COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 29, 2008

Appearances:

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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

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

and troubleshooting." I take it, Doctor, that at the time, in the middle of 2005, in the fall of '05, you would have agreed with that?
DR. CARTER:
A. Yes, I would.
COFFEY, Q.C.:
Q. And as well, to be fair here, the idea of dedicating immunohistochemistry technologists, had that, to your knowledge, been raised before at times in the past?
DR. CARTER:
A. I think it had been raised at times in the past that the technologists should subspecialize, if you will, especially in more difficult areas.
COFFEY, Q.C.:
Q. "A lack of an officially designated pathologistas directorof immunohistochemistry service. Technologists thus getting conflicting feedback from a large number of pathologists. There is no accountability for the quality of the service." Dr. Carter, you, of course, knew Dr. Ejeckam?
DR. CARTER:

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A. Yes.
COFFEY, Q.C.:
Q. But you were not stationed at the General Hospital, except for -
DR. CARTER:
A. During my locums, I was.
COFFEY, Q.C.:
Q. - your locums. Doctor, from your perspective, at the time, can you tell us, please, whether you would have seen Dr. Ejeckam, at the time, as responsible for immunohistochemistry?
DR. CARTER:
A. I certainly would have seen him as the point person for immunohistochemistry, the person that you would go to for, you know, problems with immunohistochemistry or even questions about immunohistochemistry that we, as pathologists, would have. Whether or not he had responsibility for what went on in the laboratory, I'm not certain.
COFFEY, Q.C.:
Q. And you, in fact, yourself, I take it, in July of '05 when you got involved in your effort that you described yesterday, you described yesterday your concerns or challenges that you

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faced even when you were told that certain technologists or administrative staff would be yours to utilize.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. In fact, that was problematic for you?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. In that context. So as far as you knew, I take it, he was the point person, but he would not have been officially designated, at least to your knowledge?
DR. CARTER:
A. Not to my knowledge.
COFFEY, Q.C.:
Q. And I'm asking you this because trying to get some sense of staff pathologists who happen to be in the other physical institution in the City at the time, across town at St. Clare's, that's all, so the Commissioner can get some sense of what a practising pathologist at the time thought. "A lack of standard operating procedures for grossing, fixation, tissue

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processing, block selection, positive control block selection, method optimization through systematic titration, incubation time and antigen retrieval time for each analyte." When you checked at the time, Doctor, were there any such standard operating procedures?
DR. CARTER:
A. I don't think that there were any. If they were, I was not able to get access to them.
COFFEY, Q.C.:
Q. Number four, "lack of subspecialization among pathologists, leading to the lack of in-depth knowledge about IHC technical interpretation details and pitfalls." Doctor, first of all, in relation to this, "lack of subspecialization among pathologists," at that time, was there?
DR. CARTER:
A. In 2005?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. Yes, there would have been some subspecialization. I was working there. We had a pediatric pathologist, forensic. Some

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people had a great interest in hemapath.
COFFEY, Q.C.:
Q. Jane Baron, I take it, was -
DR. CARTER:
A. Neuropathologist.
COFFEY, Q.C.:
Q. - neuropathologist. So there was some subspecialization?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. But there were other areas, I take it, in which, for example, breast pathology, you would have seen, described yourself as being particularly interested in that?
DR. CARTER:
A. Yes, so I would have been a point person for breast pathology.
COFFEY, Q.C.:
Q. Doctor, the reference to "a lack of in-depth knowledge about IHC technical and interpretation details and pitfalls," bearing in mind, at least in respect of the review that you conducted in the summer of '05, what you saw on the original slides, that grouping

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of slides you looked at, your references yesterday to lack of internal controls in some instances or internal controls not staining, from your perspective, did that reflect anything about the level of knowledge concerning that particular aspect of pathology?

DR. CARTER:

A. I didn't assess the knowledge of them. I can state that I saw that there were some problems with interpretation.

COFFEY, Q.C.:

Q. Interpretation, and we'll deal with those later on this morning. And then the reference to "a disconnect between laboratory program director, division manager, clinical site chief and laboratory director in decision making."

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. "The organizational charts indicate a complete separation of reporting structures in the technical and clinical streams with no matrixed cross reporting between technical and

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medical leadership. This leads to frustration and resentment on both sides, lack of communication, lack of accountability and lack of buy in. The division manager and program director appear enthusiastic and keen on modernizing the lab, but their efforts have not been appreciated by the pathologists and work flow changes have not been mapped out and implemented. Example, the Sakura Express implementation has failed due to lack of planning work flow changes. Superior outcomes could be achieved by ensuring better linkages between technical, managerial and medical leadership." Now there's a fair amount of information in this.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, dealing with the issue of what's described here as a disconnect, in effect, between the clinical side of the lab and the technological side of the lab, from your perspective, was there, if not a disconnect, certainly some gap?

DR. CARTER:

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A. Yes, in my experience with the--between the pathologists and lab administration more so than from pathologists and technologists.

COFFEY, Q.C.:

Q. And the reference here, Doctor, to "the division manager and program director appear enthusiastic and keen on modernizing the laboratory," Doctor, and there's a reference to "but their efforts have not been appreciated by the pathologists." Can you tell me, please, or tell us, please, from your perspective, what your view was in terms of modernizing the lab, your own view?

DR. CARTER:

A. I mean, I would be interested in keeping up and modernizing the laboratory in a general sense.

COFFEY, Q.C.:

Q. Your concern, and we'll deal with this a little bit more later I expect this morning, you referred yesterday to, in this August 1st meeting, this reference to the DAKO machine and the changeover to the Ventana, kind of explaining the results changes.

DR. CARTER:

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A. Yes.

COFFEY, Q.C.:

Q. And you have indicated to the Commissioner that you didn't accept that. You knew that, from your perspective, that was just not--that was incorrect?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Would you agree that the Ventana is a newer, more modern version of an auto stainer?

DR. CARTER:

A. Than the DAKO semi-automatic, yes.

COFFEY, Q.C.:

Q. Doctor, and did you have anything against the Ventana itself?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. If it was--if it made people's -

DR. CARTER:

A. Lives easier, as long as it was correctly optimized and used, no, I have no problem with Ventana.

COFFEY, Q.C.:

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

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COFFEY, Q.C.:
Q. In-depth knowledge, in fact?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And at times, can it be a tedious process?
DR. CARTER:
A. I've never done it, but I understand, yes, that it can be.
COFFEY, Q.C.:
Q. Doctor, the idea of "attendance by both medical and technical staff at conferences with a focus on new technology," or for that matter, I take it, new techniques, you would have been in favour of that?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. He ends that paragraph six by saying "consensus driven innovation should be the goal." Doctor, at the time, in the middle of 2005, into the fall of '05, from your perspective, who had the final decision making authority in terms of equipment acquisition?
DR. CARTER:

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A. Mr. Gulliver.
COFFEY, Q.C.:
Q. And I take it that would be so even if the equipment chosen and the manner in which it was utilized could affect the pathologist's work?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And finally, seven, "the department needs dedicated pathologist assistants to ensure gross room consistency and tissue handling, trimming and fixation," and you were in favour of pathology assistants?
DR. CARTER:
A. Agree, yes.
COFFEY, Q.C.:
Q. Doctor, and we've heard that there are four or five pathologists assistants.
DR. CARTER:
A. I think there are four.
COFFEY, Q.C.:
Q. Four now. Before the pathologists assistants were put in place, at any one time, how many pathologists, staff or residents, might be

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

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

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specimens in basically the same way. I don't recall there being any, you know, major outlyers when I was at McMaster, but I haven't really thought about it until just right now.
COFFEY, Q.C.:
Q. How about in St. John's?
DR. CARTER:
A. In St. John's, was -
COFFEY, Q.C.:
Q. Were there differences, significant differences sometimes?
DR. CARTER:
A. Things that I would have been aware of were that some people would prefer to cut their case on the day of, and other people would fix it overnight, and you know, prepare it the next day, but I think most people would fix it overnight here.
COFFEY, Q.C.:
Q. What is the--what are the potential effects of choosing one over the other?
DR. CARTER:
A. Well, there's a standardized fixation protocol for large specimens, if we're talking about lumpectomies and mastectomies, so you will

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

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Q. The idea of having everyone doing it in the same manner, for example, yesterday you referred to the idea that sometimes tissue might not be sliced thin enough or small enough to fit into the cassettes.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. In the optimum manner?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And might some pathologists then, because there's no one particular way of doing it, end up with or tend to end up with specimens that were a bit too thick?
DR. CARTER:
A. They would be a bit too thick but, I mean, the cassettes themselves would limit because they are small and they do close, so you couldn't put in a five-centimetre piece of tissue. I mean, you just couldn't do it. So you're talking about differences between a two-millimetre cut and a five-millimetre cut.
COFFEY, Q.C.:

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Q. But the--Dr. Banerjee here, elsewhere I believe, earlier in his report, does refer to, and I think you as well yesterday referred to the idea that at times the tissue would-- perhaps was too thick for the particular cassette?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And with the potential negative consequence?

DR. CARTER:

A. Negative impact, yes.

COFFEY, Q.C.:

Q. Doctor, with respect to residents, just as an aside here, who teaches a resident, for example, the appropriate way to gross a breast specimen?

DR. CARTER:

A. When they're first year residents, they would be grossing under the supervision of a pathologist, so just whoever they happen to be working with that day in whatever rotation they were on. So if they were at St. Clare's, they would do it with myself or Dr. Elms, Dr. Denic, Dr. Cook, and they would observe us and

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imitate us. For the most part, you see one, you do one. There's also standard textbooks of grossing tissues and also as part of their academic half day, different pathologists would be teaching in different topics in a didactic form, giving lectures. So then areas of grossing would be touched upon.

COFFEY, Q.C.:

Q. So I take it that it might then vary from staff pathologist to staff pathologist, depending upon his or her approach?

DR. CARTER:

A. Yes, there would be some variability.

COFFEY, Q.C.:

Q. Some variability?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. The residents might be exposed, in respect of a particular type of specimen, to just one, that particular pathologist of the day, staff pathologist's technique or if it was you one day and another doctor, another staff pathologist the next week, same sort of specimen, they might be taught slightly

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different versions of--or different versions, in fact?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, I'm going to return now, if I could, as I pointed out, to the exhibits themselves and I'll allow you to, at times focus on and perhaps elaborate on certain things in them. Exhibit P-0067, please? Doctor, this is the letter of May 24th, 2005 that Dr. Cook wrote to Dr. Williams. Did Dr. Cook consult you about the contents of this, do you recall?

DR. CARTER:

A. I don't--he never showed me the letter and asked me did I agree with it, but I mean, we would have been talking back and forth.

COFFEY, Q.C.:

Q. The second paragraph refers to--well, first of all, go back a bit. He opens by referring to a May 11, 2005 phone call from Dr. Joy McCarthy.

DR. CARTER:

A. Um-hm.

COFFEY, Q.C.:

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Q. And you've indicated that sometime before May 17th, 2005, when you attended a meeting, sometime before that, you had spoken to Dr. Cook about Peggy Deane's case?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Did you have any understanding at the time as to when the retest of Ms. Deane's tissue sample had occurred? You spoke to Dr. Cook. Did you get any sense from him as to -

DR. CARTER:

A. I would have assumed it was around that time.

COFFEY, Q.C.:

Q. And your recollection is that it was about how long before the meeting?

DR. CARTER:

A. Before the May 17th meeting?

COFFEY, Q.C.:

Q. Yes, that he spoke to you.

DR. CARTER:

A. I'm not sure. I wouldn't be able to say. I would assume it was around that time.

COFFEY, Q.C.:

Q. At the time he spoke to you, other than asking

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you to look at the slides, and as you pointed out, confirming from your perspective what he already knew himself -

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. - at that point, were you--did you get any sense that anything other than looking at the slides was expected of you? Were you expected to act upon this in any way at that point?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. Other than to attend the May 17th, 2005 meeting, were you asked to do anything before that?

DR. CARTER:

A. As I said yesterday, I think there was at least one, I thought there were two other patients that had been identified through the medical oncologists, Dr. McCarthy and Dr. Laing. There was probably, you know, discussions amongst us all, you know, what's going on and what does this mean.

COFFEY, Q.C.:

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Q. Identified, I take it, as one or two patients other than Ms. Deane identified as invasive lobular or with some particular type of cancer that should be -

DR. CARTER:

A. Something about them that clinically had made the oncologist think that maybe this case would be like Ms. Deane's case.

COFFEY, Q.C.:

Q. And these cases, the oncologists were telling you the original reports were negative?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And there was something about them and so at that point, did they say anything else, do you recall, about what they knew or understood about this at the time?

DR. CARTER:

A. Who is they?

COFFEY, Q.C.:

Q. They, the oncologists, Drs. Laing and McCarthy.

DR. CARTER:

A. That they were--you know, that they were

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worried that this might mean something bigger, that they were thinking back, you know, retrospectively about cases that they had had that, you know, they wanted to have a look at again.

COFFEY, Q.C.:

Q. So at that point, do you recall, was there any discussion or were you told about Dr. Ejeckam's intervention in '03?

DR. CARTER:

A. I would have been told about it somewhere around this time, but I wouldn't be able to pin it down for you, but this summer is when I--spring, I guess, and summer, is when I would have become aware of that.

COFFEY, Q.C.:

Q. The reference to the May 17th meeting, before I get into that though, at the time you spoke to Doctors Laing and McCarthy, did they, at that point, identify to you or suggest to you perhaps that there was a particular period that they were concerned about?

DR. CARTER:

A. Not that I recall, a time period, no.

COFFEY, Q.C.:

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Q. And Doctor, in Peggy Deane's case, did you have any understanding at that point as to who the original pathologist had been?

DR. CARTER:

A. I don't think I had on the day that I was shown them, you know. It was just sort of casual.

COFFEY, Q.C.:

Q. How about afterwards?

DR. CARTER:

A. But very shortly afterward, because I think the case was brought to that pathologist's attention.

COFFEY, Q.C.:

Q. And did you speak to--it's Dr. Ford Elms. He's going to be here.

DR. CARTER:

A. Okay.

COFFEY, Q.C.:

Q. Did you speak to Dr. Elms about that at the time?

DR. CARTER:

A. I don't remember, you know, a particular conversation, but I didn't not speak to him. I mean, we were conversing freely, you know,

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about this issue in our department.
COFFEY, Q.C.:
Q. And in the course of talking about that, I take it, so that would be Dr. Elms, Dr. Denic, yourself, Dr. Cook, who else was?
DR. CARTER:
A. At the time, it would have been Dr. Naghibi and Dr. Wadhwa.
COFFEY, Q.C.:
Q. At that stage, like in the spring of 2005, what if anything was -- do you recall what was said by the other pathologists about their views as to what might have happened? Did they have any -- did you get any sense at time, because some of this would have predated your time.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Some of it would and some of it wouldn't.
DR. CARTER:
A. I don't recall specific conversations directly related to that. I know that Dr. Elms, you know, looked at the slides and was quite concerned and was trying to find those

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

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COFFEY, Q.C.:
Q. Doctor, at the time, and we've heard from Mr. Dyer as to what he recalled about what was -- some of what was said to him at the meeting. At the time of that meeting, did you have anything to say to Mr. Dyer yourself that you recall?
DR. CARTER:
A. It was a general discussion of what the problem was and what our plan was going to be to look at it.
COFFEY, Q.C.:
Q. And he has indicated that at least one of the oncologists made a very directly pointed remark at him?
DR. CARTER:
A. No, I don't recall that happening.
COFFEY, Q.C.:
Q. You know the remark I'm talking about?
DR. CARTER:
A. Yes, that he was personally responsible for what had happened.
COFFEY, Q.C.:
Q. Or it's his fault or his lab's fault.
DR. CARTER:

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

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advice and guidance from QI on how best to disclose this information as this involves breast cancer patients across the province". So I take it, Doctor, even by that point in time it was recognized that perhaps it wasn't limited to St. John's potentially?

DR. CARTER:

A. Yes, because we tested for everybody across the province.

COFFEY, Q.C.:

Q. At that point in time, Doctor, I take it from your perspective, anyway, the retesting would occur using the Ventana machine?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Because the retest at that point, the one, two, or three patients who had been retested up to this point in time had been retested using the Ventana?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, he does go on to say that, "In closing, I would like to make the following

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recommendations for immunoperoxidase testing. One is the immediate establishment of an external proficiency testing and monitoring program for immunoperoxidase testing", and that suggests that there was not such external proficiency testing and monitoring for immunoperoxidase testing at that point.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. There was not up to that point in time?

DR. CARTER:

A. I wouldn't have direct knowledge of that, but I don't think so.

COFFEY, Q.C.:

Q. And coming out of that meeting, Doctor, what was, from your perspective, expected of you, yourself, if anything at that point?

DR. CARTER:

A. That I would begin to investigate the problem, to try to outline, in fact, if we had a problem. As I briefly said yesterday, you may find out that this all occurred on one Saturday.

COFFEY, Q.C.:

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Q. Sure.

DR. CARTER:

A. You know, something like that. So to try to put together a descriptive sort of analysis of starting with the NIDAS case and just moving out from there to see if we had any issues --

COFFEY, Q.C.:

Q. Sorry, starting with the --

DR. CARTER:

A. The index case.

COFFEY, Q.C.:

Q. Index. I just didn't hear.

DR. CARTER:

A. NIDAS, I said, index, you know, to start at NIDAS and to move out from it, and I think we initially decided that we would do Eastern Health because it was just physically easier, and then possibly go into 2001 if we didn't have enough numbers to draw any sort of conclusions. I mean, at that point I would have required an epidemiologist or somebody familiar with statistics to help, but it was just to start a descriptive.

COFFEY, Q.C.:

Q. And going away then -- so that was your

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understanding of your role?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. It anticipates, the letter does, that potentially there might be further conversions, anticipates that?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. If there's a receptor conversion, the oncologist would inform the patient?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So I take it the understanding was that as any retesting occurs, that the oncologist would be told the results?

DR. CARTER:

A. Yes, we would tell the oncologist directly. We have some form letters that we would send over so that they would have advance notice. Usually when you do an estrogen receptor, you report it and then just upload it into Meditec, and then the onus is sort of on the

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clinician to check their own work, but in this case we would send the -- fax the results directly to one of the oncologists so they could pull all the retrospective cases and then make appointments as needed with the patients and inform them of what had happened.

COFFEY, Q.C.:

Q. And, Doctor, we will see letters here, there are three of them where there's a large -- you're writing, yourself and Dr. Cook are writing letters to Dr. McCarthy.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. There are a large number of patients listed in each letter.

DR. CARTER:

A. Twenty-five plus.

COFFEY, Q.C.:

Q. Yes, a large number in the sense of certainly more than five or six at a time.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. What I'm getting at here, Doctor, is this,

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that June 29th letter --

DR. CARTER:

A. Okay.

COFFEY, Q.C.:

Q. The 25 patients. Would Dr. McCarthy or the attending oncologist, if it wasn't Dr. McCarthy, already have been told those results before that for many of those patients?

DR. CARTER:

A. For many of them, I think that she would. I mean, I can't state it with any certainty, but I know that we would be talking on the telephone.

COFFEY, Q.C.:

Q. The point would be that you might very well tell the doctor verbally, and you'd make a note in Meditec at times the reference -- sometimes there'd be references to the fact that --

DR. CARTER:

A. I would have to go back and look at each case and examine it, but, yes, I think if they had requested, you know, someone that they expected, and I had gotten a report, I would let them know. I may have reported it and

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then we made up a form letter.

COFFEY, Q.C.:

Q. So then what happened, Doctor? You start out. You leave the May 24th meeting. You understand what's required --

DR. CARTER:

A. May 17th.

COFFEY, Q.C.:

Q. May 17th, I apologize, May 17th meeting. What happens then, what did you do?

DR. CARTER:

A. I talked to Mr. Dyer and asked that a search be done for estrogen receptor negative patients in 2002, and he gave me a list of patients, and I began to request the slides, blocks, reports from those patients, select the blocks, send them to -- I think at that time we were probably using Maria Mendes' lab for -- but I would send them to Mount Sinai.

COFFEY, Q.C.:

Q. Initially?

DR. CARTER:

A. For retesting.

COFFEY, Q.C.:

Q. In the beginning?

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DR. CARTER:

A. Oh, sorry, I would send -- do it on Ventana.

COFFEY, Q.C.:

Q. Ventana, okay, at that point.

DR. CARTER:

A. I need my exhibits.

COFFEY, Q.C.:

Q. And -- well, in terms of that, the actual -- and this is why I'm asking about this, what happened in the beginning, because frankly the Commission doesn't have a whole lot of documents for the first month or two. We do have a lot in July, Maria Mendes, and all those from there, but I'm just trying to get some sense of what went on in the first month.

DR. CARTER:

A. So between May and the end of June?

COFFEY, Q.C.:

Q. Yes, May and end of June.

DR. CARTER:

A. I mean, as I described -- that was my mistake about sending them to Mount Sinai. We were still using the Ventana system. I'm not sure the date of when we turned it off, but it was some time in July, I think.

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COFFEY, Q.C.:
Q. So in the beginning, I take it Mr. Dyer provided you with a list for 2002 ER negative cases?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Local cases, St. John's cases?
DR. CARTER:
A. Yes, and after a couple of weeks, I think Don began to request them from outside of town for 2002.
COFFEY, Q.C.:
Q. Now what, if anything, had you learned by the time Dr. Cook requested the out of town cases, because that's June 14, Exhibit P-0492 -- this is this June 14th, 2005 letter to the laboratory directors throughout the province from Dr. Cook looking for all the 2002 ER and PR negatives, and at that point in time what constitutes negative is not defined or set out. Doctor, what had happened before that, if anything, in terms of your investigation, how far had you gotten?
DR. CARTER:

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A. Again, I mean, I wouldn't be able to give you numbers, but as each day passed, we were seeing a significant number of conversions there, so as each day passed, we were becoming more worried that this was a widespread thing. I know by June 29th, we had 25, but --
COFFEY, Q.C.:
Q. Yes, there were 25 done and about 16 or so conversions.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And, of course, they didn't all occur on June 27th, they occurred between May 17th --
DR. CARTER:
A. Some of them may have been before June 14th, some after, but I can't clarify it any more than that.
COFFEY, Q.C.:
Q. You were aware that Dr. Cook was looking for the cases from outside St. John's? Were you made aware that that was going to happen?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:

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Q. And by that point, from your perspective, had you thought or come to at least a tentative conclusion that perhaps we do have a problem, this is not isolated?
DR. CARTER:
A. That became, I think, clear for me fairly early on in the process.
COFFEY, Q.C.:
Q. Exhibit P-0500, please. Doctor, this is the June 29th, 2005 letter that was drafted and sent to Dr. McCarthy. Your signature is there and Dr. Cook has signed July -- effective July 13th, 2005. Was there discussion about the form or format that should be used for this letter?
DR. CARTER:
A. I think it was at the May 17th meeting or it may have been in phone calls, you know, over that month, we recognized that there as a necessity to have the patients clearly put through to a point person, if we're going to continue to use that term, at the Cancer Centre so that these patients would be dealt with. Some patients from 1997 could have been theoretically discharged from the Cancer

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Centre requiring no more oncology follow up, physicians had moved out of town, some physicians had died. I think that we had come across one. So to simply upload it into the Meditec chart, we wouldn't be at all certain that patients would not be missed, so this was sort of an official way, and we decided to address it to Dr. McCarthy, just as a point person, not that she would be responsible for doing all that work.
COFFEY, Q.C.:
Q. And, Doctor, here the patients are identified by name and MCP number, they're redacted and surgical numbers, estrogen receptor status, progesterone receptor status, I take it these are the retest results?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Now in determining whether or not to retest people at all at this point -- as you had indicated to the Commissioner now, you had asked Mr. Dyer to identify estrogen receptor negative. How is negative in that context defined at this stage?

