

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">September 2, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C. Commission Co-counsel</p> <p>Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury Doctors Kara Laing et al</p> <p>Daniel Simmons Eastern Regional Integrated Health Authority</p> <p>Ches Crosbie, Q.C./ Laura Brocklehurst. Members of the Breast Cancer Testing Class Action</p> <p>Mark Pike NL Medical Association</p> <p>Jennifer Newbury Canadian Cancer Society (NL Division)</p> <p>Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p>THIS PAGE ONLY REVISED NOVEMBER 18, 2008</p> <p style="text-align: center;">LIST OF EXHIBITS</p> <p>Exhibits entered and marked P-2300 through to P-2303 . . . Pg. 4</p> <p>Exhibits entered and marked P-2305 and P-2306 Pg. 4</p> <p>Exhibit entered and marked P-2308 Pg. 4</p> <p>Exhibit entered and marked C-0173 Pg. 4</p> <p>Exhibits entered and marked C-0225 through to C-0228 . . . Pg. 4</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>Dr. Ford Elms (Sworn)</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 4 - 383</p> <p>Examination by Ms. Jennifer Newbury Pg. 383 - 392</p> <p>Examination by Ms. Laura Brocklehurst Pgs. 392 - 398</p> <p>Examination by Mr. Peter Browne Pgs. 398 - 406</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 September 2, 2008</p> <p>2 THE COMMISSIONER:</p> <p>3 Q. Please be seated. Mr. Coffey?</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Thank you, Commissioner. The next witness is</p> <p>6 Dr. Ford Elms.</p> <p>7 DR. FORD ELMS (SWORN) EXAMINATION BY BERNARD COFFEY, Q.C.</p> <p>8 REGISTRAR:</p> <p>9 Q. Would you please state and spell your complete</p> <p>10 name for the Commission?</p> <p>11 DR. ELMS:</p> <p>12 A. Ford John Elms, F-O-R-D J-O-H-N E-L-M-S.</p> <p>13 REGISTRAR:</p> <p>14 Q. Thank you.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Commissioner, I have some new exhibits I'm</p> <p>17 going to ask that be entered, please. They</p> <p>18 are P-2300, 2301, 2302, 2303, 2305, 2306,</p> <p>19 2308, as well as C-0173, C-0225, 0226, 0227</p> <p>20 through C-0228.</p> <p>21 THE COMMISSIONER:</p> <p>22 Q. Entered.</p> <p>23 EXHIBITS ENTERED AND MARKED P-2300 THROUGH P-2303</p> <p>24 EXHIBITS ENTERED AND MARKED P-2305 AND P-2306</p> <p>25 EXHIBIT ENTERED AND MARKED P-2308</p>

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<p>1 EXHIBIT ENTERED AND MARKED C-0173</p> <p>2 EXHIBITS ENTERED AND MARKED C-0225 THROUGH C-0228</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Thank you, Commissioner. Good morning, Dr.</p> <p>5 Elms.</p> <p>6 DR. ELMS:</p> <p>7 A. Good morning.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. I'm going to ask, please, Registrar, if you</p> <p>10 could bring up Exhibit P-2308, please? And</p> <p>11 Doctor, there on the screen in front of you</p> <p>12 the exhibit is. That's your name, Ford Elms,</p> <p>13 and an education summary on page two of it,</p> <p>14 and community involvement on page three. Is</p> <p>15 this your CV, Doctor?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Doctor, could you please then give the</p> <p>20 Commissioner and overview of your educational</p> <p>21 and professional background?</p> <p>22 THE COMMISSIONER:</p> <p>23 Q. Dr. Elms, it's also in written form in the</p> <p>24 book, if you'd prefer to look at that.</p> <p>25 DR. ELMS:</p>	<p>1 Carbonear. In 1990, I then transferred to the</p> <p>2 emergency department of St. Clare's Hospital,</p> <p>3 and in 1996, I entered the pathology residency</p> <p>4 program at Memorial University. I studied</p> <p>5 there for four years and completed by</p> <p>6 licensing exams in 2001. In June of 2000, I</p> <p>7 commenced work as a staff pathologist at St.</p> <p>8 Clare's Hospital.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And are you still located there today?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Doctor, the licensing exams that you took in</p> <p>15 2000-2001, which ones were they?</p> <p>16 DR. ELMS:</p> <p>17 A. They were the Royal College certification</p> <p>18 exams.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And the Canadian?</p> <p>21 DR. ELMS:</p> <p>22 A. Yes.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And your certification is in anatomic?</p> <p>25 DR. ELMS:</p>
<p>Page 6</p> <p>1 A. Yes. I entered medical school at Memorial</p> <p>2 University in 1980 and completed the program</p> <p>3 there. I then did a rotating internship for</p> <p>4 one year. Then in June of 2005, I commenced</p> <p>5 work as a casualty officer in Carbonear</p> <p>6 Emergency Department.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. I'm sorry, in?</p> <p>9 DR. ELMS:</p> <p>10 A. As a casualty officer.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. In what year?</p> <p>13 DR. ELMS:</p> <p>14 A. In 1985 rather, sorry.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. No, no, I was -</p> <p>17 DR. ELMS:</p> <p>18 A. I'm older than that.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Thanks, Doctor.</p> <p>21 DR. ELMS:</p> <p>22 A. After four months there, I went to work as a</p> <p>23 casualty officer in the emergency department</p> <p>24 at the Grace General Hospital. I was there</p> <p>25 for 22 months and then transferred back to</p>	<p>Page 8</p> <p>1 A. General pathology.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. General pathology, okay. Now Doctor, could</p> <p>4 you give the Commissioner, please, an account</p> <p>5 of what, if any, exposure you had to</p> <p>6 immunohistochemistry during your medical</p> <p>7 school days, that would be back in the early</p> <p>8 '80s, your internship and then your residency</p> <p>9 as a pathologist in the latter part of the</p> <p>10 '90s?</p> <p>11 DR. ELMS:</p> <p>12 A. During medical school and my internship, I had</p> <p>13 no exposure to immunohistochemistry. I didn't</p> <p>14 encounter it until I began my residency and</p> <p>15 then we were studying immunohistochemistry</p> <p>16 from the point of view of the interpretation</p> <p>17 of panels of immunohistochemical stains in the</p> <p>18 diagnosis of difficult cases and in the course</p> <p>19 of that, during my residency, the testing for</p> <p>20 estrogen and progesterone receptors began.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Okay. This was while Dr. Khalifa was -</p> <p>23 DR. ELMS:</p> <p>24 A. Yes.</p> <p>25 COFFEY, Q.C.:</p>

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<p>1 Q. - here in St. John's, and you would have been</p> <p>2 a pathology resident in St. John's during the</p> <p>3 period where the IHC approach to ER/PR</p> <p>4 determination was introduced?</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. What do you recall, if anything, about your</p> <p>9 introduction to that?</p> <p>10 DR. ELMS:</p> <p>11 A. In the beginning, we were still doing the</p> <p>12 bioassay and then I became aware that we were</p> <p>13 introducing the immunohistochemical process</p> <p>14 and then it came on stream and it became a</p> <p>15 part of our assessment of breast cases.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And do you recall, Doctor, what that actually</p> <p>18 involved? I mean, you say exposure to, what</p> <p>19 made up the exposure? How were you exposed to</p> <p>20 you?</p> <p>21 DR. ELMS:</p> <p>22 A. Well, when we would get a breast case,</p> <p>23 initially we would be requested to do estrogen</p> <p>24 and progesterone receptors on a particular</p> <p>25 case. When we received the request, we would</p>	<p>1 time and did you avail of?</p> <p>2 DR. ELMS:</p> <p>3 A. Most of what was available to me at the time</p> <p>4 was what was included in our pathologist</p> <p>5 textbooks.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And do you recall generally what that was?</p> <p>8 DR. ELMS:</p> <p>9 A. Again, it was to do with the interpretation of</p> <p>10 panels of stains in the diagnosis of disease.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Doctor, do you recall what it was, during your</p> <p>13 residency then, in relation to ER/PR IHC</p> <p>14 stains that you were taught to look for back</p> <p>15 then?</p> <p>16 DR. ELMS:</p> <p>17 A. We were taught to look for nuclear staining</p> <p>18 and to assess the intensity of the staining.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And what about the intensity, what were you</p> <p>21 taught about that?</p> <p>22 DR. ELMS:</p> <p>23 A. Basically that the intensity could vary, that</p> <p>24 some tumours would be weaker, that not the</p> <p>25 entirety of a tumour would stain.</p>
<p>1 order it and then the slides would come back</p> <p>2 to the attending pathologist under whom I was</p> <p>3 working at the time, and we would then read</p> <p>4 those slides and report on them.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. And I take it the attending pathologist would</p> <p>7 be whomever you were working for at the time?</p> <p>8 DR. ELMS:</p> <p>9 A. Whomever, yes.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. And then, I take it then whatever you learned</p> <p>12 about it would be what the attending</p> <p>13 pathologist taught you?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Do you recall, Doctor--sorry about that,</p> <p>18 Doctor. Okay, Doctor, do you recall whether</p> <p>19 or not you were introduced to it at the time</p> <p>20 or learned anything at the time through</p> <p>21 reading?</p> <p>22 DR. ELMS:</p> <p>23 A. Yes, yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. What sorts of things were available at that</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. When you say intensity in this context, that</p> <p>3 means what?</p> <p>4 DR. ELMS:</p> <p>5 A. How dark the stain is basically. The</p> <p>6 indicator that we use is a brown dye and</p> <p>7 basically it's to do with how dark, how brown</p> <p>8 the nucleus looks.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Doctor, and then you said as well that so it</p> <p>11 might be--you've got to look at how brown,</p> <p>12 dark, the nuclear staining was?</p> <p>13 DR. ELMS:</p> <p>14 A. Um-hm.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. For ER/PR. What about in terms of how much of</p> <p>17 the tumour stained, percentages?</p> <p>18 DR. ELMS:</p> <p>19 A. Just that it was variable, that various</p> <p>20 tumours could stain in various ways. I was</p> <p>21 aware that there were various--that there was</p> <p>22 debate as to what percentage of tumour cells</p> <p>23 would be considered to be a positive.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And what do you recall about that?</p>

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<p>1 DR. ELMS: 2 A. In the early days, I believe we were working 3 with 30 percent. 4 COFFEY, Q.C.: 5 Q. And so that was, I take it, generally the 6 approach at St. Clare's. Would you have done 7 any time at the General Hospital? 8 DR. ELMS: 9 A. Oh yes, yeah. 10 COFFEY, Q.C.: 11 Q. And how about the Grace? 12 DR. ELMS: 13 A. Same, and the Grace as well, yes. 14 COFFEY, Q.C.: 15 Q. Was there anything written down as to this 30 16 percent figure? 17 DR. ELMS: 18 A. Not that I recall. 19 COFFEY, Q.C.: 20 Q. And when you say percentages, were there any 21 other type of stains at the time that you were 22 using or coming to a percentage determination 23 of? 24 DR. ELMS: 25 A. No.</p>	<p>1 DR. ELMS: 2 A. In the--the exam is divided into several parts 3 and one of those parts is a practical exam in 4 which you're shown unknown slides. There may 5 have been one at the time that we were 6 required to look at. 7 COFFEY, Q.C.: 8 Q. There may have been one out of what? 9 DR. ELMS: 10 A. Out of 40. 11 COFFEY, Q.C.: 12 Q. Okay. 13 DR. ELMS: 14 A. But it was not a big, a large component of the 15 exam. 16 COFFEY, Q.C.: 17 Q. Okay, that's the practical part of it. How 18 about - 19 DR. ELMS: 20 A. Yes, or of the written. 21 COFFEY, Q.C.: 22 Q. Or the written. So if it was there at all, it 23 was a very small part? 24 DR. ELMS: 25 A. Very small part.</p>
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<p>1 COFFEY, Q.C.: 2 Q. This is kind of the only one in which you were 3 called upon to actually come up with a 4 percentage or a fraction? 5 DR. ELMS: 6 A. That's correct. 7 COFFEY, Q.C.: 8 Q. Were you taught anything else, to look for 9 anything else at the time? We've heard a lot 10 now about internal controls and the usage of 11 internal controls for ER/PR. At that time, in 12 the '90s, do you recall being made aware of 13 that? 14 DR. ELMS: 15 A. No. 16 COFFEY, Q.C.: 17 Q. Doctor, again so the Commissioner can get some 18 sense of this, you wrote your exams in 2000- 19 2001? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. Do you recall what, if any, part of the 24 testing process involved testing of your 25 knowledge of IHC?</p>	<p>1 COFFEY, Q.C.: 2 Q. And I specify IHC, not particularly ER/PR. 3 DR. ELMS: 4 A. IHC in general. 5 COFFEY, Q.C.: 6 Q. IHC in general, and at that time, there would 7 have been, I take it, many dozens of IHC 8 tests? 9 DR. ELMS: 10 A. Oh yes. 11 COFFEY, Q.C.: 12 Q. Easily? 13 DR. ELMS: 14 A. Yeah, easily. 15 COFFEY, Q.C.: 16 Q. Doctor, while I'm on the topic, I take--and we 17 will come to this, you are currently the 18 director of immunohistochemistry for Eastern 19 Health? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. Are you involved in teaching residents? 24 DR. ELMS: 25 A. Yes.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And you'd certainly be aware of what exposure</p> <p>3 they got to IHC generally?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. As of right now, as we speak, how much, to</p> <p>8 your knowledge, how much do the current exams,</p> <p>9 fellowship exams or examining process, test</p> <p>10 IHC?</p> <p>11 DR. ELMS:</p> <p>12 A. I don't know.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. You don't know, okay. In terms of the</p> <p>15 residents' actual exposure to IHC though, how</p> <p>16 much do they have?</p> <p>17 DR. ELMS:</p> <p>18 A. IHC is relatively commonly done and in</p> <p>19 numerous instances, they will be--they will</p> <p>20 order immunohistochemical stains to help them</p> <p>21 in their assessment of a case.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Are they actually, to your knowledge, exposed</p> <p>24 though to what actually goes on in the lab, in</p> <p>25 terms of IHC?</p>	<p>1 A. Yes. Yes, we have a residents academic half</p> <p>2 day in pathology and the plan is to have these</p> <p>3 lectures as a portion of that.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And again, so the Commissioner has some</p> <p>6 understanding of what a residents' half day</p> <p>7 means, in a cycle of a week or a month, how</p> <p>8 much is that?</p> <p>9 DR. ELMS:</p> <p>10 A. The residents half day in pathology, what we</p> <p>11 refer to as RHDIP, which I believe has been</p> <p>12 mentioned here before -</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Yes.</p> <p>15 DR. ELMS:</p> <p>16 A. - occurs on Friday mornings and our residents</p> <p>17 are relieved of their service duties to attend</p> <p>18 to academic issues. Usually that is in the</p> <p>19 context of lectures provided by various</p> <p>20 members of the staff.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. So it would be once a week for a half day?</p> <p>23 DR. ELMS:</p> <p>24 A. Once a week.</p> <p>25 COFFEY, Q.C.:</p>
<p>1 DR. ELMS:</p> <p>2 A. Not at the present time.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Are there any plans to change that?</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Okay. What are the plans in that regard?</p> <p>9 DR. ELMS:</p> <p>10 A. I'm currently developing a series of lectures,</p> <p>11 geared towards our technologists, of histology</p> <p>12 with relation to immunohistochemistry. So</p> <p>13 that in various types of tissues, we can</p> <p>14 discuss the types of antibodies that would be</p> <p>15 expected to stain and it's not merely a matter</p> <p>16 of staining. In many tissues, it's pattern of</p> <p>17 staining, actual area of staining. One of the</p> <p>18 big areas where that would be in lymph node,</p> <p>19 and so our technologists will need to know</p> <p>20 which areas of tissues would be expected to</p> <p>21 stain and we're also throwing that open to the</p> <p>22 residents.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. You'll make it available?</p> <p>25 DR. ELMS:</p>	<p>1 Q. And as part of that process, these lectures</p> <p>2 would be offered and they'd be expected to</p> <p>3 attend them?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Do you have any estimate as to when that might</p> <p>8 come or be made available to the technologists</p> <p>9 and the residents?</p> <p>10 DR. ELMS:</p> <p>11 A. I hope to begin them next week.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And so I take it then, Doctor, this hadn't</p> <p>14 been done before, to your knowledge, in the</p> <p>15 program here?</p> <p>16 DR. ELMS:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Doctor, if we could, please, Registrar, I'm</p> <p>20 going to ask you to bring up Exhibit P-2300.</p> <p>21 Now Doctor, these are the minutes of a</p> <p>22 laboratory management committee meeting,</p> <p>23 number eight actually, of April 26, 2000, and</p> <p>24 you'll notice that you're present there, noted</p> <p>25 listed as present, as well as Dr. Cook and</p>

