 and then there are recommendations nine, ten,  
 10 eleven, twelve, thirteen into the next page.  
 11 So, Doctor, do you know if--did you just  
 12 receive something entitled "Recommendations"  
 13 and with a bunch of numbers or -  
 14 DR. CARTER:  
 15 A. That's what I think that I received, that I  
 16 looked at because I didn't receive anything,  
 17 it was just like a cut and paste of this, one,  
 18 two, three, four, five, six -  
 19 COFFEY, Q.C.:  
 20 Q. Okay. Exhibit P-2460? And, Doctor, this is  
 21 an e-mail from yourself, February 3rd, 2006 to  
 22 Dr. McCarthy and others and you write,  
 23 "Morning, Kara brought a patient pamphlet  
 24 about breast cancer pathology to our ER  
 25 meeting last night. Attached is an article I

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1 wrote for breast cancer e-publication and have  
 2 slowly been editing as a user friendly  
 3 pamphlet. I think it would be perfect for our  
 4 patients, still needs some editing, as well as  
 5 simplification of language. If I can get some  
 6 clerical/graphic this is almost ready to go.  
 7 Can you read please and offer corrections, can  
 8 I get someone to provide the  
 9 clerical/technical support I need. Thank you.  
 10 Beverley Carter." I take it that that is  
 11 referencing this article that you--is this  
 12 this article that you -  
 13 DR. CARTER:  
 14 A. For the Atlantic Breast Cancer -  
 15 COFFEY, Q.C.:  
 16 Q. Breast Cancer Newsletter. And that would be  
 17 this, I take it?  
 18 DR. CARTER:  
 19 A. That's the earliest form.  
 20 COFFEY, Q.C.:  
 21 Q. Yes. Now, Doctor, what was going on here  
 22 otherwise at that point in time, early  
 23 February, in terms of you're sending this to  
 24 these various physicians for what?  
 25 DR. CARTER:



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1 A. I think the long-term idea at that point was  
 2 to come up with some sort of pamphlet that  
 3 could be either included in the purple lupin  
 4 kit, which is given to hopefully all women at  
 5 diagnosis of breast cancer or it would be  
 6 placed in the oncologists' offices so that  
 7 they could give it to their patients as they  
 8 discuss pathology with them.  
 9 COFFEY, Q.C.:  
 10 Q. So Joy McCarthy, of course, is an oncologist,  
 11 a medical oncologist; Sharon Smith worked with  
 12 the Cancer -  
 13 DR. CARTER:  
 14 A. She would be a manager with the Cancer  
 15 Program.  
 16 COFFEY, Q.C.:  
 17 Q. Dr. Jonathan Greenland is a radiation  
 18 oncologist.  
 19 DR. CARTER:  
 20 A. And Brent Tompkins is a radiation oncologist.  
 21 COFFEY, Q.C.:  
 22 Q. So this group, did they comprise any  
 23 particular group or body?  
 24 DR. CARTER:  
 25 A. No, probably picked them, well Ms. Smith

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1 because she would be the one who would have  
 2 the resources and money, if available.  
 3 Probably just thought that those three would  
 4 be the most interested.  
 5 COFFEY, Q.C.:  
 6 Q. Now, Doctor, I have to ask "if I can get some  
 7 clerical/graphic support, this is almost ready  
 8 to go".  
 9 DR. CARTER:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. I don't want to put too fine of a point on it,  
 13 but that is almost, strikes me as almost  
 14 begging for--you're asking, but I take it you  
 15 had no resources available to you to perform  
 16 such clerical/graphical work?  
 17 DR. CARTER:  
 18 A. No, because this would have fallen outside of  
 19 my job as a pathologist and into your, you  
 20 know, your other job as a community caregiver  
 21 or, you know, contributor to education, so it  
 22 would be difficult to get secretarial or, you  
 23 know, graphic support if you wanted to make  
 24 this up into a pamphlet in our department, so  
 25 I would have to ask for their department's

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1 help.  
 2 COFFEY, Q.C.:  
 3 Q. What became of your request?  
 4 DR. CARTER:  
 5 A. We brought it to the Breast Disease Site  
 6 Group, you'd have to do the timelines for me,  
 7 but we did work on it. People read it and  
 8 commented on the language that was used in it  
 9 and we brought it to the Breast Disease Site  
 10 Group and did get the clerical support and now  
 11 I think it's being included in all the purple  
 12 lupin kits.  
 13 COFFEY, Q.C.:  
 14 Q. So that was through the Breast Site Group body  
 15 that you got the clerical -  
 16 DR. CARTER:  
 17 A. Yes, which essentially be the Cancer Program.  
 18 COFFEY, Q.C.:  
 19 Q. The Cancer Program. But as of--and the reason  
 20 I raise it is as of the beginning of February,  
 21 2006, there was no--that wasn't readily  
 22 available, you had to go outside your own--you  
 23 had to go looking -  
 24 DR. CARTER:  
 25 A. For the support?

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1 COFFEY, Q.C.:  
 2 Q. Yes.  
 3 DR. CARTER:  
 4 A. Yes, it wasn't readily available, I would have  
 5 to go outside.  
 6 COFFEY, Q.C.:  
 7 Q. Exhibit P-1748? Doctor, these are handwritten  
 8 notes I believe of Dr. Cook, February 8th,  
 9 2006. It's a meeting regarding update on  
 10 implementation of ER/PR. Present are a number  
 11 of individuals, including Drs. Cook, Ejeckam  
 12 and yourself and Fontaine, and Mr. Gulliver,  
 13 Mr. Dyer, Mr. Simms, Mr. Green and Ms. Butler,  
 14 so I take it really that's the three  
 15 technologists involved, the two technologist  
 16 managers. Dr. Ejeckam was the point person  
 17 for IHC. Dr. Cook, clinical chief; Dr.  
 18 Fontaine the General Hospital site chief, I  
 19 believe or if he hadn't already resigned, but  
 20 he was somehow involved or just been involved;  
 21 and yourself. There's some comments here  
 22 attributed to yourself and Dr. Ejeckam. It  
 23 says "Drs. Carter and Ejeckam commented on the  
 24 stain for ERS and PRS seems to be good  
 25 correlation and reproducibility with ER