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

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

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

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it infiltrating lobular, it's not a classic strictly defined infiltrating lobular, or there's something with the testing.
COMMISSIONER:
Q. So while the result itself might be considered positive on the strict percentage basis --
DR. CARTER:
A. In terms of clinical management of the patient, yes.
COMMISSIONER:
Q. You would have wanted to look at that because of that sort of inconsistency in what you might expect and what you --
DR. CARTER:
A. Expected results and true results.
COMMISSIONER:
Q. Thank you.
COFFEY, Q.C.:
Q. Now, Doctor, the idea of utilizing surrogate markers, you know, in pathology generally, I mean, in the past, would you have utilized them in, for example, evaluating ER/PR when you're looking -- you look through a microscope and see something and you do your estimate for percentage or see no staining,

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and yet there's a particular type of cancer surrogate marker, would that ever figure into your approach to doing your job?

DR. CARTER:

A. Certainly that's what I was taught to do and what I practised. I wouldn't say that it happened every time.

COFFEY, Q.C.:

Q. Yes, but in terms of --

DR. CARTER:

A. It also is sort of a subconscious thing that you do, so you wouldn't -- you just know that when you look at lobulars, this is the way they're supposed to behave.

COFFEY, Q.C.:

Q. I take it, Doctor, in terms of that very point, the idea of surrogate markers or surrogate factors, is that limited to breast pathology or does that cut across pathology in one form or another generally?

DR. CARTER:

A. There would be surrogate markers that you would use in other instances -- I'm trying to quickly go through, but, I mean, if you had a melanoma, skin cancer, and it didn't express

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S100 or melanae (phonetic), I mean, you would rethink your diagnosis. So there's expected behaviour from certain tissues.

COFFEY, Q.C.:

Q. This -- the idea, as you say, subconsciously perhaps or only semiconsciously kind of being alert to sensing a certain way, bearing in mind what I'm bringing to this in the way I do it, or I expect to see, can that be influenced by the frequency with which you do or don't do something in the sense of if you're doing breast pathology all the time is what I'm -- in your case, for example, would you be more alert to potentially surrogate markers and their potential significance from day to day than if you only did a breast case once a week or once a month?

DR. CARTER:

A. That actually hasn't been studied because there's a lot of interest in that and whether or not people subspecialize -- the last time I looked, it had not been studied, but it's my experience and many of my colleagues anecdotal belief that, yes, the more cases you see, the better you get at them, and some things are so

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subspecialized, not to do with this inquiry, but somebody who's operating, say, on your pancreas or your bile ducts, that that should probably be restricted to, you know, people who do it a fair amount.

COFFEY, Q.C.:

Q. And in this context, and I raise it now because you've referred to it, we've heard from some pathologists who have indicated that they might see a breast case on average once a month and ER/PR.

DR. CARTER:

A. Here in St. John's, yes --

COFFEY, Q.C.:

Q. Or particularly outside St. John's in some instances, and they acknowledge, well, yes, they would know invasive lobular should be positive. That was what -- they understood that from their training, but -- or ER negative, PR positive, is relatively infrequent.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. But they would just attribute it to -- it

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wouldn't stand out at the time for them because they just saw so few of them, and they would just chalk it up to this happens to fall into the 1 in 10 or 1 in 20 category, this particular case.

DR. CARTER:

A. And I think that most people who are involved in oncology, I mean, have a basic sort of tenet that the statistics, you know, are to be applied and to be recognized and utilized, but that cancer is largely a process that often does the unexpected and does what it wants. So, I mean, if I saw something that was negative, I wouldn't say an absolute statement this should be positive.

COFFEY, Q.C.:

Q. Doctor, you've indicated that -- I think you said several minutes ago that early on you realized that in terms of your involvement that perhaps this was a wider problem.

DR. CARTER:

A. Than 2002.

COFFEY, Q.C.:

Q. Yes. Doctor, what was it about what you were seeing that caused you to think that?

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

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cases, and the third page, there's a 2000 case, a 2005, as you pointed out, although it may have originated in '03, Western Memorial number, and a 2000, a 2001, and then a 2002 case out of Clarenville, but given an RI number, and again an '03 case. Doctor, you here uses generally either just positive or negative as your descriptor of the status.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. What was your practice in terms of would you use positive, negative, use a percentage, or might you vary?
DR. CARTER:
A. At that time, my practice would have been -- I would say most of the time I probably would have just said positive and negative and sometimes I would have used a percentage point with it.
COFFEY, Q.C.:
Q. And here, for example, at the beginning of the second page there's a reference to positive [10 percent moderate to strong positivity], and then -- that's ER, and PR is positive,

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

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DR. CARTER:
A. Yes. I mean, if I signed it out, perhaps I was reading a Mount Sinai report the minute before I signed it out, and I did it, but there was no strict way of reporting that I did. My reporting will be variable.
COFFEY, Q.C.:
Q. The handwriting here on these, Doctor, whose is that, do you know?
DR. CARTER:
A. I don't think so.
COFFEY, Q.C.:
Q. Okay, and as well the second last case in this exhibit, there's again a descriptor inside brackets [weak to moderate 30 percent positive].
DR. CARTER:
A. That case is from Clarenville.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. And I think that they had for a long time used Mount Sinai as their testing, so that may be a report from Mount Sinai as well.
COFFEY, Q.C.:

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

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could just go back to P-0500, please. That second last case here the one that's referred to as Clarenville.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Where was that originally tested, do you recall, Doctor?
DR. CARTER:
A. I haven't gone back and looked at these cases as part of this in detail. My understanding is that some time in the early 2000's Clarenville had made the decision to switch their estrogen receptor testing to Mount Sinai.
COFFEY, Q.C.:
Q. And so do you recall how this case was identified because it wouldn't have been within the Health Science Centre system?
DR. CARTER:
A. No. Again I haven't gone back in detail.
COFFEY, Q.C.:
Q. Okay.
DR. CARTER:
A. Perhaps it was from one of the oncologists

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

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

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

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

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

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

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there and made a phone call. This was actually thought through.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. Doctor, go on to the next page of this, second page, you say, you begin that here by saying, "it will be necessary to have a computerized data base for this project". And then you spell out what the certain of the things that it should included and you list them, in effect, I take it, searchable and utilizable spreadsheet.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. That's what you were looking at.

DR. CARTER:

A. I mean, in the initial part, this is a very basic approach to it. I mean, we're just getting a descriptive analysis. I don't think it would stand up to a lot of statistical mining for research purposes, but it was just to get a description, put it into some sort of database where we could begin to manipulate it

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and see if something stood out.

COFFEY, Q.C.

Q. Now, Doctor, were you ever actually, in practice then, offered the services of someone who could build a computerized database?

DR. CARTER:

A. I don't think so, no.

COFFEY, Q.C.

Q. Okay. Yourself, do you have any facility or skill with computerized databases?

DR. CARTER:

A. I can fill out an Excel spreadsheet and I can manipulate it, but probably would have needed something more sophisticated than that. And I mean, it's just not a very good use of my time.

COFFEY, Q.C.

Q. And so, what I'm getting at here is even at this stage when you're embarking upon this, you, yourself recognized that it would be useful to have someone with that skill set available.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

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Q. And you requested it.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. And there was no one actually identified, no individual that you can recall.

DR. CARTER:

A. Not that I can recall, no.

COFFEY, Q.C.

Q. Page three of this exhibit, Doctor, is a July 19th, 2005 letter from Dr. Cook to yourself. He acknowledges receipt of your July 14th letter. He states, "I certainly accept"--"it's been stated in your letter and will ensure that you obtain the necessary resources to carry out your suggestions". And that's copied to Dr. Williams.

Doctor, you described yesterday how that turned out by the end of the month, beginning of August in terms of what happened with respect to that. Have you ever spoken to Dr. Cook--did you speak to him at that time about your frustrations?

DR. CARTER:

A. Yes, I did.

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COFFEY, Q.C.

Q. And what, if anything, did he tell you?

DR. CARTER:

A. The timelines, if you look at the memos and things are kind of strict. This had been going on from May 17, so it's not July 14th this happened and then July 29th that happened. But in the months of May and June and July I was, as it became more formalized, I was trying to become more rigorous in my approach to it. And had been repeatedly asking for specific entities that I talked about yesterday and was having frustration getting that. Also just having physical people on the ground doing a lot of this work. I talked to Dr. Cook about it, I mean, he would sympathize with it and state his support for it and say that he would talk to Dr. Williams about it to see what could happen, but he had no authority to tell people on the technical half, I guess we're calling it, of the laboratory, how the resources should be allocated.

COFFEY, Q.C.

Q. In terms of--just so the Commissioner, again,

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can get some sense of, as you point out, July 14th just didn't happen and your letter begins on July 14th as per discussions or many discussions.

DR. CARTER:

A. So, we may have been doing it for three weeks. And Dr. Cook may have said you got to get this down on paper.

COFFEY, Q.C.

Q. Exhibit P-0508, please. Now, this is a July 18th, 2005 letter. It's from yourself and Dr. Cook to Dr. McCarthy and this is the second of the three reporting letters as it were. It says, "as per our previous discussions, repeat ER and PR has been performed on the following patients initially identified as estrogen receptor negative. The results are as follows" and here sometimes there's, again, positive and simply the words "positive" and "negative" used sometimes, longer descriptors such as for the first patient here, 100 percent strong nuclear positivity in both instances for ER and PR. And then the fourth patient, moderate nuclear staining and 60 percent strong nuclear staining and 80 percent

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for PR for that fourth patient on the first page. And as we look through this, it varies. Now, I take it Doctor, this is signed on the fourth page by yourself and Dr. Cook.

DR. CARTER:

A. Um-hm.

COFFEY, Q.C.

Q. There are, I think, 33 patients, roughly, here. We can count them up, but there's approximately that.

DR. CARTER:

A. I think 19 had -

COFFEY, Q.C.

Q. Converted or so. And again, we can just kind of look through it and calculate it, but I'm getting at, in this context, Doctor, is this, this is written July 18th, signed off. I take it the actual work of doing the retesting had occurred in the weeks before this.

DR. CARTER:

A. I would assume that it had been done between June 29th which was the previous letter and this date.

COFFEY, Q.C.

Q. Yes, and July 18th. So, Doctor, really by the

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time you wrote the July 14th letter formalizing your request and your plan, would it be safe for the Commissioner to accept that, from your perspective, accept that most of the July 18th patients listed in that letter had already been retested by July 14th.

DR. CARTER:

A. Yes, I would agree with that most of them would have -

COFFEY, Q.C.

Q. Had already occurred. Doctor, if we could look again, to give the Commissioner some sense of what was going on in that time frame, Exhibit P-1697. Here, Doctor, this is another letter of July 14th, 2005. It's from yourself to Dr. O'Malley at Mount Sinai and you write, "as per our telephone conversation of July 13th, 2005 could you please have ER/PR staining done on the following and also provide interpretation for same". I believe there are 13 blocks, at least, anyway listed there. Yes, there are nine on the first page and four on the second. And you conclude by saying "I would appreciate a return of the blocks as soon as you have finished them".

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Could you bring up please, Exhibit P-2189? Is this your handwriting, Doctor?

DR. CARTER:

A. Yes, it is.

COFFEY, Q.C.

Q. And you've written Mary Butler, pathology, HSC, "Mary, send the following blocks to me" and you list them. And if we check and compare certainly the block numbers, in this particular letter, we've redacted the middle numbers in the surgical number, but they are, in effect, generally the same blocks, aren't they?

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. And Mary Butler has written to you, "still looking for blocks that are circled" and there are a couple of them there. Doctor, and you've written here, I think, FOM, as per our telephone discussion on this, it says July 16th, '05, "perform ER/PR staining and provide interpretation and please return blocks". I take it this was a draft of the text that ends up in your letter?

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

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

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

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

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We cannot take responsibility for these patients with regards to notifying them of this new information." I take it, Doctor, that this was kind of a formal response to saying "well, we can identify or deal with all but two."

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And asking that those two be addressed?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. By your and Dr. Cook's office. Exhibit P-2360? This is an e-mail, Doctor, of July 25th, 2005 from yourself to Dr. Gallagher. It reads "1997 to" it should be 2004, "ER negative, don't care about PR. ER/PR slides controls and H & E of that block report. I'm looking at histologic type grade, internal controls, external controls, date of testing." Signed Beverley Clarke (sic.) and he had written to you on July 24th saying, subject is a question, "I just wanted to check again the criteria on the breast cancers that they want

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us to send to St. John's. January 1997 to December 2004, ER and PR negative, both negative, block, H/E slide, ER/PR slides and report?" Now, and of course, you responded in the way you did on July 25. Do you recall how it was you came to communicate with Dr. Gallagher in Gander?

DR. CARTER:

A. I mean, I don't recall this in particular. They would have phoned when they had--I think my name was listed on many of the e-mails that I would act as a consultant on this process, if they wanted.

COFFEY, Q.C.:

Q. Do you recall any of the contacts you had with the pathologists outside St. John's?

DR. CARTER:

A. I know that I had them, that if they telephoned me or e-mailed me, in this case, and asked me questions about the process, I would have. In an official capacity, I think there was a couple of memos that I was cosigner on with Dr. Cook, but largely it would be informal, I would think.

COFFEY, Q.C.:

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Q. Exhibit P-0492, please? Doctor, that June 14th 2005 memo from Dr. Cook. He had concluded by saying, and this went to Dr. Gallagher and others, "if you have any questions"--concerns or questions, please feel free to contact him or yourself?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So right from the beginning, that was so. Doctor, why the--if we could go back then to P-2360? Doctor, why the focus on ER?

DR. CARTER:

A. As opposed to the PR?

COFFEY, Q.C.:

Q. Yes, because you say "ER negative, don't care about PR."

DR. CARTER:

A. "Don't care about PR." I think the estrogen receptor had come up as the most important molecule, most important thing, protein that we would be looking at, in terms of ER/PR. There's been literature that changes over time about the value of progesterone receptor status in determining response to hormone

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therapy. Sometimes it's very important and sometimes not at all, but from the scientific point of view, I was looking at estrogen receptor and seeing if there was a problem with that testing and I think, from Barry's point--sorry, Dr. Gallagher's point number two, he says "both negative" and I was interested in the ER negative, irrespective of the status of PR.

COFFEY, Q.C.:

Q. And by--so Doctor, if you just took ER negatives, without regard to the PR status, from your perspective at the time, would that then, assuming that all patients could be so identified as ER negative, appropriately identified, would that capture any one who could be affected by this process?

DR. CARTER:

A. There's two different processes going on. One is to identify patients who can be clinically affected by this. The other one is a scientific investigation of what had gone on with the particular antibody in the lab. So it depends what your question is about the process.

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COFFEY, Q.C.:
Q. Why don't we deal with each of them in turn? Clinically?
DR. CARTER:
A. So clinically, if you're looking at estrogen receptor negative, almost all of the patients who are estrogen receptor negative are progesterone receptor negative. So you would be talking about a very small number of patients who would be ER negative, PR positive, usually quoted somewhere around three to five percent of all patients tested there. In terms of the scientific assessment, I guess at that time, I thought that my role was to figure out what happened to estrogen receptor, what, if anything, had happened to estrogen receptor.
COFFEY, Q.C.:
Q. Doctor, at any point in the process, when you were involved in it, did you ever come to any views as to the past results having involved more than expected number of ER negatives PR positives?
DR. CARTER:
A. At that time?

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COFFEY, Q.C.:
Q. Yes, or any point thereafter.
DR. CARTER:
A. Yes, I mean, we saw a lot of ER negative PR positives.
COFFEY, Q.C.:
Q. So when did that come--begin to come home to you, that you were seeing a lot of--in the original reports, ER negatives, PR positives?
DR. CARTER:
A. I think, again subconsciously, I may have recognized that the--trying to think about it now, I mean, the first time I remember sort of seeing it was when we had the spreadsheets at the tumour panel, when the large cohort had come back. So you're just looking at, you know, a large -
COFFEY, Q.C.:
Q. Listing.
DR. CARTER:
A. - list of numbers, so I mean the pattern becomes available.
COFFEY, Q.C.:
Q. And that would have been--because there are different groupings of returns. The largest

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return in numbers was in January of '06, but there were fairly significant numbers of returns back in September and October.
DR. CARTER:
A. And I'm not sure at which time it was, but, you know, the image that I have is of seeing it on a spreadsheet. There's a lot of ER negative PR positive here.
COFFEY, Q.C.:
Q. And they would be, depending upon the study one looks at, between three and five percent, should be in that category?
DR. CARTER:
A. Yeah.
COFFEY, Q.C.:
Q. I think that's the figure you just used and we've heard 3.8 here from other witnesses and so on, but there's--it's five percent or so or less?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-0529, please? Doctor, this is a letter from--your name is not on it, but it's a letter of July 27th, 2005, to Dr. Watters at

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McGill University. It's from Dr. Cook, copied to Doctors Williams and Mr. Gulliver. He writes "as discussed, we are in the process of evaluating our ER and PR immunoperoxidase stains. We will be forwarding two unstained labelled slides to your lab. These slides will be stained for estrogen and progesterone receptors via immunoperoxidase technique. Once the slides are stained, they can be forwarded to my office. I anticipate that we may be evaluating anywhere from 40 to 50 cases. Of course, we will be reimbursing you for this service. I certainly appreciate your help in this difficult situation."
Do you recall what the nature of--what you knew about the nature of Dr. Watters and McGill University's involvement?
DR. CARTER:
A. This would have occurred at or around the same time that we began to suspect that there may have been an issue with the Ventana staining, and in the course of discussions with people in labs across Canada, it was found that Dr. Watters had a Ventana machine. I think it was the exact same model as we had. So I mean, it

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would just be another quality control practice that you would take our slides, send them to their machine and see if we got the same sort of results, and I think we were going to report them, as opposed to when we sent the note to Dr. O'Malley, we asked her to report them, because then we wanted to do a QC between pathologists' interpretation skills and I think when we talked to Dr. Watters, they felt that they were really quite busy and that pathologists couldn't provide that practice, but the lab could restain slides for us if that's what we wanted to do.

COFFEY, Q.C.:

Q. And was that done, do you know?

DR. CARTER:

A. Yes. I'm not sure about the 40 to 50 cases, but we did send some cases up to Dr. Watters for staining.

COFFEY, Q.C.:

Q. Do you recall what happened?

DR. CARTER:

A. The slides were returned to Dr. Cook, I think, and we looked at them together. I'm not sure if there was anyone else there besides myself

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and Dr. Cook, but the slides had a technical problem with them. They were uninterpretable for us and I'm not sure what happened after that.

COFFEY, Q.C.:

Q. Exhibit P-0508? Doctor, this is this July 18th letter. Just on this, again there is a variety of--well, variety, it's either positive--the simple words positive and negative are used, or again, in this case, a descriptor using the words positive or negative or positivity or negativity, but--positivity, I'm sorry, and a percentage. Is there any particular significance to utilizing one format or another here?

DR. CARTER:

A. There is evidence, going back as far as 2001, that patients who have one percent or greater staining may show response to hormonal manipulation, Tamoxifen or aromatase inhibitors, and that paper largely came out of people who, again, were using Dr. Allred's system, not only of testing but also of reporting and in the Allred score--I don't know if you've gone through that already?

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COFFEY, Q.C.:

Q. We have, the Allred scoring, yes.

DR. CARTER:

A. So the Allred score, you would give a score for intensity and also a score for quantity and then you would put them together. So an Allred score, that would be equivalent to one percent would respond on some level to hormonal manipulation. So the practice is to give an intensity, which would be the strong, the moderate, the weak that you see there, and then a percentage.

COFFEY, Q.C.:

Q. And so that's where that reporting style or format would be associated with that, and but there are others that are just simply positive or negative?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. In terms of these particular patients, for example, looking at the second page and the third patient is just described as negative/negative. Let me see if I can find one here. Go back to the--yes, on the first

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page, the second patient is described simply as positive/positive, as is the second last patient on the first page. But in other instances, the weak, moderate or strong is used and an actual percentage. Was there any significance to your--for example, the second last patient using positive and positive, on the first page, but then going to a modified Allred description, why would you choose for this patient to use positive/positive and then an Allred approach in the second one?

DR. CARTER:

A. I'm not sure that that's what happened. I would guess, and as I said, I haven't gone back and looked at all these cases in detail, but I would guess that the ones that just say positive or negative were reported by me. The ones that give a longer descriptor were either reported by somebody from Mount Sinai and perhaps me being influenced by reading a Mount Sinai report immediately before.

COFFEY, Q.C.:

Q. Okay, and Doctor, here, on this July 18th letter, all the patients on the first page are 2002 cases, at least have 2002 surgical

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numbers, all those on the second page, look down through it, all those on the third page and all those on the fourth. So at least the reporting as of July 18th were all 2002 cases.

DR. CARTER:

A. So this would have been the retrospective cases.

COFFEY, Q.C.:

Q. Doctor, while we're on the topic, Exhibit P-0535. Here, Doctor, this is a letter of July 29th, 2005. It's again addressed to Dr. McCarthy, and on the last page, there's a place for yourself and Dr. Cook's signature. Do you know if this letter was ever sent, the July 29th one?

DR. CARTER:

A. I would assume so, but now that you're asking the question.

COFFEY, Q.C.:

Q. Just because a signed copy versus the unsigned copies, and it was around this time, and we'll deal with it momentarily, there was a decision made to kind of hold off and wait for the Ventana situation to be clarified somewhat. So I'm just wondering if at that point in

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time, if you recall actually sending--actually signing and sending the July 29th letter.

DR. CARTER:

A. I don't have a specific memory of it. I would assume that it went, but I don't know.

COFFEY, Q.C.:

Q. Now Doctor, here, these on the first page of this letter, these are all 2002 cases listed there. Second page are all 2002. On the third page, there are--there's a mixture of '02 and then you'll see an '05 case in the third entry, a 2000 case, some '03 cases toward the bottom of the page, all the way down, and then going on to the next page, the top of the page, three '03 cases and then five '04 cases. So Doctor, by the end of July then, what had happened in respect of what sorts of cases were being retested?

DR. CARTER:

A. We were still doing the retrospective cases and we were doing cases that would have been identified by the oncologists for retesting.

COFFEY, Q.C.:

Q. If they fall into the '02, they would be there anyway, but if they fall into these other

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years -

DR. CARTER:

A. I don't think we had moved out of the 2002 cohort at that time in a retrospective kind of view.

COFFEY, Q.C.:

Q. So the '03, '04 and '05 and 2000 cases here are probably the ones identified by oncologists in particular for retesting?

DR. CARTER:

A. Or by other people. I mean, I'm trying to think now if anybody else had telephoned us, but these ones would have been requested to the lab.

COFFEY, Q.C.:

Q. And I take it then that these would have been done probably actually retested sometime between July 18th and July 29th?

DR. CARTER:

A. That would be my assumption.

COFFEY, Q.C.:

Q. Doctor, here, there are--as these were ER, generally I take it ER negative cases that were being retested to start?

DR. CARTER:

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A. Yes, again, but there would have been surrogate marker cases that would have arisen.

COFFEY, Q.C.:

Q. Was the conversion rate of these cases, again, about 50 percent?

DR. CARTER:

A. I think so. Again, I don't have my numbers with me.

COFFEY, Q.C.:

Q. We can actually--we can count them up, but in effect, by the end of July, had you had confirmed really what you had found in June and the first part of July?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, if we could, please, Exhibit P-1743? Doctor, this is your--this is an e-mail from Pat Wegrynowski of July 28th, 2005 to yourself, and this is just confirming, I take it, the arrangement that you referred to yesterday that had been made with her to come down and look at the lab.