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<p>1 others, and at the bottom of the page, 2 paragraph 8.4, "a list of new tests offered 3 was presented." Look to the next page, they 4 are indicated to be HER2/neu expression, FISH 5 techniques, cytogenetics and auto antibodies 6 to three different conditions. Doctor, was 7 this--would this reflect the introduction of 8 HER2/neu in St. John's around that time? 9 DR. ELMS: 10 A. I don't recall the exact discussion, but it 11 would have been at least to inform the staff 12 that this test was to be offered. 13 COFFEY, Q.C.: 14 Q. And Doctor, in terms of HER2/neu, at the time, 15 were you involved in ordering and reporting 16 HER2/neu cases? 17 DR. ELMS: 18 A. Yes. 19 COFFEY, Q.C.: 20 Q. Were you given any training in that regard? 21 DR. ELMS: 22 A. No, we were given information provided by the 23 manufacturer. 24 COFFEY, Q.C.: 25 Q. That would be the manufacturer of the -</p>	<p>1 stains several years before? 2 DR. ELMS: 3 A. There was much more information provided as to 4 interpretation, so that, as I said, we were 5 given visual information, because the 6 interpretation of HER2/neu is more complex 7 than that of ER. 8 COFFEY, Q.C.: 9 Q. Exhibit P-1867, please. Doctor, these are-- 10 this is a quality initiatives report for April 11 1st '99 through March 31st, 2000. It's 12 prepared by Mr. Whalen and Dr. Cook and I just 13 refer to it because--I'm sorry, at page 22, 14 please. Go back here a bit. Actually, this 15 is the one at page 19, begins the quality 16 initiatives report for 2000 to 2001, executive 17 summary, and at page 22 of the exhibit it's 18 noted in passing that yourself and a number of 19 other physicians have passed your exams. So 20 you then, if I could, please, Exhibit P-0479, 21 page eight, please? This is a listing of 22 Eastern Health pathologists staff turnover. 23 Look down at 3.02, Ford Elms is listed there. 24 It's the second entry, June 1st, 2000. 25 DR. ELMS:</p>
<p>1 DR. ELMS: 2 A. Of the antibody. 3 COFFEY, Q.C.: 4 Q. - of the antibody. And what sorts of 5 information or what sort of information would 6 that have been? 7 DR. ELMS: 8 A. HER2/neu is assessed on a scale of zero to 9 three plus and so we were given information as 10 to what appearance each of these stains would 11 have, so we'd know what was considered to be a 12 one plus or a two plus or a three plus. 13 COFFEY, Q.C.: 14 Q. And so I take it this would be textual 15 information? 16 DR. ELMS: 17 A. Textual and visual. 18 COFFEY, Q.C.: 19 Q. Visual, okay. 20 DR. ELMS: 21 A. We had colour photographs as well. 22 COFFEY, Q.C.: 23 Q. Doctor, how did what happened in relation to 24 HER2/neu, such as it was, you described, 25 compare with what had happened with ER and PR</p>	<p>1 A. Yes. 2 COFFEY, Q.C.: 3 Q. So that's when you actually started then or is 4 that correct? 5 DR. ELMS: 6 A. I started on the 12th of June. 7 COFFEY, Q.C.: 8 Q. Okay, that's fine. It's close. Doctor, tell 9 the Commissioner, please, then, in terms of ER 10 and PR reporting, by the time you began in the 11 middle of 2000 on staff at St. Clare's, I 12 understand from evidence we've heard that 13 ER/PR had already been utilized in St. John's 14 really going back to 1997? 15 DR. ELMS: 16 A. Yes, that's true. 17 COFFEY, Q.C.: 18 Q. Through '98, '99 and 2000, in effect through 19 most of your residency? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. Before having a staff position, as a resident, 24 would you actually report ER/PR results? 25 DR. ELMS:</p>

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<p>1 A. Not independently. I would see them--the 2 process of residency training is a process of 3 increasingly graded responsibility. I would 4 see them and assess them and assess the case 5 myself and then sign them out with my 6 attending. 7 COFFEY, Q.C.: 8 Q. And Doctor, what was your approach or what 9 were you taught in terms of--first of all, 10 what were you taught, as opposed to your 11 approach, what were you taught in terms of how 12 it should be reported, ER and PR? 13 DR. ELMS: 14 A. That we reported positivity or negativity and 15 that initially, as I said, there was 16 considered a cut off of, I believe it was 30 17 percent. 18 COFFEY, Q.C.: 19 Q. So how would you have reported it? 20 DR. ELMS: 21 A. In those days, that it was positive or 22 negative. 23 COFFEY, Q.C.: 24 Q. And you'd simply say ER is positive or 25 negative and PR is positive or negative?</p>	<p>1 DR. ELMS: 2 A. No. 3 COFFEY, Q.C.: 4 Q. Never actually had anybody come back and say 5 "well, what do you mean by positive or 6 negative?" 7 DR. ELMS: 8 A. No. No, I had no contact of that nature. 9 COFFEY, Q.C.: 10 Q. Doctor, this 30 percent, did that ever change, 11 the approach to that? 12 DR. ELMS: 13 A. Yes, after I began work at St. Clare's, there 14 was a debate--we became aware of debate as to 15 exactly what constituted a positive. Was 16 greater than 30 percent positive? Was greater 17 than ten percent positive? Some were saying 18 that any staining at all would be considered 19 positive. 20 COFFEY, Q.C.: 21 Q. What do you recall then happened? In what 22 context did that debate occur and what 23 happened? 24 DR. ELMS: 25 A. We decided at the time that it would be</p>
<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. And wouldn't use a percentage? 5 DR. ELMS: 6 A. No. 7 COFFEY, Q.C.: 8 Q. And in your own mind, it was--if it was 30 or 9 less or less than 30, or do you recall? 10 DR. ELMS: 11 A. If it's less than 30. 12 COFFEY, Q.C.: 13 Q. Less than 30. So if you saw 30, 33 percent, 14 say a third, then you would simply report it 15 as positive? 16 DR. ELMS: 17 A. As positive. 18 COFFEY, Q.C.: 19 Q. Did you ever have, during your residency, any 20 occasion to discuss or be questioned by any 21 oncologists as to what you meant by positive? 22 DR. ELMS: 23 A. No. 24 COFFEY, Q.C.: 25 Q. In fact, even after your residency?</p>	<p>1 prudent for us to report percentages and give 2 that information to the oncologists and the 3 oncologists could then decide. 4 COFFEY, Q.C.: 5 Q. Do you recall having any discussion with the 6 oncologists about that? 7 DR. ELMS: 8 A. I didn't personally. 9 COFFEY, Q.C.: 10 Q. Were you told that anyone did? 11 DR. ELMS: 12 A. Not that I recall. 13 COFFEY, Q.C.: 14 Q. Do you recall who participated in this debate? 15 DR. ELMS: 16 A. It was within the staff at St. Clare's. 17 COFFEY, Q.C.: 18 Q. At the time? 19 DR. ELMS: 20 A. Yes. 21 COFFEY, Q.C.: 22 Q. And what--do you recall what era this would 23 have been? It was after you became a staff 24 person? 25 DR. ELMS:</p>

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<p>1 A. 2000 to 2001.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Okay, and at that time, the clinical chief was</p> <p>4 whom, do you recall?</p> <p>5 DR. ELMS:</p> <p>6 A. Clinical chief at that--I'm not sure if it was</p> <p>7 Dr. Haegert or Dr. Cook at that point.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Okay, depending upon which -</p> <p>10 DR. ELMS:</p> <p>11 A. Yeah.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. - on which part of that period, it could be</p> <p>14 one or the other, and in any case, I take it</p> <p>15 the site chief though at St. Clare's would</p> <p>16 have been Dr. Cook?</p> <p>17 DR. ELMS:</p> <p>18 A. Yes.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Doctor, you have the advantage, of course, of</p> <p>21 having been a resident throughout the time</p> <p>22 when this was introduced, the first several</p> <p>23 years. When you were a resident, was there</p> <p>24 any understanding amongst the--that you could</p> <p>25 tell amongst the residents as to whether or</p>	<p>1 Q. We've seen memos involving Dr. Khalifa</p> <p>2 introducing or telling people that ER/PR IHC</p> <p>3 staining reporting by pathologists is going to</p> <p>4 be expected of them and explaining how it was</p> <p>5 to be done and so on. As a resident, did you</p> <p>6 see such memos?</p> <p>7 DR. ELMS:</p> <p>8 A. I don't recall.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And your recollection of being introduced to</p> <p>11 IHC was through the staff person or persons</p> <p>12 from time to time you were assigned to?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Exhibit P-2301, please. Doctor, this is a--</p> <p>17 appear to be minutes of an OR practice meeting</p> <p>18 of November 29, 2001 and you're not present</p> <p>19 for it, but you are, if we go down the page,</p> <p>20 paragraph B, there's a reference to "Glenda</p> <p>21 requested site forms for specimen policy" and</p> <p>22 that lady would be Glenda Tapp. "Ford Elms,</p> <p>23 pathologist at St. Clare's, is currently</p> <p>24 reviewing the lab manual to verify if content</p> <p>25 is still accurate. Glenda will follow up with</p>
<p>1 not any, one or more pathologist staff members</p> <p>2 had any particular expertise in</p> <p>3 immunohistochemistry, kind of a go-to person?</p> <p>4 DR. ELMS:</p> <p>5 A. No. No, we had some--I recall we had one</p> <p>6 lecturing RHDIP from Dr. Khalifa about sort of</p> <p>7 the basic technique of how it was done, but -</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. How what was done?</p> <p>10 DR. ELMS:</p> <p>11 A. How the immunohistochemical test was</p> <p>12 performed.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Immunohistochemistry, period?</p> <p>15 DR. ELMS:</p> <p>16 A. Yes.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Not ER/PR?</p> <p>19 DR. ELMS:</p> <p>20 A. Not ER/PR specifically, no.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Okay.</p> <p>23 DR. ELMS:</p> <p>24 A. And there was no go-to person per se.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 Dr. Elms." I refer you to this, Doctor, and</p> <p>2 there's a reference to Catherine Parnell out</p> <p>3 to the side, because I wanted to ask you were</p> <p>4 you ever involved in kind of examining manuals</p> <p>5 for St. Clare's?</p> <p>6 DR. ELMS:</p> <p>7 A. At the time that this occurred, I had, in</p> <p>8 discussions with Ms. Tapp, identified that we</p> <p>9 wanted to be sure that their copy of our</p> <p>10 policies was up to date and so Ms. Parnell was</p> <p>11 our lead technologist in our lab at the time</p> <p>12 and I asked her if she would provide that</p> <p>13 material to Ms. Tapp.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And what was the status of the written</p> <p>16 policies and procedures that existed at St.</p> <p>17 Clare's at the time, in terms of how current</p> <p>18 they were?</p> <p>19 DR. ELMS:</p> <p>20 A. In terms of how current they were, I'm not</p> <p>21 sure what the date was on them at the time.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. So this would be in late--this is November</p> <p>24 2001.</p> <p>25 DR. ELMS:</p>