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1 results and comparison with Mount Sinai, less  
 2 so for PR. All agreed that implementation  
 3 date of March 31, 2006 seems feasible." And  
 4 then they go on to talk about the potential  
 5 for digital, using a digital image analyzer.  
 6 Doctor, I have two questions in this regard,  
 7 at the time what was the nature then of your  
 8 involvement in the effort to restart ER/PR?  
 9 DR. CARTER:  
 10 A. I think we had optimized the protocols at that  
 11 time. Ken and I had picked two that we  
 12 thought were suitable and we were beginning  
 13 some on-site testing, we were using those to  
 14 assess the staining with known values that we  
 15 knew from Mount Sinai.  
 16 COFFEY, Q.C.:  
 17 Q. And you describe here the correlation, I take  
 18 it the ER was pretty good, the PR perhaps at  
 19 that point, less so.  
 20 DR. CARTER:  
 21 A. Yeah, but I think we had shown some great  
 22 improvement. I would have been involved too  
 23 as a breast person, I think I would have been  
 24 invited there as the person who was going to  
 25 be reading a lot of these.

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1 COFFEY, Q.C.:  
 2 Q. Now the potential usage of this visual image  
 3 analyzer, at that time what was the situation  
 4 from your perspective?  
 5 DR. CARTER:  
 6 A. It was brought up at that meeting I think that  
 7 maybe all of the people there, I'm not sure,  
 8 but I certainly didn't think it was necessary  
 9 that we would have a visual analyzer.  
 10 COFFEY, Q.C.:  
 11 Q. Is there any downside to utilizing?  
 12 DR. CARTER:  
 13 A. Takes up a lot of my time and provides no  
 14 better results than if I had not used it.  
 15 COFFEY, Q.C.:  
 16 Q. And perhaps you can describe that to the  
 17 Commissioner, why is that?  
 18 DR. CARTER:  
 19 A. If you're looking at estrogen receptor  
 20 testing, you have most of your cases are going  
 21 to be clearly negative or clearly positive,  
 22 which takes just a few minutes, so that's 80  
 23 percent of your cases. So the 20 percent of  
 24 them that are left, a great proportion of  
 25 them, maybe 80 percent again are going to be

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1 somewhere between 40 and 75, so it takes you a  
 2 few, a little while longer to read, but it's  
 3 not a pivot point for treatment, so it's not  
 4 something that you would need to examine in  
 5 detail. So an image analyzer would be useful  
 6 for cases that are somewhere between, say 5  
 7 and 15, what we're calling low expressors,  
 8 where you really want to be sure of your cut-  
 9 off point, but with image analyzers, the way  
 10 that they are now, to read a whole slide, you  
 11 can't teach the computer how to do it, so you  
 12 actually have to look at a field, input that  
 13 into the computer, look at the next field, in  
 14 put that into the computer, look at the next  
 15 field, input that, so by the time I've looked  
 16 at the five fields, I've already made my  
 17 impression of how many percent it is, but I've  
 18 added on all this extra computer work and  
 19 there's no evidence really to show that the  
 20 image analyzer provides a more reliable result  
 21 than a human pathologist. And it was quite  
 22 expensive as well, it would have been  
 23 resources and teaching that I felt were best  
 24 put elsewhere.  
 25 COFFEY, Q.C.:

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1 Q. The sentence here, "All agreed to the  
 2 implementation date of March 31, 2006 seems  
 3 feasible." We understand it didn't actually  
 4 occur until February 1, 2007. What happened  
 5 between the beginning of February and or after  
 6 the beginning of February to make it less or  
 7 unfeasible at that point, because it didn't  
 8 happen?  
 9 DR. CARTER:  
 10 A. I think that there were other issues raised as  
 11 they were going through the items on the  
 12 spreadsheet.  
 13 COFFEY, Q.C.:  
 14 Q. Okay.  
 15 DR. CARTER:  
 16 A. And it was decided at that point that we  
 17 weren't going to do or they, Dr. Denic and Dr.  
 18 Cook, weren't going to go ahead and start any  
 19 sort of testing unless they had a reasonable  
 20 amount of those things firmly in place.  
 21 COFFEY, Q.C.:  
 22 Q. That's on the recommendation spreadsheet.  
 23 DR. CARTER:  
 24 A. Yes, the spreadsheet that was -  
 25 COFFEY, Q.C.:

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1 Q. And this would be the time going into March or  
 2 April that Dr. Cook left as clinical chief and  
 3 Dr. Denic took over?  
 4 DR. CARTER:  
 5 A. Yes.  
 6 COFFEY, Q.C.:  
 7 Q. Exhibit P-1400? This is a letter of February  
 8 8th, 2006, it's from yourself, Doctor, to Dr.  
 9 Cook and it reads, "Please accept this as  
 10 official notice of my resignation. As you  
 11 know over the past last eight months I have  
 12 had many differences of opinion with the team  
 13 regarding the processes, work assignments and  
 14 goals for the successful institution of an  
 15 ER/PR, HER2/neu immunohistochemical laboratory  
 16 at Eastern Health. It is clear to me that we  
 17 will not be able to resolve our differences.  
 18 I cannot, as a fellowship trained breast  
 19 pathologist, agree with the direction in which  
 20 this process is proceeding; therefore I feel  
 21 that resigning is the best option for me and  
 22 for the team. My last day at Eastern Health  
 23 will be Wednesday, February 23rd, 2006.  
 24 Please remove my name from the call schedule,  
 25 so that I may complete already assigned work.