DR. CARTER:

A. Um-hm.

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COFFEY, Q.C.:
Q. Doctor, you described yesterday what you eventually learned about the amount of documentation or lack thereof that the lab had, the technologists, technology side of the lab. As a pathologist, what--the time you learned, as you learned more about it, what was your reaction as a pathologist?
DR. CARTER:
A. To the fact that there was no documentation?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I mean, I wasn't happy that there was no documentation. I mean, it's a basic sort of tenet of laboratory life, actually increasingly becoming more of all health care that you document everything, but especially when you're doing laboratory testing and I don't just mean immunohistochemistry, but even if you get your blood taken, all of those machines, there's lots of documentation, lots of quality control.
COFFEY, Q.C.:
Q. Had you had any sense before this process that

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that was the state of affairs?
DR. CARTER:
A. I would have thought, I think, coming in that these things were basic laboratory practice.
COFFEY, Q.C.:
Q. So you had no inkling that this was the state of affairs before the middle of 2005?
DR. CARTER:
A. No, I certainly thought that the antibodies would have been validated before use. Standard operating procedures for maintenance, things like that. No, I would have thought that they were in place.
COFFEY, Q.C.:
Q. Exhibit P-0076, please? Doctor, this is a memo. It's styled to all pathologists, pathology residents in Department of Pathology, St. John's Hospitals, Eastern Health. It's from Dr. Cook and yourself. It's dated July 28th, 2005. It's re: optimal assessment and reporting of hormone receptor status in infiltrating carcinoma, and a space for Dr. Cook and your signatures. This is nine paragraphs, so numbered, and it begins by saying "when ordering and reporting ER/PR

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status in infiltrating carcinoma of the breast" and there is, in effect, a checklist, as it were.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. A how-to and a checklist relating to what to do in relation to ER/PR status for breast cancer. Doctor, why was this drafted?
DR. CARTER:
A. I think it's--can I see the date on it again, please?
COFFEY, Q.C.:
Q. Yes, it's July 28th.
DR. CARTER:
A. July 28th. By that time, and again, this memo was probably written or thought about a few days before the date there. I think by that time, we had looked at a significant number of slides or I had looked at a significant number of slides where I had identified that there were issues with it. Also, when we were sending it out, we were going to be over inclusive and ask for everything in a report, so if you go through them, you'll just see

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that we're giving sort of a step-by-step of what people should do.
COFFEY, Q.C.:
Q. So I take it was this motivated by--the drafting of this motivated by any concern that perhaps not everyone knew everything that they should know about it?
DR. CARTER:
A. I mean, I don't want to make definitive statements about the spreadsheets, because they haven't been rigorously studied and that sort of thing, but these were trends that we had seen, looking at those cases.
COFFEY, Q.C.:
Q. And I take it, if there was a lack or potential lack of knowledge by certain pathologists or pathology residents that this was meant to -
DR. CARTER:
A. Educate.
COFFEY, Q.C.:
Q. - remediate that, correct it?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:

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Q. Doctor, just go down through this briefly, "select a block that contains infiltrating carcinoma and normal and or benign breast epithelium," which is, I take it, the internal control issue?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. "When reporting, always check internal and external controls. The external positive control should show some variability of staining throughout the tissue selection." Doctor, what is that meant to address?

DR. CARTER:

A. The external positive control?

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. Statement No. 3?

COFFEY, Q.C.:

Q. And the variability, yes.

DR. CARTER:

A. Immunohistochemistry largely is a--is it present or is it absent type of testing, so if you're looking at a melanoma, as I mentioned

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earlier, you look is S100 present or absent, you're not looking at the amount of S100 that's present. With estrogen receptor, progesterone receptor and a couple of other immunohistochemistry stains, we do in a semi-quantitative analysis, so you're looking at it for its presence or absence, but also the degree to which it's present. So when you have a control tissue that you're essentially comparing your test against, you want to make sure that there was some variability throughout your tissue, however you go about picking your controls, so that patients on either end of the spectrum, the very strongly positive, which is not really a worry; that those that are weakly positive and/or negative will not be missed. So your control must show some variability.

COFFEY, Q.C.:

Q. Must show character--involve all of those characteristics in part of it weak positivity and then part of it moderate perhaps and strong.

DR. CARTER:

A. You would have a negative, a clearly positive

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and then you would have one that's somewhere between the two, but you would like to move down towards the 10 percent, but that's not always possible.

COFFEY, Q.C.:

Q. And that's if you have, for example, three separate controls. This relates to the external positive control should show some variability of staining throughout the tissue section.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So this presupposes one external control.

DR. CARTER:

A. Yes, so you could use a, like we saw in some of the previous ones, you could use a tumour that expresses at 40 percent with a very weakly staining, internal, native epithelium, something like that. It's easier just to use a sausage type, which is what you just described with the three tissue sections.

COFFEY, Q.C.:

Q. Here the negative, "external negative control, if made available should show no staining".

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Why would you say or did you say "if made available"?

DR. CARTER:

A. It was my practise prior to coming to St. John's is that external negative controls were read by the laboratory, they wouldn't come to the attention of the pathologist.

COFFEY, Q.C.:

Q. In St. John's at that point, in July, 2005, were there external negative controls being run at all do you know, in this context?

DR. CARTER:

A. I don't think that they were run at all.

COFFEY, Q.C.:

Q. Paragraph five, "Internal negative control, stroma, vascular, endothelium, should show no staining." So I take it the idea of an internal negative control with an ER/PR, there should be -

DR. CARTER:

A. So if you have a breast cancer around that, you'll have some supporting tissue, some blood vessels that feed the cancer, so you'd just have to make sure--those things are supposed to be negative for estrogen, so you'd just

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have to make sure that they are negative as well.

COFFEY, Q.C.:

Q. Paragraph six, "Internal breast epithelium should show some positivity, but not diffuse." What does that relate to?

DR. CARTER:

A. Again, if you're looking at benign or native breast epithelium, you should see some positivity in it. It's a very rare case where you would find that the internal breast epithelium would show a hundred percent positivity. If it does, then again you'd think about the degree of optimization of your antibody.

COFFEY, Q.C.:

Q. And you think about it and potentially question whether or not -

DR. CARTER:

A. Yes, potentially there would be a problem with it.

COFFEY, Q.C.:

Q. And paragraph 7, "If the external positive control is negative, the test is invalid." So I take it if the external positive control

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doesn't stain, you'd have a problem?

DR. CARTER:

A. Yes. So that would be an absolute statement there.

COFFEY, Q.C.:

Q. And you'd have to repeat it. "If the external negative control is positive, the test is invalid."

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Fair enough. In paragraph 9, Doctor, "If the internal control shows aberrant staining, the test may be invalid, please refer to Dr. Bev Carter." So, Doctor, what in this, could you elaborate please on paragraph 9?

DR. CARTER:

A. I had said earlier that the internal control should show some variability, i.e. (not diffuse), but you could have a case where somebody was a very high expressor of estrogen, either due to medication that they're taking or their age or just their estrogenic status, so it wouldn't necessarily, because your internal control is diffusely

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positive, it wouldn't necessarily mean that your test was invalid and conversely and more controversial, you may have an internal control that would be entirely negative.

COFFEY, Q.C.:

Q. Now what then, if you received such a phone call or for example you received a phone call or just yourself were analysing tissue, the external control did work, positive and negative controls if they were there did work, Doctor, stain or not stained, as appropriate, what would then be your approach with internal controls? Perhaps you could just take the Commissioner through that?

DR. CARTER:

A. Well if the internal control was negative, is that what we're saying?

COFFEY, Q.C.:

Q. Well first of all, we'll assume it's positive, it is working in the sense that the internal control, you expected to stain -

DR. CARTER:

A. Show some variability and it does.

COFFEY, Q.C.:

Q. And it stains appropriately and the external

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controls are working, what do you then do?

DR. CARTER:

A. I would report the test, I'm not sure I understand your question.

COFFEY, Q.C.:

Q. Okay, fair enough. So everything is working, is fine. If the internal control does not stain.

DR. CARTER:

A. So if the internal control is negative, then I would look at other things surrounding that idea, so -

COFFEY, Q.C.:

Q. What are the possible explanations?

DR. CARTER:

A. If you had a small portion of tissue that is an internal control, like one gland or two glands and it's negative, I mean just by chance you may have hit the one or two glands in that woman's breast that don't express any estrogen.

COFFEY, Q.C.:

Q. Okay, that's one possibility, what are the other possibilities? And what would you do if you came across an internal control that

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wasn't staining?
DR. CARTER:
A. Well I would look at other aspects of the testing process, so like you said, you'd look at your external controls. I would look a the tumour, so if my internal control was negative and tumour was positive, I would be fine, you know and if everything else had worked out. I would look at how much internal control is there, so if I have half a slide full of native epithelium and it's all negative, that's a problem. If I have one glad that's negative, I mean, then that would bear looking at.
COFFEY, Q.C.:
Q. Doctor, if the tumour stains negative and the internal control is negative?
DR. CARTER:
A. So again you're narrowing down the possibilities become, you know, more and more to when you wouldn't accept that it would -
COFFEY, Q.C.:
Q. So what then would be your approach? What is, from your perspective, the appropriate approach then?

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DR. CARTER:
A. The same sort of thing, hopefully the same sort of thing that you would look around and see other indicators that tell you that the test is good, you know, what was the run like, is this a high grade cancer in a young female, so you'd have other -
COFFEY, Q.C.:
Q. Look at the surrogate markers issue, examine that. Might you re-run the test at times?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Now, Doctor, we have as well, we've seen reference in some requisition forms, okay, there's a couple of notes where there is reference to external controls staining weakly and this was in the days when there was just one external control.
DR. CARTER:
A. Uh-hm.
COFFEY, Q.C.:
Q. What, if anything, would be the significance of an external control staining weakly?
DR. CARTER:

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

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

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COFFEY, Q.C.:
Q. Now, Doctor, do you know what these sheets were?
DR. CARTER:
A. I don't know for certain, but I think that these were the sheets that the lab assistants and technologists were using to identify cases.
COFFEY, Q.C.:
Q. Were you involved in these particular sheets themselves?
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. And the handwriting itself, I take it, is not yours?
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. Now, Doctor, I would ask you then to turn to--and Registrar, to turn to P-2477. And, Doctor, this is--do you recognize this document first of all?
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. And it's entitled "Breast Receptors" as we go through these sheets. What is this document?
DR. CARTER:
A. This was a chart that I used, it's a spreadsheet type format, but it wasn't an electronic spreadsheet that I think, again, Judy Thomas actually made the chart for me, where I was entering patients as they were being identified through the review or identified from oncologists and then I was filling in--do you want me to go through each one of the columns?
COFFEY, Q.C.:
Q. Yes, I'll be taking you through them, Doctor. Before I do, the handwriting here, "ER" just crossed out and then there's "ER/PRR". Doctor, just on that point because we sometimes see rather than just PR, PRR, what's that mean?
DR. CARTER:
A. I'm not certain but I think this is reference to a completely different thing. We were making up canned text, do you know of canned text, for the computer, so if you were reading

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an estrogen receptor and progesterone receptor case that was positive, you would tell the secretary to call up ER/PRR and if it was negative, you would ask them to call up, I think that says ER/PR -
COFFEY, Q.C.:
Q. ER/PR is negative -
DR. CARTER:
A. I think it's completely unrelated to what the spreadsheets are about, I think it's--Judy and I were working on canned text.
COFFEY, Q.C.:
Q. And for what purpose at that point, canned text?
DR. CARTER:
A. This would have been before we had decided to suspend the testing, but as we had recognized that there was a lot of variability in the type of testing, so we wanted to develop a stylized format or standardized report or canned text that a pathologist would use, because everybody is saying the same thing over and over again, the secretary has just entered it into the computer and can call it up as a canned text so they don't have to type

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the same thing over and over again, it would just come up. If you pressed ER/PR in a particular field, it would come up with all the common words there and they would just fill in the percentages, things that were subject to change.
COFFEY, Q.C.:
Q. And why I pursue that a bit more is this was being pursued by yourself and Judy -
DR. CARTER:
A. Sorry, Ms. Thomas is a secretary, so she would have been designing them.
COFFEY, Q.C.:
Q. Ms. Thomas, and this was in the summer of 2005, probably?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Before that then, such a canned text for these purposes did not exist, to your knowledge.
DR. CARTER:
A. To my knowledge, no.
COFFEY, Q.C.:
Q. Okay. Doctor then, if you could take us then across the column headings and describe what

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each of them relates to?
DR. CARTER:
A. Well the first three would be the patient's name, the surgical number and the MCP number, so they would just be unique identifiers for the patients and then you would have three there, so they're easy to cross-reference and make sure you're talking about the same patient. The next category would be tumour type and as I've explained earlier, that may be helpful as a surrogate marker to what you would expect. The tumour grade, we do grading of breast cancers according to Nottingham Grading System, where we look at different aspects of the tumour and it's been found loosely to be correlated with prognosis, but also it's been shown to be in association with estrogen receptor testing on a very loose basis, but lower grade tumours tend to be positive more often than higher grade tumours.
COFFEY, Q.C.:
Q. And the grading rums from what to what, Doctor?
DR. CARTER:
A. Just one, two or three. The block number then

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would be the block that the original test had been performed on, the original report, the estrogen receptor status and progesterone receptor status off of the report, say in 2002 or in 1999, controls on the original, I think here I was talking about external controls for the purposes of this column, then the repeat test and then a page--sorry, an area for comments, just anything that had come up, as I stated earlier, this was sort of a descriptive document and I think eventually I added in the date of the test and the name of the pathologist, if you look over at page 9, for example. So it was meant to be a fluid thing that was subject to change.
COFFEY, Q.C.:
Q. Looking at page 9 and you pointed out that the columns got added to, as time went on.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And you anticipated that really in the beginning that that would probably happen.
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. Now, Doctor, the information, looking back at page 1, the information to fill this in was coming from where? I take it the patient's name you would get from--where would you get the patient's name from?
DR. CARTER:
A. As far as I can remember in the beginning, Mr. Dyer and Mr. Gulliver were giving me the list of the patient's names.
COFFEY, Q.C.:
Q. So it was just a list of names?
DR. CARTER:
A. No, they would give me the report.
COFFEY, Q.C.:
Q. Okay, that's what I was getting at. So you have the pathology report -
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. - or reports, for that matter, for any one patient.
DR. CARTER:
A. I think some of the patients have two, yes.
COFFEY, Q.C.:

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Q. Identified by Mr. Dyer and Mr. Gulliver.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Were, you, yourself, involved in doing any searches of Meditec in relation to this?
DR. CARTER:
A. I would have asked for searches to be done, but I wouldn't have performed them, I don't think.
COFFEY, Q.C.:
Q. And the people in this context, your understanding was--who was actually performing the Meditec searches that you asked for?
DR. CARTER:
A. I think Mr. Dyer and Mr. Gulliver would be performing.
COFFEY, Q.C.:
Q. So if a pathology report says the source of information, usually.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. We have the patient's name and their MCP number would be on that report.

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DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And a surgical number.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Now here, looking at the surgical numbers, you've listed SS's, SG, I believe.
DR. CARTER:
A. Yes, SG.
COFFEY, Q.C.:
Q. SU and--that's in the main, the first two letters. What was the significance of those, if any?
DR. CARTER:
A. SS, for the most part, would refer to St. Clare's; SG would be the Grace; and SU would be the General Hospital.
COFFEY, Q.C.:
Q. And I take it at that point you were only looking at the St. John's cases?
DR. CARTER:
A. Yes, but I think there were some outside as well here.

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

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all the original pathology reports to do it.
DR. CARTER:
A. Perhaps they may have been metastases or another specimen with breast, they may have called it infiltrating carcinoma.
COFFEY, Q.C.:
Q. Without identifying it as ductal or lobular for example?
DR. CARTER:
A. Yes, but infiltrating carcinoma, that bear statement is interpreted as infiltrating ductal.
COFFEY, Q.C.:
Q. Ductal, okay, but again, the information for the tumour type, such as is listed here on these pages, you would have just simply have gleaned off the pathology report?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. This is not your analysis of the original slides?
DR. CARTER:
A. No.
COFFEY, Q.C.:

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Q. The tumour grade, again the information here is from the pathology reports?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. The original reports. It's not you making a determination.
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. Using the original slides yourself. The block number?
DR. CARTER:
A. When people are doing the gross description of the case, so sometimes they will say in it Block A has been sent for estrogen receptor, progesterone receptor testing. But often that was not included in the report which was why we eventually included it in our canned texts. Also there are internal comments on reports that are not available to the patient's chart, so the technologists when they enter into the computer what sort of procedure, so sometimes on that you can see Block A has been sent to Ken--Mr. Green for testing, so we picked it up

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that way.
COFFEY, Q.C.:
Q. That's what I'm getting at, how were you able to identify that, if it wasn't on the pathology reports?
DR. CARTER:
A. There's different kinds of pathology reports that you can get, so I would assume I got the type, I don't know what it's called, that would include the patient, the stuff that goes on the patient chart, all that information, but as well, portions of internal comments, lab kind of comments, when you can simply get a report that is just a diagnosis, you can get it--that doesn't include the diagnosis, so you can manipulate the computer many ways.
COFFEY, Q.C.:
Q. Meditec to give you different types of reports.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Any one of which might be called a pathology report, but might relate to different aspects of it.

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DR. CARTER:
A. Yes, I mean, we would call it the pathology report.
COFFEY, Q.C.:
Q. And so your observation at the time in reviewing the pathology report simpliciter, okay, I'll call it that, that very often the block numbers were not actually identified by the pathologist.
DR. CARTER:
A. That's correct.
COFFEY, Q.C.:
Q. Occasionally they were, but very often they weren't.
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. But there was a way, because of the type of print-out that you got, of you looking at this internal material.
DR. CARTER:
A. And sometimes it would be--I would suspect that most of the time I got the block number off of a slide when I got it.
COFFEY, Q.C.:

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Q. Okay.
DR. CARTER:
A. It wasn't a common practice for us to include that.
COFFEY, Q.C.:
Q. And I was going to ask you, the other way you could identify the block number was look a the slides.
DR. CARTER:
A. Simply when I got the slides, yes.
COFFEY, Q.C.:
Q. So I take it on the slide itself it would be identified by the surgical number and at times, the block number as well?
DR. CARTER:
A. All slides have their surgical number and their block number--well, they should, yes.
COFFEY, Q.C.:
Q. So in filling out the block number here, the sources were the pathology reports, simpliciter, the internal comments coming from Meditec you understand related to the technology end of the lab, and potentially and/or the actual slides, the original slides themselves. The original report, ER and PR

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

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black marker and then saw it would just cover up everything else.

COFFEY, Q.C.:

Q. Okay, and then there are some references here, we go down to more at the bottom of the page, on the first page, the third and fourth last entries under ER/PR are written in as "NEG", do you see that?

DR. CARTER:

A. They would be the same as the dash dash, the negative, negative.

COFFEY, Q.C.:

Q. Okay, so negative, negative and just a simple dash--a simple dash means negative in your world filling these out?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Now there are other entries here, I'll just, the second row on this page, "WK" would be weak, I take it or is it?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. "NEG" circled, one percent and then "WK 1 dash

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two percent 'N' circled." Could you just translate that for us, what that means?

DR. CARTER:

A. Weak one percent, which I would consider a negative; weak one to two percent and I would assume that the N with the circle around it would mean negative again.

COFFEY, Q.C.:

Q. And then we go down a bit further, I take it there's a, sixth row, "WK" would be weak, slash less than 5 percent?

DR. CARTER:

A. Yes, I think so.

COFFEY, Q.C.:

Q. Doctor, if I could--too far, I'm just going to go back. Page 2 of the exhibit, the third last--I'm sorry, here Doctor, on page two toward the bottom of the page, third last entry under "Original report E/R" and there's a positive sign, do you see that?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So why would that have been--it's an '02 case, why would that have been retested at that

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point, do you know or being looked at at the time?

DR. CARTER:

A. It would have ended up in the, somehow in the data sheets, I don't know why, I mean I'm looking at, it was called infiltrating ductal carcinoma, I'm not sure it was picked up in the group.

COFFEY, Q.C.:

Q. Doctor, anywhere and just looking further up the page here, the fourth entry under "PR" there's a positive.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. ER negative, PR positive. What would the positive in this context, a positive sign signify?

DR. CARTER:

A. Going by my usual practice, I would think it would be greater than 10 percent.

COFFEY, Q.C.:

Q. We go over then to, I'll going to go back to the first page, and again to give the Commissioner some sense of this, in repeat

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receptors, which I take it is the results of the Ventana retests at this point.

DR. CARTER:

A. It would have been a mixture, I think, of Ventana and Mount Sinai, I don't have dates on this.

COFFEY, Q.C.:

Q. And here, as we go down through the first page, there's a positive. Is there any significance to the circle?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. And there's some positive signs and then the third entry is negative negative here and if you go down the sixth row, has S/80 percent P, S/100 percent P, would that be strong positive 80 percent?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, go down a bit--I apologize, further down the first page, page 2, there we are, page 1, the fourth last entry, fourth last row, there's a negative and a negative

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under the ER and then a negative negative under the PR, do you see that?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. What would that signify?

DR. CARTER:

A. I don't remember. If you look back in block number, there's two blocks there, so I would presume that we tested two blocks.

COFFEY, Q.C.:

Q. Two blocks, okay. And then under the column section, just going to run down through some of the columns and perhaps you can expand--I'm sorry, some of the comments in the comment section. First of all, I'll back up, where you have no entry in the comment section, what, if anything, did that mean?

DR. CARTER:

A. It would have meant at the time that nothing really struck me as unique to that case or something that struck me that was there on a case I had already written it on another case.

COFFEY, Q.C.:

Q. And a third row on the first page, you've

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noted "good internal control".

DR. CARTER:

A. So there probably was, we're always searching for nice controls to use in the immunohistochemistry department.

COFFEY, Q.C.:

Q. Now here the original report had been negative negative and then on repeat it was negative negative.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So I take it this would not be a conversion?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. So the blue may not then signify a conversion, this blue highlight or whatever it did signify. You would agree, would you?

THE COMMISSIONER:

Q. Were the repeats always on the same block?

DR. CARTER:

A. No, they weren't always on the same block, they were if we could find that block easily, but if it wasn't available for whatever

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reason, we would select another block.

THE COMMISSIONER:

Q. Okay, thank you.

COFFEY, Q.C.:

Q. And here then on the fourth row you've written "review of original equals positive", what was that, Doctor?

DR. CARTER:

A. If you look at the chart, it says "negative negative".

COFFEY, Q.C.:

Q. Yes, for the original report, yes.

DR. CARTER:

A. And review of the original is that this case is in fact positive and so it's probably an error on my part, introducing the data into the table, so I mean, I'm guessing again, but maybe the surgical number was wrong or I read the report incorrectly.

COFFEY, Q.C.:

Q. So this is not one that, from your perspective, had been reported wrongly by the pathologist?

DR. CARTER:

A. Again, I don't know because this is, you know,

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very preliminary data entered by me, not rigorously controlled, not checked or whatever, so I'm just going on memory, but I would think because it hasn't been retested, that there is a data entry error on my part.

COFFEY, Q.C.:

Q. Because you've noted here there is no indication that it was actually retested.

DR. CARTER:

A. Yes, I'm just taking all these little facts and trying to come up with a plausible explanation.

COFFEY, Q.C.:

Q. And then here, Doctor, you've noted the next--in the fifth row, you've written in "skin specimen", why would you note that?

DR. CARTER:

A. There would probably be something on the slide that either showed skin or was a skin specimen or that I thought was interesting from an educational point of view.