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<p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. The operating room personnel are looking to</p> <p>4 see if they have the latest version of what</p> <p>5 the pathology department's written policies</p> <p>6 and procedures were?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Presumably as they affected the OR?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Do you recall whether or not there was any</p> <p>15 such written policies in relation to</p> <p>16 immunohistochemistry?</p> <p>17 DR. ELMS:</p> <p>18 A. I don't believe there was.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And how up to date or otherwise the policies</p> <p>21 that did exist at the time were, you can't</p> <p>22 recall right now?</p> <p>23 DR. ELMS:</p> <p>24 A. I don't recall the dates.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 Q. Yes.</p> <p>2 DR. ELMS:</p> <p>3 A. There is a core textbook of anatomic pathology</p> <p>4 called--well, it's Ackerman's Surgical</p> <p>5 Pathology, and there's an extensive appendix</p> <p>6 in the back of Ackerman that was always</p> <p>7 stressed to us to be our guide for grossing,</p> <p>8 and so when we needed information as to how to</p> <p>9 prepare particular specimens, that was the</p> <p>10 reference we used.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. And did Ackerman's provide any guidance as to</p> <p>13 how it should be, the format for reporting?</p> <p>14 DR. ELMS:</p> <p>15 A. No. Actually, I believe there were</p> <p>16 suggestions in another appendix in the</p> <p>17 textbook as to forms.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Now at St. Clare's at the time, was there any</p> <p>20 particular requirement for how you should</p> <p>21 report, for example, ER and PR?</p> <p>22 DR. ELMS:</p> <p>23 A. Other than what we've already addressed, no.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Which is the, as you said, the change in 2000</p>
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<p>1 Q. Was there anyone, that you could tell, at the</p> <p>2 time who was responsible for updating the</p> <p>3 written policies?</p> <p>4 DR. ELMS:</p> <p>5 A. My assumption was that it was a role of the</p> <p>6 technical management of the lab, but I had no</p> <p>7 specific indication as to who that was.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Were there any written policies and procedures</p> <p>10 for the pathologists at the time?</p> <p>11 DR. ELMS:</p> <p>12 A. I don't recall.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. You don't recall there being any?</p> <p>15 DR. ELMS:</p> <p>16 A. No.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Now Doctor, in terms of written guides at the</p> <p>19 time, this would be late 2001, at St. Clare's,</p> <p>20 what would you use as a written aid or guide?</p> <p>21 What sorts of things?</p> <p>22 DR. ELMS:</p> <p>23 A. You mean in terms of grossing procedures and</p> <p>24 handling of specimens?</p> <p>25 COFFEY, Q.C.:</p>	<p>1 to 2001, the decision to go to percentages?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Doctor, during your residency period, can you</p> <p>6 give us some estimate as to how many ER/PR</p> <p>7 cases you might have co-examined with an</p> <p>8 attending physician, an approximation as to</p> <p>9 how -</p> <p>10 DR. ELMS:</p> <p>11 A. I would say three maybe four a month.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And St. Clare's itself, I take it, there was a</p> <p>14 lot of breast surgery, comparatively speaking,</p> <p>15 going on at St. Clare's, compared to other</p> <p>16 sites?</p> <p>17 DR. ELMS:</p> <p>18 A. Yes, and that estimate is sort of based</p> <p>19 overall on my experience during my residency.</p> <p>20 I would have seen more at St. Clare's in the</p> <p>21 times I rotated through there.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. So it would be three to four, on average,</p> <p>24 throughout the whole of your residency?</p> <p>25 DR. ELMS:</p>

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Which would be 35 to 50 a year, depending up
 4 three to four a month?
 5 DR. ELMS:
 6 A. Depending on rotations. In each year, we
 7 would rotate through various areas so that you
 8 didn't spend an entire year at anatomic
 9 pathology, and where I was doing general
 10 pathology, six months of my total residency
 11 was outside of anatomic pathology entirely.
 12 COFFEY, Q.C.:
 13 Q. So for a particular period of time, you would
 14 have seen a lot or relatively speaking,
 15 frequently?
 16 DR. ELMS:
 17 A. Relatively speaking, yeah.
 18 COFFEY, Q.C.:
 19 Q. Frequently seeing ER/PR cases.
 20 DR. ELMS:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. And then for extended periods, you wouldn't
 24 see them at all probably?
 25 DR. ELMS:

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1 A. Wouldn't see them at all.
 2 COFFEY, Q.C.:
 3 Q. Exhibit C-0225, please. Now Doctor, this is a
 4 matter of a surgical specimen number from
 5 2001. You'll see that there.
 6 DR. ELMS:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. And it's indicated to be received that would
 10 be August 14th, 2001, so it'll give you some
 11 sense of the time frame, and Doctor, what I'd
 12 do is just ask--take you to page two of the
 13 exhibit, addendum number one, okay. So I take
 14 it then, Doctor, and to put this in context
 15 for the Commissioner, perhaps you could just
 16 outline for us generally then, in terms of a
 17 breast case in 2001, how the report would get
 18 prepared, entered, addendums and so on,
 19 perhaps you could just take us through that?
 20 DR. ELMS:
 21 A. I don't recall if we were, at that time,
 22 ordering them routinely or if we were
 23 requested to order them by the oncologists.
 24 But in any event, the necessity for doing one,
 25 either as a request or as a routine, was

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1 there. We would order the stain. It did not
 2 preclude the initial sign out of the case, so
 3 oftentimes a case would be signed out with
 4 immunohistochemistry for ER/PR pending. Then
 5 when we would get the stains, we would assess
 6 the stains and report them.
 7 COFFEY, Q.C.:
 8 Q. And then in terms of signing out the case
 9 initially, I take it you would dictate what
 10 you saw?
 11 DR. ELMS:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. And your views, interpretation of what you
 15 were seeing, and that would be entered. It
 16 would be reviewed and there's some kind of an
 17 electronic signature?
 18 DR. ELMS:
 19 A. Yes.
 20 COFFEY, Q.C.:
 21 Q. And then if you wanted to add an addendum,
 22 could you just take the Commissioner through
 23 actually how is that done? What would happen?
 24 DR. ELMS:
 25 A. We would identify the case and specify that we

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1 were dictating an addendum on a particular
 2 case and then dictate the contents of the
 3 addendum. That would be entered in there as a
 4 specific field in the data entry program in
 5 which addenda are entered, and then the
 6 entered document, so to speak, would be
 7 brought back to us and we could review the
 8 addendum in the same way that you would review
 9 your original sign out, correct any errors and
 10 then apply an electronic signature.
 11 COFFEY, Q.C.:
 12 Q. And then if there was a second addendum, you'd
 13 dictate--in fact, this is another addendum and
 14 -
 15 DR. ELMS:
 16 A. The same process.
 17 COFFEY, Q.C.:
 18 Q. Same process would be repeated?
 19 DR. ELMS:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Doctor, in terms of pathology reports, can you
 23 tell the Commissioner, please, is there any
 24 particular methodology or practices to where
 25 an addendum ends up physically within the

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1 report?

2 DR. ELMS:

3 A. It ends up appended to the report. Generally

4 they come, actually, before the rest of the

5 report and in the case of an addendum the

6 clinical will already have received the

7 initial report, so all the other information

8 is there is information the clinician already

9 has. And the above that then occurs the

10 addenda.

11 COFFEY, Q.C.:

12 Q. Yeah. At least your sense of it is is that

13 the addenda would keep getting added to the

14 front of the document, as it were?

15 DR. ELMS:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. Do you have any experience, though, with

19 addenda or addendums being put kind of

20 inserted halfway through or toward the end or

21 -

22 DR. ELMS:

23 A. It's not something I've noticed, certainly not

24 halfway through a report. It would either be

25 at the beginning of it or at the end of it,

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1 but I haven't really -

2 COFFEY, Q.C.:

3 Q. You haven't actually kind of examined them to

4 see -

5 DR. ELMS:

6 A. No.

7 COFFEY, Q.C.:

8 Q. - see what the result is. Just on that point,

9 again, so the Commission have some sense of

10 what it is you as a pathologist actually see,

11 okay, you would initially dictate your report,

12 the initial report?

13 DR. ELMS:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. You would get kind of a draft, as it were,

17 typed?

18 DR. ELMS:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. Would you get that in writing, like in paper

22 or would you get that on a computer screen?

23 DR. ELMS:

24 A. That's on paper.

25 COFFEY, Q.C.:

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1 Q. And if it's satisfactory, you'd do what?

2 DR. ELMS:

3 A. If it was satisfactory, there is also a batch

4 in the computer, so we get paper documents

5 that we can review, however, they're also

6 batched within the sign out program as a part

7 of Meditech and so then we can sign them out

8 in the computer at the time that we're

9 reviewing them on paper.

10 COFFEY, Q.C.:

11 Q. So you look at the paper, that's fine, bring

12 up that, scroll through or bring up that one

13 and apply your electronic signature?

14 DR. ELMS:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. If you want to make a change, what would

18 happen?

19 DR. ELMS:

20 A. There's two ways we could do it. You could

21 dictate and have the secretaries make the

22 additions or you could do it yourself, you can

23 enter into the actual program and do it

24 yourself.

25 COFFEY, Q.C.:

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1 Q. And then, Doctor, when it comes time then, for

2 example, in the ER/PR cases where you want to

3 do an addendum, just use, for example,

4 Addendum No. 1, the ER/PR results.

5 DR. ELMS:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. You would dictate the fact that you're doing

9 an addendum and whatever it was you wanted to

10 say about the ER/PR?

11 DR. ELMS:

12 A. Yes.

13 COFFEY, Q.C.:

14 Q. And the tape would go away to be transcribed?

15 DR. ELMS:

16 A. Yes.

17 COFFEY, Q.C.:

18 Q. When it would come back to you, what form

19 would it be?

20 DR. ELMS:

21 A. In the same form that you see here on the

22 screen, it would be ask I would expect a

23 clinician to see it.

24 COFFEY, Q.C.:

25 Q. So it would be--the full report would be

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<p>1 there, the body of the report?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Plus the addendum?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And then if you were satisfied, you could</p> <p>10 enter, go into the computer and apply your</p> <p>11 electronic signature to the addendum?</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And then if there was a second addendum, when</p> <p>16 you dictated that, Addendum No. 1 and the</p> <p>17 report would show up?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. So whatever way in which they were being</p> <p>22 entered by whomever was doing the formatting,</p> <p>23 as it were, at some point it would cross, the</p> <p>24 paper version of it would cross your desk?</p> <p>25 DR. ELMS:</p>	<p>1 negative." Signed electronically by yourself,</p> <p>2 October 10th, 2001. Doctor, I'm not asking</p> <p>3 you to remember this particular case, per se,</p> <p>4 but a reference to here in the first addendum,</p> <p>5 "has been technically unsatisfactory on two</p> <p>6 occasions. A repeat attempt will be made."</p> <p>7 Doctor, can you tell us, please, about in</p> <p>8 2001, at least, and perhaps before that, what</p> <p>9 your experience was with ER and PR slides here</p> <p>10 in St. John's?</p> <p>11 DR. ELMS:</p> <p>12 A. On occasion we would have slides that had</p> <p>13 technical difficulties, and those could be of</p> <p>14 a number of things. Sometimes there would be</p> <p>15 wrinkles in the slide, sometimes we would have</p> <p>16 what's referred to as knife chatter, which is</p> <p>17 when the--knife chatter, which is when the</p> <p>18 slide is being cut, the block vibrates against</p> <p>19 the microtome blade. In some instances tissue</p> <p>20 was boiling off slides. Those are, in the</p> <p>21 technical difficulties that I remember, those</p> <p>22 would be the ones that come to mind.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Idea of reporting just positive or negative</p> <p>25 here, this is your recollection of, at least</p>
<p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Because this particular one, Doctor, certainly</p> <p>4 comports with your account of--you see page 4</p> <p>5 there's the electronic signature, yourself,</p> <p>6 August 24th, 2001, and then the actual body of</p> <p>7 the report itself, including the pathology</p> <p>8 interpretation, gross and so on. And we go</p> <p>9 back and the second page of the exhibit we see</p> <p>10 Addendum No. 1. This is dated entered</p> <p>11 September 25th, 2001 at 1000 hours. And it's</p> <p>12 indicated to be addendum signed, signature on</p> <p>13 file by yourself, September 26th, 2001. And</p> <p>14 here's it's written "Immunohistochemical</p> <p>15 staining is negative for progesterone</p> <p>16 receptors. The immunohistochemical staining</p> <p>17 for estrogen receptors has been technically</p> <p>18 unsatisfactory on two occasions. A repeat</p> <p>19 attempt will be made and an addendum issued</p> <p>20 once this investigation has been performed."</p> <p>21 And this is September, 2001. And then we look</p> <p>22 up above, we see Addendum No. 2, October 10th,</p> <p>23 2001, entered at 922 hours. And then it's</p> <p>24 written, "Immunohistochemical stains for</p> <p>25 estrogen and progesterone receptors are</p>	<p>1 as of the latter, well, two thirds of the way</p> <p>2 through 2001 you were still using positive and</p> <p>3 negative?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. At that point. Now, this particular case,</p> <p>8 Doctor, I have it here, it did end up, it's</p> <p>9 Addendum No. 4, actually, on the first page of</p> <p>10 it, indicates that this was, in fact, retested</p> <p>11 at--sent to Mount Sinai in probably 2006 and</p> <p>12 was retested and the estrogen and progesterone</p> <p>13 were reported as zero, zero percent, which had</p> <p>14 accorded with your record back in 2001.</p> <p>15 Doctor, these technical problems that you</p> <p>16 referred to in 2001, had the existed back into</p> <p>17 your days as a resident?</p> <p>18 DR. ELMS:</p> <p>19 A. I don't recall that being an issue during my</p> <p>20 residency.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Okay. Again now, again, with the benefit of</p> <p>23 looking at it from 2008 looking back, because</p> <p>24 you began your residency in 19 -</p> <p>25 DR. ELMS:</p>