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1 I would be happy to meet with you at your  
 2 convenience to discuss the transition of my  
 3 duties to my successor. Signed Beverley  
 4 Carter." And you've written on this, "Please  
 5 note I have been informed that I have to give  
 6 three months' notice; therefore, the leaving  
 7 date is May 3rd, '06. Signed Bev Carter."  
 8 Doctor, what was going on here at this point  
 9 in time?  
 10 DR. CARTER:  
 11 A. This, I think, was a day or two after the  
 12 meeting that we just described when we talked  
 13 about the image analyzer. It was a reflection  
 14 really of my relationship with Mr. Gulliver  
 15 and Mr. Dyer over the eight months, I guess  
 16 I've said here, from when the estrogen  
 17 receptor issue had come out. I felt it was  
 18 not a very good working relationship. I felt  
 19 that their in-depth knowledge of processes  
 20 that they were making definitive decisions  
 21 about was not great. We still had difficulty  
 22 with the work assignments, the technologists  
 23 were still being kept in other duties, as  
 24 opposed to being in immunohistochemistry at  
 25 all the time and we had had the meeting, we

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1 had discussed consensus guidelines for HER2  
 2 testing as well, where it was decided that we  
 3 wouldn't use the antibody for HER2 testing or  
 4 we would begin to explore the possibility that  
 5 we wouldn't--that had been recommended at the  
 6 Canadian Consensus, and the idea that we would  
 7 spend a lot of money and time getting this  
 8 image analyzer, I just felt that it was an  
 9 unworkable relationship.  
 10 COFFEY, Q.C.:  
 11 Q. And that is what led to this letter?  
 12 DR. CARTER:  
 13 A. Yes.  
 14 COFFEY, Q.C.:  
 15 Q. Did you, in fact then leave in May? What  
 16 actually happened?  
 17 DR. CARTER:  
 18 A. No.  
 19 COFFEY, Q.C.:  
 20 Q. Because I mean, leaving in different senses,  
 21 leaving different positions but still  
 22 remaining geographically in the same location,  
 23 that's what I'm -  
 24 DR. CARTER:  
 25 A. No, when I wrote the letter, there was a lot

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1 of discussion with Dr. Cook and then Dr. Denic  
 2 when the transition of the clinical chiefs  
 3 happened. Some discussions with Dr. Williams  
 4 where they expressed interest in my staying on  
 5 site and after many discussions an idea to  
 6 revamp and revitalize the Quality Management  
 7 Program where it wouldn't be a committee, as  
 8 previously described in the memo that we  
 9 looked at yesterday, but now would become a  
 10 division of the department with staffing and  
 11 resources. I decided that I would stay.  
 12 COFFEY, Q.C.:  
 13 Q. Exhibit P-2461? Now, Doctor, yesterday you  
 14 had indicated that there had been at least one  
 15 instance in which you had acted as chair of  
 16 the Physician Review Panel?  
 17 DR. CARTER:  
 18 A. Yes, February 10th.  
 19 COFFEY, Q.C.:  
 20 Q. And these are these February 10th, 2001 (sic.)  
 21 panelling letters, I'll call them.  
 22 DR. CARTER:  
 23 A. 2006.  
 24 COFFEY, Q.C.:  
 25 Q. 2006, I apologize. So there are a number of

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1       them here. The format that these letters  
 2       took, they all generally follow the same  
 3       similar format.  
 4 DR. CARTER:  
 5     A. Yes.  
 6 COFFEY, Q.C.:  
 7     Q. Had that been decided upon well before  
 8       February 10th?  
 9 DR. CARTER:  
 10    A. The format of the letters?  
 11 COFFEY, Q.C.:  
 12    Q. Yes, the format.  
 13 DR. CARTER:  
 14    A. I think we decided that we would put a  
 15       preamble, you know, about when the patient had  
 16       been diagnosed and then what their original  
 17       reports were and then what their treatment  
 18       decisions would be.  
 19 COFFEY, Q.C.:  
 20    Q. Then these were, in the second paragraph of  
 21       all these refers to the patient was discussed  
 22       at a panel review on February 9th, so what I  
 23       wanted to ask you about really was this, in  
 24       terms of at that point in time, I take it you  
 25       were acting chair because other people were

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1       just absent, certain other people.  
 2 DR. CARTER:  
 3     A. Dr. Laing would be chair of the meetings at  
 4       most times, I think Dr. McCarthy attended  
 5       occasionally, but that night the two medical  
 6       oncologists who were present didn't want to  
 7       chair for whatever reason. I didn't ask, I  
 8       just volunteered that I would chair.  
 9 COFFEY, Q.C.:  
 10    Q. Exhibit P-1102? Doctor, this is some e-mail  
 11       exchanges of February 13th, 2006. The first  
 12       of them is from Debbie Parsons to a number of  
 13       individuals, including yourself, deals with  
 14       future ER/PR meetings and that same day you  
 15       responded to Debbie Parsons, but addressed  
 16       your comment to Heather Predham. "As I have  
 17       recently resigned from my position with  
 18       Eastern Health, I am quite busy covering call  
 19       and attempting to clue things up at my desk, I  
 20       will not be taking part in further ER/PR panel  
 21       meetings." And you wish her well in the  
 22       endeavour. And you offer to act in the short  
 23       term in a consultative manner for any specific  
 24       issue that might arise at the meetings and  
 25       then that is forwarded on, that same day by

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1       Debbie Parsons to Denise Dunn to pass on to  
 2       Dr. Williams. Did you continue to participate  
 3       in the ER/PR panelling, do you recall?  
 4 DR. CARTER:  
 5     A. I don't recall specifically, I may have.  
 6 COFFEY, Q.C.:  
 7     Q. Exhibit P-2064? Now, Doctor, these are  
 8       Laboratory Medicine Program minutes of March  
 9       10th, 2006. Drs. Williams, Denic and Cook are  
 10      present, this is Mr. Gulliver. On the second  
 11      page, paragraph one under "New Business" says  
 12      "Dr. Carter, Dr. Denic presented a proposal  
 13      which will see Dr. Carter being appointed as a  
 14      quality control co-ordinator for the pathology  
 15      service. There was general agreement to move  
 16      forward and arrange a meeting with Dr. Carter  
 17      to discuss." So I take it that that's the  
 18      subject matter you referred to several minutes  
 19      ago.  
 20 DR. CARTER:  
 21    A. Yes.  
 22 COFFEY, Q.C.:  
 23    Q. Exhibit P-2068 please? And this is minutes of  
 24       a meeting of March 28th, 2006, Discipline of  
 25       Laboratory Medicine. The call to order was by