COFFEY, Q.C.:

Q. And here, Doctor, the fifth row says "HSC SU7761-01" and you've got "XX" there and then you've got "HSC SU9323-01". Now the SS meant

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here -
DR. CARTER:
A. St. Clare's.
COFFEY, Q.C.:
Q. St. Clare's and the HSC SU would be, I take it the Health Sciences -
DR. CARTER:
A. Most likely, yes.
COFFEY, Q.C.:
Q. Surgical number, for the same surgical number, the corresponding one, I take it, here.
DR. CARTER:
A. 7761 corresponds to SS1148-01, I believe. So these probably would be two other specimens on that same patient that I noted for some reason.
COFFEY, Q.C.:
Q. And you've written, in the row below, "stain dirty."
DR. CARTER:
A. That's usually a lot of background staining, so often a lot of native things that can interfere with the test, endogenous peroxidases haven't been quenched off the slide.

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COFFEY, Q.C.:
Q. Would this comment be in relation to the retest slides or the original slides?
DR. CARTER:
A. I would think for the original slides. That's what I was commenting on. I think for the retest slides, I was just entering. But again, not rigorously examined.
COFFEY, Q.C.:
Q. Now here, for the fifth, sixth and seventh rows on this page, under controls on original, you've got a question mark.
DR. CARTER:
A. Oh, okay. Sorry, yes.
COFFEY, Q.C.:
Q. See those? What does that mean?
DR. CARTER:
A. That means that there was no control slide--there was no control tissue on the slides and I was not a--because sometimes they did the control on a separate slide and sometimes they put the control tissue exactly on the slide.
COFFEY, Q.C.:
Q. On the patient slide?
DR. CARTER:

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A. On the patient slide, thank you, yes. So this is I couldn't--there was no control slide and I couldn't find the external control.
COFFEY, Q.C.:
Q. Now here, as well, while we're on this particular row, I take it the first and second and fourth entry, fourth rows, where you've got a positive, controls on original, you've got--the first of them, you've noted "positive report only" positive meaning that there were external controls?
DR. CARTER:
A. I would think that that's what it means.
COFFEY, Q.C.:
Q. And then positive would--but it was in the report only. A positive without a reference to the report only, would that suggest that, in fact, you did see the external control slide for that particular surgical number, like these?
DR. CARTER:
A. I would think that the "report only" maybe refers to the fact that I couldn't get the original slides.
COFFEY, Q.C.:

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Q. And then a positive though, without any kind of qualification, probably meant you might have seen the -
DR. CARTER:
A. Probably.
COFFEY, Q.C.:
Q. Now there though, then we go down further, past that series of three question marks, you've written for the last five out of the last six rows, you've written "no".
DR. CARTER:
A. So there would be no control tissue on the patient slide.
COFFEY, Q.C.:
Q. And you didn't see the external control slides?
DR. CARTER:
A. I didn't see--I don't think I saw any external controls in this, for the purposes of this investigation.
COFFEY, Q.C.:
Q. Doctor, if we could go back then to the comments column, you've written under the row "stain dirty" you've written in the next row, "only"--is it "L lymph node with tumour"?

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DR. CARTER:
A. Yes, so this was not a breast case, but a metastases from the breast, I would assume. So there'd be no internal control with that tissue, by definition.
COFFEY, Q.C.:
Q. And then the next two rows, you've written in "internal control of ER negative." Is that a slash?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. PR positive?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Same thing again, so what did that mean in respect of these two surgical numbers?
DR. CARTER:
A. That when I looked at the original slides, at the patient's sample slide, the patient's report would have gone out as negative for estrogen receptor and negative for progesterone receptor and when I was looking around the slide, internal control was

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present, but when I looked at the estrogen receptor slide, the internal control was negative and when I looked at the progesterone receptor slide, the tumour was negative and the internal control showed appropriate staining.
COFFEY, Q.C.:
Q. So, just here, just on this point, the Commissioner follow this, perhaps we'll just deal with the ninth row one first, the first of these two right here. The surgical number here is SU647-02.
DR. CARTER:
A. Um-hm.
COFFEY, Q.C.:
Q. It's infiltrating ductal carcinoma, tumour grade three, block number C. The original report is negative. Dash, dash means negative, negative, ER and PR. You did not--there were no controls on the original, no external control tissue, and on repeat receptors, the ER and PR was negative in both instances?
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. Now here, Doctor, what, if anything, then would be the significance of finding--because on repeat, both that case and, in fact, the one below it, which is SU4741-02, they are not conversions?
DR. CARTER:
A. No, they're not.
COFFEY, Q.C.:
Q. At least at that time, they're both -
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. - originally negative and on repeats, negatives. What, if anything, is the significance of finding that the internal control for ER was negative and PR was positive?
DR. CARTER:
A. The significance for these cases?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I don't think there's a particular significance for these two, but there's a

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significance -
COFFEY, Q.C.:
Q. Overall.
DR. CARTER:
A. - in general, that you would want your internal controls to show some variable positivity.
COFFEY, Q.C.:
Q. And in fact, the PRs, it had shown it?
DR. CARTER:
A. So the PR was good internal control, what we would call good internal control, and the ER was not.
COFFEY, Q.C.:
Q. Doctor, were these cases that were originally examined, not only these but all of these, in fact, throughout that June, July process, were they ever retested in Mount Sinai overall, do you know?
DR. CARTER:
A. The ones that were retested?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. At the--on the Ventana system?

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COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I think so, but I'm not certain of that, but yes, I think so.
COFFEY, Q.C.:
Q. Now the next entry is, in the comments column, is "internal control adequate".
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Here, repeat receptors is noted not done. Do you know, at that point, why that hadn't been done up to that point?
DR. CARTER:
A. No, I have no specific recollection of it. I'm sure that it probably was going to be done as a part of the retrospective.
COFFEY, Q.C.:
Q. And just hadn't been redone up to that point on the Ventana?
DR. CARTER:
A. You know, and the other likelihood is that it was a perfect slide that would have no need for any kind of error or deficiency in it, but

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I don't know.
COFFEY, Q.C.:
Q. And you do note here, the internal controls--saying "internal control adequate" I take it that would be both controls in this context?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Internal control for ER negative PR weak, I take it that would fall into a similar category to these two above here, internal control negative PR positive, except that the PR is negative?
DR. CARTER:
A. It was faint, but it was there when you looked. It was there.
COFFEY, Q.C.:
Q. Now Doctor, on the second page, of these--and it is a form of a spreadsheet, the third row, you've written "fixation terrible." What is--it's negative and then positive on--are you able to pick that out?
DR. CARTER:
A. RPT, I would assume I mean repeat.
COFFEY, Q.C.:

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Q. On repeat, okay. Now in saying "fixation terrible" I take it you would be looking at the original slides?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. A particular--well, the slide made from Block G I presume?
DR. CARTER:
A. Yes. Two blocks were tested, so maybe the first time it was negative/negative, the second time negative/positive in Block E, but again, I'm not certain.
COFFEY, Q.C.:
Q. E and G, I take it G, the "fixation terrible" you're referring to Block G?
DR. CARTER:
A. That's what it seems to be what I'm doing on this.
COFFEY, Q.C.:
Q. Doctor, if we look down then through the comments sections here, you got "internal control negative." Now that would signify that there was an internal control but it had controls but they had stained negatively?

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DR. CARTER:
A. On my first look through, yes.
COFFEY, Q.C.:
Q. And ER weakly positive, would that be a comment in relation to the control, internal control tissue or overall ER?
DR. CARTER:
A. I think it would be comment on overall, if you look under the original, ER, I've got down weak.
COFFEY, Q.C.:
Q. Yes, and then you got "internal control negative. ER/PR missing, reported negative."
DR. CARTER:
A. So I wouldn't have been able to have access to the slides.
COFFEY, Q.C.:
Q. And then "internal controls negative." Negative, now, and then there's a--the style becomes negative sign circled, internal control.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. So I take it that means the internal control

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is there, it's negative, or there's -
DR. CARTER:
A. It could be either or actually.
COFFEY, Q.C.:
Q. Or no internal control?
DR. CARTER:
A. Yeah, it could be either or. Generally, I think it would mean negative internal control.
COFFEY, Q.C.:
Q. I apologize, Doctor, just this is very sensitive there now. Okay, the third row, third last row on the second page, you've got "invasive micropapillary"?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Why would you note that, Doctor?
DR. CARTER:
A. It's a very rare, relatively rare type of tumour. I was probably making a note there that I would show it to the residents.
COFFEY, Q.C.:
Q. And then below that, there's a reference to METS?

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DR. CARTER:
A. So it would be metastases. I don't know if this was a metastases or the patient had metastases.
COFFEY, Q.C.:
Q. Now Doctor, in the course of doing this work, you were looking at the original slides, the original pathology reports, you were noting the repeat receptors results. You were getting those results from where?
DR. CARTER:
A. From Ventana.
COFFEY, Q.C.:
Q. From the Ventana machine.
DR. CARTER:
A. And from Mount Sinai, depending on when it happened, around when we shut off the machine.
COFFEY, Q.C.:
Q. So as they were coming--as the repeat testing was being done on the Ventana machine and -
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. - became available, you would make a note of it?

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DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And some of the time, I take it that it would be you actually doing the analysis yourself or were you doing, in fact, at this point, all of the analysis of the repeats on the Ventana?
DR. CARTER:
A. The actual reading of them?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. Probably Dr. Cook and Dr. Naghibi, but largely me.
COFFEY, Q.C.:
Q. Now here, on the third page, in the first row, you've written "not working" and the ER and PR is--there's a figure there, but it's scratched out. Do you recall -
DR. CARTER:
A. I would assume that I'm referring to the internal control not working. These would all be done on different days, different times of day. This was all being squeezed in with my regular work. So sometimes I would say

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

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"done on MET, not done on original." I believe that says "not done on original." What is the second row entry?

DR. CARTER:

A. The second row entry?

COFFEY, Q.C.:

Q. Yes, this one here, page four.

DR. CARTER:

A. Oh, skin.

COFFEY, Q.C.:

Q. Skin, oh, I apologize. It's skin, okay. And so the next entry in the comments column below that, "ER internal controls not working."

DR. CARTER:

A. Correct.

COFFEY, Q.C.:

Q. Okay. Which is, in effect, the same as negative?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So Doctor, go down through the fifth page, there are a number of entries for internal controls negative. So in a number of these instances, I take it, Doctor, what you are

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seeing on the original slides was that there was internal--there was normal tissue there that could have been used as an internal control. It just hadn't stained?

DR. CARTER:

A. For the most part, I would assume that that's what I meant, yes.

COFFEY, Q.C.:

Q. And it hadn't stained though, from what you could see?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Occasionally, Doctor, we go on to the sixth page, there's a reference, third last row, to slides lost. So I take it occasionally then the original slides were not available?

DR. CARTER:

A. That's correct.

COFFEY, Q.C.:

Q. Because above that, you've written, in the fifth last row, "no slides." You've got a question mark.

DR. CARTER:

A. And then Dr. Wadhwa's name is after it, her

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first name, and I'm not sure what I'm referring to there.

COFFEY, Q.C.:

Q. We go on to the page seven, again there are a number of entries for internal controls negative, and then when you would write in, for example, in these first two rows here, on page seven, "internal control negative" and you got a slash WK, weak, would that signify that the ER was negative and the PR was weak? Is that the sort of -

DR. CARTER:

A. That may be what it referred to or that it was so weak that I would have called it negative, so either or.

COFFEY, Q.C.:

Q. In the main here, Doctor, you are concentrating of ER or PR or were you concentrating on either, you're just making observations on both, in this process?

DR. CARTER:

A. We were looking at both, but you know, I tend to think of estrogen receptor status as the most important, so more emphasis would definitely be placed on that test.

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COFFEY, Q.C.:

Q. Page eight, there are a number of entries again for negative control or negative internal control, or you've got written in INT, which I take it is internal control negative?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Okay. Page ten, again some entries for internal control negative, and then page 11, again a number of entries. In the comments column, you said "internal control negative" or the mathematical sign, in fact, circle with a slash through it.

DR. CARTER:

A. I would think that that would be my way of saying that there was no internal control on that slide.

COFFEY, Q.C.:

Q. No internal control, okay.

DR. CARTER:

A. But I can't be certain that some of the ones that say negative internal control don't mean that as well.

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COFFEY, Q.C.:
Q. Yes. This page is a good example of it. You've got internal control negative a number of times, written, internal control and a negative sign with a circle around it, and then a number of other instances, you've got the symbol for it. In fact, it is no.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. The mathematical symbol.
DR. CARTER:
A. So I would assume I used both things reliably throughout, but I can't guarantee that.
COFFEY, Q.C.:
Q. And here, the second row is this mark, and by that circle with a slash through it, you mean no?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And so if indeed that's what you meant at the time, there would be no internal control. Same thing appears in the fifth row, the seventh and eighth rows.

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DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And then, Doctor, we come to page 12 and where there are names, surgical numbers and MCP numbers, and of course, the names and MCP numbers here are redacted, but and then they go on, there's a page 13, page 14, page 15, 16, 17, and it ends on page 18 with two entries and there's no data though other than in those three columns, names, surgical number and MCP number.
DR. CARTER:
A. Um-hm.
COFFEY, Q.C.:
Q. Do you recall why that was?
DR. CARTER:
A. I think these would be cases then that Judy Quinlan was identifying through whatever information she had been given, and placing them at least initially into the--it's not really a spreadsheet, but that's what we're calling it, but it's not an electronic spreadsheet, into the table for me because a considerable amount of my time was being taken up with clerical sort of duties.

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COFFEY, Q.C.:
Q. Now Doctor, these documents that we've just looked at, what, if any, records did you make during June and July of 2005 concerning your work on your examination that you set out on? Does this summarize your work?
DR. CARTER:
A. Yes, it does summarize my work, but I've tried to make the point to the Commissioner that this is my data entry and my writing and I think you can take the general concepts that I'm saying from it, but the specifics of it, none of this has been--you know, the data entry has not been verified by a second person, things that you would do before you presented something as being absolute fact. But I think trends are fine to take from it.
COFFEY, Q.C.:
Q. And Doctor, your comment about--earlier to the Commissioner about your observations about either an absence of internal control tissue on the original slides or internal control tissue was there, it just wasn't stained appropriately from your perspective?

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DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. This is reflected here in this material, isn't it?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, were there some patients for whom there were, in fact, two surgical numbers? Would there have been some patients, do you think?
DR. CARTER:
A. Two or more, yes. Most people would undergo several procedures as part of their treatment.
COFFEY, Q.C.:
Q. And a reference to--let's go to--just go back a bit here. The first entry here on page four, under comments, "done on MET, not done on original." Why would that be, Doctor? I take it that--I'd suggest that the ER/PR test was done on the metastases, but had not been done on the original?
DR. CARTER:
A. Or it may suggest that the repeat receptors

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were done on metastases, not on the original, because we couldn't find the original blocks. It may have been sent outside.

COFFEY, Q.C.:

Q. Doctor, as you were doing or going through this process in June and July, you would have finished this--first, I should ask you, this process, you had finished this by when, what we've seen here?

DR. CARTER:

A. I hadn't finished anything at all.

COFFEY, Q.C.:

Q. No, I appreciate that.

DR. CARTER:

A. I stopped this on August the 2nd

COFFEY, Q.C.:

Q. That's what I'm getting at. So August -

DR. CARTER:

A. I stopped this on August the 2nd.

COFFEY, Q.C.:

Q. - as of August 2, anything that we see reflected here, any work, this is what I'm trying to ask you, any work that we see reflected here had occurred on or before August 2?

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DR. CARTER:

A. I would say that that's true, yes.

COFFEY, Q.C.:

Q. Doctor, your observations and your thoughts at the time, were you communicating them to anyone?

DR. CARTER:

A. I would have been communicating them to Dr. Cook.

COFFEY, Q.C.:

Q. And what you were seeing, were at times you showing him the slides?

DR. CARTER:

A. I think that we did look at some slides together.

COFFEY, Q.C.:

Q. Did you communicate your observations to anyone else?

DR. CARTER:

A. Not in any official manner, but I don't think either that, you know, we were keeping quiet about it. So I think that we would -

COFFEY, Q.C.:

Q. Within the office certainly, around the building, within the pathology office at St.

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Clare's, you wouldn't--you're saying, you wouldn't say to the Commissioner that "I didn't tell anybody. I might very well have spoken to other doctors about it."

DR. CARTER:

A. Yeah, and I think everybody knew that there was something going on, and everybody had little pieces of information about it.

COFFEY, Q.C.:

Q. And if they asked you something about it, one of your colleagues?

DR. CARTER:

A. I would answer.

COFFEY, Q.C.:

Q. Doctor, do you recall how many then cases you looked at?

DR. CARTER:

A. I think I counted them up on the weekend. I think there's 97, but I'm not sure. My figures are at home.

COFFEY, Q.C.:

Q. And you used what to count? Was it this sheet here, these sheets?

DR. CARTER:

A. Yes, I didn't use the patient name or

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anything. I used--did it on, I think, the redacted sheets.

COFFEY, Q.C.:

Q. Doctor, were there--there would have been then, I take it, patients for whom there'd be more than one surgical number, and you've referred to that.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. There might be two or three in fact.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Were there any patients you came across that had had repeat ER/PR testing done before 2005?

DR. CARTER:

A. I think so, yes.

COFFEY, Q.C.:

Q. And do you recall--and repeat on the same surgical number, is what I'm -

DR. CARTER:

A. Yes, so I would have seen cases, just say, September 1st, 2002, a few cases, September 1st, 2002, and then repeated again on

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

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

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Commissioner, in your review, you came across one or two cases where that was so?
DR. CARTER:
A. You have to--I think I have a fair memory of one case, and there's probably a few more, but it's not a common finding.
COFFEY, Q.C.:
Q. Do you recall how much that case had changed on retest?
DR. CARTER:
A. It was significant. I mean, I think it had gone from weakly positive to positive, but I feel uncomfortable commenting on it if I don't have the case in front of me.
COFFEY, Q.C.:
Q. And in light of what happened in 2005, would that have been considered, applying the 2005 process, would that have been considered a conversion at the time?
DR. CARTER:
A. Again, I would have to see the case. If it was -
COFFEY, Q.C.:
Q. If you went from five percent to -
DR. CARTER:

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A. To 80.
COFFEY, Q.C.:
Q. - to 80 percent.
DR. CARTER:
A. Yeah, then that would be conversion.
COFFEY, Q.C.:
Q. Conversion. So there may have been at least one or two instances that you saw that, looking back on it, from the vantage point of 2005, had converted in the earlier years, at some point, on the DAKO, it had converted?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Up to that point, had you ever heard that or been--like within your, within Eastern Health, while you were working there, that there had been such cases in the past, rarely, but there had been?
DR. CARTER:
A. As a specific, no.
COFFEY, Q.C.:
Q. Well, as a non-specific?
DR. CARTER:
A. Well, as I explained earlier, I think many of

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us have had experiences where we've ordered retesting on a case, for a variety of reasons. So I would have known that retesting was going on, but I wouldn't have known that retesting that was of significance to the clinical management of the patient had gone on.

COFFEY, Q.C.:

Q. Your observation about that one -

THE COMMISSIONER:

Q. Mr. Coffey?

COFFEY, Q.C.:

Q. Sure, Commissioner.

THE COMMISSIONER:

Q. Is what you're talking about, retesting in that sense, a kind of thing that I would think of as the normal part of what a pathologist does in the sense of when you get a slides, you say to yourself "there's something about this that I don't trust and want it done again before I give an opinion"?

DR. CARTER:

A. Yes.

THE COMMISSIONER:

Q. And are there other kinds of occasions when you might want to go back and order a retest

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after you've given an opinion?

DR. CARTER:

A. Yes. If I gave an opinion on a case and the clinician thought that that wasn't congruent with what they thought about the patient, they may request or discuss with you and you may decide that you're going to request the retest. You could bring it to your colleagues and, you know, show it to them, sign it out because, you know, you feel confident with your diagnosis and then show it to your colleagues and your colleagues say "no, I'm not really happy with that. Just retest it."

THE COMMISSIONER:

Q. Okay, thank you.

COFFEY, Q.C.:

Q. Doctor, did you bring that -- at least one or two instances that you did come across, did you bring that to Dr. Cook's attention?

DR. CARTER:

A. I don't think so, no.

COFFEY, Q.C.:

Q. Can you tell the Commissioner did you bring it to anyone else's attention?

DR. CARTER:

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A. I don't think so, no. I would have thought that it was handled when it had happened.

COFFEY, Q.C.:

Q. Doctor, that sort of instance in terms of the overall retesting that eventually occurred through Mount Sinai, were those cases retested?

DR. CARTER:

A. I'm sorry, I don't understand your question.

COFFEY, Q.C.:

Q. In the case of the one or two instances that you came across that had been conversions that you saw in the reports --

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Using -- for example, using the DAKO, or around the time of the Ventana switch over, for example, again I don't know, but say the DAKO, we'll just assume it was retested on the DAKO years ago, and upon retest the result was clinically different -- significantly different, do you know if those particular cases were retested at Mount Sinai?

DR. CARTER:

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A. I have no knowledge of how they selected cases for retest outside of the cases that I was involved in.

COFFEY, Q.C.:

Q. So the Mount Sinai --

DR. CARTER:

A. I don't know what they used for their selection criteria for that.

COFFEY, Q.C.:

Q. Doctor, if we could, please, Exhibit P-0539. Doctor, these are handwritten notes of the meeting of August -- relating to the meeting of August 1st, 2005, and the source of them is VP Medical, which would be Dr. Williams. On page three, and you won't see those actually in the book there, Doctor, just a couple of -- you recounted your recollection of the meeting itself yesterday, but in the typed version he's noted here, August 1, 2005, and he attributes comments or certain comments under these bullets to certain individuals. Here there's a reference from Dr. Cook, "Eleven cases sent to Mount Sinai, negative and variable positives. Some areas of disagreement. One case, 10 percent positive

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came back negative. Some minor variations". So I take it that would be that one instance you referred to?

DR. CARTER:

A. As the false positive, but this is the first time that I've seen this.

COFFEY, Q.C.:

Q. Oh, yes, these notes, yes, I appreciate that. Would that have come up, do you think, during the August 1st meeting, like, the fact that there was a problem, potential problem with the Ventana? Perhaps I'll just let you look down through this first. There's certain comments attributed to you.

DR. CARTER:

A. But this is not the August 1st meeting that I talked about, the big meeting, I don't think. I think this is an earlier meeting in the day.

COFFEY, Q.C.:

Q. Oh, okay, this is an earlier meeting in the day. Okay, a smaller -- and so how many meetings of August 1 do you recall attending?

DR. CARTER:

A. I mean, I would need to look at this again, but I think this was just a small meeting in

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Dr. Williams office where we discussed the cases, I think, that this is about that went up for quality control, and then there was the August 1st administrative meeting that was later in the afternoon.

COFFEY, Q.C.:

Q. So a smaller group of, in fact, doctors had met earlier in the day; yourself, Dr. McCarthy, and Dr. Cook, and Dr. Williams, I presume. These are his notes.

DR. CARTER:

A. And I would have to look at them.

COFFEY, Q.C.:

Q. But your recollection is that there were separate meetings amongst a smaller group of you outside of the administrative group?

DR. CARTER:

A. On August 1st?

COFFEY, Q.C.:

Q. Or before that?

DR. CARTER:

A. Yes, sometimes -- I mean, there would be different meetings with lots of people.

COFFEY, Q.C.:

Q. So, Doctor, looking at this, amongst the

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

DR. CARTER:

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A. I'm not sure what it is that I am referring to there.