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<p>1 A. '96.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Six, so just before Dr. Khalifa got involved?</p> <p>4 DR. ELMS:</p> <p>5 A. Um-hm, yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Locally, with this process. With the benefit</p> <p>8 now of hindsight, can you think about kind of</p> <p>9 what changed over time, if anything, that you</p> <p>10 recall, like, in terms of technical problems</p> <p>11 and stuff, when you first became aware of them</p> <p>12 and how things developed?</p> <p>13 DR. ELMS:</p> <p>14 A. During those days there were periods in which</p> <p>15 we would have issues with, as I said, a slide</p> <p>16 in which the tissue had boiled off, for</p> <p>17 instance, or in which there was knife chatter.</p> <p>18 It seemed to me to be sporadic.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. That was your -</p> <p>21 DR. ELMS:</p> <p>22 A. That was my feeling -</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. You don't have any real recollection of it</p> <p>25 during your residency, but certainly this is</p>	<p>1 had a small wrinkle on the edge and I was</p> <p>2 still able to assess the majority of the</p> <p>3 lesion, then I would accept that. If there</p> <p>4 was a problem that I felt compromised my</p> <p>5 interpretation, I'd reorder it and discuss it</p> <p>6 with the lead technologist at the time, which</p> <p>7 was Ms. Butler.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Do you recall having such discussions?</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And what do you recall about them?</p> <p>14 DR. ELMS:</p> <p>15 A. Specifically it was in the context of slides</p> <p>16 in which the tissue had boiled off the slide,</p> <p>17 and I would call and discuss it with Ms.</p> <p>18 Butler and I was told that they were working</p> <p>19 on the problem, that they recognized it and</p> <p>20 were working on it to try to solve it.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Were you ever told what the result of that</p> <p>23 was?</p> <p>24 DR. ELMS:</p> <p>25 A. Not specifically.</p>
<p>1 you're on the staff now for about a year and a</p> <p>2 half?</p> <p>3 DR. ELMS:</p> <p>4 A. Yes.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Just over a year, anyway, in, like, 2001?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And there were periods then, sporadically,</p> <p>11 where this would happen?</p> <p>12 DR. ELMS:</p> <p>13 A. An individual slide here and there.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Any other problems at the time that you</p> <p>16 noticed, that you were aware of?</p> <p>17 DR. ELMS:</p> <p>18 A. No. Those three were the common areas where</p> <p>19 you'd have a problem if you were going to have</p> <p>20 a problem.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And how were those problems addressed?</p> <p>23 DR. ELMS:</p> <p>24 A. I would--if there was--if I was satisfied that</p> <p>25 I could assess the slide, if, for instance, I</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Of those inquiries, they were working on it?</p> <p>3 DR. ELMS:</p> <p>4 A. Yeah. No specifically. This was also a</p> <p>5 sporadic thing. I mean, if I had a problem</p> <p>6 with one slide, I'd be--it would be awhile</p> <p>7 before I'd see another slide with the same</p> <p>8 problem.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Do you ever recall there being a period or</p> <p>11 periods when there were problems with a number</p> <p>12 of slides during like a month or two, that you</p> <p>13 recall?</p> <p>14 DR. ELMS:</p> <p>15 A. No, not a prolonged thing with them, a</p> <p>16 multitude of cases, no.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Doctor, I'm just here while I'm on the topic,</p> <p>19 I notice here in Addendum No. 3 there's a</p> <p>20 reference to this case having been reviewed at</p> <p>21 the request of Dr. Bob Williams. But I'm just</p> <p>22 going to ask you, down below there's reference</p> <p>23 to infiltrating ductal carcinoma.</p> <p>24 DR. ELMS:</p> <p>25 A. Um-hm.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And we've seen references at times,</p> <p>3 pathologists use the word "invasive". Is</p> <p>4 there any difference between infiltrating and</p> <p>5 invasive?</p> <p>6 DR. ELMS:</p> <p>7 A. No. I would use them synonymously.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Synonymously. Doctor, here, Doctor, looking</p> <p>10 at Addendum 1 on this particular exhibit C-</p> <p>11 0225, page 2 of the exhibit, when you would</p> <p>12 dictate this addendum and then sign it out,</p> <p>13 this particular one, September 26th, 2001,</p> <p>14 asserting that "has been technically</p> <p>15 unsatisfactory on two occasions. A repeat</p> <p>16 attempt will be made." Do you ever recall</p> <p>17 getting any inquiries from oncologists about</p> <p>18 this?</p> <p>19 DR. ELMS:</p> <p>20 A. No.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Like, expressions of concern or -</p> <p>23 DR. ELMS:</p> <p>24 A. No.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 Q. And do you recall what, if any, the</p> <p>2 circumstances were, what sorts of things would</p> <p>3 occasion it?</p> <p>4 DR. ELMS:</p> <p>5 A. You mean specifically to review the estrogen</p> <p>6 and progesterone receptor?</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Yes.</p> <p>9 DR. ELMS:</p> <p>10 A. I know I was asked to repeat them on</p> <p>11 occasion. There's a couple of instances as a</p> <p>12 result of the Inquiry that I now can speak to,</p> <p>13 but to remember overall, no, I don't recall</p> <p>14 the exact issues.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Okay. And we'll be speaking about Ms. Deane's</p> <p>17 case.</p> <p>18 DR. ELMS:</p> <p>19 A. Um-hm.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And one or two others. But--because the</p> <p>22 documents refer to cases at times. But other</p> <p>23 than those specific instances, again, so the</p> <p>24 Commissioner have some sense of it, your</p> <p>25 recollection of how often this would happen,</p>
<p>Page 54</p> <p>1 Q. You're fairly--you're fairly emphatic about</p> <p>2 that. You'd recall, in fact, if there were</p> <p>3 such instances?</p> <p>4 DR. ELMS:</p> <p>5 A. If there were such instances, I'd recall it, I</p> <p>6 would expect to.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Were you ever asked by oncologists to do a</p> <p>9 repeat?</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. ER/PR?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Do you recall the first such time you were</p> <p>18 asked to do that?</p> <p>19 DR. ELMS:</p> <p>20 A. No.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Do you recall how often you were asked?</p> <p>23 DR. ELMS:</p> <p>24 A. Rarely.</p> <p>25 COFFEY, Q.C.:</p>	<p>Page 56</p> <p>1 like, in the run of a year how often do you</p> <p>2 think you might have been asked to repeat</p> <p>3 ER/PR by an oncologist?</p> <p>4 DR. ELMS:</p> <p>5 A. Perhaps a couple of times a year. I don't</p> <p>6 remember it being a prominent occurrence.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And again, to put this in context, Doctor, in</p> <p>9 the course of a year, you would report how</p> <p>10 many cases, not ER/PRs, just how many cases,</p> <p>11 period?</p> <p>12 DR. ELMS:</p> <p>13 A. At most 50.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Fifty a year?</p> <p>16 DR. ELMS:</p> <p>17 A. At most.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. ER/PR?</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. No, but say how many IHC cases would you</p> <p>24 report a year at -</p> <p>25 DR. ELMS:</p>

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1 A. IHC cases overall?
 2 COFFEY, Q.C.:
 3 Q. Yes.
 4 DR. ELMS:
 5 A. It's very difficult to say. I'd order, I'd
 6 say, probably between a third or more of my
 7 cases. Most of what we see is biopsies. It's
 8 not all that common to have to do
 9 immunohistochemistry on many biopsy cases. So
 10 a third, I would say, would be an upper
 11 estimate of the numbers that I had to order.
 12 COFFEY, Q.C.:
 13 Q. And how many would you do a year, a third of
 14 what? Again, rough figures, how many--I'm
 15 just trying to get some sense of -
 16 DR. ELMS:
 17 A. I do, I guess, between 1500 and 2000 cases a
 18 year.
 19 COFFEY, Q.C.:
 20 Q. So about a third of them might involve IHC?
 21 DR. ELMS:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. And again, I'm not holding you to, obviously,
 25 to this, because you're doing this arithmetic,

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1 obviously, just thinking about it now. But
 2 maybe a couple of times a year you might be
 3 asked to repeat an ER/PR by an oncologist?
 4 DR. ELMS:
 5 A. At most.
 6 COFFEY, Q.C.:
 7 Q. At most. How about repeating other types of
 8 IHC tests?
 9 DR. ELMS:
 10 A. You mean would I be requested to do it or
 11 would -
 12 COFFEY, Q.C.:
 13 Q. Yeah, requested -
 14 DR. ELMS:
 15 A. - I take it upon myself?
 16 COFFEY, Q.C.:
 17 Q. - as opposed to you doing it, taking it upon
 18 yourself?
 19 DR. ELMS:
 20 A. I don't recall ever being asked to repeat a
 21 test that wasn't ER/PR.
 22 COFFEY, Q.C.:
 23 Q. So what IHC repeats there were for ER/PR -
 24 DR. ELMS:
 25 A. It's not entirely true to say that. I wasn't

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1 requested to -
 2 COFFEY, Q.C.:
 3 Q. Oh, requested.
 4 DR. ELMS:
 5 A. - I would occasionally order one myself if I
 6 had a technical problem with a particular
 7 slide.
 8 COFFEY, Q.C.:
 9 Q. And as an example we just looked at then?
 10 DR. ELMS:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. That would be a repeat?
 14 DR. ELMS:
 15 A. Yeah.
 16 COFFEY, Q.C.:
 17 Q. Doctor, did you ever receive or become aware
 18 of any complaints by oncologists about IHC
 19 tests?
 20 DR. ELMS:
 21 A. No.
 22 COFFEY, Q.C.:
 23 Q. Or expressions of concern about--by them
 24 about, you know, the quality or the results or
 25 -

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1 DR. ELMS:
 2 A. No.
 3 COFFEY, Q.C.:
 4 Q. In situations where you would be asked to
 5 repeat the ER/PR, in those relatively few
 6 cases, was it explained to you why that was
 7 they wanted it repeated?
 8 DR. ELMS:
 9 A. I don't recall specifically.
 10 COFFEY, Q.C.:
 11 Q. All right. So just from your perspective
 12 someone would ask and -
 13 DR. ELMS:
 14 A. Yeah, it--I don't recall being given specific
 15 reasons.
 16 COFFEY, Q.C.:
 17 Q. Doctor, in terms of requesting an initial
 18 ER/PR case, leaving aside whether it's
 19 repeated or not, right, just an initial case,
 20 what actually did that involve by you, what
 21 did you actually physically have to do?
 22 DR. ELMS:
 23 A. It would involve identifying a tissue block
 24 and then I would fill out a requisition form
 25 for it. That form up until our labs were

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<p>1 consolidated, that form would go up to our lab 2 and the block would be cut in our lab and sent 3 to the Health Sciences. After it was--after 4 services were consolidated the request would 5 be faxed to the Health Sciences and staff at 6 the Health Sciences would then obtain the 7 block and carry out the stain and transfer the 8 stain back to me.</p> <p>9 COFFEY, Q.C.: 10 Q. Transfer the stained slides? 11 DR. ELMS: 12 A. The slides, yes. 13 COFFEY, Q.C.: 14 Q. And you would examine them and report? 15 DR. ELMS: 16 A. Yes. 17 COFFEY, Q.C.: 18 Q. And if a physician or when a physician would 19 ask you to repeat an ER/PR, what would that 20 actually involve then, what would you have to 21 do? 22 DR. ELMS: 23 A. It would involve the same process. Usually I 24 would order it on the same block. 25 COFFEY, Q.C.:</p>	<p>1 Q. But if we could look, please, at Exhibit P- 2 2149, page 32? Doctor, this is one filled out 3 in your handwriting? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. Is surgical No. SS5577-02. The date is 2002, 8 July, '07, 26. And here circled is estrogen 9 and progesterone receptors? 10 DR. ELMS: 11 A. Yes. 12 COFFEY, Q.C.: 13 Q. So I take it would circle that, fill out the 14 top part of the form and circle this? 15 DR. ELMS: 16 A. Yes. 17 COFFEY, Q.C.: 18 Q. If we look please, at page 38? Doctor, this 19 is the same surgical pathology number. It's 20 on block A. The one we were just looking at 21 is block A, as well. Go back, the date is 22 again the same at the top. But if you go down 23 through this, at the bottom, hysto tech 24 initially is P. Welsh, they completed July 25 30th, I believe, '02. And then there's an "M.</p>
<p>Page 62</p> <p>1 Q. Um-hm. Any particular reason for that at the 2 time? 3 DR. ELMS: 4 A. No, just that that block was already on site 5 at Health Sciences, in all likelihood, and 6 more accessible. 7 COFFEY, Q.C.: 8 Q. And would you have to fill out a requisition 9 form? 10 DR. ELMS: 11 A. Yes. 12 COFFEY, Q.C.: 13 Q. If we could, please, Exhibit P-2149? Now, 14 Doctor, these are a whole series of--I take it 15 these are the sorts of requisition forms 16 you've been speaking of? 17 DR. ELMS: 18 A. Yes. 19 COFFEY, Q.C.: 20 Q. The particular wording of ones may have 21 changed from time to time, I take it, as it 22 revised? 23 DR. ELMS: 24 A. Yes. 25 COFFEY, Q.C.:</p>	<p>Page 64</p> <p>1 Butler, Please repeat ER/PR August 28th, '02." 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. Would this--whose handwriting would that be, 6 do you know? 7 DR. ELMS: 8 A. I'm not sure. It doesn't look like mine. 9 COFFEY, Q.C.: 10 Q. And so that's, that particular block 11 apparently, the ER/PR got repeated on. If we 12 could go back, if we could just go back, 13 please, to page 32, you'll see that's the same 14 one, the page we just looked at before, it's 15 block A. If you look, please, at, I'm just 16 going to go to page 34, same exhibit. And 17 this is for block SS-5464-02, it's for July 18 25th, '02, a special procedure request form. 19 It's block J, it's yourself and Dr. Elms, that 20 would be your handwriting, I take it, up 21 there? 22 DR. ELMS: 23 A. Yes. 24 COFFEY, Q.C.: 25 Q. Estrogen/progesterone receptors are circled</p>

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<p>1 and filled out as P. Welsh, July 30th, '02. 2 Go to page 36 of the same exhibit. That's the 3 same surgical block number, SS-5464-02, July 4 25, '02, block J, yourself. And this one 5 again is P. Welsh, July 30th, 02, M. Butler, 6 "Please repeat ER/PR, August 28th, '02." If 7 we go back, please--so that appears again to 8 be a repeat? 9 DR. ELMS: 10 A. Yes. 11 COFFEY, Q.C.: 12 Q. One for July 25th, one for July 26th. If we 13 go back, please, to page 35? Actually, I'll 14 go back--sorry. Page 35. This is a special 15 procedure request form SS5481-02, block D. 16 It's yourself. It's dated July 24, 2002. 17 This is your handwriting up here? 18 DR. ELMS: 19 A. Yes. 20 COFFEY, Q.C.: 21 Q. Again, estrogen/progesterone receptors are 22 circled. And it's P. Welsh, July 30th, '02. 23 If we go to page 37 of the same exhibit, P- 24 2149, we'll see that's the same surgical 25 number, SS541-02, block D. It's your name.</p>	<p>1 A. Yes. 2 COFFEY, Q.C.: 3 Q. If it was positive, if it was nuclear 4 staining, the percentage? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. And in the external control you'd be looking 9 for what? 10 DR. ELMS: 11 A. I would be looking for positivity of the stain 12 in the cells, I expected--I expect it would be 13 staining, and no staining or very weak 14 staining, at most, in other tissues, no 15 staining, preferably. 16 COFFEY, Q.C.: 17 Q. Sorry? 18 DR. ELMS: 19 A. If you have a piece of tissue in which there 20 is tumour or other breast tissue and then 21 other besides breast, ductal tissue, I would 22 expect there to be staining in the ductal 23 tissue, but I wouldn't expect there to be 24 staining in the remainder. So I wouldn't 25 expect, for instance, blood vessel cells to be</p>
<p>1 July 24th, '02. Again, this one is P. Welsh, 2 July 30th, '02. M. Butler, "Please repeat 3 ER/PR, August 28th, '02." Doctor, this is in 4 the summer of 2002 and it appears that on 5 three different days you made three different 6 requests for three different patients for 7 ER/PR and three of them ended up getting 8 repeated, at least sometime in August, 2002. 9 Was there anything in particular in the summer 10 of 2002 that you recall about that was 11 problematic? 12 DR. ELMS: 13 A. Not that I recall. 14 COFFEY, Q.C.: 15 Q. Now, Doctor, at that point in time, this would 16 be the summer of 2002, in examining in ER and 17 PR patients' slides, what would you be looking 18 for? 19 DR. ELMS: 20 A. Nuclear positivity and the external control 21 and the amount of tumour that was staining 22 positive. 23 COFFEY, Q.C.: 24 Q. The percentage? 25 DR. ELMS:</p>	<p>1 staining. 2 COFFEY, Q.C.: 3 Q. Now at that time were you thinking of internal 4 controls at that point in ER/PR in the summer 5 of 2002? 6 DR. ELMS: 7 A. No. 8 COFFEY, Q.C.: 9 Q. In terms of external controls, what would you 10 be looking for in the external controls? 11 DR. ELMS: 12 A. If I see breast duct tissue, I would expect 13 that to be staining, if there was breast - 14 COFFEY, Q.C.: 15 Q. In the external control slide? 16 DR. ELMS: 17 A. - in the external control. If there was 18 tumour, I'd expect the tumour to be staining. 19 COFFEY, Q.C.: 20 Q. And staining how? 21 DR. ELMS: 22 A. Again, nuclear staining. 23 COFFEY, Q.C.: 24 Q. And any particular amount of staining or like 25 percentages, high percentage, low percentage?</p>