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1       Dr. Denic and a number of individuals present,  
 2       including yourself and a number of other  
 3       pathologists. Under "New Business: quality  
 4       assurance, Dr. Denic thanked Dr. Cook for his  
 5       work and then implementation of the new  
 6       Quality Assurance Program was discussed at  
 7       length. Dr. Beverley Carter will act as the  
 8       manager of the new Quality Management Program  
 9       for the Pathology Department. There will be a  
 10      technical member and a clerical member of the  
 11      team. Dr. Carter will act independently and  
 12      answer to quality management team. This is  
 13      supported by Dr. Williams, the VP." So there  
 14      was a statement, apparently, I gather by Dr.  
 15      Denic to this effect, advised in the meeting.  
 16 DR. CARTER:  
 17    A. Yes.  
 18 COFFEY, Q.C.:  
 19    Q. And then it's noted "Dr. Morris-Larkin  
 20       expressed concern about being audited." Now,  
 21       and then there's a note "Dr. Denic stated that  
 22       random slides would be audited. Dr. Carter  
 23       says that the random cases will be picked by  
 24       the technologist who is working with the  
 25       Quality Management Program. Dr. Morris-Larkin

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1 expressed the feeling that one pathologist  
 2 should not do all of the auditing. Dr. Denic  
 3 also stated that there will be policies put in  
 4 place regarding the auditing. Dr. Cook stated  
 5 there was no QA committee before November,  
 6 2004." And we saw yesterday that you had been  
 7 involved in that, back in 2004. What was this  
 8 concern then, your feeling about the concern  
 9 here, voiced by Dr. Larkin.  
 10 DR. CARTER:  
 11 A. That they would be audited? I think again it  
 12 reflects that they weren't used to random  
 13 review and quality management programs at that  
 14 time. I had come from McMaster where we had  
 15 it. I was quite comfortable with someone else  
 16 looking at my work.  
 17 COFFEY, Q.C.:  
 18 Q. And toward the middle of the page, there's a  
 19 note, "Dr. Morris-Larkin offered to help with  
 20 the QA".  
 21 DR. CARTER:  
 22 A. Yes.  
 23 COFFEY, Q.C.:  
 24 Q. So I take it, after it was -- as it was  
 25 explained.

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1 DR. CARTER:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. They became more accepting of the idea.  
 5 DR. CARTER:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. And it ends with, "Dr. Denic thinks it is very  
 9 important that the QA Committee meets to be  
 10 put in place as soon as possible. By then sub-  
 11 specialization, Dr. Denic encouraged the idea  
 12 of pathologists sub-specializing". I take it,  
 13 by this point in time, the beginning of '06,  
 14 March, sub-specialization or the idea of it  
 15 was more accepted locally?  
 16 DR. CARTER:  
 17 A. Yes. I think in November of 2005, we had the  
 18 first meeting of the breast sub-specialty  
 19 group, but I think --  
 20 COFFEY, Q.C.:  
 21 Q. November, 2005?  
 22 DR. CARTER:  
 23 A. This is March of 2006?  
 24 COFFEY, Q.C.:  
 25 Q. This is '06, yes.

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1 DR. CARTER:  
 2 A. Yes, so I think we were on board for about  
 3 three or four months before this.  
 4 COFFEY, Q.C.:  
 5 Q. Before this.  
 6 DR. CARTER:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. By that point in time it was generally  
 10 accepted?  
 11 DR. CARTER:  
 12 A. I would say, yes.  
 13 COFFEY, Q.C.:  
 14 Q. As an idea.  
 15 DR. CARTER:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Exhibit P-2462. Here, Doctor, are minutes of  
 19 a laboratory managers meeting of April 12th,  
 20 2006. Under paragraph "C", second paragraph,  
 21 it's noted, "The senior technologist in  
 22 pathology is being reassigned to work with Dr.  
 23 Carter, who is now in charge of a pathology QA  
 24 program. She will work to put protocols and  
 25 procedures in place, as well as review slides

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1 each day". Who was that?  
 2 DR. CARTER:  
 3 A. Catherine Parnell is the technologist that  
 4 she's referring to. The second sentence in  
 5 that is incorrect, that was not the job  
 6 description that she had, but it was another  
 7 point of disagreement with the lab management.  
 8 COFFEY, Q.C.:  
 9 Q. Could you tell us then what that was about?  
 10 DR. CARTER:  
 11 A. I had written a document to outline a quality  
 12 management program, so it was very similar to  
 13 the document from October, 2004, but it was  
 14 much broader-based. It included a preamble  
 15 about the theory of quality management, why it  
 16 was necessary, talking about the errors in  
 17 medicine report from 1999 that sort of acted  
 18 as the impetus for all this sort of work, and  
 19 went through what we would be doing in the  
 20 quality management department, which was  
 21 monitoring things from the pre-analytic, the  
 22 analytic, and post-analytic period. We would  
 23 also be monitoring things such as turnaround  
 24 time for biopsies, emergency cases, that sort  
 25 of thing, and also be doing customer

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1 satisfaction; in our case, physician  
 2 satisfaction, surveys, and within that, I had  
 3 written that there will be a very minor role  
 4 played to writing policies and procedures and  
 5 this would be a supervisory or a consultative  
 6 sort of opinion or position, and reviewing  
 7 slides each day, that would be quality control  
 8 in the lab, it wouldn't be under the auspices  
 9 of a quality management program. That would  
 10 be actual lab work. We would be monitoring  
 11 what was going on in the lab. That continued  
 12 to be a point of disagreement, what Dr.  
 13 Williams had accepted as my proposal of  
 14 quality management, and what management in the  
 15 laboratory thought a quality management  
 16 program should be doing.

17 COFFEY, Q.C.:  
 18 Q. So they thought it should involve what,  
 19 actually writing --

20 DR. CARTER:  
 21 A. Writing policies and procedures, which I think  
 22 are basic lab tenets. I mean, those are  
 23 things that would be done by everybody in the  
 24 lab and under the auspices of management of  
 25 the laboratory. It wouldn't be a quality

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1 management issue.