COFFEY, Q.C.:

Q. Was there known variability in the results over the years locally?

DR. CARTER:

A. But in the results of what?

COFFEY, Q.C.:

Q. Well, presumably the ER/PR in this context?

DR. CARTER:

A. That there's variable results for ER/PR?

COFFEY, Q.C.:

Q. Known variability in the results over the years?

DR. CARTER:

A. I'm not sure what that is in reference to. People would know that ER shows variable results from patient to patient, people would know that there are false negatives, false positives, built in. I'm not sure what that sentence is about.

COFFEY, Q.C.:

Q. And then there's a remark attributed to you, "Tumour Board discussion, talked about issue which has been found". Do you recall what

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that was about?
DR. CARTER:
A. No, I don't.
COFFEY, Q.C.:
Q. And, "The memory of this case back when the patient was lobular cancer carcinoma tested negative", I take it that would be a reference at least indirectly to Peggy Deane?
DR. CARTER:
A. I would think so.
COFFEY, Q.C.:
Q. And "June to November, 2002, follow up that year and no positive reports", what was that about, Doctor?
DR. CARTER:
A. Again I'm not sure what the context of this is, but when I have been looking at stacks of papers that had come to me, eventually I was getting stacks of positive and negative -- you know, all of the ER/PR cases, not just the negatives, it had switched to getting those, and I was looking through them to try to find the negatives and I came across a period where there had been no positive results come out of one of the hospital sites in St. John's for a

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period of time. I guess it was June to November.
COFFEY, Q.C.:
Q. Do you recall which hospital site that was?
DR. CARTER:
A. Health Science Centre, and this is again a very quick review. This is not to be taken as fact, this is myself searching quickly through a pile of papers.
COFFEY, Q.C.:
Q. I take it this was an observation of yours at the time and you were querying it?
DR. CARTER:
A. Yes, that there was a significant period of time where everything seemed to be negative.
COFFEY, Q.C.:
Q. Doctor, just so the Commissioner can get some sense of this, as between the General Hospital and St. Clare's, who was doing the bulk of the breast surgery?
DR. CARTER:
A. In 2005?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:

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A. St. Clare's.
COFFEY, Q.C.:
Q. And bearing in mind that while you did examine the 2001 ones, for example, we know that, who had been doing the bulk of it in 2002?
DR. CARTER:
A. I think it was more equal, but I didn't look at that, but I think over time people have switched to St. Clare's -- surgeons have switched to St. Clare's because the mammographic facilities, things that they may require during surgery are located there, and probably just through attrition of surgeons.
COFFEY, Q.C.:
Q. And when you arrived your first year, the summer of '03 at St. Clare's, approximately how many breast surgeries was St. Clare's doing annually, do you know?
DR. CARTER:
A. In '03, I was at the Health Science Centre.
COFFEY, Q.C.:
Q. Yes, I apologize, yes, because you showed up in August of '03.
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. In August of '04?
DR. CARTER:
A. I can give you sort of the statistics that I give out to everybody. I mean, there's about 300 cases of breast -- there's 300 patients with breast cancer diagnosed in Newfoundland every year based on population statistics. About 200 of those 300 would be seen in the St. John's area, and probably about two-third to three-quarters of those would be seen at St. Clare's.
COFFEY, Q.C.:
Q. Those statistics reflect what time frame, what particular year or years?
DR. CARTER:
A. I mean, when I came here, I asked because there was some question of what site I was going to work at. So I would have asked people at the Cancer Centre, that's a ball park of what's going on.
COFFEY, Q.C.:
Q. I take it then that that at least somewhat had some influence on you arrival at St. Clare's?
DR. CARTER:

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A. I mean, it was largely determined by where the vacancy existed, but, you know, I'm sure I could have managed to switch from one site to the other if I thought it was needed.

COFFEY, Q.C.:

Q. Doctor, here it goes on to say or note that you reported here or said here, "The 16 of 25 conversions have been reported", which is consistent with that June 29th letter. "Dr. Kwan notified, Dr. Boone notified". Why would there be a reference to them here?

DR. CARTER:

A. Again I don't know -- I don't know -- it's the first time I've seen this. Maybe the two -- remember that Dr. McCarthy had sent back two cases and said that we don't know who these are, so maybe we tracked them down and those surgeons were at least the person who performed the initial surgery. So it may have some contact, but -- I'm doing a little bit of guessing here.

COFFEY, Q.C.:

Q. And, "Ten have been notified by NCTR", that's ten of what?

DR. CARTER:

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A. I think that's NCTRF, probably the old name for the Cancer Centre.

COFFEY, Q.C.:

Q. "Ten have been notified".

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Notified of the what, change in results?

DR. CARTER:

A. I would assume so, but again I'm guessing.

COFFEY, Q.C.:

Q. And, "Four already on appropriate treatment". The fact that ten have been notified and four were already on appropriate treatment, if you did indeed report that --

DR. CARTER:

A. I don't know how I would have known that.

COFFEY, Q.C.:

Q. The only place you'd find that out from is from --

DR. CARTER:

A. From an oncologist.

COFFEY, Q.C.:

Q. Oncologist. So if indeed it came from you, then, in fact, it was only --

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DR. CARTER:

A. Hearsay.

COFFEY, Q.C.:

Q. Hearsay from Dr. McCarthy, and it may have even been, in fact, Dr. McCarthy's comments for all we know here because she's at this meeting too.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor -- bring up, please, Exhibit P-0079. I'm going to ask you about a comment here. On the second page, you conclude by saying, "I regret not being able to participate fully in this process, but I'm very uncomfortable placing my professional licensure in the forefront of this operation and risking my reputation, etc, as an expert in breast pathology". Doctor, at the time, you know, coming out of that August 1st meeting and going into August 2nd, what was your concern overall about the direction this was taking and who was in -- who was in control?

DR. CARTER:

A. I think my largest concern was with the

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management structure that we had in the lab, that this was, I mean, a fairly serious issue, and a lot of the decisions that were being made were being made by the management team in the lab, which I felt at that meeting had demonstrated that they didn't have a lot of in depth knowledge of the issues that were at hand, and I thought that this investigation could go down some wrong paths.

COFFEY, Q.C.:

Q. Doctor, had there been anything said at the August 1st meeting in relation to this, attributing the reasons for the conversion from DAKO to the Ventana switch over? You recall you told the Commissioner about that yesterday that the press release or --

DR. CARTER:

A. The big meeting?

COFFEY, Q.C.:

Q. The big meeting.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. The written document, whether it was a memo or a press release or whatever, that the --

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DR. CARTER:
A. I think it was some sort of release because there was some discussion about they were, you know -- this was ready to go.
COFFEY, Q.C.:
Q. Was there anything said at the meeting that led you to believe or conclude or understand that that was, in fact, the way that they intended to go, despite your observations that you couldn't attribute this to just a change from one piece of machinery to the other?
DR. CARTER:
A. After I left the meeting that they were going to continue to --
COFFEY, Q.C.:
Q. No, by the time you left the meeting?
DR. CARTER:
A. I would have thought that they were going to abandon that idea.
COFFEY, Q.C.:
Q. Okay, that was your --
DR. CARTER:
A. That was my understanding.
COFFEY, Q.C.:
Q. Based upon what?

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

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

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A. There was a high degree of agreement. There was one case that I can think of that was called positive that I felt was negative, but other than that, I don't recall it standing out as a large issue.
COFFEY, Q.C.:
Q. And you attributed that particular case to what, the difference in view?
DR. CARTER:
A. There was a lot of background staining on that case that was interpreted --
COFFEY, Q.C.:
Q. It was interpreted as nuclear staining, and in your view it wasn't nuclear staining, it was simply background?
DR. CARTER:
A. Non-specific cytoplasmic staining.
COFFEY, Q.C.:
Q. Doctor, what about the internal controls issue in terms of your observations of those slides, the original slides? Did you think any of them should have been reported at all in 2002? I mean, looking at those 90 odd, we just looked at them now, should they have been reported, bearing in mind the total number of

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them that there were either no internal controls or internal controls did not stain?

DR. CARTER:

A. That's a very difficult question to answer. If you saw one slide in the condition that we've discussed with no internal control or negative internal controls, poor fixation, within 200 other slides that were, you know, quite adequate -- if I had seen them all in a row, as I did this time, then it's very easy to spot trends.

COFFEY, Q.C.:

Q. And to say, no, it shouldn't have been reported?

DR. CARTER:

A. Yes, then you wouldn't report it, but if I had seen that in isolated case, and I'm sure that I have because i think that I'm in that group -- I'm not sure specifics of my case, but, yes, I think I would have reported it as an isolated event, but not if I had seen it over and over, you know, in time.

COFFEY, Q.C.:

Q. And, Doctor, harking back to, Doctor, the September 1st, 2004 minutes of a meeting where

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Dr. Fontaine is reported to have said that he understood that you wanted to look at all the ER/PR HER2/neu slides in St. John's --

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. If someone, not yourself because you weren't here at the time, but if someone had done that back in 2000 or 2001, and all the slides were going through one or two individuals?

DR. CARTER:

A. It would have been more likely that they would have seen that.

COFFEY, Q.C.:

Q. If they were aware to look for internal controls?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And to see that they were stained appropriately, they would have been aware that the internal controls are not staining --

DR. CARTER:

A. Yes, in my opinion.

COFFEY, Q.C.:

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Q. At times they were not staining more frequently than should be accepted?

DR. CARTER:

A. In my opinion, yes, they probably would have.

COFFEY, Q.C.:

Q. Doctor, the -- when you arrived in St. John's, I want to ask you about external controls first, your understanding. Were you seeing external control slides?

DR. CARTER:

A. When I first arrived as a locum at the Health Sciences Centre, I think at that point they were still doing external controls that were being reported separately, and I wouldn't have seen those, I wouldn't have been included in the roster of people who would --

COFFEY, Q.C.:

Q. Examine them.

DR. CARTER:

A. Examine them, because my presence was unreliable, I was in and out, covering people for vacation. I think when I started work in August of -- sorry, yes, August of 2004, I think that they were on the slide by that point. I think the transition had been made.

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COFFEY, Q.C.:

Q. And in the earlier time when you were kind of substituting for people doing the locums --

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. If you reported an ER/PR case at the time, would you have asked to see the external control slide?

DR. CARTER:

A. No, we would have -- I would have assumed that the process had been followed and that the controls were appropriate.

COFFEY, Q.C.:

Q. Being read by another pathologist?

DR. CARTER:

A. Yes, and appropriately reported.

COFFEY, Q.C.:

Q. And that would -- so your understanding when you arrived to do locums in August of '03, even though you were at the Health Sciences Centre because that's where you went initially, was that the external control slides for ER/PR were being read by some other pathologist and reported as being

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appropriately stained?
DR. CARTER:
A. Yes, and it switched somewhere in that first year to having the slide -- control slide on the patient slide.
COFFEY, Q.C.:
Q. But when you first arrived, your understanding is you wouldn't go looking for the external control slide, even in August, 2003?
DR. CARTER:
A. No, if I wasn't provided with it, then the assumption was that it was being read.
COFFEY, Q.C.:
Q. And that was, for yourself, even being at the Health Sciences Centre?
DR. CARTER:
A. Yes. If you had --
COMMISSIONER:
Q. Mr. Coffey, when it's convenient -- sorry, I didn't mean to interrupt you, Dr. Carter. Carry on.
DR. CARTER:
A. That's okay. I mean, if you had difficulty with your case or questions, you could ask for the external control, but I don't recall doing

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

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

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A. And QI, and I'm not sure who was from what area.
COFFEY, Q.C.:
Q. Doctor, on another note to assist you -- perhaps before I leave this, I did want to ask you something. You had a concern about this purported press release or whatever it was, whatever one would wanted to term it, being utilized. Did anyone else express any concerns about it being utilized that you recall at the meeting? I take it, you weren't concerned about the idea of a press release, you were concerned about the content?
DR. CARTER:
A. The contents -- that's what you're asking me, what anyone else said about the contents?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I don't -- I don't think so.
COFFEY, Q.C.:
Q. And I'm not suggesting they did. I'm just kind of asking --
DR. CARTER:
A. I don't think so.

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COFFEY, Q.C.:
Q. Support on your side, as it were, that's what I'm --
DR. CARTER:
A. No, I think as the discussion ensued, then, you know, people were expressing concerns, but I think I was the person who expressed it initially.
COFFEY, Q.C.:
Q. And as you explained your approach and your reservations, others took part in the discussion then?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And by the end of it, your understanding was that they had accepted your view in that regard?
DR. CARTER:
A. That was my understanding.
COFFEY, Q.C.:
Q. Doctor, did anyone, do you recall, express any reservations that you recall at that meeting to the idea of informing the public at large, not as to what they would be informed, but

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informing them about the problem?
DR. CARTER:
A. The discussion that I remember that went around that because that's when I was involved in that sort of thing, was I don't think there was a reluctance to inform the patients. I'm not sure about the public, but there was not reluctance to disclose to them, but to know your facts before you disclose. That was kind of the thing.
COFFEY, Q.C.:
Q. Who was expressing that?
DR. CARTER:
A. I was expressing that before they disclose to people, they should know what it is that they are disclosing. Other people in the room would have had other opinions.
COFFEY, Q.C.:
Q. Do you recall who expressed them and what?
DR. CARTER:
A. I don't remember it being a big part of the conversation.
COFFEY, Q.C.:
Q. Okay.
DR. CARTER:

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A. That we were there, but I know that Mr. Tilley was saying that he wanted some info and he wanted it in a timely fashion, or hurry up and get some ideas, and I remember that was one of my comments.
COFFEY, Q.C.:
Q. And what do they need to know?
DR. CARTER:
A. Well, they need to know that it's not technology that's causing the problem. That was my issue, that they didn't know what it was that they were going to release, so to stand up and say that we have a problem, you need to have a little bit more information than that before you start to tell people.
COFFEY, Q.C.:
Q. How much more did you think was necessary?
DR. CARTER:
A. I've never really thought about it.
COFFEY, Q.C.:
Q. For example, like, from the patient's perspective, you know, if a patient's tissue sample was being retested or it was going to be retested -- I appreciate if it had been retested, you understood that they should be

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told the result.
DR. CARTER:
A. Yes, they should be told the result.
COFFEY, Q.C.:
Q. How about being told that they were being retested?
DR. CARTER:
A. I mean, this is not my area of expertise, disclosure ethics, those sorts of things. If a decision -- if a sound scientific decision had been made that, yes, there was an issue here and we were going to retest.
COFFEY, Q.C.:
Q. And I take it by August 1st, that decision had been made, we are going to retest?
DR. CARTER:
A. Not that we were going to retest everyone retrospectively. I mean, we were certainly heading in that direction, but we were still, I think, working on a subset of patients to see if we could outline the problem a little more clearly.
COFFEY, Q.C.:
Q. So up to the time that you left or resigned on August 2nd --

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DR. CARTER:
A. Yes, I think shortly after that they decided to do just a large retrospective analysis of everybody, but we were certainly heading in that direction.
COFFEY, Q.C.:
Q. Doctor, your understanding of that August 1st larger meeting, the administrative meeting, I'll call it --
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Was what, what was the purpose of the meeting?
DR. CARTER:
A. I understood it to be a routine meeting of senior administration and other people who were involved with the issue. I thought that it was a routine briefing meeting, I guess you would call it.
COFFEY, Q.C.:
Q. And you spoke of this yesterday, but I just want to be certain I understand it. You asked to go to the meeting or were asked?
DR. CARTER:
A. I asked.

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

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DR. CARTER:
A. Of which --
COFFEY, Q.C.:
Q. "Of which 20 percent serious". Serious disagreement, I take it, and approximately 60 percent agreement, "PR is problematic". Do you recognize the handwriting, Doctor?
DR. CARTER:
A. Most of it is my handwriting, some of it is not.
COFFEY, Q.C.:
Q. This is probably Dr. Cook's?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And the date --
DR. CARTER:
A. That's Dr. Cook's as well.
COFFEY, Q.C.:
Q. But the body of the text is yours?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. So would that -- to assist you, Doctor, what was going on here at the time?

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

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DR. CARTER:
A. Yes, and --
COFFEY, Q.C.:
Q. And Mount Sinai's.
DR. CARTER:
A. And Mount Sinai's --
COFFEY, Q.C.:
Q. Test results for those 11.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-1990. Now here, Doctor, do you recognize any of this?
DR. CARTER:
A. Again I wrote it. Some of it is Dr. Cook's.
COFFEY, Q.C.:
Q. With the exception of, "Received July 29th, 2005", would be Dr. Cook's.
DR. CARTER:
A. And, "So many cases from Mount Sinai, and notified on the original report are --
COFFEY, Q.C.:
Q. "Notified ten" on the original report?
DR. CARTER:
A. Yes, I didn't write that or -- can I control

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the mouse?
COFFEY, Q.C.:
Q. Yes, you go right ahead.
DR. CARTER:
A. I didn't write this.
COFFEY, Q.C.:
Q. "Eleven cases from Mount Sinai", you didn't write. What then --
DR. CARTER:
A. And this down here is not my writing as well.
COFFEY, Q.C.:
Q. The body of it here, this portion -- I'm sorry, go ahead.
DR. CARTER:
A. No, that's fine.
COFFEY, Q.C.:
Q. The middle portion right there, I take it, is yours?
DR. CARTER:
A. Yes, it is.
COFFEY, Q.C.:
Q. And it started out with, "ER/PR us/them". Us would be --
DR. CARTER:
A. St. John's Eastern Health.

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COFFEY, Q.C.:
Q. Ventana?
DR. CARTER:
A. Yes, and "them" would be Mount Sinai. Again this is the first time that I've seen this --
COFFEY, Q.C.:
Q. In years?
DR. CARTER:
A. In years. Thank you.
COFFEY, Q.C.:
Q. And "us", I take it -- ER would be faint, 10; faint, 10 -- F10, F5, would be faint 5?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And then would be "negative", and then 2 percent, 2 percent, and so on all the way down.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And then the PR, similar sort of analysis?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:

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

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COFFEY, Q.C.:
Q. And I take it this is ER/PR and then there's some results?
DR. CARTER:
A. Uh-hm.
COFFEY, Q.C.:
Q. So I take it this is your interpretation, looking at the stain slides that came back?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And then there's "edge artifact". Now could you describe -- tell the Commissioner what that means because it's referred to twice here?
DR. CARTER:
A. I think it actually was a finding throughout all of the slides, but I would like to look at them. We sent some cases up to Dr. Watters at McGill who had a Ventana machine which was similar or identical to the one that we had, and when we received the slides, a lot of the staining was uninterpretable. They had a technical problem with their Ventana at the time.

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COFFEY, Q.C.:
Q. Now do you know -- did they actually use the Ventana there or did they end up using the DAKO because the Ventana wasn't available?
DR. CARTER:
A. There may have been a second run to them.
COFFEY, Q.C.:
Q. Okay, because we've heard something about that from some witnesses.
DR. CARTER:
A. Yes. The first time that we sent it up, I thought that this was it, but there may have been a second run.
COFFEY, Q.C.:
Q. So there was certainly one returned group of slides from McGill that you remember, that you had a problem interpreting because of some technical problem with the production of them?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Page two of this exhibit, do you recognize any of this handwriting?
DR. CARTER:
A. It's Dr. Don Cook.

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COFFEY, Q.C.:
Q. And while we're at it, page three?
DR. CARTER:
A. Dr. Cook.
COFFEY, Q.C.:
Q. So it's Dr. Cook's handwriting. Here, Doctor, on page two of the exhibit, it says, "Received July 29th, 2005", and it's numbered 1 to 11, 2002 cases, and presented to August 1st, 2005 meeting with steering group. DAKO, and original is crossed out, Ventana, and Mount Sinai Hospital, MSH. Did you ever see this before, do you know?
DR. CARTER:
A. It doesn't look familiar to me.
COFFEY, Q.C.:
Q. Okay. The idea of presenting the information contained in this, if this is indeed those 11 cases that were sent to Mount Sinai for slide production and reporting, if indeed this is the 11, do you ever recall that being presented at the August 1st meeting, either of the August 1st --
DR. CARTER:
A. At the large meeting?

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COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I don't think it was presented at the large meeting, you know, in this format. The synopsis of it might have been mentioned there. In the smaller meeting that you showed me the minutes to, or Dr. Williams notes from prior to the lunch break, we were talking about false positives, but again these are all new documents for me. I mean, I would have to put them together. I know this is probably some of the material that we used to make the decision not to use the Ventana any more.
COFFEY, Q.C.:
Q. At that point in time?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, in relation to that, that particular aspect of the matter, what, if anything, do you know about what happened then with respect to the Ventana and ER/PR locally, what was done?
DR. CARTER:

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A. We decided to send our cases on a go forward basis to Mount Sinai for testing. We started a plan where prior to sending the case up to Mount Sinai, they would cut some slides here, they would supposedly stain the slides here, and then it went through a bunch of permutations. It started off that all of the pathologists would read the slides, make their opinion, and then the slides would be sent to myself and I would read the slides, make my opinion, so we would be comparing pathologists, comparing technologies, and making sure that our technology was equivalent to their technology. Then I think we decided to forego the step of comparing pathologists, and eventually we just stopped doing any sort of parallel testing. I don't even think that we did very much parallel testing at all at that time.

COFFEY, Q.C.:

Q. Of course, testing eventually did resume in 2007?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

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Q. Locally.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. What, if any, changes were made, do you know?

DR. CARTER:

A. In the lab?

COFFEY, Q.C.:

Q. Yes, in the lab.

DR. CARTER:

A. We had dedicated staff, we had proper validation, optimization, standard operating procedures. I'm not sure if the physical move of the histochemistry lab was done before or after 2005, but --

COFFEY, Q.C.:

Q. The optimization process, who was the pathologist directly involved in that?

DR. CARTER:

A. I think it would have been Dr. Elms. Dr. Fontaine, he was involved for a while, Dr. Makarla, and myself.

COFFEY, Q.C.:

Q. And what was your role?

DR. CARTER:

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A. I think I worked with them on optimizing the larger aspect of the recipe, if you will, for performing, so Mr. Green, Mr. Simms, and I, looked at antibody exposure time, so how long you let it sort of bake together, As well as antigen retrieval timing. So we compared various protocols and picked out a few that we thought were showing, you know, very good results, which would be one step of the whole process. I would look at slides for the group or answer questions about it.

COFFEY, Q.C.:

Q. If we could -- while I'm on that, at this point in time, you're aware that Mr. Dyer has testified about a couple of voice messages that you left for him.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Do you -- have you looked at the transcripts of those, have you reviewed the transcripts, do you know?

DR. CARTER:

A. I have looked at the handwritten -- the typewritten transcript.

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COFFEY, Q.C.:

Q. I'll bring it up -- have the registrar bring it up, please, Exhibit P-2361, please.

DR. CARTER:

A. And I've read portions of his testimony. Is that what you mean?

COFFEY, Q.C.:

Q. Sure.

DR. CARTER:

A. I've read portions of it, but I don't know if I specifically read all around that, but I have the general gist of what was said.

COFFEY, Q.C.:

Q. Now he's indicated these were voice messages left by yourself for him in August 2005. What was the point in you leaving these messages, Doctor?

DR. CARTER:

A. I think the main point--I mean, I think there were two points, and one, we had come out of a very heated meeting where I thought that some things had been settled and that we were moving forward, and they had essentially spent the time since that meeting trying to prove things that I had said during the meeting were

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untrue, and the way that I heard it was at the request of Dr. Williams that they were doing this. I felt it would have been more appropriate for someone to telephone me and ask me to substantiate or not what I had said during the meeting, and I also felt that they were wasting a lot of time doing this, that this was unnecessary work. That we had an issue and that we should move forward.

COFFEY, Q.C.:

Q. Doctor, just looking at message number two first, you note that or stated "I'm sure that Don" that would be Don Cook had told Mr. Dyer that you had withdrawn from the project after the meeting on Monday, which would be August 1, due to the fact--"due to what I felt was incorrect handling of the validation and just lack of cooperation between pathologists and administrative technical staff here. So I won't be involved any more," and you go on to say "you guys are the ones that are going to be identifying the true negatives, so you don't really need to discredit me. You can put your effort into that."