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<p>1 DR. ELMS: 2 A. No, I wouldn't be assessing percentages on 3 control. 4 COFFEY, Q.C.: 5 Q. Would you be--I appreciate you wouldn't be 6 assessing or making a percentage call, but 7 would you be looking to see if it was strongly 8 stained, moderately stained, weakly stained or 9 would any staining suffice? 10 DR. ELMS: 11 A. You want at least moderate staining. 12 COFFEY, Q.C.: 13 Q. Now if we look at the same exhibit, P-2149, 14 and look at page 41, now this is 15 immunoperoxidase request form. It's surgical 16 number happens to be SS5754-02. It's for 17 September 9th, 2002. You're the pathologist. 18 Ductal carcinoma is the diagnosis. And this 19 would be your handwriting, I take it, here? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. And it's dated completed is September 12th, 24 '02 by Ms. Butler. And it's indicated to be 25 somebody's handwritten "rush" there. But the</p>	<p>1 A. When we get our slides back, we would get a 2 copy of the form that you see there and the 3 technologist's signature would be indicated at 4 the bottom. 5 COFFEY, Q.C.: 6 Q. And you understood that to be what? 7 DR. ELMS: 8 A. That the controls had been checked. 9 COFFEY, Q.C.: 10 Q. And checked by, do you have any understanding 11 about who would have checked them? 12 DR. ELMS: 13 A. There were various people, as I remember. I 14 believe at one point Dr. Robb was looking at 15 them. But I was also of the understanding 16 that there were technologists who were reading 17 them. 18 COFFEY, Q.C.: 19 Q. Do you recall who gave you that understanding? 20 DR. ELMS: 21 A. No, not specifically. 22 COFFEY, Q.C.: 23 Q. Do you have any understanding about whether or 24 not technologists were trained to read 25 external control slides for ER/PR?</p>
<p>1 top of the page says, "ER control weak but 2 working." See that? 3 DR. ELMS: 4 A. Yes. 5 COFFEY, Q.C.: 6 Q. Do you know whose handwriting that is? 7 DR. ELMS: 8 A. No. 9 COFFEY, Q.C.: 10 Q. Doctor, at that point in time, this would be 11 September, 2002, like the middle of '02, June, 12 July, August, September, '02, would you 13 actually see the external control slides? 14 DR. ELMS: 15 A. Not necessarily. There was--I can't speak to 16 dates, but there was a period when we were not 17 receiving external controls; the external 18 controls would be reviewed at the Health 19 Sciences before the slides were released. 20 COFFEY, Q.C.: 21 Q. And then how would you know that they were 22 being looked at and someone was determining 23 them to be satisfactory, how would that be 24 communicated to you? 25 DR. ELMS:</p>	<p>1 DR. ELMS: 2 A. No. 3 COFFEY, Q.C.: 4 Q. Who would be--from your perspective at the 5 time, who would have been responsible for 6 determining whether or not they should be 7 reading them at all? 8 DR. ELMS: 9 A. The laboratory director. 10 COFFEY, Q.C.: 11 Q. You don't recall who gave you the 12 understanding but certainly at one point you 13 felt or understood that the technologists at 14 the General Hospital were reading the external 15 controls for ER/PR? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. And were noting? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. That they were satisfactory? 24 DR. ELMS: 25 A. Yes.</p>

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1 COFFEY, Q.C.:

2 Q. Doctor, a reference to "ER control weak but

3 working", now at that time in 2002 what would

4 you have understood that to mean?

5 DR. ELMS:

6 A. That the control stain was paler than, or

7 pale, at least, but that it had been assessed

8 as being satisfactory.

9 COFFEY, Q.C.:

10 Q. Doctor, would you at the time or did you at

11 the time have any concern that if that was so,

12 that a tumour that was, in fact, positive,

13 patient's tumour that was, in fact, positive

14 but weakly positive, like not very strongly

15 positive for ER, might not stain? Whatever

16 had caused the external control to stain

17 weakly, whatever process, part of the process

18 that caused that to happen might also have a

19 negative influence on the outcome?

20 DR. ELMS:

21 A. No.

22 COFFEY, Q.C.:

23 Q. It didn't occur to you at the time?

24 DR. ELMS:

25 A. No.

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1 COFFEY, Q.C.:

2 Q. Do you recall whether that was ever discussed

3 amongst the pathologists?

4 DR. ELMS:

5 A. No.

6 COFFEY, Q.C.:

7 Q. So from your perspective at the time, I take

8 it, Doctor, it would be fair to say that,

9 look, if the form came back and said the

10 external controls were working, then from your

11 perspective and understanding, that would

12 suffice?

13 DR. ELMS:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. Here when we look at this particular page,

17 there's no reference to the PR control at all?

18 DR. ELMS:

19 A. No.

20 COFFEY, Q.C.:

21 Q. So what would you have understood about the PR

22 control?

23 DR. ELMS:

24 A. That it had been read as well.

25 COFFEY, Q.C.:

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1 Q. So no reference at all meant--if I have the

2 slides, the patient slides in my hands --

3 DR. ELMS:

4 A. I'm assuming that the technologists have read

5 them and rather than not being done, that the

6 PR was not --deemed worthy of comment.

7 COFFEY, Q.C.:

8 Q. Doctor, knowing what you do now in 2008 with

9 reference to ER control weak but working,

10 would that cause you concern now?

11 DR. ELMS:

12 A. It would certainly make me want to look at the

13 slide and see what they meant by weak.

14 COFFEY, Q.C.:

15 Q. Yes, and I'll be discussing more with you now

16 about what you've learned in the intervening

17 time. Again I take it that in the middle of

18 2002, we looked at those three just a little

19 while ago in July, into August, 2002, and now

20 this one in September, 2002. At the time, did

21 you have any unease or misgivings at all about

22 reporting ER/PR?

23 DR. ELMS:

24 A. You mean in general?

25 COFFEY, Q.C.:

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1 Q. Yes.

2 DR. ELMS:

3 A. No.

4 COFFEY, Q.C.:

5 Q. And you weren't made aware by anybody else of

6 any?

7 DR. ELMS:

8 A. No.

9 COFFEY, Q.C.:

10 Q. Exhibit P-2173, please. Doctor, this is a

11 series of immunoperoxidase request forms for

12 2003, and I'll be taking you to some of them.

13 I'm going to ask you now about Dr. Ejeckam,

14 okay. We understand that he came to St.

15 John's in 2002.

16 DR. ELMS:

17 A. Uh-hm.

18 COFFEY, Q.C.:

19 Q. When did you first meet him?

20 DR. ELMS:

21 A. Upon his arrival.

22 COFFEY, Q.C.:

23 Q. And, Doctor, in the summer and fall of 2002,

24 particularly the fall of 2002--I take it in

25 the summer, they would be relatively short,

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1 people on holidays, relatively short staffed,
 2 but in the fall of 2002, how much or how often
 3 would the pathologists at St. Clare's get
 4 together with the pathologists at the General
 5 Hospital?
 6 DR. ELMS:
 7 A. We got together at our departmental meetings.
 8 I'm not sure how frequently they were taking
 9 place in the fall of 2002.
 10 COFFEY, Q.C.:
 11 Q. And from time to time, looking back on it now,
 12 how often did you get together. I appreciate
 13 that in any particular month, you might not
 14 know, but generally what has been the practise
 15 over the years.
 16 DR. ELMS:
 17 A. Monthly or bi-monthly.
 18 COFFEY, Q.C.:
 19 Q. There would be a meeting, and would it be at
 20 one site or the other?
 21 DR. ELMS:
 22 A. Generally at the Health Sciences.
 23 COFFEY, Q.C.:
 24 Q. How long would the meetings run?
 25 DR. ELMS:

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1 A. A couple of hours.
 2 COFFEY, Q.C.:
 3 Q. What sorts of things would be discussed?
 4 DR. ELMS:
 5 A. The running of the department, issues to do
 6 with training of the residents.
 7 COFFEY, Q.C.:
 8 Q. How about cases or problems with --
 9 DR. ELMS:
 10 A. Not at those meetings, no.
 11 COFFEY, Q.C.:
 12 Q. Were there meetings where cases would be
 13 discussed or problems with the technical
 14 process?
 15 DR. ELMS:
 16 A. At St. Clare's we have a difficult case round
 17 every week in which people have cases that
 18 they're not sure about and want to share with
 19 their colleagues. We also have a consultation
 20 process whereby we can circulate slides
 21 through the department, but difficult cases in
 22 that way would often be brought to our
 23 difficult case rounds at a multi-head
 24 microscope where all of us would sit and
 25 review specific cases.

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1 COFFEY, Q.C.:
 2 Q. And that sort of process, did you ever attend
 3 that at the General Hospital?
 4 DR. ELMS:
 5 A. When I was a resident.
 6 COFFEY, Q.C.:
 7 Q. Okay, back in your residency days, but after
 8 the residency?
 9 DR. ELMS:
 10 A. No.
 11 COFFEY, Q.C.:
 12 Q. Now, Doctor, here on page five of the Exhibit
 13 P-2173, this is SS9015-02, March 18th, '03.
 14 In fact, it's a case for Dr. Denic, but ER/PR
 15 is requested and there are two signatures, Mr.
 16 Green and Ms. Butler, two different dates,
 17 March 21st, 2003; April 28, 2003, checked by
 18 Dr. Ejeckam. Here at the top, though, it has
 19 noted Dr. Elms has ER/PR control. Then page
 20 seven of the same exhibit, SS2190-03, March
 21 26th '03, and again this particular one has
 22 written on it, "Dr. Elms has ER/PR control"
 23 and we can look through it there. I'll just
 24 take you to one more, page nine of the
 25 Exhibit, SS2345-03, March 31st, '03, "Dr. Elms

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1 has ER/PR controls". This sort of reference
 2 to you having the controls, what would that be
 3 about?
 4 DR. ELMS:
 5 A. By that time the controls were being sent to
 6 us. Dr. Ejeckam was checking them and was
 7 sending them to us, and they would be put on
 8 one of the trays of slides that was being sent
 9 back to St. Clare's. There was no specific
 10 attempt to send them to me as opposed to
 11 anyone else.
 12 COFFEY, Q.C.:
 13 Q. Oh, okay, it just happened at the time that
 14 you were the one who had obtained them?
 15 DR. ELMS:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. Doctor, how were you able then to look at the
 19 control slides, ER external control slide and
 20 a PR external control slide, and relate it to
 21 particular cases?
 22 DR. ELMS:
 23 A. My understanding was that the control that was
 24 being done was a batch control, so that you
 25 had a batch of ER/PRs being done and one slide

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<p>1 of known staining characteristics was included</p> <p>2 with that batch as a control.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. How were you able to tell, for example, if</p> <p>5 three different cases came back to St.</p> <p>6 Clare's?</p> <p>7 DR. ELMS:</p> <p>8 A. Because that slide was being sent with that</p> <p>9 batch. I assume that they were all done on</p> <p>10 the same run.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Was there anything about the external control</p> <p>13 slide itself, anything written on it that</p> <p>14 would lead you to--to play detective, as it</p> <p>15 were, and go back and relate it?</p> <p>16 DR. ELMS:</p> <p>17 A. Not at the time.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. At that time, no.</p> <p>20 DR. ELMS:</p> <p>21 A. Not that I recall, no.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. So if you wanted to actually determine</p> <p>24 conclusively from your perspective that a</p> <p>25 particular external control slide was run with</p>	<p>1 copied to Barry Dyer and all technical staff,</p> <p>2 Immunohistochemistry. Doctor, when did you</p> <p>3 first become aware of the subject matter of</p> <p>4 this?</p> <p>5 DR. ELMS:</p> <p>6 A. At the point of that memo.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. So before that, were you alerted at all to any</p> <p>9 problems or concerns about ER/PR stains, or</p> <p>10 the other six stains for that matter?</p> <p>11 DR. ELMS:</p> <p>12 A. No.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Or IHC stains generally?</p> <p>15 DR. ELMS:</p> <p>16 A. No.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And when you received this, did you discuss it</p> <p>19 with anybody at the time, do you recall?</p> <p>20 DR. ELMS:</p> <p>21 A. Not that I recall.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Did you ask any questions of anybody, what's</p> <p>24 this all about?</p> <p>25 DR. ELMS:</p>
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<p>1 a particular patient slide, what would you</p> <p>2 have to have done?</p> <p>3 DR. ELMS:</p> <p>4 A. I would have to call the technologist and ask.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Look at Exhibit P-0113, please. Doctor, this</p> <p>7 is Dr. Ejeckam's memo of April 4th, 2003, to</p> <p>8 pathologists at the Health Sciences Centre,</p> <p>9 St. Clare's, and out of town hospitals. The</p> <p>10 subject is immunohistochemical stains, and the</p> <p>11 Commissioner has seen this before. This is</p> <p>12 the one that reads, "Kindly note that</p> <p>13 immunohistochemical stains with the following</p> <p>14 antibodies", and it lists a number of them,</p> <p>15 the last two are ER and PR, "have remained</p> <p>16 unreliable, erratic, and, therefore, unhelpful</p> <p>17 for diagnostic purposes. Consequent on the</p> <p>18 above, staining with these antibodies will</p> <p>19 stop forthwith until we can solve their</p> <p>20 reliability, sensitivity, and specificity", I</p> <p>21 suspect it should read, "problems. Efforts</p> <p>22 are underway and hopefully a solution will be</p> <p>23 found within the next four to six weeks. You</p> <p>24 will be duly informed when such stains can</p> <p>25 resume", and it's signed by Dr. Ejeckam and</p>	<p>1 A. No.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. At the time you would have been at St.</p> <p>4 Clare's, that would be April, 2003.</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. How many pathologists would there have been at</p> <p>9 St. Clare's at the time, do you think?</p> <p>10 DR. ELMS:</p> <p>11 A. Six.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Including yourself?</p> <p>14 DR. ELMS:</p> <p>15 A. Including myself.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Dr. Cook would be the site chief?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. He was also the clinical chief?</p> <p>22 DR. ELMS:</p> <p>23 A. Yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Dr. Denic?</p>