2 COFFEY, Q.C.:  
 3 Q. And this was a point of contention, I take it,  
 4 that continued for some time?

5 DR. CARTER:  
 6 A. Well, Catherine Parnell came on board with the  
 7 QMP Program, and we did design, I think, a  
 8 fairly nice and I think it would stand up well  
 9 across Canada, program for looking at pre-  
 10 analytic, post-analytic, and the analytic  
 11 aspects of the test cycle. We do have in place  
 12 monitoring programs for things that are  
 13 important for semi-objective measurements of  
 14 pathology. So that would be turnaround times,  
 15 how fast you get out your biopsy, how fast you  
 16 get out your cancer specimen. She also sends  
 17 out -- well, actually, it's switched now,  
 18 Catherine has since retired, so there's a new  
 19 technologist there, who will send out a  
 20 customer satisfaction, and then you compare  
 21 them year to year and see if there's areas in  
 22 your program that have been identified by your  
 23 clients as needing improvement. So I think  
 24 that aspect of it is actually running really  
 25 quite well, and almost, you know, run smoothly

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1 on its own, doesn't really require anyone.  
 2 The policy and procedures, I think greater  
 3 emphasis is being placed on that now, and a  
 4 lot of policies and procedures are coming out  
 5 of there.

6 COFFEY, Q.C.:  
 7 Q. And, Doctor -- registrar, please, Exhibit P-  
 8 1365. This is Dr. Williams letter of April  
 9 20th, 2006, to Dr. Denic, as clinical chief.  
 10 He's writing regarding the quality assurance  
 11 program for pathology services within the St.  
 12 John's component of Eastern Health. This  
 13 proposal has been approved, he notes, and is  
 14 now being resourced. A Tech III has been  
 15 assigned to the program on a full time basis.  
 16 In addition, full time secretarial support  
 17 will be provided to the program for a six  
 18 month period initially. Did both of those  
 19 things happen? Was a Tech III actually  
 20 assigned to that program on a full time basis?

21 DR. CARTER:  
 22 A. She did, but I don't think that she came at  
 23 that time. Again I -- what's the date on  
 24 this?

25 COFFEY, Q.C.:

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1 Q. This is April 20th.

2 DR. CARTER:  
 3 A. I think that Catherine probably was freed up  
 4 in September to begin, and --

5 COFFEY, Q.C.:  
 6 Q. Full time secretarial support for the first  
 7 six months.

8 DR. CARTER:  
 9 A. I think we chose to have half time secretarial  
 10 support for a year. I think that's what we  
 11 chose to do, but, yes, we did get those  
 12 things.

13 COFFEY, Q.C.:  
 14 Q. And he writes, "I understand that now you and  
 15 Bev Carter will be the -- who will be the  
 16 quality control leader for this initiative,  
 17 will now follow up on this matter with a view  
 18 to implementing this quality control  
 19 initiative effective May 1, 2006". Now,  
 20 Doctor, how was this going to sit then with  
 21 your regular clinical duties?

22 DR. CARTER:  
 23 A. Theoretically, I would be cut 20 percent on my  
 24 clinical duties.

25 COFFEY, Q.C.:

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1 Q. Cut --  
 2 DR. CARTER:  
 3 A. So if I was to be in the operating room, and  
 4 the average pathologist takes 50 cases, I  
 5 would take 20 percent less.  
 6 COFFEY, Q.C.:  
 7 Q. Oh, 20 percent -- not cut to 20, cut by --  
 8 DR. CARTER:  
 9 A. No, cut by.  
 10 COFFEY, Q.C.:  
 11 Q. And you're assured then -- Dr. Denic is  
 12 assured, or Dr. Williams assures Dr. Denic and  
 13 yourself of his full support. Exhibit P-2469.  
 14 This is minutes of a pathology quality  
 15 management committee, May 2nd. This would be  
 16 2006, I gather. You're present, and it notes,  
 17 "Discussion began regarding low attendance at  
 18 meetings. Bev Carter and Nash Denic agreed to  
 19 send a formal request/reminder to members  
 20 illustrating the importance of attending these  
 21 meetings", and then Dr. Cook, "Terms of  
 22 reference were discussed, and Nash discussed  
 23 organization within the QMP Department". Now,  
 24 Doctor, your involvement then in this  
 25 continued for how long or up until when?

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1 DR. CARTER:  
 2 A. Sometime in the summer of 2007.  
 3 COFFEY, Q.C.:  
 4 Q. And why did you leave? You did leave it, I  
 5 take it?  
 6 DR. CARTER:  
 7 A. Yes, we had the pathologist's portion, I will  
 8 call it, as I talked about earlier, the  
 9 monitoring of things such as turnaround times,  
 10 the correlation between frozen sections, final  
 11 diagnosis, all those things that are in the  
 12 document, we had that up and running  
 13 relatively smoothly and repeated meetings had  
 14 shown that the definite thrust of the  
 15 committee would be towards policy and  
 16 procedure, which I think are very important  
 17 for a lab, but not something that I'm really  
 18 interested in writing, although I have written  
 19 quite a number of them for the lab, and I just  
 20 thought that I would do other things with my  
 21 time.  
 22 COFFEY, Q.C.:  
 23 Q. Exhibit P-1754. Doctor, these are notes of a  
 24 meeting of June 30th, 2006. Present are a  
 25 number of individuals, including yourself.