Doctor, the concern about validation,

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incorrect handling of the validation, this would be the validation of what?

DR. CARTER:

A. The validation on the new Ventana that had been introduced 2004.

COFFEY, Q.C.:

Q. Yes, validation of what, what -

DR. CARTER:

A. Oh sorry, estrogen receptor and progesterone receptor, but it had arisen out of a generalized discussion at the long meeting on August 2nd, if that's how we're going to refer to it.

COFFEY, Q.C.:

Q. That would be August 1st, actually.

DR. CARTER:

A. August 1st, sorry. Where we had been discussing the advantages of the fully automated Ventana versus the semi-automated DAKO, and there was statements made that, you know, it's just sort of a load and go. You just put the slides in, that there's no need for local optimization and validation.

COFFEY, Q.C.:

Q. And I take it you disagree with that sort of

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an assertion?

DR. CARTER:

A. Yes, I do.

COFFEY, Q.C.:

Q. Doctor, I'm going to look at message number one.

DR. CARTER:

A. These messages actually were sent at the same time. There was just a cut off.

COFFEY, Q.C.:

Q. And you've indicated that, here, I understand, "instead of identifying and finding the cases and blocks on the greater than 200 women who are identified as negative" and I take it by that point in time, you knew or understood that at least locally there'd be about 200 negatives?

DR. CARTER:

A. Yes, we had a series that we had retested and I think Dr. Cook had gone back and looked through a certain period, just on the computer.

COFFEY, Q.C.:

Q. And this, "trying to prove things that I said were wrong" I take it is in relation to this,

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what you had described this morning as and referred to in one of the notes of a meeting that perhaps, or there were no negatives between point A and point B in 2002?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Over a several month period?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. You've indicated from a particular hospital. Doctor, do you know, in that regard, whether or not there has ever been an analysis done as to which hospital the conversions arose in, which particular hospital, one as opposed to the other, or were they equally distributed between the two, or has there ever been an analysis done of that?

DR. CARTER:

A. I don't think there's been an analysis done of that.

COFFEY, Q.C.:

Q. And I say between the two, actually to include the Grace even before 2000.

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

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

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

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we sent up to Mount Sinai which showed cases that were negative by the original pathologist were positive on Ventana and then were negative up in Mount Sinai, and this is especially true for the progesterone and less true for the estrogen, both of which, in that meeting, were decided were important." So what was that about, Doctor?
DR. CARTER:
A. These were the variability of results between the results on retesting on the Ventana and the results on the Mount Sinai retesting, if you will, so those handwritten charts that you just showed.
COFFEY, Q.C.:
Q. In fact, if we could, Exhibit P-1990? Actually, I have that as--oh yes, there it is. This would be the chart, I take it?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Yes, and perhaps you could just, just running down through the numbers here, just perhaps using the cursor, explain to the Commissioner what you're talking about here?

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DR. CARTER:
A. So in the first case, under the estrogen receptor column, under us, it's F10. I would assume that that means faint and ten, which case the patient would meet criterion for being considered positive, and when we sent it up to Mount Sinai, they called it negative.
COFFEY, Q.C.:
Q. In their world, that was zero or less than one?
DR. CARTER:
A. That was less than one percent.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. So number two, would be a faint ten changed to a two percent, so on Mount Sinai's one percent cut off, that would be a positive. Clinical practice in our group and in many centres across Canada, that would be considered positive and considered negative. Sorry, the first one, F10 would be considered positive, I would think. I'm not an oncologist. And the two would be considered a negative. Faint five and the two, clinically there would be no

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

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changed to moderate 55 percent, which would be a good positive for us, and a negative in Mount Sinai. So that would be a significant change, recognizing that progesterone is not as clinically important as the estrogen is, but from an optimization point of view, this would be an important change in values. The next one is strong five percent, I think, and negative would not really be of any significance. Moderate ten percent, two percent. Again, you're on that cusp where in one instance the patient would be considered positive and in one instance be considered negative. The next one is moderate five percent and negative in Mount Sinai. Again, that would be of some significance, but not in the routine clinical practice in our Cancer Centre. The next one is 100 percent to five percent. Again, maybe our progesterone is staining a little bit too bright. That's a significant change between the 100 percent and the five percent. The next two are both negative for us and them. Wouldn't be of any significance. The 100 and 90, the same thing. Then we had a moderate 60 percent, which was a

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

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

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O'Malley indicated that negative in their world was either zero or less than one.
DR. CARTER:
A. Less than one, okay.
COFFEY, Q.C.:
Q. So there's at least four where you've described in the progesterone instance that there was, from your perspective, a significant difference here?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Between Mount Sinai and the Ventana locally.
THE COMMISSIONER:
Q. Dr. Carter, you indicated that in the course of one of these meetings, I believe you said Mr. Gulliver had indicated that the Ventana could be a load and go kind of -
DR. CARTER:
A. I'm not sure if it was Mr. Gulliver or Mr. Dyer.
THE COMMISSIONER:
Q. Okay.
DR. CARTER:
A. But there was statements that it was a load

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and go.
THE COMMISSIONER:
Q. Did you have any reason to believe that there had not been any validation process when the Ventana use was commenced? You didn't connect the two, did you?
DR. CARTER:
A. After that meeting?
THE COMMISSIONER:
Q. Yes.
DR. CARTER:
A. I would have asked about the validation process for it.
THE COMMISSIONER:
Q. Okay, but did--do you--it may be a question that you don't know anything about, but did you know or have any reason to believe that when the Ventana came into use, a validation exercise was undertaken by those in the lab?
DR. CARTER:
A. I would have assumed that that had happened. It's basic lab practice.
THE COMMISSIONER:
Q. So you proceeded on the understanding that that would have occurred?

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

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oncologists, as best you could tell, had not noticed this lack of positive results?

DR. CARTER:

A. But I mean, that's partially true. I think the statements that I made there were again, I have been told that they had had a meeting where they said that they didn't want me involved in the process. They'd prefer to have another pathologist there. That I was trying to find evidence and possibly manufacturing evidence to make them look bad, so they would prefer to work with another pathologist.

COFFEY, Q.C.:

Q. Who's them?

DR. CARTER:

A. Oh, sorry, Mr. Dyer and Mr. Gulliver.

COFFEY, Q.C.:

Q. Okay.

DR. CARTER:

A. So I mean, that was sort of the background to the telephone call.

COFFEY, Q.C.:

Q. Okay.

DR. CARTER:

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A. And what I was trying to say there was "how can you think that I am trying to make you guys look bad when we were talking about trends in it, I was explaining that this could very well be pathologists. This could very well be oncologists. In this period of time, a certain number went out and nobody noticed." That was what I was trying to say there. I mean, I can't comment on the voracity of this transcription. I assume it's proper, but -

COFFEY, Q.C.:

Q. But in terms of yourself at the time, that was how this came up? You're telling the Commissioner this has to be read in the context of what was said on August 1st?

DR. CARTER:

A. And I think at that time, and on August 1st, and I think this is probably a day later or two days later, I was still firm in the belief that we didn't know what went on. So people were making all of these statements, we're going to this way, but it hadn't yet been investigated properly, where you could look at in an objective kind of sense and see.

COFFEY, Q.C.:

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Q. And Doctor, have you ever been--witness any exchange between pathologists and oncologists about this, about who should or shouldn't have noticed this?

DR. CARTER:

A. Oh yes, it would come up at many meetings, I think.

COFFEY, Q.C.:

Q. Between, involving the oncologists and pathologists, exchanges between them.

DR. CARTER:

A. I can remember being at a meeting where Don brought it up that trends, you know, were present, usually in the context of the turn over of staff that had occurred, so the trends could not be expected to be recognized in pathology because of the number of pathologists that were looking at these cases and in oncology as well, the same thing would apply, I think to a lesser degree, but I'm not sure. They had fewer turnovers, but they still had a larger group of oncologists seeing these results.

COFFEY, Q.C.:

Q. More consistently, I take it?

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DR. CARTER:

A. Pardon me?

COFFEY, Q.C.:

Q. More consistently, the oncologists would have been--was Don raising this is the context of they were in a better position, perhaps, because they had fewer turnovers and there were fewer -

DR. CARTER:

A. I don't think there was any sort of accusatory thing, I think it was a supportive thing. We didn't see the trends because there was so many of us and you guys didn't see the trends because there was so many of you.

COFFEY, Q.C.:

Q. Now, Doctor, if I could have you look at, please, Exhibit P-0546? This is an e-mail you sent, I gather to--on August 3rd, 2005, to Heather Predham?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And you would have just met her.

DR. CARTER:

A. Yes, she was at the meeting and I think

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someone higher up in her organization was also there.

COFFEY, Q.C.:

Q. And what was the purpose in sending--your purpose in sending her this e-mail?

DR. CARTER:

A. To offer her references and a consultative opinion if she felt that she required one. She was at the meeting, I thought that she was well spoken, she had taken it upon herself to go through the scientific literature and had brought a bunch of articles for people to look at, so I was just offering her my consultative opinion.

COFFEY, Q.C.:

Q. And how much interaction did you have with her then afterward?

DR. CARTER:

A. Informally I would see her in the hallways and talk with her and we were together on the tumour panel. I think there were several other large meetings of people involved in the issue that I would have been on the same committee meetings with her.

COFFEY, Q.C.:

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Q. Exhibit P-0925 please? Doctor, these are the typed version of Dr. Cook's notes and there are just a couple of them I am going to refer you to, a couple of particular parts. On page 4, there's a note for July 15th, 2005, you are not in attendance, but the fifth bullet says, "Dr. Carter to check with Mount Sinai to see if change in sensitivity over time with testing they used." Do you know what that is about? This is in the middle of July.

DR. CARTER:

A. No. Do you have any more context for it?

COFFEY, Q.C.:

Q. Well this is just to point out they had reviewed an earlier meeting, Dr. Cook was to contact pathologists in other centres to get cases submitted. Terry is advising ever patient slide was processed along a control slide. Control slides are read, no reporting done until control read is positive and then Dr. Carter, someone has noted that Dr. Carter is to check with Mount Sinai to see if the change in sensitivity over time with the testing they used. Were you ever asked to approach Mount Sinai about whether they

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noticed any changes?

DR. CARTER:

A. I don't recall it specifically.

COFFEY, Q.C.:

Q. Okay, and again, you're not at the meeting, noted to be there, so--page 6 of this exhibit is a note of a meeting of July 21st, 2005 at 10:30 a.m. You are in attendance, noted to be here at this, yourself, Dr. Cook and Dr. Williams and here it says "In past, it didn't seem to be a clear picture. Sentinel case, reviewed old slides, program would not always run a control. Clear test didn't work. Dr. Carter feels there was a problem in 2002. Some runs on retrospect were not normal. Inconsistency from one batch to another. Current Ventana is picking up to much. Have sent out a"--that's probably "a sampling"--something--"results and sent to Mount Sinai. Dr. Carter also doing some work on quality control and use them as controls. Important for Dr. Carter to have all reports for ER/PR for each year. Techs may need to be trained on immunoperoxidase and need controlled access to the room. Training of techs in

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immunohistochemistry, need separate service, need QA and proficiency testing. Need to have an external consultant to come to the lab and do QA." Doctor, in relation to this, these notes and they are Dr. Williams' notes, the assertion or the attribution to you of Dr. Carter feels there was a problem in 2002, and this is the middle of, well July 21st, can you recall having by that point reached that conclusion and it's clear that the test didn't work?

DR. CARTER:

A. By that time we would have had two of our batches back.

COFFEY, Q.C.:

Q. Yes, two results. You've had the 58.

DR. CARTER:

A. There was some problem. I'm not sure that I thought it was confined to 2002 at that point, but we were still investigating 2002.

COFFEY, Q.C.:

Q. The reference to "inconsistency from one batch to another" what does that refer to? And "some runs on retrospect were not normal"?

DR. CARTER:

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A. I'm not sure what they mean by runs and batches, I don't know if he's talking about groups that we looked at.

COFFEY, Q.C.:

Q. See, that's what I was asking about, did you ever get an opportunity to analyze these earlier results in relation to whether or not they were run on particular days or particular weeks.

DR. CARTER:

A. I don't think I ever had that information, I mean, that was information I was interested in.

COFFEY, Q.C.:

Q. Because some runs, the idea of identifying particular runs, were you ever able to identify particular runs?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. For example, in order to identify runs, I take it you would need the worksheets?

DR. CARTER:

A. I wouldn't have to know what date each case was tested on, which was one of my parameters

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I was looking at, but I couldn't get results on.

COFFEY, Q.C.:

Q. If we could, I just bring up one, Exhibit P-2190? Can we go to page 9, please? Doctor, there has been evidence here that this is a worksheet, you'll see it's labelled one to forty-eight when you look down through it, sort of worksheets that would have been used on the DAKO autostainer. In the course of your review in June and July of 2005, did you ever have access to these sorts of sheets?

DR. CARTER:

A. I don't recognize these sheets, no.

COFFEY, Q.C.:

Q. Okay. You can see here the antibody is referred to and a surgical number, you'd be able to tell, presumably then if on a particular day, a particular run occurred? Well, a particular run, a particular set of slides was from a particular surgical block was run that day, you didn't see any such -

DR. CARTER:

A. No. And you would want to see more information than this, you would want to see a

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tie in with the machine.

COFFEY, Q.C.:

Q. Oh yes.

DR. CARTER:

A. So there's usually some computer, you know, the computer makes some note internally that they have done that run that day and this is just a handwritten -

COFFEY, Q.C.:

Q. Doctor, the computer, I take it that the DAKO uses a computer or did use a computer.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Did you ever ask--I appreciate by the time you got involved in the review, the DAKO was gone, the DAKO machine?

DR. CARTER:

A. It went in March of 2004, so I would have been here doing some locums.

COFFEY, Q.C.:

Q. Pardon me?

DR. CARTER:

A. I would have been here doing some locums.

COFFEY, Q.C.:

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Q. Oh no, by the time '05, it was long gone.

DR. CARTER:

A. Yes, it wasn't in use, I don't know where it was, I assume it was gone.

COFFEY, Q.C.:

Q. Did you ever make any inquiries about where the computer was?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. But from your perspective, you had understood that perhaps there would be computer records somehow from which -

DR. CARTER:

A. Yes, usually you can, I mean, I'm not a computer expert, but usually you can ask the computer to tell you this sort of thing and it can tell you what the run was, what--any issues that had arisen during the run, what cases were run at that time.

COFFEY, Q.C.:

Q. Exhibit P-0925 please? Page 7, Doctor. This is, here, although you're not in attendance, this is the meeting that afternoon, apparently they agreed to get Dr. Carter the information

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she needs. "Dr. Carter to do only this service. Mary Butler to report and take direction from Dr. Carter. Judy Quinlan to report to Dr. Carter. Will arrange someone from QA to be assigned." Now while you were involved, was there anybody from QA assigned?

DR. CARTER:

A. I don't think he means assigned to me, maybe to the project, so I think that would be maybe Heather Predham, maybe.

COFFEY, Q.C.:

Q. The first four would be your -

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Now, Exhibit P-0081 please? Doctor, this is a letter to Dr. Williams and Dr. Cook. I take it this is your handwriting, August 8th, 2005?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And you signed it at the bottom. What was--how did you come to write this letter?

DR. CARTER:

A. We looked at the handwritten notes a little

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earlier where I had the "Us" "Them" columns, so I had just derived those for Dr. Cook because a lot of this is being done in between all your regular work, so I had just jotted down the numbers for him and gave them to him. And we had decided at or around this time to shut down the Ventana system and Dr. Williams and Dr. Cook wanted some formal numbers written down as to why I thought that the Ventana system needed to be evaluated as well, and these are my numbers.

COFFEY, Q.C.:

Q. Doctor, did you ever receive any response from anyone in relation to the evaluation of or examination of the Ventana system in relation to ER/PR? Did you ever receive any response? You made the assertion that it should be investigated further, the Ventana, did you ever get any response?

DR. CARTER:

A. I'm not sure that I was expecting one, I think I probably was expecting that we would be doing this and Don and I were just moving forward with the parallel testing, the pathologist verses pathologist comparisons,

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those sorts of things.

COFFEY, Q.C.:

Q. Here, Doctor, just looking down through this then, your second paragraph and you're, of course, dealing only for cases seen at the Health Sciences Centre in 2002, this relates to.

DR. CARTER:

A. Health Care Corporation, so it would have been at both sites.

COFFEY, Q.C.:

Q. Yes. "Have patients identified as ER negative using a ten percent cut-off point or other surrogate markers, such as male gender and/or favourable histologic subtype of a low positivity, 87." The ten percent cut-off, readily apparent, I hope.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. "The other surrogate markers, such as male gender and/or favourable histologic subtype with a low positivity" what are you referring to there?

DR. CARTER:

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A. It used to be thought, but actually it's no longer true, that virtually all men with breast cancer are estrogen receptor positive. I think now it's agreed that they probably reflect the female population as well, so they would be down around 75, 80 percent, maybe at the upper end of that. But at that time, I was trying to pick out any male breast cancers that had unusual staining patters and then the favourable histologic subtypes would be the mucinous cases that would have something around a 10 or 20 or 30 percent where I would be expecting a higher percent positivity.

COFFEY, Q.C.:

Q. And totally them, that is the 10 percent cut-off and those other surrogate markers, you would come up with--identified 87 cases?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Number of patients undergoing ER testing during that time period at the Health Care Corporation, 189, based upon Mr. Gulliver's figures.

DR. CARTER:

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A. Yes.
COFFEY, Q.C.:
Q. Then 87 over 189, 46 percent negative rate, that, I take it, is just simply the arithmetic itself?
DR. CARTER:
A. Yes, I mean there were cases that they gave me that they said these are 87 cases that are ER negative, say for example from January 1st to June 30th, and then in that time, they told me that there was 189 cases of estrogen receptor done, so we had a 46 percent negative rate.
COFFEY, Q.C.:
Q. And of the 87 cases, 18 are not being retested, so you have a balance of 69 retested, 43 have converted and read by both yourself and Dr. Cook, using the Ventana. So at that point, a 62 percent conversion rate.
DR. CARTER:
A. In this subset.
COFFEY, Q.C.:
Q. In that subset. Now assuming a 62 percent conversion rate of all 87 negatives, you'd have 54 positives and 33 true negatives, which is 17.5 percent true negative rate using the

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Ventana.
DR. CARTER:
A. Which is now too low.
COFFEY, Q.C.:
Q. Now your assertion below that, you say, "I believe that the idea that the DAKO system, both its performance and interpretation greatly under-estimated the number of women who would benefit from hormonal manipulation of their breast cancer and should be investigated." Now just based upon those figures and the conversions, you thought that -
DR. CARTER:
A. There is a 46 percent negative rate.
COFFEY, Q.C.
Q. Which is far too high.
DR. CARTER:
A. Which is too high, yes.
COFFEY, Q.C.
Q. And from these numbers, it would also appear that the Ventana system is overestimating the number of patients who are ER positive. What kind of percentage would you have expected to be ER positive, if the test was optimized and

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optimally carried out.
DR. CARTER:
A. It should be around 75 to 80 percent, most people would agree 75 percent is where you would start to look at your population.
COFFEY, Q.C.
Q. And you go on to---"couple this finding with the recent 60 percent disagreement with Mount Sinai Hospital on crude progesterone status (positive versus negative and not percentile staining) and it appears that we have another system that needs investigating". I take it that 60 percent disagreement is those figures that -
DR. CARTER:
A. Those hand written little tables that we just looked at. But again, here I was trying to emphasis that this is something that you're doing in between doing everything else. This is very preliminary and very raw numbered.
COFFEY, Q.C.
Q. Exhibit P-0562. Doctor, this is an e-mail of August 9th, 2005 from Debbie Parsons to a number of individuals, not including yourself, but the subject is Dr. Carter's retesting

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results. She says, "I have Dr. Carter's retesting results entered in the database and have summarized the results as attached. And I think I may be able to get the Tamoxifen prescribed by MCP number from pharmacy". Do you recall giving Ms. Parsons your retesting results?
DR. CARTER:
A. No, I'm not sure, who is Ms. Parsons?
COFFEY, Q.C.
Q. Debbie Parsons and again, she is -
DR. CARTER:
A. I don't know.
COFFEY, Q.C.
Q. - I'm trying to remember. Mr.?
MR. BROWNE:
Q. Dr. Williams' assistant.
COFFEY, Q.C.
Q. Dr. Williams, that was it, I was trying to remember whose assistant she was. She was Dr. Williams' assistant. So, in terms of the retesting results, the actual numbers -
MR. BROWNE:
Q. (Inaudible).
COFFEY, Q.C.

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

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

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DR. CARTER:
A. No, I don't think Dr. Cook and I--he might have, the first day or two, but no, I think I was pretty firm and he was accepting of that.
COFFEY, Q.C.
Q. Doctor, did you ever refuse to do anything for anyone?
DR. CARTER:
A. In my life, I'm sure -
COFFEY, Q.C.
Q. No, in this context. I appreciate the comment, perhaps you have. Doctor, have you ever--August 2nd, I appreciate you withdrew and you indicated why and what you were withdrawing from, but for the Commissioner's benefit, after that, I mean, in terms of anyone ask you for advice or input, did you ever refuse to provide it, that you can recall, in relation to this ER/PR -
DR. CARTER:
A. Not that I can recall. I mean, if somebody asked me to do something and I was busy, I mean, I would just -
COFFEY, Q.C.
Q. Oh, I -

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DR. CARTER:
A. - or whatever, but again, context, -
COFFEY, Q.C.
Q. But what I'm getting at is this, if you were-- as time went on, because your name does appear a number of other times throughout this whole matter including the tumour panel.
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. So, in terms of, in the normal course, if you were asked to do something, if you were available to do it or able to do it, did you do so?
DR. CARTER:
A. I think so, yes.
COFFEY, Q.C.
Q. Exhibit P-2172, please. Now, Doctor, I'm going to ask you, do you recognize the handwriting on this?
DR. CARTER:
A. No, I don't. This my writing, yes, sorry, I thought you meant the first one.
COFFEY, Q.C.
Q. Okay, the first one, yes, that's whose

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handwriting? Yours?

DR. CARTER:

A. No, that's not my handwriting.

COFFEY, Q.C.

Q. That's not yours, okay.

DR. CARTER:

A. I don't recognize it.

COFFEY, Q.C.

Q. And then it says, "a little bit rushed, but you get the idea, Bev, I'm on holiday Friday, vacation". This sort of form, slide ID, staining antibody, antigen retrieval, antibody time block, A block or B, previous result/new result. Do you recognize any of this material?

DR. CARTER:

A. Yes, these would be the optimizations that I referred to earlier.

COFFEY, Q.C.

Q. And the hand writing in this context is whose?

DR. CARTER:

A. It's not mine. I would assume having seen that I'm writing to Ken, it would Mr. Green or Mr. Simms, that's who I was working with on the issue.

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COFFEY, Q.C.

Q. Okay. And then starting at page five of this exhibit, what sort of a form is this, do you know?

DR. CARTER:

A. This is the computer generated run form.

COFFEY, Q.C.

Q. I take it then as we go through these, these would reflect an effort to optimize various stains.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. And do you recall when this occurred, this process?

DR. CARTER:

A. Not exactly.

COFFEY, Q.C.

Q. Were you asked to assist though, at times, the technologist in doing so?

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. You did, yes.

MR. BROWNE:

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Q. (Inaudible) dates on some -

COFFEY, Q.C.