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<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. Who else, do you recall? 5 DR. ELMS: 6 A. Dr. Cook, Dr. Denic, myself, Dr. Vaze, I 7 believe Dr. Gorechi was there at the time, and 8 Dr. Wadwa. 9 THE COMMISSIONER: 10 Q. Excuse me, Mr. Coffey. Do I take it, Dr. Elms, 11 from your answer to Mr. Coffey's question that 12 when you received this memo, up until that 13 point you had no reason to believe, as Dr. 14 Ejeckam has said, that the stains were 15 unreliable and erratic? 16 DR. ELMS: 17 A. That's correct. 18 THE COMMISSIONER: 19 Q. So nothing in your practise had led you to 20 that conclusion? 21 DR. ELMS: 22 A. That's correct. 23 COFFEY, Q.C.: 24 Q. No discussion amongst the pathologists that 25 you recall about that?</p>	<p>1 part of a panel of investigating a tumour. 2 COFFEY, Q.C.: 3 Q. And what significance, if any, would that 4 have? 5 DR. ELMS: 6 A. For instance--well, let's look, for instance, 7 at the Cds. These are all stains that are 8 used in the investigation of lymphoma. CD3 9 and CD5 are T cell markers. We do use other T 10 cell markers besides those. CD20 and CD 79A 11 are B cell markers and again we use others. 12 Lymphoma is also assessed by means of another 13 process called floctometry, and in some 14 instances those same antibodies would be 15 looked at. In other cases, there would be 16 other specific antibodies done on the 17 floctometry. 18 COFFEY, Q.C.: 19 Q. That's the lymphomas? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. The other -- 24 DR. ELMS: 25 A. The CEA again is a epithelial marker and it's</p>
<p>1 DR. ELMS: 2 A. Not that I recall. We have a very collegial 3 environment at St. Clare's. I'm sure there 4 must have been some sort of discussion, but 5 nothing that I recall specifically. 6 COFFEY, Q.C.: 7 Q. Now these other stains referred to as CK34, 8 CD3, CD5, CD20, CD79, and CEA, in relation to 9 them, upon being told that they were 10 unreliable, erratic, unhelpful, had you been 11 using those stains or would you have been 12 using those stains? 13 DR. ELMS: 14 A. Yes. 15 COFFEY, Q.C.: 16 Q. Before that? 17 DR. ELMS: 18 A. Yes. 19 COFFEY, Q.C.: 20 Q. So to be told that presumably they're so 21 unreliable that he's shutting down the 22 processing for a while, you at the time had no 23 concerns, though, about it? 24 DR. ELMS: 25 A. Not--no, no. Each of those stains is used as a</p>	<p>1 used as one of a battery of epithelial 2 markers, so that if I was looking at a tumour, 3 I wouldn't rely solely on my CEA, and the same 4 occurs with the 34 BE12. 5 COFFEY, Q.C.: 6 Q. If, though, the CEA or the CK34, if it's part 7 of a battery, at times presumably it could be 8 the swing vote, as it were, on the battery? 9 Do you understand what I'm talking about? 10 DR. ELMS: 11 A. I understand what you're saying. No, I 12 wouldn't say it would be a swing vote. It's 13 one part of a series of components used in the 14 assessment of a case. 15 COFFEY, Q.C.: 16 Q. Now with respect to the six stains, other than 17 ER/PR, do you know what, if anything, happened 18 in relation to that? 19 DR. ELMS: 20 A. My understanding was that the problem was 21 corrected and the staining was brought back on 22 line. 23 COFFEY, Q.C.: 24 Q. Do you recall who advised you of that, and how 25 you became aware of it?</p>

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<p>1 DR. ELMS: 2 A. Not off the top of my head. I would assume it 3 was Dr. Ejeckam. 4 COFFEY, Q.C.: 5 Q. And ER and PR, what about them? They're not 6 part of a battery of tests, I take it? 7 DR. ELMS: 8 A. No, they're not. However, Dr. Ejeckam was 9 looking into the situation, so I assume that 10 he had the situation under control. 11 COFFEY, Q.C.: 12 Q. So, Doctor, at the time, do you recall any 13 discussion at all about this subject matter 14 amongst the pathologists at St. Clare's? 15 DR. ELMS: 16 A. Not that I recall. 17 COFFEY, Q.C.: 18 Q. Page two of the Exhibit is a memo of May 2nd, 19 2003, from Dr. Ejeckam. Again it's to the 20 same group of pathologists, and the subject 21 matter is ER/PR immunohistochemical stains, 22 and he informs all of you that he had 23 rectified the difficulties and you can now 24 resume regular requests for these antibody 25 stains. "I will, however, like to bring the</p>	<p>1 Q. What sorts of issues were they? 2 DR. ELMS: 3 A. Well, the kinds of issues you just mentioned 4 to do with fixation and the various other 5 elements of the report, the stuff that he's 6 bringing to our attention. 7 COFFEY, Q.C.: 8 Q. And do you recall--what, if anything, do you 9 recall was actually done, that you were made 10 aware of was being done to actually address, 11 for example, the fixation issues? 12 DR. ELMS: 13 A. I don't recall anything being done from that. 14 I read that there was a caution that these 15 things can be a problem, but I don't take from 16 that that there was identified specifically a 17 problem. 18 COFFEY, Q.C.: 19 Q. So as far as you knew or were aware, having 20 received this memo, at least at St. Clare's as 21 far as you knew, other than read the memo and 22 discuss it in a general manner? 23 DR. ELMS: 24 A. Yes. 25 COFFEY, Q.C.:</p>
<p>1 following information to your attention", and 2 he goes on at some length about aspects of the 3 ER/PR staining process. Do you recall 4 receiving this? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. Do you recall whether there was any discussion 9 by you with anybody or anything you overheard 10 by others involving this memo, any talk about 11 this? 12 DR. ELMS: 13 A. I don't recall specific discussions. 14 COFFEY, Q.C.: 15 Q. How about generally? 16 DR. ELMS: 17 A. Generally, yes, I would think we talked about 18 it. 19 COFFEY, Q.C.: 20 Q. And in what context, do you recall? 21 DR. ELMS: 22 A. That the staining had been problematic and was 23 now resolved and that there were issues in the 24 memo that we should pay attention to. 25 COFFEY, Q.C.:</p>	<p>1 Q. No actual steps taken? 2 DR. ELMS: 3 A. Not that I was made aware of, not that I 4 recall in any event. 5 COFFEY, Q.C.: 6 Q. Paragraph three on the second page of the memo 7 refers to internal controls. Is this the 8 first time that you had become aware of this 9 in the context of the ER/PR? 10 DR. ELMS: 11 A. I would think yes, yes, it was around that 12 time I became aware of it. 13 COFFEY, Q.C.: 14 Q. And what, if anything, did that cause you to 15 do? 16 DR. ELMS: 17 A. It caused me to look at the internal controls, 18 as he says there, as a second level control. 19 COFFEY, Q.C.: 20 Q. And for what purpose then, what process did 21 you -- you hadn't been going through that 22 process before because you hadn't been aware 23 of the necessity, but beginning at this point 24 in time, what would you do then? 25 DR. ELMS:</p>

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<p>1 A. Again as a second level control, I would 2 either have seen the control, the external 3 control myself or had been made aware that it 4 had been checked, and then in the course of 5 examining my slide, I would look at it to see 6 if there was staining in normal duct tissue. 7 COFFEY, Q.C.: 8 Q. And if there wasn't? 9 DR. ELMS: 10 A. If there wasn't, it would be a concern 11 certainly, but there are cases in which normal 12 ducts can be negative, so one case like that 13 would not spur my attention. 14 COFFEY, Q.C.: 15 Q. If the--the tumour, I take it, stained? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. And the normal tissue didn't stain, you'd be 20 somewhat comfortable with that? 21 DR. ELMS: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. With the tumour staining, anyway, with the 25 external control staining?</p>	<p>1 percent, and this consensus statement of 2 November 1st to the 3rd, 2002, National 3 Institute of Health. Now by May of 2003, what 4 was your practise in terms of reporting ER and 5 PR? 6 DR. ELMS: 7 A. As a general rule, to report percentages. 8 COFFEY, Q.C.: 9 Q. Did you have any understanding as to what the 10 cutoff, as it were, was for positivity? 11 DR. ELMS: 12 A. That there was a debate that overall my 13 assumption was that 10 percent was being 14 considered as a cutoff, however, I was also 15 aware that on the horizon was, as you see in 16 number three there, the idea that 1 percent 17 might well be a cutoff. 18 COFFEY, Q.C.: 19 Q. Do you recall any particular debate, for 20 example, or discussion with the oncologist 21 about this? 22 DR. ELMS: 23 A. No. 24 COFFEY, Q.C.: 25 Q. So any discussion that did occur would have</p>
<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. If the external control stained, but the 5 tumour didn't stain, and the normal tissue 6 didn't stain, would you have a concern? 7 DR. ELMS: 8 A. In an isolated instance, it would be something 9 to bear in mind, but I wouldn't look at an 10 isolated instance as being significant enough 11 to negate the case. 12 COFFEY, Q.C.: 13 Q. Would you make any note on the reports or 14 report you did? 15 DR. ELMS: 16 A. No. 17 COFFEY, Q.C.: 18 Q. Did you ever make any inquiries, do you 19 recall? 20 DR. ELMS: 21 A. I don't recall having had an opportunity to. 22 COFFEY, Q.C.: 23 Q. Doctor, with reference to paragraph five to 24 the reporting of ER/PR, and there's different 25 percentages you'll see; five, ten, and one</p>	<p>1 been within the pathology circles? 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. If at the time you were reporting simply 6 something as positive or negative for 7 2002/2003, if you reported something as 8 negative, what was the cutoff you were using 9 at the time yourself? 10 DR. ELMS: 11 A. In that instance, I would be--that would be 12 negative, I would see no staining. 13 COFFEY, Q.C.: 14 Q. So you had gone to the percentage yourself? 15 DR. ELMS: 16 A. Yes, in general. 17 COFFEY, Q.C.: 18 Q. By that point, and if, however, you didn't use 19 a percentage in that time period, if we 20 examined all the cases you reported, and you 21 used the word negative? 22 DR. ELMS: 23 A. That meant no staining. 24 COFFEY, Q.C.: 25 Q. No staining. The 10 percent wouldn't have</p>

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<p>1 figured into your calculation?</p> <p>2 DR. ELMS:</p> <p>3 A. No, no.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Unlike back in your early days when you would</p> <p>6 actually do the arithmetic in your head and if</p> <p>7 it was under 30, it was --</p> <p>8 DR. ELMS:</p> <p>9 A. Yes.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. It was determined negative. Doctor, paragraph</p> <p>12 seven is ER positive tumours, and got a list</p> <p>13 of them there, and Dr. Ejeckam has, in fact,</p> <p>14 told us that lobular should have been included</p> <p>15 in that list.</p> <p>16 DR. ELMS:</p> <p>17 A. Uh-hm.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Before receiving this memo in May of 2003,</p> <p>20 were you aware that certain types of breast</p> <p>21 tumours would tend to be statistically ER</p> <p>22 positive?</p> <p>23 DR. ELMS:</p> <p>24 A. No.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 could be relatively unusual?</p> <p>2 DR. ELMS:</p> <p>3 A. I hadn't been up to this point, no.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. You had not been?</p> <p>6 DR. ELMS:</p> <p>7 A. No.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Up to this point. In fact, it's not mentioned</p> <p>10 here, so even having read this, you wouldn't</p> <p>11 have been aware of that.</p> <p>12 DR. ELMS:</p> <p>13 A. No.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And you didn't go and look further?</p> <p>16 DR. ELMS:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. When did you first become aware that lobular</p> <p>20 invasives --</p> <p>21 DR. ELMS:</p> <p>22 A. Lobular invasive? I believe it was around</p> <p>23 when Dr. Carter started with us.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Do you recall what year that was?</p>
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<p>1 Q. You weren't--did you make any inquiries</p> <p>2 yourself at that time, having received this</p> <p>3 memo, as to how often, what percentages one</p> <p>4 might expect positivity in?</p> <p>5 DR. ELMS:</p> <p>6 A. You mean to look at actual numbers of how many</p> <p>7 tubulars I'd expect?</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Sure.</p> <p>10 DR. ELMS:</p> <p>11 A. No.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Having received this, did that information</p> <p>14 then have any influence upon your approach to</p> <p>15 looking at the slides?</p> <p>16 DR. ELMS:</p> <p>17 A. It was a piece of information that I would</p> <p>18 keep in my mind. I don't see many tubular</p> <p>19 carcinomas, or papillaries for that matter,</p> <p>20 but it was certainly information that I would</p> <p>21 have been aware of.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. And then were you aware or had you been aware-</p> <p>24 -I take it you hadn't been aware then, I take</p> <p>25 it, that lobular invasive ER negative tumours</p>	<p>1 DR. ELMS:</p> <p>2 A. No.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. I take it whenever she showed up, I take it on</p> <p>5 the permanent staff at St. Clare's?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes, yeah, exactly.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. You would have become aware of that. In what</p> <p>10 context then would you have become aware of</p> <p>11 it?</p> <p>12 DR. ELMS:</p> <p>13 A. Just in informal discussions with Dr. Carter.</p> <p>14 When she came as a breast pathologist, she was</p> <p>15 very interested in our breast service, and we</p> <p>16 all saw her as a source of information. So in</p> <p>17 informal discussions with Dr. Carter, subjects</p> <p>18 like this would come up.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. I take it before she arrived on the staff,</p> <p>21 there was no one there who you would think of</p> <p>22 as a breast pathologist in the way you did</p> <p>23 her?</p> <p>24 DR. ELMS:</p> <p>25 A. No, there wasn't.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. Had there been anyone during your time in St.</p> <p>3 John's in the General Hospital site, or the</p> <p>4 Grace, for that matter, whom you would have</p> <p>5 thought of as a breast pathologist?</p> <p>6 DR. ELMS:</p> <p>7 A. No.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Doctor, before I go to the June 19, 2003, memo</p> <p>10 from Dr. Ejeckam to Mr. Gulliver at page five</p> <p>11 of P-0113, just on the issue of specialization</p> <p>12 which breast pathology is on my mind, during</p> <p>13 your residency and then in the first--in the</p> <p>14 years since really, in terms of specialization</p> <p>15 amongst pathologists in St. John's, how many</p> <p>16 pathologists would you describe as being</p> <p>17 specialized?</p> <p>18 DR. ELMS:</p> <p>19 A. Dr. Robb had an interest in lymphoma and</p> <p>20 molecular genetics. I know Dr. Wadden had a</p> <p>21 special interest in dermapathology, but in</p> <p>22 terms of people who were actually sub-</p> <p>23 specialized pathologists, Dr. Khalifa had a</p> <p>24 sub-specialty in gynepathology, but none</p> <p>25 functioned specifically as that. We were all</p>	<p>1 DR. ELMS:</p> <p>2 A. It was discussed and considered. Most of my</p> <p>3 time, the atmosphere that I understand it was</p> <p>4 about getting people, rather than getting</p> <p>5 specific people.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. I take it there just wasn't sufficient</p> <p>8 personnel?</p> <p>9 DR. ELMS:</p> <p>10 A. There wasn't sufficient-- yeah, it was of that</p> <p>11 nature.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. After Dr. Carter arrived, we're aware--we've</p> <p>14 seen a document where there's a reference to</p> <p>15 Dr. Fontaine having raised at the General</p> <p>16 Hospital the idea of her looking at all ER/PR</p> <p>17 slides?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Did that ever come up at St. Clare's, do you</p> <p>22 know?</p> <p>23 DR. ELMS:</p> <p>24 A. I remember there was discussion about her sub-</p> <p>25 specializing in breast and what form that</p>
<p>Page 102</p> <p>1 general pathologists, so to speak, in terms of</p> <p>2 our assessment of cases.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. I take it some pathologists, though, would do</p> <p>5 a particular type of work more than others</p> <p>6 would?</p> <p>7 DR. ELMS:</p> <p>8 A. Would have a greater interest in it. They</p> <p>9 certainly wouldn't-- their case loads would</p> <p>10 not reflect that. They would still receive</p> <p>11 cases the way all of us did. However, if, for</p> <p>12 instance, I had a problem with a skin case, I</p> <p>13 would be more inclined to ask Dr. Wadden's</p> <p>14 opinion.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Okay. During your period in St. John's as a</p> <p>17 pathologist dating back to your residency days</p> <p>18 and continuing on, do you ever recall any</p> <p>19 effort or efforts throughout that time period,</p> <p>20 now more than a decade, to move towards</p> <p>21 specialization?</p> <p>22 DR. ELMS:</p> <p>23 A. It was --</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Or sub-specialization.</p>	<p>Page 104</p> <p>1 would take. It wasn't--as I remember, it</p> <p>2 wasn't considered feasible for her to just</p> <p>3 solely see breast cases, but I remember there</p> <p>4 being discussion as to how her expertise would</p> <p>5 be utilized.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And the discussion, did it get any further</p> <p>8 than being talked about, do you recall? I</p> <p>9 appreciate in '05 onward, we'll come to that.</p> <p>10 DR. ELMS:</p> <p>11 A. At the time, I'm not sure. I know she was</p> <p>12 receiving consultations from outside the city.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. The idea that she might, even without</p> <p>15 reporting them, look at all ER/PR slides, do</p> <p>16 you recall that ever being raised with you?</p> <p>17 DR. ELMS:</p> <p>18 A. I don't recall that.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. In that case, she would have ended up looking</p> <p>21 at some of your slides in that context if that</p> <p>22 had happened.</p> <p>23 DR. ELMS:</p> <p>24 A. Yes.</p> <p>25 COFFEY, Q.C.:</p>