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1 It's regarding the re-implementation of ER/PR  
 2 testing, and toward the bottom of the page is  
 3 a note, "Bev has written a fixation protocol  
 4 to be sent out to other centres". Nash is  
 5 attributed with the remark, "Issue of fixation  
 6 over weekend. Clinical practice has to be  
 7 adjusted. pre-analytic issues still, may have  
 8 to put in waiver". Do you recall how was it  
 9 you came to write this fixation protocol, when  
 10 did you do it, and to whom was it distributed?  
 11 DR. CARTER:  
 12 A. It would be as a part of the quality  
 13 management program that I wrote it. I'm not  
 14 sure when I wrote it, some time before June of  
 15 2007, and who is it sent to, you said?  
 16 COFFEY, Q.C.:  
 17 Q. Yes, I'm asking --  
 18 DR. CARTER:  
 19 A. I'm not sure if it's been sent at all. I'm  
 20 not sure if it's been approved yet. Like,  
 21 somebody who's continuing with the committee  
 22 would be able to tell you that a bit more.  
 23 COFFEY, Q.C.:  
 24 Q. Okay. Exhibit P-2441. Doctor, you made  
 25 reference to the breast disease site group for

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1 Eastern Health. This is a document that says  
 2 the development of a breast disease site group  
 3 for Eastern Health, the first meeting of the  
 4 breast disease site group of St. John's  
 5 hospitals of Eastern Health took place in June  
 6 of 2006.  
 7 DR. CARTER:  
 8 A. Uh-hm.  
 9 COFFEY, Q.C.:  
 10 Q. Would that be about -- the breast disease site  
 11 group.  
 12 DR. CARTER:  
 13 A. That would be the multidisciplinary team, yes.  
 14 COFFEY, Q.C.:  
 15 Q. Okay. Now you did refer just a moment ago to  
 16 November, 2005.  
 17 DR. CARTER:  
 18 A. That would be the breast pathology sub-  
 19 speciality team. Sorry, there's a lot of  
 20 repetition.  
 21 COFFEY, Q.C.:  
 22 Q. Oh, no, I appreciate that. So who did that  
 23 involve?  
 24 DR. CARTER:  
 25 A. That would have been myself, Dr. Don Cook, Dr.

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1 Bibi Naghibi.  
 2 COFFEY, Q.C.:  
 3 Q. Okay, and you referred to that yesterday.  
 4 DR. CARTER:  
 5 A. Part of that -- Marjan Afrouzian was also on  
 6 it for a short period.  
 7 COFFEY, Q.C.:  
 8 Q. Exhibit -- so I take it then by November of  
 9 '05, locally it was acknowledged that there  
 10 should be only certain or a limited number of  
 11 pathologists involved, if possible, in breast  
 12 pathology?  
 13 DR. CARTER:  
 14 A. In certain aspects of breast pathology, yes.  
 15 COFFEY, Q.C.:  
 16 Q. Certain aspects of it. Exhibit P-1739.  
 17 Doctor, this is a letter of July 14th, 2006,  
 18 at least is a draft of one, to yourself and  
 19 Dr. Cook. It's from Dr. Williams, "As a  
 20 result of ongoing quality review process,  
 21 could you please review the following cases",  
 22 and there are actually eight of them listed.  
 23 They're redacted, the names and so on here,  
 24 but -- also bring up then Exhibit P-1150,  
 25 please, registrar. This is a letter of July

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1 28th, 2006, from Dr. Williams, again to  
 2 yourself and Dr. Cook, and he writes, "As a  
 3 result of the ongoing quality review of the  
 4 immunohistochemistry service, several cases  
 5 were identified as having results that  
 6 conflicted with those previously reported.  
 7 Would you please review those cases and update  
 8 their clinical file as necessary. You should  
 9 retain a list of these cases in your files for  
 10 future reference, if necessary". Now, Doctor,  
 11 which -- what was being reviewed here? Is  
 12 this the DCIS issue?  
 13 DR. CARTER:  
 14 A. I think that's what it refers to. So cases  
 15 that have been sent to Mount Sinai as part of  
 16 the large retrospective review, a certain  
 17 number of them came back as having no  
 18 infiltrating carcinoma, so Dr. Cook and I  
 19 would go back and look at the case and  
 20 sometimes it would be just a matter that the  
 21 wrong block from the case was sent up, and  
 22 then other ones we would look and have a  
 23 diagnostic discrepancy with the original  
 24 pathologist. I'm not sure if those redacted  
 25 cases are that, but I think that that's what

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1 they are.  
 2 COFFEY, Q.C.:  
 3 Q. And so your involvement in that review then  
 4 was what, the nature of your involvement in  
 5 the DCIS review?  
 6 DR. CARTER:  
 7 A. On a consultative basis, they would ask me to  
 8 look at slides and then I would review them  
 9 with Dr. Cook and, when Dr. Cook was  
 10 unavailable, Dr. Denic, if there was any  
 11 discrepancy. If I agreed with the original  
 12 pathologist, I would just sign off on it.  
 13 COFFEY, Q.C.:  
 14 Q. And I take it, if you didn't, you would inform  
 15 them of that too.  
 16 DR. CARTER:  
 17 A. Pardon me?  
 18 COFFEY, Q.C.:  
 19 Q. If you differed with the original pathologist  
 20 in that regard, you would make your views  
 21 known as well.  
 22 DR. CARTER:  
 23 A. Yes, and then I would bring it to Dr. Cook or  
 24 Dr. Denic. Sometimes we would sign it out.  
 25 Sometimes we would send it out for a third

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1 consultative opinion.  
 2 COFFEY, Q.C.:  
 3 Q. Exhibit P-1170. Doctor, this is a letter of  
 4 August 10, 2006, from yourself.  
 5 DR. CARTER:  
 6 A. Uh-hm.  
 7 COFFEY, Q.C.:  
 8 Q. And it's the Quality Management Program and  
 9 your capacity in that regard, to Dr. Denic.  
 10 You write, "In order to implement the fixation  
 11 policy enclosed, the following actions will  
 12 have to be considered," and you have a list of  
 13 things that would have to be considered, and  
 14 then if we look at Page 2 of this exhibit,  
 15 "St. John's hospitals of Eastern Health,  
 16 Policy for Fixation of human tissues," and you  
 17 have a policy there with six numbered  
 18 paragraphs. Would this be your fixation  
 19 policy that you were asked to draft?  
 20 DR. CARTER:  
 21 A. One of the--  
 22 COFFEY, Q.C.:  
 23 Q. At least one of the (unintelligible).  
 24 DR. CARTER:  
 25 A. Yes.



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1 COFFEY, Q.C.:

2 Q. Doctor--because this is August '06, why had it

3 taken that long, from your perspective, for

4 someone to draft a fixation policy?

5 DR. CARTER:

6 A. I don't know if anyone had been asked to draft

7 one.

8 COFFEY, Q.C.:

9 Q. I appreciate when you were asked because

10 there's a reference in late June and here you

11 are in early August and you've got one.