Q. Yes, on some of them, some do have some dates. Yes, on the computer runs themselves, they're August 25. I just go back. Thank you. It seems I seen that before. Sorry, I'm gone well beyond, page five and the run start/run completed, that's August 25, 2005 and 25 again on page six. So, the same thing on page seven. So, if this occurred at that time, you were probably involved at the end of August trying to assist the technologists at that time -

DR. CARTER:

A. As you were flicking through that, my writing shows up at the end when I'm talking about very dirty stains, things like that, if you keep on going. There, that's my writing, so that was the beginning of my return to Mr. Simms or Mr. Green.

COFFEY, Q.C.

Q. Beginning at page 14 of the exhibit, page 15. The purpose in you producing this material would be to given them advice as to your views on whether this particular run or particular

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block, sorry, slide was well done or not.

DR. CARTER:

A. Well, the protocol number would be on one edge of the chart. So, on this page that we're looking now, PRA 316 KE, that would mean something to the technologists as progesterone and then run number 316. So, it would say in it that they had used a certain antibody concentration, that they had exposed the ingredients for a certain period of time and that they had used antigen retrieval and other things and then I would comment on what each one of the runs would look like to me. And then from my comments to them and sometimes you would look at the slides together. We would pick out which protocol numbers we thought were more appropriate.

COFFEY, Q.C.

Q. And on that particular page, back to page 14, as we get down through the page, I think you'll see ER begins.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. These are the ERs and then some PRs and so on.

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I take it these continue on through page, we're at page 19 now, 20, 21 -

DR. CARTER:

A. There are a lot of them, yes.

COFFEY, Q.C.

Q. - 22, all the way up through page 24 of the exhibit. If we could look at Exhibit P-1738. Doctor, these are notes, Dr. Cook's notes of a meeting. He says, "spoke to Trish and Dr. Bev Carter, September 21st, 2005". Do you know if and I think you referred to this yesterday, I asked you about whether you were there when Trish had her exit interview.

DR. CARTER:

A. Her exit? I don't think I was there for her exit. I was there when she was in the St. Clare's site. I thought her exit interview was just with Dr. Williams.

COFFEY, Q.C.

Q. Only Dr. Williams, okay. And the time when you met with her at the time, did she discuss any observations she had made up to that point? This seem to be Dr. Cook's account of, at least, certain things that Ms. Wegrynowski is telling him. I'm not suggesting you were

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there.

DR. CARTER:

A. I don't recall Trish explaining specific aspects of her report. Actually I remember Trish telling me that she couldn't, that this was peer review and we went--my friend and I took her to dinner and movie and I sort of asked, how's it going? And she said, I'm not telling you, this is peer review. So, I don't think I was at any meeting where she discussed that.

COFFEY, Q.C.

Q. Exhibit P-1953, page two, please. This the minutes of an anatomical pathology, October 4th, 2005 meeting. Doctor, an update on ER/PR status and the note here, this is a meeting at the General Hospital site. If you look back, you'll see the people listed there.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. From that site.

DR. CARTER:

A. Yes, I've looked at this before.

COFFEY, Q.C.

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Q. Okay. And it says, "we are still in the process"--"the media has gotten a hold of the issue"--"we are still in the process of determining how extensive this problem is. In view of this discussion with Dr. Cook, he's appointed Dr. Beverley Carter as the point person for HER2/neu testing. With this in mind, there is some sentiment from the pathologists that Dr. Carter should review all breast cases with a back-up person to cover in her absence. A letter to this effect will be sent to Dr. Cook stating opinion of the pathologists at this site and this will be discussed with Dr. Carter as well". What do you recall about that, Doctor?

DR. CARTER:

A. Actually, I'm not familiar with this at all.

COFFEY, Q.C.

Q. The subject matter here of this.

DR. CARTER:

A. I'm not sure what he's talking about for a point person for HER2 testing. I found out that there had been a meeting of the pathologists over at the General site where they had expressed this concern, that they

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would like all cases to be transferred over to St. Clare's, but I found that out on the day that it began. So, there was no letter or discussion with me.

COFFEY, Q.C.

Q. And when did that happen, in fact?

DR. CARTER:

A. Probably some time in late 2005. I had no issue with it. I mean, that was my, sort of, ongoing theme. I welcome all the breast cases.

COFFEY, Q.C.

Q. And Doctor, but who was it discussed--because it appears to have been in early October, you didn't learn about this sentiment at the General until, in fact, it had happened.

DR. CARTER:

A. Yes, it was happening that day, yes.

THE COMMISSIONER:

Q. Mr. Coffey, wherever you find a spot, we'll take the afternoon break.

COFFEY, Q.C.

Q. Okay, thank you. I'm going to go to the next exhibit P-0634. Doctor, this is a letter, a memo of October 12th, 2005. It's from Dr.

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Williams to yourself. It's concerning the panel ER/PR results and he writes, "Dr. Carter, Dr. Cook has just informed me you've agreed to sit on this panel, Don will be on it in ex officio capacity to ensure that all information is available from the laboratory medicine program. You'll be there as an expert in the area of breast pathology and help with the deliberations of the panel". He thanks you for your help. Doctor, how was it that you came to be on the panel?

DR. CARTER:

A. Dr. Cook and I think, Dr. Williams were telling me about the panel and asked me if I was interested in serving on it.

COFFEY, Q.C.

Q. So, they approached you.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. Exhibit P-2457. Now these, Doctor, I take it are--I think this is minutes of the first meeting of October 13, 2005, your name is there to the top right. And I take it then, Doctor, when you could or were available then

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from that point on, you attended these panel meetings?

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. Okay. I'll then come back and ask you some questions about that after the break. Thank you, Commissioner.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey.

COFFEY, Q.C.

Q. Thank you, Commissioner. Registrar, Exhbit P-1305, please. Doctor, these are the minutes of the physician panel meeting number two, October 20th, 2005. You're present right here, noted to be present.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. Form for taking minutes. Dr. Laing distributed a form that could be used by the secretary to assist when taking minutes at meetings and the form consisted of, and it lists a number of things. "After a review of

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

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patient's name and the MCP number, which of course, here are redacted.

If we could look now at Exhibit P-1368? This is the same minutes, October 13th, 2005. The major change is reflective of the October 20th minutes. Here, on the left-hand side, under patient information, there's space for the name and MCP number. There's an entry for OPUS number as well, and then the date of pathology is noted, particular date by day, month and year. Pathology specimen number/site and then the surgical number would have been there, and site being whether it's the right or left breast noted here.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, why was this changed? Why was this information, the OPUS number, date of pathology specimen number and site added?

DR. CARTER:

A. I think the OPUS number was added so that you could have access to the Cancer Centre chart. There's a different charting system. I can't really speak intelligently about it. The

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other one, because many patients would have more than one surgery performed and in some rare instances, you may have bilateral disease sites as well, so I think it was added just to clarify exactly what we were talking about and to provide more access to the computer charts.

COFFEY, Q.C.:

Q. Doctor, the date of pathology means what in this context?

DR. CARTER:

A. I would assume the date that the original--usually the date that we have is the date that the original specimen was received in the laboratory.

COFFEY, Q.C.:

Q. Okay, then that appears on the pathology reports then, the date received?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. That wouldn't necessarily mean the date that ER/PR was reported?

DR. CARTER:

A. No. I don't think we had a way to know that. We had difficulty finding that out.

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COFFEY, Q.C.:

Q. Doctor, on that very point, there are a number of cases that, I believe in some C exhibits we saw when Ms. Butler, if I recall correctly, was here, at times the specimen would be received, say on--I'll just pick a date, September 1st, or in that particular instance, perhaps late in '02, December '02, January '03 and wasn't reported until May of '03. Now I understand Dr. Ejeckam had stopped testing for a while, but I take it that you were not able actually to tell generally when actual retest--not retest, I'm sorry, the original test occurred?

DR. CARTER:

A. You could tell when it was reported. That would be on the pathology report, but that didn't necessarily correlate with when it was performed. Some people reported, you know, the next day, as soon as they get the slides, and for some people, it would be on their desk while they're waiting for other aspects of the case or waiting for their own personal schedule to clear.

COFFEY, Q.C.:

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Q. So there was no way, based upon the record, of actually ascertaining, that you could tell, when exactly the test was done?

DR. CARTER:

A. Not that I know of.

COFFEY, Q.C.:

Q. And even then, even if you could go to the computer and find out when a test was run, using computer data, you'd still have to go and try and ascertain when the doctor actually interpreted it?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Which might be different than the day it was entered on Meditec?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And signed off on Meditec might be a different day again?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, when you were conducting your

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investigation in June and July of '05, did you make any effort to record who the reporting, original reporting pathologist had been?

DR. CARTER:

A. At some point the spreadsheets, the tables changed, and I'm not sure what the date is, but the first few tables, they don't have that column and then I added in date of testing, the pathologist and we started to look at that.

COFFEY, Q.C.:

Q. And I take it that would be for the same reason that you'd want to know whether the problem was centred on a particular pathologist or -

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. - particular days of the week or whatever, if you could?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, while we're on the subject of pathologists and who did the tests and

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reviews, were you ever made aware of any concerns expressed by a pathologist at the General Hospital in early August 2005 about the nature of the review?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. What do you recall about that?

DR. CARTER:

A. Well, since then, I've read -

COFFEY, Q.C.:

Q. Sure.

DR. CARTER:

A. - there's a document in exhibit, so it's hard to separate one from the other, but at the time, I think the pathologists at the General site, and I'm not sure it was restricted to the General site, they were very reluctant with having another pathologist come in and review their work.

COFFEY, Q.C.:

Q. In the context of this ER/PR review that you had embarked upon.

DR. CARTER:

A. Yes.

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COFFEY, Q.C.:

Q. Exhibit P-1994? Doctor, that's some notes, a typed account too that Dr. Cook provided to the Commission of August 5, 2005, a meeting with a number of pathologists.

DR. CARTER:

A. Yes, this is what was I was referring to.

COFFEY, Q.C.:

Q. So when you were told that they had concerns, what, if anything--who were you told by, and what, if anything, was your response?

DR. CARTER:

A. I was told by Dr. Cook that they had concerns. My response was something along the lines of that this was a process that was, you know, sanctioned by administration, so you know, it would go on and Don would need to facilitate the smoothing of that. I mean, a lot of people were very upset and frightened and, you know, didn't know what was going on. I didn't view it as a major barrier.

COFFEY, Q.C.:

Q. When did you first become aware of this concern?

DR. CARTER:

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A. Is it August the 5th is the date there?

COFFEY, Q.C.:

Q. Well, that is August 5. Now by then, you had already withdrawn, in effect, yourself.

DR. CARTER:

A. Oh, yeah, that's right. No, it was before that.

COFFEY, Q.C.:

Q. It was before, you were aware of that.

DR. CARTER:

A. We were trying to get together a lot of processes about parallel testing and canned text, those sorts of things.

COFFEY, Q.C.:

Q. So sometime before August 1st, you would have been made aware of the concern, but when exactly, you can't recall?

DR. CARTER:

A. On or around, because this is talking about the parallel process that I described, not the retrospective process. This is the parallel process.

COFFEY, Q.C.:

Q. Okay, the parallel process.

DR. CARTER:

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A. I think.

COFFEY, Q.C.:

Q. Okay. So it's "we should ensure that no bias is introduced into the ongoing study." Now which parallel process are you referring to?

DR. CARTER:

A. We put up an exhibit a little earlier, or you put up an exhibit a little earlier where we talked about after the DAKO had been shut off and the Ventana was being used, and we had some problem with the Ventana. Dr. Cook wrote a memo that said from now on we would be testing at Mount Sinai.

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. And I think bullets three through six are about send the block to the technologist first, have them cut it, they will send it--they will stain it and send it to you. You read it. You make your reading and you send -

COFFEY, Q.C.:

Q. You, individual pathologist A, B, C, whoever they are?

DR. CARTER:

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A. Yes.
COFFEY, Q.C.:
Q. And you make your determination?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And send that along to Dr. Carter?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Okay, and it was then Dr. Carter's review -
DR. CARTER:
A. I think this is what they're--the study that they're referring to there, that they didn't feel that their work should be audited.
COFFEY, Q.C.:
Q. Because you had understood that at the time, at least, some of them felt that what you would be doing in reviewing their determination of the slides would be, in effect, an audit?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit -

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

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

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

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appreciate you were not at this meeting and it's possible, I take it, that these actual concerns might be in relation to the retest issue?

DR. CARTER:

A. Yes, when it was expressed with me --

COFFEY, Q.C.:

Q. When it was raised with you, though --

DR. CARTER:

A. It was talking about the parallel testing, that they didn't want to report their work and then have me to compare it.

COFFEY, Q.C.:

Q. Exhibit P-2458. Doctor, here this is a fax transmission. It's 15 pages, including the cover sheet, October 19th, 2005, to yourself from Dr. Williams. He writes, "Bev, this is the article I was referencing", signed, Bob, and then there's an article by Dr. Neil Love, and you can see here it's printed off the internet, dating September 30th, 2005, and then there are -- on the next page is a reference to ER testing inter-laboratory variability, and it comes from a publication in 2004 by Lippincott Williams and Wilkins,

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and goes on for two pages, that does, and then there's other material involving an abstract, I take it, from Biotech Histochem, 1992, and there's other material here.

DR. CARTER:

A. Uh-hm.

COFFEY, Q.C.:

Q. Do you recall how - the larger article, if I could, at page eight is a publication entitled "Assessment of tissue estrogen and progesterone receptor levels, a survey of current practice, techniques, and quantisation methods" by Layfield, et al, and this is a 2000 publication. Doctor, do you recall why it was or how it was that Dr. Williams came to send this to you?

DR. CARTER:

A. It would have been a part of many discussions that we had had about the estrogen receptor issue. I think the first paper by Dr. Love, the second last paragraph, they're talking about a lot of the variability from site to site, but that seems to be the theme of most of them, what are some areas that could be possibilities. I don't recall the specific

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context of the question -- of the discussion, but it would have just been an exchange of articles.

COFFEY, Q.C.:

Q. I take it, did you at times provide him with material, Dr. Williams, do you recall?

DR. CARTER:

A. Yes, I think so.

COFFEY, Q.C.:

Q. Exhibit P-1807. Doctor, this is an e-mail, November 16th, 2005, from Dr. Cook to Dr. Mullen, and he writes, "Hi Brendan, could you and Bev Carter follow up on particular surgical specimen reported as ER zero percent, PR zero percent", and he cross-references it. "Bev may also want to see the slides. I do hope Bev is treating all of you well and using her people skills at an optimal level. Many thanks, Don Cook". Dr. Carter, I take it you were at Mount Sinai at the time?

DR. CARTER:

A. Yes, I was.

COFFEY, Q.C.:

Q. Why were you there at that point?

DR. CARTER:

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A. I had booked conference leave. It was in -- I think it was in November in New Orleans, and actually Hurricane Katrina happened, so I still had the time booked off and I talked with Dr. O'Malley and Dr. Mullen, and I was still working on some of my textbook chapters -- Dr. O'Malley is the editor of that textbook, and I went up there, I think for a week, and just looked at some estrogen/progesterone cases with Dr. Mullen, looked at some consults with Dr. O'Malley, and worked on the textbook.

COFFEY, Q.C.:

Q. Okay. Exhibit P-0101. Doctor, this is that December 7th, 2005 letter from yourself to Dr. Williams. Doctor, here just looking through the letter, other than the opening, beginning at the bottom of the first page, the paragraph, "the most important of these is organization" -- well, in the paragraph above, you note that there are multiple major issues that must be addressed prior to any breast testing being reported locally, and then, "The most important of these is the organization of the immunohistochemistry laboratory", and you

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go on to speak about that, and education of technologists. You continue on to the top of the next page, "The need for technologists to document the optimization and validation of every antibody" is referenced, the need to define standard operating procedures is there in the middle of that paragraph, the need for all antibody specification sheets to be available in readily available format, and appropriate organizational chart be prepared and designed, and some system be put in place to address individual pathologist's complaints and concerns about IHC. Now, Doctor, I take it those in the main would refer to technologist activities?

DR. CARTER:

A. Yes, so far.

COFFEY, Q.C.:

Q. So far, and I want to ask you about here, "appropriate positive and negative controls must be selected for ER/PR and HER2/neu", and then you go on to talk about IHC technologists need to be trained in the basic of interpretation of them so that appropriately stained slides only leave the laboratory.

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From your perspective, who should be reading the control slides?

DR. CARTER:

A. Negative controls, I think, should be read by technologists. I think that positive controls for the most part can be read by technologists.

COFFEY, Q.C.:

Q. I take it, the external ones?

DR. CARTER:

A. Sorry, external ones, yes, external controls.

COFFEY, Q.C.:

Q. And the selection of appropriate positive and negative controls, in your experience who actually does the selection?

DR. CARTER:

A. Well, here in St. John's, we do, the pathologists do so far. I think at McMaster, they were produced by the technologists.

COFFEY, Q.C.:

Q. And you go on then and talk about a microscope is necessary for the use of the technologists, and then on the next page, the first full paragraph beginning, "The pathologists must standardize their approach". I take it then

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what's spelled out here in this paragraph relates to changes involving practice by pathologist locally you felt were necessary?

DR. CARTER:

A. Yes, I think there was some more about education somewhere, but --

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. Essentially, yes.

COFFEY, Q.C.:

Q. Actually here in the third line.

DR. CARTER:

A. Oh, okay.

COFFEY, Q.C.:

Q. "Should be educated about block selection in breast cancer cases, should be taught basic information about the reporting of predictive factors in breast cancer, including aspects of internal control, surrogate markers, and handling of discordant results, and serious consideration should be given to limited number of pathologists reporting these often difficult diagnosis. Standardized reporting should be used", which includes certain

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information. Doctor, as of December 7th, 2005, I take it that you were telling Dr. Williams that from your perspective changes were needed by both the technologists and in relation to the pathologists, as a group -- as groups?

DR. CARTER:

A. Yes, and I think the biggest thing that I was asking for in this case was some sort of document that had said that these things were being looked at. I know that many of these things were actually in place, were being worked on, but I wanted it written down that we have taken this seriously and we have gone through it and looked at it all.

COFFEY, Q.C.:

Q. Exhibit P-0694? This, I take it, Doctor, is Dr. Williams' acknowledgement on December 14th, 2005 of your December 7th letter and he writes, "I've asked Dr. Don Cook and Terry Gulliver to review all the recommendations made by Dr. Banerjee and Ms. Wegrynowski and provide me with the spreadsheet of these recommendations indicating our progress and status with respect to implementation. Dr.

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Banerjee has agreed to participate in a conference call, if required." And he goes on to say once there is a full review of the recommendations that were made and we achieve consensus, a decision will be made about timeframes and so on, about re-instituting the service. Doctor, this list and a spreadsheet of the recommendations, did you see those?

DR. CARTER:

A. I have seen them on a number of occasions.

COFFEY, Q.C.:

Q. Did you see them fairly early on after they were initially--we understand they were initially produced in mid December, 2005.

DR. CARTER:

A. I'm not sure when I first saw them, I'm not sure.

COFFEY, Q.C.:

Q. Now in terms, Doctor, because you had written on December 7th that Dr. Banerjee and Ms. Wegrynowski had stated there were multiple major issues that must be addressed. How did you know that?

DR. CARTER:

A. I had seen the list of recommendations from

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Ms. Wegrynowski's report, but not her report.

COFFEY, Q.C.:

Q. How would you do that? We've seen the report and it's kind of listed--her recommendations are listed at various points in it.

DR. CARTER:

A. I mean, I received a sheet of papers, it was probably about 16 or 17 of them there. Dr. Banerjee's report I hadn't seen, I had spoken to him, I had an idea of what may have been going on and things that you would see in the hallway, you know.

COFFEY, Q.C.:

Q. Changes that you were observing, I take it.

DR. CARTER:

A. Yes, I mean, Trish leaves and--sorry, Ms. Wegrynowski leaves and then the next day, you're buying a fridge, so it's not hard to put two and two together.

COFFEY, Q.C.:

Q. Doctor, Exhibit P-0047 please?

THE COMMISSIONER:

Q. The Registrar is prepared this time.

COFFEY, Q.C.:

Q. Thank you, very much. Doctor, this is Ms.

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Wegrynowski's report of November 9th or dated November 9th, 2005, just if you go to page, for example, page 5 of it, you'll see under paragraph 2.1, there are recommendations one through three. Then paragraph 2.2, "Processing" and then there are recommendations four, five, six, seven and eight. In paragraph three, 3.1, there's text and then there are recommendations nine, ten, eleven, twelve, thirteen into the next page. So, Doctor, do you know if--did you just receive something entitled "Recommendations" and with a bunch of numbers or -

DR. CARTER:

A. That's what I think that I received, that I looked at because I didn't receive anything, it was just like a cut and paste of this, one, two, three, four, five, six -

COFFEY, Q.C.:

Q. Okay. Exhibit P-2460? And, Doctor, this is an e-mail from yourself, February 3rd, 2006 to Dr. McCarthy and others and you write, "Morning, Kara brought a patient pamphlet about breast cancer pathology to our ER meeting last night. Attached is an article I

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wrote for breast cancer e-publication and have slowly been editing as a user friendly pamphlet. I think it would be perfect for our patients, still needs some editing, as well as simplification of language. If I can get some clerical/graphic this is almost ready to go. Can you read please and offer corrections, can I get someone to provide the clerical/technical support I need. Thank you. Beverley Carter." I take it that that is referencing this article that you--is this this article that you -

DR. CARTER:

A. For the Atlantic Breast Cancer -

COFFEY, Q.C.:

Q. Breast Cancer Newsletter. And that would be this, I take it?

DR. CARTER:

A. That's the earliest form.

COFFEY, Q.C.:

Q. Yes. Now, Doctor, what was going on here otherwise at that point in time, early February, in terms of you're sending this to these various physicians for what?

DR. CARTER:

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A. I think the long-term idea at that point was to come up with some sort of pamphlet that could be either included in the purple lupin kit, which is given to hopefully all women at diagnosis of breast cancer or it would be placed in the oncologists' offices so that they could give it to their patients as they discuss pathology with them.

COFFEY, Q.C.:

Q. So Joy McCarthy, of course, is an oncologist, a medical oncologist; Sharon Smith worked with the Cancer -

DR. CARTER:

A. She would be a manager with the Cancer Program.

COFFEY, Q.C.:

Q. Dr. Jonathan Greenland is a radiation oncologist.

DR. CARTER:

A. And Brent Tompkins is a radiation oncologist.

COFFEY, Q.C.:

Q. So this group, did they comprise any particular group or body?

DR. CARTER:

A. No, probably picked them, well Ms. Smith

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because she would be the one who would have the resources and money, if available. Probably just thought that those three would be the most interested.

COFFEY, Q.C.:

Q. Now, Doctor, I have to ask "if I can get some clerical/graphic support, this is almost ready to go".

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. I don't want to put too fine of a point on it, but that is almost, strikes me as almost begging for--you're asking, but I take it you had no resources available to you to perform such clerical/graphical work?

DR. CARTER:

A. No, because this would have fallen outside of my job as a pathologist and into your, you know, your other job as a community caregiver or, you know, contributor to education, so it would be difficult to get secretarial or, you know, graphic support if you wanted to make this up into a pamphlet in our department, so I would have to ask for their department's

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help.

COFFEY, Q.C.:

Q. What became of your request?

DR. CARTER:

A. We brought it to the Breast Disease Site Group, you'd have to do the timelines for me, but we did work on it. People read it and commented on the language that was used in it and we brought it to the Breast Disease Site Group and did get the clerical support and now I think it's being included in all the purple lupin kits.