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<p>1 Q. You don't recall that ever being raised?</p> <p>2 DR. ELMS:</p> <p>3 A. I don't recall, no.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Looking at the June 19, 2003, memo of Dr.</p> <p>6 Ejeckam to Mr. Gulliver, this is not addressed</p> <p>7 to yourself.</p> <p>8 DR. ELMS:</p> <p>9 A. No.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. It's to Mr. Gulliver. It's on the-- the last</p> <p>12 page of the memo, it's copied to Dr. Robb, Dr.</p> <p>13 Cook, Dr. Parai, and Barry Dyer. Could you</p> <p>14 tell me, please, Doctor, were you made aware</p> <p>15 of the existence of this memo in 2003?</p> <p>16 DR. ELMS:</p> <p>17 A. Not that I remember, no.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. You've seen it since, I take it, the subject</p> <p>20 matter, this is one where Dr. Ejeckam, he</p> <p>21 concludes the first paragraph by saying,</p> <p>22 "Despite the fact that the problem seems to</p> <p>23 have been arrested, which is the erratic</p> <p>24 results of immunostains, the state of</p> <p>25 immunostaining at the General Hospital,</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. You didn't become --</p> <p>3 DR. ELMS:</p> <p>4 A. No.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Like, over at St. Clare's sitting around at</p> <p>7 times --</p> <p>8 DR. ELMS:</p> <p>9 A. No.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Having a chat about --</p> <p>12 DR. ELMS:</p> <p>13 A. No.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Ejeckam's concerns.</p> <p>16 DR. ELMS:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Okay. Doctor, here when we look at the last</p> <p>20 page of this, we see it's copied to Dr. Cook</p> <p>21 as clinical chief, and site chief, St.</p> <p>22 Clare's, Dr. Parai as the site chief, and</p> <p>23 Barry Dyer, the manager of histopathology.</p> <p>24 IHC, from your perspective being a staff</p> <p>25 pathologist at St. Clare's at the time, June,</p>
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<p>1 Department of Laboratory Medicine and</p> <p>2 Pathology, is still unsatisfactory".</p> <p>3 DR. ELMS:</p> <p>4 A. Yes.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. And he goes on at some length about that?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Okay. In fact, the end of paragraph three on</p> <p>11 the second page of the memo, he says, "To do</p> <p>12 less would simply become a gamble where you</p> <p>13 may win or lose. This, obviously, will spell</p> <p>14 disaster".</p> <p>15 DR. ELMS:</p> <p>16 A. Uh-hm.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And the memo is written with that sort of tone</p> <p>19 at times in it. Do you recall the concerns or</p> <p>20 the nature of these concerns about the future</p> <p>21 of immunohistochemistry being discussed in</p> <p>22 2003?</p> <p>23 DR. ELMS:</p> <p>24 A. I wasn't involved in discussions that I</p> <p>25 recall.</p>	<p>1 2003, who would you have seen a responsible</p> <p>2 for IHC?</p> <p>3 DR. ELMS:</p> <p>4 A. Dr. Ejeckam.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Was your-- when would he first then, from your</p> <p>7 perspective, have become responsible for it?</p> <p>8 DR. ELMS:</p> <p>9 A. I'm not sure as to the exact date when he</p> <p>10 became the one with oversight of the</p> <p>11 immunohistochemistry procedures.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Do you recall who first advised you of that?</p> <p>14 DR. ELMS:</p> <p>15 A. No.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And the manner in which you first became aware</p> <p>18 of that --</p> <p>19 DR. ELMS:</p> <p>20 A. No.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. He was the go to person, as it were?</p> <p>23 DR. ELMS:</p> <p>24 A. Yes, I'm not sure when that occurred.</p> <p>25 COFFEY, Q.C.:</p>

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<p>1 Q. Did you ever have occasion to speak to Dr. 2 Ejeckam about--you know, in 2002, 2003, 2004, 3 about a particular problem or problems with 4 IHC yourself? 5 DR. ELMS: 6 A. Not that I recall. 7 COFFEY, Q.C.: 8 Q. So then, Doctor, after the suspension of the 9 ER/PR testing in 2003 and its resumption of 10 the same effectively a month later, your own 11 practise then would have changed in the 12 context of you looking for internal control? 13 DR. ELMS: 14 A. Yes. 15 COFFEY, Q.C.: 16 Q. In terms of looking for staining in that, and 17 anything else? 18 DR. ELMS: 19 A. I would have been more conscious of the issues 20 that he discussed. 21 COFFEY, Q.C.: 22 Q. Particularly -- 23 DR. ELMS: 24 A. That he brought to our attention. 25 COFFEY, Q.C.:</p>	<p>1 A. Chai. That's one of our residents. 2 COFFEY, Q.C.: 3 Q. Resident, and this would be an example of, I 4 take it, a resident being involved? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. In the process, and this then--your 9 handwriting here? 10 DR. ELMS: 11 A. No, that would be Chai's. 12 COFFEY, Q.C.: 13 Q. The resident. 14 DR. ELMS: 15 A. The resident's, yes. 16 COFFEY, Q.C.: 17 Q. So March 19th, 2003, it would have been--the 18 ER/PR was ordered, we see that here, and then 19 date completed, April 28th '03, M. Butler, 20 checked by Dr. Ejeckam. In this context, 21 "checked by Dr. Ejeckam" would have been 22 interpreted by you as what? 23 DR. ELMS: 24 A. That he had reviewed the controls. 25 COFFEY, Q.C.:</p>
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<p>1 Q. The fixation issue? 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. Related issues, and processing issues. In 6 terms of oversight then for ER/PR from that 7 point on, did you have any understanding about 8 anyone who was responsible for it in a general 9 way? 10 DR. ELMS: 11 A. In a general way, I knew that Dr. Ejeckam was 12 the physician with oversight, and I assumed as 13 well that our laboratory manager was also 14 involved in the process and that it was a 15 shared oversight between the two of them. 16 COFFEY, Q.C.: 17 Q. And the manager here is? 18 DR. ELMS: 19 A. Mr. Dyer--well, Mr. Dyer and Mr. Gulliver. 20 COFFEY, Q.C.: 21 Q. Exhibit P-2173, please, page 11, please. 22 Doctor, this is immunoperoxidase request form, 23 SS2033-03, March 19th, 2003. The pathologist 24 is yourself and -- 25 DR. ELMS:</p>	<p>1 Q. Page 15 of the same exhibit is surgical number 2 SS8560-02. It's March 12, '03. See here? 3 DR. ELMS: 4 A. Yes. 5 COFFEY, Q.C.: 6 Q. This would be your handwriting? 7 DR. ELMS: 8 A. Yes. 9 COFFEY, Q.C.: 10 Q. Blocks B and -- 11 DR. ELMS: 12 A. E. 13 COFFEY, Q.C.: 14 Q. E, Elms, ER/PR testing, signed by Ms. Butler, 15 May 2nd '03, checked by Dr. Ejeckam. I take 16 it the same significance? 17 DR. ELMS: 18 A. Yes. 19 COFFEY, Q.C.: 20 Q. In other words, checked by him. Here, Doctor, 21 this seemingly spans the time that the 22 suspension occurred. This would be March 12th 23 '03 would be when it was ordered, see that? 24 DR. ELMS: 25 A. Uh-hm.</p>

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1 COFFEY, Q.C.:

2 Q. It's reported May 2nd '03.

3 DR. ELMS:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. And April 4th '03 is the date that memo --

7 DR. ELMS:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. Announcing the suspension of ER/PR testing was

11 sent around. Was there any particular--I'll

12 just bring you to one other one, page 22 of

13 the same exhibit. It's SS1549-03, and the

14 date is 03/03, hard to tell what the final

15 figure is, March, 2003. It's your

16 handwriting, isn't it?

17 DR. ELMS:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Block 3E, ER/PR, and M. Butler, May 2nd '03,

21 checked by Dr. Ejeckam.

22 DR. ELMS:

23 A. Yes.

24 COFFEY, Q.C.:

25 Q. So, Doctor, during the time period that the

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1 testing was suspended, you apparently had some

2 ER/PR cases outstanding or being done?

3 DR. ELMS:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. Was there anything in particular done at that

7 time frame when these cases came back or

8 finally reported, were they handled in any

9 particular way, do you recall?

10 DR. ELMS:

11 A. Not that I --

12 COFFEY, Q.C.:

13 Q. Having received the memos.

14 DR. ELMS:

15 A. Not that I recall. I mean, I received things,

16 checked by Dr. Ejeckam.

17 COFFEY, Q.C.:

18 Q. Now in the same exhibit, P-2173, if we could

19 go, please, to page 56. This is

20 immunoperoxidase request form, SS5231-02, it's

21 Block 6C. The pathologist is indicated to be

22 yourself. It's dated May 23rd '03, and the

23 block itself is an '02 block, and written here

24 is "Repeat" ER/PR, requested by Dr. Zaidi, and

25 ER/PR is the test, M. Butler, May 29th, '03.

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1 DR. ELMS:

2 A. Yes.

3 COFFEY, Q.C.:

4 Q. Do you recall what this was about?

5 DR. ELMS:

6 A. I know I had been requested to repeat the test

7 by Dr. Zaidi. As to why, I'm not sure.

8 COFFEY, Q.C.:

9 Q. Would you have made any inquiries at the time,

10 do you recall?

11 DR. ELMS:

12 A. I would assume, yes. I mean, he would have

13 either called or sent a requisition asking for

14 it, and if I talked to him on the phone, I'm

15 sure I asked what the problem was originally,

16 but I don't recall this particular case

17 specifically.

18 THE COMMISSIONER:

19 Q. Mr. Coffey, wherever you can find an

20 appropriate place to take the morning break.

21 COFFEY, Q.C.:

22 Q. That'll be fine, Commissioner, right now,

23 thank you.

24 THE COMMISSIONER:

25 COFFEY, Q.C.:

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1 Q. Take fifteen minutes.

2 (RECESS)

3 THE COMMISSIONER:

4 Q. Mr. Coffey.

5 CROSBIE, Q.C.:

6 Q. Commissioner, I'd like to introduce Laura

7 Brocklehurst from my office. She'll be here

8 off and on over the next few weeks.

9 THE COMMISSIONER:

10 Q. Thank you, Mr. Crosbie. Welcome, Ms.

11 Brocklehurst.

12 MS. BROCKLEHURST:

13 Q. Thank you.

14 COFFEY, Q.C.:

15 Q. Bring up, Registrar, please, Exhibit P-2407,

16 page 72, please. Doctor, this is a surgical

17 pathology #5903-01. The date would be 2001,

18 probably September 24th, it's hard to know.

19 Looking down below, the date is at the bottom

20 right hand side of that page indicates it

21 probably is September 24th, 09/24. It's Block

22 1E. The pathologist is indicated to be F.