12 Certainly there is the draft of it but before

13 that, I take it, everyone would have realized

14 that fixation was an issue--

15 DR. CARTER:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. --back in the middle of '05 potentially here,

19 and yet there was no fixation policy so -

20 DR. CARTER:

21 A. I mean, it would be, I guess, the classic case

22 of everyone assuming that the next person was

23 the person who is responsible for doing that.

24 COFFEY, Q.C.:

25 Q. Exhibit P-2328, now these are Pathology

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1 Quality Management Committee minutes of

2 October--I apologize, 2328 - October 3, 2006,

3 Doctor. You're present and under

4 Implementation of Policies, Fixation, it's

5 noted "it has been written and submitted by

6 Nash Denic and Barry Dyer with no response to

7 date. Right now, there's a 24- to 36-hour

8 turnaround time. Eventually, shiftwork will

9 help resolve this problem. B. Carter to add a

10 rider to policy." Do you recall what this was

11 about, Doctor?

12 DR. CARTER:

13 A. The policy, when it was written when it was

14 thought to be in its final form, then it would

15 have to be signed off. Administrative people

16 would probably be able to give you a more

17 intelligent answer, but in order for it to be

18 accepted, you know, as a policy of Eastern

19 Health, it would have to be signed off by the

20 appropriate authorities, and I guess we were

21 sending it to Nash Denic and - sorry, Dr.

22 Denic - and Mr. Dyer for that purpose. Right

23 now there is a 24- to 36-hour turnaround time,

24 I'm not sure what that means, and "eventually,

25 shiftwork will help resolve this problem," I'm

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1 not sure what that means. It doesn't really

2 make that much sense. That's the first time

3 I've seen this in awhile.

4 COFFEY, Q.C.:

5 Q. Exhibit P-2466, Doctor, this is a letter of

6 November 2, 2006. Well, it's a form letter, I

7 take it because it's from yourself and Ms.

8 Parnell.

9 DR. CARTER:

10 A. Yes.

11 COFFEY, Q.C.:

12 Q. "Dear Doctor, a Pathology Quality Management

13 Program for the St. John's hospitals of

14 Eastern Health has been newly formed. As part

15 of this initiative, we would like to find out

16 how our preferred clientele talk to physicians

17 about our service. Please take the time to

18 file the enclosed survey, and return it in a

19 self-addressed envelope." I take it, this is

20 the survey you referred to earlier?

21 DR. CARTER:

22 A. Yes, it is.

23 COFFEY, Q.C.:

24 Q. A customer satisfaction survey. Was this sent

25 out?

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1 DR. CARTER:

2 A. Yes, it was sent out in November, I believe,

3 of 2006 and hopefully in November of 2007.

4 COFFEY, Q.C.:

5 Q. And what was the response?

6 DR. CARTER:

7 A. I wouldn't be able to give you the numbers.

8 COFFEY, Q.C.:

9 Q. Yes.

10 DR. CARTER:

11 A. But we sent out, I think, a hundred, somewhat

12 random but somewhat directed to all types of

13 physicians who would use our service. I think

14 we got back maybe somewhere around 40.

15 COFFEY, Q.C.:

16 Q. Uh-hm.

17 DR. CARTER:

18 A. And there was a wide variety of information

19 that you could glean from it. I don't think I

20 can summarize it in a couple of sentences.

21 COFFEY, Q.C.:

22 Q. Here, Doctor, just looking at the form

23 unfilled out, there's a listing of possible

24 topics - "Overall Satisfaction Rating,"

25 "Quality of Professional Interactions" and so

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1 on, "Diagnostic Accuracy" - and there are  
 2 various numbers for rating between one being  
 3 poor to five excellent, and then the next page  
 4 here it's three. Are numbers for each of  
 5 these, I take it, filled in the category,  
 6 "Overall Satisfaction Rating," under 143,  
 7 below average 9, average 10, good 13, and  
 8 excellent 2?  
 9 DR. CARTER:  
 10 A. So that would be the number of respondents  
 11 that had ticked off in each one of those  
 12 categories.  
 13 COFFEY, Q.C.:  
 14 Q. In those particular categories, and we're only  
 15 going to look through the page here on that  
 16 and under the next page, Page 4, under  
 17 Comments, I take it -  
 18 DR. CARTER:  
 19 A. So the text is what the comment was, and then  
 20 the number after it is what number that  
 21 physician had given for their overall rating  
 22 for the service. So this physician for the  
 23 first one takes two weeks approximately. That  
 24 physician gave it a four.  
 25 COFFEY, Q.C.:

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1 Q. In terms of the overall -  
 2 DR. CARTER:  
 3 A. You know, they were overall satisfied, so it  
 4 gives you some indication of, you know, how  
 5 the physician has felt about the service in  
 6 general, so if somebody gives you ones on  
 7 everything, then, you know, you would take  
 8 that comment in a different way than somebody  
 9 who gives you a variety of ratings on each  
 10 one.  
 11 COFFEY, Q.C.:  
 12 Q. And what was done with this, Doctor, these  
 13 results?  
 14 DR. CARTER:  
 15 A. They would form part of the report from the  
 16 Quality Management Program, so these would  
 17 have been given to Dr. Denic. The survey had  
 18 the option, I think, if you could sign the  
 19 report or not.  
 20 COFFEY, Q.C.:  
 21 Q. Uh-hm.  
 22 DR. CARTER:  
 23 A. Many of the physicians signed it. It's a very  
 24 open sort of community, so for the comments  
 25 that were less than favourable I think he

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1 would, if possible, speak to the physician who  
 2 had filled out the survey, and also address it  
 3 and see if it was something that should be  
 4 addressed. There's one that begins, "I am a  
 5 surgeon," that says to "not include," for  
 6 example, "microscopic details in a pathology  
 7 report. Seems well below standard of care."  
 8 In fact, standard of care now is to move away  
 9 from using microscopic details. They're  
 10 proven over examination not to be that much  
 11 help to the clinician and often sometimes  
 12 confusing, so just because they said it  
 13 doesn't, you know, mean that it's true, so Dr.  
 14 Denic would take that comment and would maybe  
 15 not act on that as quickly as somebody that  
 16 says, "You know, I think that the lab is doing  
 17 a pretty good job but, listen, I have this  
 18 case and I want something done about it."  
 19 COFFEY, Q.C.:  
 20 Q. Okay. And if we could please, Exhibit P-2467.  
 21 THE COMMISSIONER:  
 22 Q. Mr. Coffey, when you (unintelligible).  
 23 COFFEY, Q.C.:  
 24 Q. Yes, I appreciate that. This is an e-mail of  
 25 November 19, 2006, from Ms. Predham to Ms.