COFFEY, Q.C.:

Q. So that was through the Breast Site Group body that you got the clerical -

DR. CARTER:

A. Yes, which essentially be the Cancer Program.

COFFEY, Q.C.:

Q. The Cancer Program. But as of--and the reason I raise it is as of the beginning of February, 2006, there was no--that wasn't readily available, you had to go outside your own--you had to go looking -

DR. CARTER:

A. For the support?

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COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. Yes, it wasn't readily available, I would have to go outside.

COFFEY, Q.C.:

Q. Exhibit P-1748? Doctor, these are handwritten notes I believe of Dr. Cook, February 8th, 2006. It's a meeting regarding update on implementation of ER/PR. Present are a number of individuals, including Drs. Cook, Ejeckam and yourself and Fontaine, and Mr. Gulliver, Mr. Dyer, Mr. Simms, Mr. Green and Ms. Butler, so I take it really that's the three technologists involved, the two technologist managers. Dr. Ejeckam was the point person for IHC. Dr. Cook, clinical chief; Dr. Fontaine the General Hospital site chief, I believe or if he hadn't already resigned, but he was somehow involved or just been involved; and yourself. There's some comments here attributed to yourself and Dr. Ejeckam. It says "Drs. Carter and Ejeckam commented on the stain for ERs and PRs seems to be good correlation and reproducibility with ER

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results and comparison with Mount Sinai, less so for PR. All agreed that implementation date of March 31, 2006 seems feasible." And then they go on to talk about the potential for digital, using a digital image analyzer. Doctor, I have two questions in this regard, at the time what was the nature then of your involvement in the effort to restart ER/PR?

DR. CARTER:

A. I think we had optimized the protocols at that time. Ken and I had picked two that we thought were suitable and we were beginning some on-site testing, we were using those to assess the staining with known values that we knew from Mount Sinai.

COFFEY, Q.C.:

Q. And you describe here the correlation, I take it the ER was pretty good, the PR perhaps at that point, less so.

DR. CARTER:

A. Yeah, but I think we had shown some great improvement. I would have been involved too as a breast person, I think I would have been invited there as the person who was going to be reading a lot of these.

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COFFEY, Q.C.:

Q. Now the potential usage of this visual image analyzer, at that time what was the situation from your perspective?

DR. CARTER:

A. It was brought up at that meeting I think that maybe all of the people there, I'm not sure, but I certainly didn't think it was necessary that we would have a visual analyzer.

COFFEY, Q.C.:

Q. Is there any downside to utilizing?

DR. CARTER:

A. Takes up a lot of my time and provides no better results than if I had not used it.

COFFEY, Q.C.:

Q. And perhaps you can describe that to the Commissioner, why is that?

DR. CARTER:

A. If you're looking at estrogen receptor testing, you have most of your cases are going to be clearly negative or clearly positive, which takes just a few minutes, so that's 80 percent of your cases. So the 20 percent of them that are left, a great proportion of them, maybe 80 percent again are going to be

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

COFFEY, Q.C.:

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Q. The sentence here, "All agreed to the implementation date of March 31, 2006 seems feasible." We understand it didn't actually occur until February 1, 2007. What happened between the beginning of February and or after the beginning of February to make it less or unfeasible at that point, because it didn't happen?

DR. CARTER:

A. I think that there were other issues raised as they were going through the items on the spreadsheet.

COFFEY, Q.C.:

Q. Okay.

DR. CARTER:

A. And it was decided at that point that we weren't going to do or they, Dr. Denic and Dr. Cook, weren't going to go ahead and start any sort of testing unless they had a reasonable amount of those things firmly in place.

COFFEY, Q.C.:

Q. That's on the recommendation spreadsheet.

DR. CARTER:

A. Yes, the spreadsheet that was -

COFFEY, Q.C.:

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Q. And this would be the time going into March or April that Dr. Cook left as clinical chief and Dr. Denic took over?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Exhibit P-1400? This is a letter of February 8th, 2006, it's from yourself, Doctor, to Dr. Cook and it reads, "Please accept this as official notice of my resignation. As you know over the past last eight months I have had many differences of opinion with the team regarding the processes, work assignments and goals for the successful institution of an ER/PR, HER2/neu immunohistochemical laboratory at Eastern Health. It is clear to me that we will not be able to resolve our differences. I cannot, as a fellowship trained breast pathologist, agree with the direction in which this process is proceeding; therefore I feel that resigning is the best option for me and for the team. My last day at Eastern Health will be Wednesday, February 23rd, 2006. Please remove my name from the call schedule, so that I may complete already assigned work.

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I would be happy to meet with you at your convenience to discuss the transition of my duties to my successor. Signed Beverley Carter." And you've written on this, "Please note I have been informed that I have to give three months' notice; therefore, the leaving date is May 3rd, '06. Signed Bev Carter." Doctor, what was going on here at this point in time?

DR. CARTER:

A. This, I think, was a day or two after the meeting that we just described when we talked about the image analyzer. It was a reflection really of my relationship with Mr. Gulliver and Mr. Dyer over the eight months, I guess I've said here, from when the estrogen receptor issue had come out. I felt it was not a very good working relationship. I felt that their in-depth knowledge of processes that they were making definitive decisions about was not great. We still had difficulty with the work assignments, the technologists were still being kept in other duties, as opposed to being in immunohistochemistry at all the time and we had had the meeting, we

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had discussed consensus guidelines for HER2 testing as well, where it was decided that we wouldn't use the antibody for HER2 testing or we would begin to explore the possibility that we wouldn't--that had been recommended at the Canadian Consensus, and the idea that we would spend a lot of money and time getting this image analyzer, I just felt that it was an unworkable relationship.

COFFEY, Q.C.:

Q. And that is what led to this letter?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Did you, in fact then leave in May? What actually happened?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. Because I mean, leaving in different senses, leaving different positions but still remaining geographically in the same location, that's what I'm -

DR. CARTER:

A. No, when I wrote the letter, there was a lot

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of discussion with Dr. Cook and then Dr. Denic when the transition of the clinical chiefs happened. Some discussions with Dr. Williams where they expressed interest in my staying on site and after many discussions an idea to revamp and revitalize the Quality Management Program where it wouldn't be a committee, as previously described in the memo that we looked at yesterday, but now would become a division of the department with staffing and resources. I decided that I would stay.

COFFEY, Q.C.:

Q. Exhibit P-2461? Now, Doctor, yesterday you had indicated that there had been at least one instance in which you had acted as chair of the Physician Review Panel?

DR. CARTER:

A. Yes, February 10th.

COFFEY, Q.C.:

Q. And these are these February 10th, 2001 (sic.) panelling letters, I'll call them.

DR. CARTER:

A. 2006.

COFFEY, Q.C.:

Q. 2006, I apologize. So there are a number of

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them here. The format that these letters took, they all generally follow the same similar format.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Had that been decided upon well before February 10th?

DR. CARTER:

A. The format of the letters?

COFFEY, Q.C.:

Q. Yes, the format.

DR. CARTER:

A. I think we decided that we would put a preamble, you know, about when the patient had been diagnosed and then what their original reports were and then what their treatment decisions would be.

COFFEY, Q.C.:

Q. Then these were, in the second paragraph of all these refers to the patient was discussed at a panel review on February 9th, so what I wanted to ask you about really was this, in terms of at that point in time, I take it you were acting chair because other people were

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just absent, certain other people.

DR. CARTER:

A. Dr. Laing would be chair of the meetings at most times, I think Dr. McCarthy attended occasionally, but that night the two medical oncologists who were present didn't want to chair for whatever reason. I didn't ask, I just volunteered that I would chair.

COFFEY, Q.C.:

Q. Exhibit P-1102? Doctor, this is some e-mail exchanges of February 13th, 2006. The first of them is from Debbie Parsons to a number of individuals, including yourself, deals with future ER/PR meetings and that same day you responded to Debbie Parsons, but addressed your comment to Heather Predham. "As I have recently resigned from my position with Eastern Health, I am quite busy covering call and attempting to clue things up at my desk, I will not be taking part in further ER/PR panel meetings." And you wish her well in the endeavour. And you offer to act in the short term in a consultative manner for any specific issue that might arise at the meetings and then that is forwarded on, that same day by

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Debbie Parsons to Denise Dunn to pass on to Dr. Williams. Did you continue to participate in the ER/PR panelling, do you recall?

DR. CARTER:

A. I don't recall specifically, I may have.

COFFEY, Q.C.:

Q. Exhibit P-2064? Now, Doctor, these are Laboratory Medicine Program minutes of March 10th, 2006. Drs. Williams, Denic and Cook are present, this is Mr. Gulliver. On the second page, paragraph one under "New Business" says "Dr. Carter, Dr. Denic presented a proposal which will see Dr. Carter being appointed as a quality control co-ordinator for the pathology service. There was general agreement to move forward and arrange a meeting with Dr. Carter to discuss." So I take it that that's the subject matter you referred to several minutes ago.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Exhibit P-2068 please? And this is minutes of a meeting of March 28th, 2006, Discipline of Laboratory Medicine. The call to order was by

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Dr. Denic and a number of individuals present, including yourself and a number of other pathologists. Under "New Business: quality assurance, Dr. Denic thanked Dr. Cook for his work and then implementation of the new Quality Assurance Program was discussed at length. Dr. Beverley Carter will act as the manager of the new Quality Management Program for the Pathology Department. There will be a technical member and a clerical member of the team. Dr. Carter will act independently and answer to quality management team. This is supported by Dr. Williams, the VP." So there was a statement, apparently, I gather by Dr. Denic to this effect, advised in the meeting.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And then it's noted "Dr. Morris-Larkin expressed concern about being audited." Now, and then there's a note "Dr. Denic stated that random slides would be audited. Dr. Carter says that the random cases will be picked by the technologist who is working with the Quality Management Program. Dr. Morris-Larkin

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expressed the feeling that one pathologist should not do all of the auditing. Dr. Denic also stated that there will be policies put in place regarding the auditing. Dr. Cook stated there was no QA committee before November, 2004." And we saw yesterday that you had been involved in that, back in 2004. What was this concern then, your feeling about the concern here, voiced by Dr. Larkin.

DR. CARTER:

A. That they would be audited? I think again it reflects that they weren't used to random review and quality management programs at that time. I had come from McMaster where we had it. I was quite comfortable with someone else looking at my work.

COFFEY, Q.C.:

Q. And toward the middle of the page, there's a note, "Dr. Morris-Larkin offered to help with the QA".

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So I take it, after it was -- as it was explained.

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DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. They became more accepting of the idea.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And it ends with, "Dr. Denic thinks it is very important that the QA Committee meets to be put in place as soon as possible. By then sub-specialization, Dr. Denic encouraged the idea of pathologists sub-specializing". I take it, by this point in time, the beginning of '06, March, sub-specialization or the idea of it was more accepted locally?

DR. CARTER:

A. Yes. I think in November of 2005, we had the first meeting of the breast sub-specialty group, but I think --

COFFEY, Q.C.:

Q. November, 2005?

DR. CARTER:

A. This is March of 2006?

COFFEY, Q.C.:

Q. This is '06, yes.

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DR. CARTER:

A. Yes, so I think we were on board for about three or four months before this.

COFFEY, Q.C.:

Q. Before this.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. By that point in time it was generally accepted?

DR. CARTER:

A. I would say, yes.

COFFEY, Q.C.:

Q. As an idea.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Exhibit P-2462. Here, Doctor, are minutes of a laboratory managers meeting of April 12th, 2006. Under paragraph "C", second paragraph, it's noted, "The senior technologist in pathology is being reassigned to work with Dr. Carter, who is now in charge of a pathology QA program. She will work to put protocols and procedures in place, as well as review slides

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each day". Who was that?

DR. CARTER:

A. Catherine Parnell is the technologist that she's referring to. The second sentence in that is incorrect, that was not the job description that she had, but it was another point of disagreement with the lab management.

COFFEY, Q.C.:

Q. Could you tell us then what that was about?

DR. CARTER:

A. I had written a document to outline a quality management program, so it was very similar to the document from October, 2004, but it was much broader-based. It included a preamble about the theory of quality management, why it was necessary, talking about the errors in medicine report from 1999 that sort of acted as the impetus for all this sort of work, and went through what we would be doing in the quality management department, which was monitoring things from the pre-analytic, the analytic, and post-analytic period. We would also be monitoring things such as turnaround time for biopsies, emergency cases, that sort of thing, and also be doing customer

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

COFFEY, Q.C.:

Q. So they thought it should involve what, actually writing --

DR. CARTER:

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

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management issue.

COFFEY, Q.C.:

Q. And this was a point of contention, I take it, that continued for some time?

DR. CARTER:

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

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

COFFEY, Q.C.:

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

DR. CARTER:

A. She did, but I don't think that she came at that time. Again I -- what's the date on this?

COFFEY, Q.C.:

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Q. This is April 20th.

DR. CARTER:

A. I think that Catherine probably was freed up in September to begin, and --

COFFEY, Q.C.:

Q. Full time secretarial support for the first six months.

DR. CARTER:

A. I think we chose to have half time secretarial support for a year. I think that's what we chose to do, but, yes, we did get those things.

COFFEY, Q.C.:

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

DR. CARTER:

A. Theoretically, I would be cut 20 percent on my clinical duties.

COFFEY, Q.C.:

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

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

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

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Eastern Health. This is a document that says the development of a breast disease site group for Eastern Health, the first meeting of the breast disease site group of St. John's hospitals of Eastern Health took place in June of 2006.
DR. CARTER:
A. Uh-hm.
COFFEY, Q.C.:
Q. Would that be about -- the breast disease site group.
DR. CARTER:
A. That would be the multidisciplinary team, yes.
COFFEY, Q.C.:
Q. Okay. Now you did refer just a moment ago to November, 2005.
DR. CARTER:
A. That would be the breast pathology sub-speciality team. Sorry, there's a lot of repetition.
COFFEY, Q.C.:
Q. Oh, no, I appreciate that. So who did that involve?
DR. CARTER:
A. That would have been myself, Dr. Don Cook, Dr.

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

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

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they are.
COFFEY, Q.C.:
Q. And so your involvement in that review then was what, the nature of your involvement in the DCIS review?
DR. CARTER:
A. On a consultative basis, they would ask me to look at slides and then I would review them with Dr. Cook and, when Dr. Cook was unavailable, Dr. Denic, if there was any discrepancy. If I agreed with the original pathologist, I would just sign off on it.
COFFEY, Q.C.:
Q. And I take it, if you didn't, you would inform them of that too.
DR. CARTER:
A. Pardon me?
COFFEY, Q.C.:
Q. If you differed with the original pathologist in that regard, you would make your views known as well.
DR. CARTER:
A. Yes, and then I would bring it to Dr. Cook or Dr. Denic. Sometimes we would sign it out. Sometimes we would send it out for a third

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

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COFFEY, Q.C.:
Q. Doctor--because this is August ’06, why had it taken that long, from your perspective, for someone to draft a fixation policy?
DR. CARTER:
A. I don’t know if anyone had been asked to draft one.
COFFEY, Q.C.:
Q. I appreciate when you were asked because there’s a reference in late June and here you are in early August and you’ve got one. Certainly there is the draft of it but before that, I take it, everyone would have realized that fixation was an issue--
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. --back in the middle of ’05 potentially here, and yet there was no fixation policy so -
DR. CARTER:
A. I mean, it would be, I guess, the classic case of everyone assuming that the next person was the person who is responsible for doing that.
COFFEY, Q.C.:
Q. Exhibit P-2328, now these are Pathology

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Quality Management Committee minutes of October--I apologize, 2328 - October 3, 2006, Doctor. You’re present and under Implementation of Policies, Fixation, it’s noted "it has been written and submitted by Nash Denic and Barry Dyer with no response to date. Right now, there’s a 24- to 36-hour turnaround time. Eventually, shiftwork will help resolve this problem. B. Carter to add a rider to policy." Do you recall what this was about, Doctor?
DR. CARTER:
A. The policy, when it was written when it was thought to be in its final form, then it would have to be signed off. Administrative people would probably be able to give you a more intelligent answer, but in order for it to be accepted, you know, as a policy of Eastern Health, it would have to be signed off by the appropriate authorities, and I guess we were sending it to Nash Denic and - sorry, Dr. Denic - and Mr. Dyer for that purpose. Right now there is a 24- to 36-hour turnaround time, I’m not sure what that means, and "eventually, shiftwork will help resolve this problem," I’m

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not sure what that means. It doesn’t really make that much sense. That’s the first time I’ve seen this in awhile.
COFFEY, Q.C.:
Q. Exhibit P-2466, Doctor, this is a letter of November 2, 2006. Well, it’s a form letter, I take it because it’s from yourself and Ms. Parnell.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. "Dear Doctor, a Pathology Quality Management Program for the St. John’s hospitals of Eastern Health has been newly formed. As part of this initiative, we would like to find out how our preferred clientele talk to physicians about our service. Please take the time to file the enclosed survey, and return it in a self-addressed envelope." I take it, this is the survey you referred to earlier?
DR. CARTER:
A. Yes, it is.
COFFEY, Q.C.:
Q. A customer satisfaction survey. Was this sent out?

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DR. CARTER:
A. Yes, it was sent out in November, I believe, of 2006 and hopefully in November of 2007.
COFFEY, Q.C.:
Q. And what was the response?
DR. CARTER:
A. I wouldn’t be able to give you the numbers.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. But we sent out, I think, a hundred, somewhat random but somewhat directed to all types of physicians who would use our service. I think we got back maybe somewhere around 40.
COFFEY, Q.C.:
Q. Uh-hm.
DR. CARTER:
A. And there was a wide variety of information that you could glean from it. I don’t think I can summarize it in a couple of sentences.
COFFEY, Q.C.:
Q. Here, Doctor, just looking at the form unfilled out, there’s a listing of possible topics - "Overall Satisfaction Rating," "Quality of Professional Interactions" and so

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on, "Diagnostic Accuracy" - and there are various numbers for rating between one being poor to five excellent, and then the next page here it's three. Are numbers for each of these, I take it, filled in the category, "Overall Satisfaction Rating," under 143, below average 9, average 10, good 13, and excellent 2?

DR. CARTER:

A. So that would be the number of respondents that had ticked off in each one of those categories.

COFFEY, Q.C.:

Q. In those particular categories, and we're only going to look through the page here on that and under the next page, Page 4, under Comments, I take it -

DR. CARTER:

A. So the text is what the comment was, and then the number after it is what number that physician had given for their overall rating for the service. So this physician for the first one takes two weeks approximately. That physician gave it a four.

COFFEY, Q.C.:

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Q. In terms of the overall -

DR. CARTER:

A. You know, they were overall satisfied, so it gives you some indication of, you know, how the physician has felt about the service in general, so if somebody gives you ones on everything, then, you know, you would take that comment in a different way than somebody who gives you a variety of ratings on each one.

COFFEY, Q.C.:

Q. And what was done with this, Doctor, these results?

DR. CARTER:

A. They would form part of the report from the Quality Management Program, so these would have been given to Dr. Denic. The survey had the option, I think, if you could sign the report or not.

COFFEY, Q.C.:

Q. Uh-hm.

DR. CARTER:

A. Many of the physicians signed it. It's a very open sort of community, so for the comments that were less than favourable I think he would, if possible, speak to the physician who had filled out the survey, and also address it and see if it was something that should be addressed. There's one that begins, "I am a surgeon," that says to "not include," for example, "microscopic details in a pathology report. Seems well below standard of care." In fact, standard of care now is to move away from using microscopic details. They're proven over examination not to be that much help to the clinician and often sometimes confusing, so just because they said it doesn't, you know, mean that it's true, so Dr. Denic would take that comment and would maybe not act on that as quickly as somebody that says, "You know, I think that the lab is doing a pretty good job but, listen, I have this case and I want something done about it."

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COFFEY, Q.C.:

Q. Okay. And if we could please, Exhibit P-2467.

THE COMMISSIONER:

Q. Mr. Coffey, when you (unintelligible).

COFFEY, Q.C.:

Q. Yes, I appreciate that. This is an e-mail of November 19, 2006, from Ms. Predham to Ms. Elliott and Pat Pilgrim. She writes, "I met with Bev Carter, Ford Elms, Don Cook, Nash Denic and Susan Bonnell on Friday afternoon. We reviewed the presentation for Monday and it's very good and comprehensive. As always, Bev's comments in the meeting were a little bit alarmist in nature, but she is only speaking about ER/PR testing at the presentation, and then Dr. Howell called me on Friday afternoon and told me that he would anticipate that I would be asking," and she goes on from there about something else dealing with an executive meeting. Doctor, the comment attributing to you being a "little bit alarmist in nature," had anyone at that time in relation to this teleconference, video conference - I think video conference, in fact, that occurred in November - did anybody say to you that perhaps you were "a bit alarmist?" Anybody brought that to your attention?

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DR. CARTER:

A. No, and I think what Heather is referring to there goes to the third paragraph. I think, during the course of that discussion, I was

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expressing concern. I wouldn't view it as alarmist but, anyway, I was expressing concern that maybe a lot of the recommendations and changes that had been recommended weren't happening as quickly as I would have liked them, and they decided to do a College of American Pathologists audit on the lab to see how they do.

COFFEY, Q.C.:

Q. To see how they do.

DR. CARTER:

A. And then they decided to have Ms. Wegrynowski come back and do a formal audit. I don't think she was speaking about what I was talking about at the presentation.

COFFEY, Q.C.:

Q. No. So you say that you felt that they intended to have Ms. Wegrynowski come back?

DR. CARTER:

A. No, no, eventually they asked her to come back.

COFFEY, Q.C.:

Q. Did they?

DR. CARTER:

A. Yeah, I don't know if that was their intent all along.

COFFEY, Q.C.:

Q. No, this is November of '06 and Ms. Wegrynowski had been here and gone twice.

DR. CARTER:

A. Oh, she had been here, okay.

COFFEY, Q.C.:

Q. So here there's certainly a CAP audit anticipated, a CAP audit out of documentation mostly. Did you ever hear about how that went?

DR. CARTER:

A. Not officially. I think Dr. Elms and Dr. Denic went with her and I thought that it had gone well, but I'm not certain.

COFFEY, Q.C.:

Q. And, if you could, Commissioner, one last exhibit, Exhibit P-1425, and, Doctor, this is a slide show presentation which we understand was given in this video conference. I ask, please, if we could go to Page 29, please? It's all pitfalls in ER testing by Dr. Bev Carter. I take it then, this would be the presentation that you gave at the time?

DR. CARTER:

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A. Yes.

COFFEY, Q.C.:

Q. And the audience, target audience, was your fellow pathologists, generally?

DR. CARTER:

A. Yes, and across-the-province technologists from the lab, and I think from any lab, and I think the invitation had extended to clinicians involved in the issue.

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. Kind of.

COFFEY, Q.C.:

Q. If we go on then through - I'm just running through them here up to Page 54 of the exhibit, "How To Get a Perfect Result." I take it, that was how you concluded it.

DR. CARTER:

A. Yes, I think so.

COFFEY, Q.C.:

Q. I guess we'll go to the next result, and we end up at Page 59 with--by Dr. Cook, so the level of detail here was intended, you know, to be how detailed, how intensive, the presentation?

DR. CARTER:

A. I'm not sure I understand the question.

COFFEY, Q.C.:

Q. I take it, you were speaking to technologists and pathologists who you would expect to know something about this to start.

DR. CARTER:

A. Yes. Yeah.

COFFEY, Q.C.:

Q. And was this intended kind of as an overall full-primer for them - full primer - full lesson, as it were.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. They wouldn't know as much as you did about it. Apparently, that's a fact but -

DR. CARTER:

A. Yeah, I mean, this was a teaching--I regard this as a teaching opportunity. I'm sure some of the people there knew a lot about what I was talking about, and some didn't.

COFFEY, Q.C.:

Q. Thank you, Commissioner.

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THE COMMISSIONER:

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

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 29th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 29th day of July, A.D., 2008

Judy Moss

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