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1 Elliott and Pat Pilgrim. She writes, "I met  
 2 with Bev Carter, Ford Elms, Don Cook, Nash  
 3 Denic and Susan Bonnell on Friday afternoon.  
 4 We reviewed the presentation for Monday and  
 5 it's very good and comprehensive. As always,  
 6 Bev's comments in the meeting were a little  
 7 bit alarmist in nature, but she is only  
 8 speaking about ER/PR testing at the  
 9 presentation, and then Dr. Howell called me on  
 10 Friday afternoon and told me that he would  
 11 anticipate that I would be asking," and she  
 12 goes on from there about something else  
 13 dealing with an executive meeting. Doctor,  
 14 the comment attributing to you being a "little  
 15 bit alarmist in nature," had anyone at that  
 16 time in relation to this teleconference, video  
 17 conference - I think video conference, in  
 18 fact, that occurred in November - did anybody  
 19 say to you that perhaps you were "a bit  
 20 alarmist?" Anybody brought that to your  
 21 attention?  
 22 DR. CARTER:  
 23 A. No, and I think what Heather is referring to  
 24 there goes to the third paragraph. I think,  
 25 during the course of that discussion, I was

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1 expressing concern. I wouldn't view it as  
 2 alarmist but, anyway, I was expressing concern  
 3 that maybe a lot of the recommendations and  
 4 changes that had been recommended weren't  
 5 happening as quickly as I would have liked  
 6 them, and they decided to do a College of  
 7 American Pathologists audit on the lab to see  
 8 how they do.  
 9 COFFEY, Q.C.:  
 10 Q. To see how they do.  
 11 DR. CARTER:  
 12 A. And then they decided to have Ms. Wegrynowski  
 13 come back and do a formal audit. I don't  
 14 think she was speaking about what I was  
 15 talking about at the presentation.  
 16 COFFEY, Q.C.:  
 17 Q. No. So you say that you felt that they  
 18 intended to have Ms. Wegrynowski come back?  
 19 DR. CARTER:  
 20 A. No, no, eventually they asked her to come  
 21 back.  
 22 COFFEY, Q.C.:  
 23 Q. Did they?  
 24 DR. CARTER:  
 25 A. Yeah, I don't know if that was their intent

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1 all along.  
 2 COFFEY, Q.C.:  
 3 Q. No, this is November of '06 and Ms.  
 4 Wegrynowski had been here and gone twice.  
 5 DR. CARTER:  
 6 A. Oh, she had been here, okay.  
 7 COFFEY, Q.C.:  
 8 Q. So here there's certainly a CAP audit  
 9 anticipated, a CAP audit out of documentation  
 10 mostly. Did you ever hear about how that  
 11 went?  
 12 DR. CARTER:  
 13 A. Not officially. I think Dr. Elms and Dr.  
 14 Denic went with her and I thought that it had  
 15 gone well, but I'm not certain.  
 16 COFFEY, Q.C.:  
 17 Q. And, if you could, Commissioner, one last  
 18 exhibit, Exhibit P-1425, and, Doctor, this is  
 19 a slide show presentation which we understand  
 20 was given in this video conference. I ask,  
 21 please, if we could go to Page 29, please?  
 22 It's all pitfalls in ER testing by Dr. Bev  
 23 Carter. I take it then, this would be the  
 24 presentation that you gave at the time?  
 25 DR. CARTER:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. And the audience, target audience, was your  
 4 fellow pathologists, generally?  
 5 DR. CARTER:  
 6 A. Yes, and across-the-province technologists  
 7 from the lab, and I think from any lab, and I  
 8 think the invitation had extended to  
 9 clinicians involved in the issue.  
 10 COFFEY, Q.C.:  
 11 Q. Yes.  
 12 DR. CARTER:  
 13 A. Kind of.  
 14 COFFEY, Q.C.:  
 15 Q. If we go on then through - I'm just running  
 16 through them here up to Page 54 of the  
 17 exhibit, "How To Get a Perfect Result." I  
 18 take it, that was how you concluded it.  
 19 DR. CARTER:  
 20 A. Yes, I think so.  
 21 COFFEY, Q.C.:  
 22 Q. I guess we'll go to the next result, and we  
 23 end up at Page 59 with--by Dr. Cook, so the  
 24 level of detail here was intended, you know,  
 25 to be how detailed, how intensive, the

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1 presentation?  
 2 DR. CARTER:  
 3 A. I'm not sure I understand the question.  
 4 COFFEY, Q.C.:  
 5 Q. I take it, you were speaking to technologists  
 6 and pathologists who you would expect to know  
 7 something about this to start.  
 8 DR. CARTER:  
 9 A. Yes. Yeah.  
 10 COFFEY, Q.C.:  
 11 Q. And was this intended kind of as an overall  
 12 full-primer for them - full primer - full  
 13 lesson, as it were.  
 14 DR. CARTER:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. They wouldn't know as much as you did about  
 18 it. Apparently, that's a fact but -  
 19 DR. CARTER:  
 20 A. Yeah, I mean, this was a teaching--I regard  
 21 this as a teaching opportunity. I'm sure some  
 22 of the people there knew a lot about what I  
 23 was talking about, and some didn't.  
 24 COFFEY, Q.C.:  
 25 Q. Thank you, Commissioner.

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1 THE COMMISSIONER:

2 Q. We'll start in the morning at 9:30. Thank  
3 you.

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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 29th day of July, 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 29th day of July, A.D., 2008  
13 Judy Moss

Inquiry on Hormone Receptor Testing

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