23 Elms, and do you recognize the handwriting?

24 DR. ELMS:

25 A. That's mine.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And here under comments-- well, first of all,</p> <p>3 M. Butler, date completed, September 28th '01,</p> <p>4 and then M. Butler, October 4th '01, Dr. K.</p> <p>5 Laurence is referred to, and it's written</p> <p>6 here, "Please repeat ER again, stain totally</p> <p>7 negative in non-neoplastic breast tissue".</p> <p>8 DR. ELMS:</p> <p>9 A. Yes.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Whose handwriting is this?</p> <p>12 DR. ELMS:</p> <p>13 A. That's mine.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. What would this be referring to?</p> <p>16 DR. ELMS:</p> <p>17 A. I had--I had a case in which I obviously had a</p> <p>18 problem and felt that the negative staining</p> <p>19 was not acceptable.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. So non-neoplastic breast tissue --</p> <p>22 DR. ELMS:</p> <p>23 A. That would be normal breast tissue.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And suggesting that you had concerns about it</p>	<p>1 A. Not formally, no.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Not formally. Formally, in the sense of, I</p> <p>4 take it, just not doing it in the sense of</p> <p>5 kind of every case like you would now --</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. If you were doing it now, you'd --</p> <p>10 DR. ELMS:</p> <p>11 A. Just not doing it every case, exactly.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. But at that time, I mean, in relation to this</p> <p>14 particular case, anyway, something must have</p> <p>15 caused you to --</p> <p>16 DR. ELMS:</p> <p>17 A. For some reason, it must have stood out, yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. But you can't recall now why in particular</p> <p>20 this was?</p> <p>21 DR. ELMS:</p> <p>22 A. No.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Have you made any effort to ascertain why it</p> <p>25 was?</p>
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<p>1 being normal breast tissue?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Normal in the sense of not cancerous?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Being totally negative?</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And why would you have been concerned about</p> <p>14 that at the time?</p> <p>15 DR. ELMS:</p> <p>16 A. I would have to see the slide to be able to</p> <p>17 say what it was that specifically tweaked me</p> <p>18 to that one.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Because at that time, and again this would be</p> <p>21 September/October, 2001, you have indicated</p> <p>22 you weren't in particular looking to see</p> <p>23 whether internal controls were staining or</p> <p>24 not?</p> <p>25 DR. ELMS:</p>	<p>1 DR. ELMS:</p> <p>2 A. I beg your pardon?</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Have you made any effort since to ascertain,</p> <p>5 like, knowing that you were going to be coming</p> <p>6 and testifying?</p> <p>7 DR. ELMS:</p> <p>8 A. I didn't know about this particular case.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Oh! If we could look, please, at Exhibit P-</p> <p>11 2302. Doctor, this is a Physician Services</p> <p>12 Liaison Committee minutes of March 15th, 2005.</p> <p>13 It's a record of decisions, it's styled.</p> <p>14 There are a number in attendance. You're</p> <p>15 listed as one of the guests, yourself, Dr.</p> <p>16 Denic, Dr. Fontaine, and Dr. Jenkins by phone,</p> <p>17 and Juanita Barrett. There's paragraph four,</p> <p>18 presentation discussion relating to pathology</p> <p>19 issues?</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Nash Denic, Dan Fontaine, Ford Elms, provided</p> <p>24 issues aging workforce, retirements,</p> <p>25 recruitment and retention. L. Bryant to</p>

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<p>1 forward a copy of the presentation from the 2 co-chairs to the medical directors in medicine 3 for review and feedback? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. Do you recall, Doctor, what this was about? 8 This would be the spring, March of '05--well, 9 winter of 2005, actually. 10 DR. ELMS: 11 A. This was one phase of a period when we were 12 attempting to bring to government issues of 13 concerns that we had with regard to 14 recruitment and retention of pathologists. At 15 the time, we were the lowest paid in the 16 country, and it had been difficult for quite 17 some time to--not so much to recruit people, 18 but certainly to retain them, and whatever 19 difficulties that were there in recruitment 20 were magnified by the difficulties in 21 retention, and we had gone through various 22 routes through the NLMA. I had earlier to 23 this been on the Salaried Physician's 24 Negotiating Committee, and the issue was one 25 that the committee had been putting forward to</p>	<p>1 A. Yes. 2 COFFEY, Q.C.: 3 Q. There were concerns expressed about it 4 increasingly as time went on? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. And finally there have been problems. 9 DR. ELMS: 10 A. Yes. 11 COFFEY, Q.C.: 12 Q. This is, in fact--as it turns out, I take it, 13 this is actually a month before--I won't say 14 to the day, but pretty well a month before 15 Peggy Dean's case was identified? 16 DR. ELMS: 17 A. Somewhere in that vicinity. 18 COFFEY, Q.C.: 19 Q. We'll see that in a moment. Exhibit C-0173, 20 please. Doctor, this is a special procedure 21 request form. This is one of those 22 immunohistochemistry forms. This particular 23 one is for SS4884-02. It's dated June 26th, 24 2002. Block--what would that have been? 25 DR. ELMS:</p>
<p>1 government in negotiations. This was an 2 attempt to clarify the issue for various 3 parties involved, and if you go back to the 4 attendees, you've got members from the 5 Department of Health and Community Services, 6 Dr. Jenkins specifically is a Medical Director 7 in Corner Brook, so we were trying to impress 8 upon the various governing bodies that this 9 was an issue, and we were warning that in the 10 near future there would be a crunch in 11 pathology manpower. 12 COFFEY, Q.C.: 13 Q. And has that come to fruition? 14 DR. ELMS: 15 A. Yes. 16 COFFEY, Q.C.: 17 Q. You were doing so--this is a presentation of 18 March 15, 2005, so I take it that this was not 19 the first time that this had been voiced? 20 DR. ELMS: 21 A. No, it wasn't. 22 COFFEY, Q.C.: 23 Q. It was recognized that it was going to be a 24 problem? 25 DR. ELMS:</p>	<p>1 A. Block X and Block AA. 2 COFFEY, Q.C.: 3 Q. Block X and AA, and the patient's name is 4 Margaret Dean, the pathologist, and it's 5 lobular carcinoma. I take it that this is 6 your handwriting? 7 DR. ELMS: 8 A. Yes. 9 COFFEY, Q.C.: 10 Q. The request is for ER and PR? 11 DR. ELMS: 12 A. Yes. 13 COFFEY, Q.C.: 14 Q. And it's indicated to be date completed by P. 15 Welsh, July 4th '02? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. If we could look, please, at Exhibit C-0156. 20 These are some pathology reports for Ms. 21 Deane's case. In particular, Doctor, if you 22 could look, please, at page two. First of 23 all, go back to page one, I'm sorry. It's for 24 specimen #02 SS484, which would be the same 25 number we just looked at on the requisition</p>

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<p>1 form?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And it's indicated to be received June 21st</p> <p>6 '02. Doctor, the significance of that is what,</p> <p>7 what does that mean in this context here?</p> <p>8 DR. ELMS:</p> <p>9 A. What do you mean, the --</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Received that date.</p> <p>12 DR. ELMS:</p> <p>13 A. That is the date that the specimen was</p> <p>14 received in the laboratory.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And here there's a comment, "Case was verbally</p> <p>17 discussed by phone with Dr. David Pace,</p> <p>18 Wednesday, June 26th, 2002, at 4:15 p.m". I</p> <p>19 take it that that would be some note that you</p> <p>20 would have made at the time?</p> <p>21 DR. ELMS:</p> <p>22 A. Yes, some discussion that I would have had</p> <p>23 with Dr. Pace.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Just to record that, in fact, you had talked</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Sure, and here, Doctor, overall, I take it,</p> <p>3 this was characterized by yourself as an</p> <p>4 infiltrating lobular carcinoma?</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And then Addendum #1, and above that on the</p> <p>9 page, it's indicated to be entered July 8th,</p> <p>10 2002, and signed electronically on July 10th</p> <p>11 '02 by yourself, immunohistochemical staining</p> <p>12 for estrogen and progesterone receptors shows</p> <p>13 weak staining for progesterone receptors in</p> <p>14 less than 10 percent of lesional cells,</p> <p>15 negative staining for estrogen receptors.</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And then, Doctor, above that, Addendum 2,</p> <p>20 which is entered August 21st '02, and signed</p> <p>21 out the same day when we look at the next</p> <p>22 page, there's a HER2/neu status?</p> <p>23 DR. ELMS:</p> <p>24 A. Yes.</p> <p>25 COFFEY, Q.C.:</p>
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<p>1 to him about it?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Okay. If we go to the second page of the</p> <p>6 exhibit, pathological interpretation, and you</p> <p>7 have an interpretation here. Doctor, here</p> <p>8 under "Mass right breast, excisional biopsy",</p> <p>9 you've got "invasive lobular carcinoma".</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Widespread lobular carcinoma in situ.</p> <p>14 DR. ELMS:</p> <p>15 A. In situ.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And you go on from there, and you finally note</p> <p>18 by saying, "Please see tumour summary", which</p> <p>19 is, I take it, the detailed --</p> <p>20 DR. ELMS:</p> <p>21 A. The detailed --</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Analysis.</p> <p>24 DR. ELMS:</p> <p>25 A. List you see just below it.</p>	<p>1 Q. So, Doctor, I take it then that in 2002, at</p> <p>2 least in respect of that surgical specimen</p> <p>3 number, SS484, you would have looked at it for</p> <p>4 diagnosis purposes?</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Pathological interpretation, and recorded your</p> <p>9 observations, ordered the ER/PR test, and</p> <p>10 reported it?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. As indicated here in Addendum #1, and then</p> <p>15 later the same summer, reported the HER2/neu?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Doctor, can you tell us, please, after that</p> <p>20 when you next recall hearing about Peggy Deane</p> <p>21 or being involved?</p> <p>22 DR. ELMS:</p> <p>23 A. It was when I was contacted to repeat her</p> <p>24 estrogen receptor.</p> <p>25 COFFEY, Q.C.:</p>

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1 Q. And that would be in 2005 as we'll see in a
 2 moment. Do you recall who contacted you?
 3 DR. ELMS:
 4 A. I believe it was Dr. McCarthy or Dr. Laing.
 5 COFFEY, Q.C.:
 6 Q. And do you recall the circumstances?
 7 DR. ELMS:
 8 A. At that point, Ms. Deane had had several
 9 courses of chemotherapy and the oncologists
 10 were concerned-- just to be sure, just to
 11 leave on stone unturned, Ms. Deane was a young
 12 woman with young children, and having gone
 13 through several courses of chemotherapy, they
 14 were considering that there was very little
 15 else that could be done, and they wanted to,
 16 as I say, make sure there was no stone
 17 unturned and that there was no possibility
 18 they could give the woman Tamoxifen at that
 19 point.
 20 COFFEY, Q.C.:
 21 Q. That was the way it was explained to you?
 22 DR. ELMS:
 23 A. That was the way it was explained to me.
 24 COFFEY, Q.C.:
 25 Q. Was there any discussion about invasive

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1 lobular and whether it should or shouldn't be
 2 positive or negative at that time?
 3 DR. ELMS:
 4 A. Not on my first contact that I recall, no.
 5 COFFEY, Q.C.:
 6 Q. So you had a contact, and it was your first
 7 contact that caused you to do the retest?
 8 DR. ELMS:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. So you got this explanation, we'd like you to
 12 check again?
 13 DR. ELMS:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. If you would.
 17 DR. ELMS:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. So what did you do?
 21 DR. ELMS:
 22 A. I reviewed the case to identify an appropriate
 23 block and then ordered the estrogen and
 24 progesterone receptor testing.
 25 COFFEY, Q.C.:

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1 Q. And then what happened, Doctor?
 2 DR. ELMS:
 3 A. I got the slide back and it was positive. So
 4 I immediately telephoned, again I believe it
 5 was Dr. Rorke at that time to let him know the
 6 result while I had the slide on my stage. I
 7 knew they were waiting for it and I knew the
 8 significance of it. So I called him right
 9 away to let him know.
 10 COFFEY, Q.C.:
 11 Q. And why Dr. Rorke, do you recall?
 12 DR. ELMS:
 13 A. I believe his name had been given to me, that
 14 Dr. McCarthy was to be out of town or
 15 something of that nature. It was a--I was
 16 told he would be the one to call.
 17 COFFEY, Q.C.:
 18 Q. And so while you still had it there, as you
 19 say, on your stage, on the microscope in fact?
 20 DR. ELMS:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. You called Dr. Rorke?
 24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. And told him what?
 3 DR. ELMS:
 4 A. That this woman's repeat test was positive.
 5 COFFEY, Q.C.:
 6 Q. And did he say anything at the time?
 7 DR. ELMS:
 8 A. I recall expressing a certain amount of relief
 9 that now at least there was something that
 10 they could do for this woman.
 11 COFFEY, Q.C.:
 12 Q. And was that you expressed that or him or
 13 both?
 14 DR. ELMS:
 15 A. Him, and myself as well. It was the--but he
 16 was the one who said "we can now look at
 17 giving Ms. Deane Tamoxifen."
 18 COFFEY, Q.C.:
 19 Q. And okay then, then what happened, Doctor, in
 20 terms of Ms. Deane, in terms of your
 21 involvement?
 22 DR. ELMS:
 23 A. That was the end of my involvement.
 24 COFFEY, Q.C.:
 25 Q. Did you speak to anyone else about it at that

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1 time?

2 DR. ELMS:

3 A. I don't recall. I may have spoken to Dr.

4 McCarthy a couple of days later, but I don't

5 recall that for sure.

6 COFFEY, Q.C.:

7 Q. How about any other pathologists?

8 DR. ELMS:

9 A. I then went to my supervisor, Dr. Cook, and

10 informed him that this situation had occurred.

11 COFFEY, Q.C.:

12 Q. And what did you tell him had happened?

13 DR. ELMS:

14 A. That an isolated estrogen receptor case had

15 been originally reported negative, stained

16 negative, and was now staining positive, and

17 that this might result in a complaint on this

18 particular case.

19 COFFEY, Q.C.:

20 Q. And why did you--why might it result in a

21 complaint?

22 DR. ELMS:

23 A. Well, Ms. Deane had originally been told she

24 was negative and had now been through several

25 courses of chemotherapy and now our test was

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1 coming up positive.

2 COFFEY, Q.C.:

3 Q. Doctor, do you recall how long it was between

4 the time you first looked at the new slide,

5 the new ER and PR slides and phoned Dr. Rorke,

6 I appreciate you got Dr. Rorke on the phone

7 right away -

8 DR. ELMS:

9 A. Um-hm.

10 COFFEY, Q.C.:

11 Q. - how long passed before you told Dr. Cook

12 about this?

13 DR. ELMS:

14 A. It was within 24 hours. If I remember

15 correctly, it was the same afternoon.

16 COFFEY, Q.C.:

17 Q. And why were you concerned to tell him right

18 away?

19 DR. ELMS:

20 A. Because he was site chief and I believe at the

21 time he may have been clinical chief, and I

22 felt he needed to know.

23 COFFEY, Q.C.:

24 Q. Doctor, at the time, was there any adverse

25 event form or anything similar to that filled

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1 out in relation to this?

2 DR. ELMS:

3 A. I don't recall.

4 COFFEY, Q.C.:

5 Q. Okay. I take it, it didn't cross your mind at

6 the time to do that?

7 DR. ELMS:

8 A. Not at the time.

9 COFFEY, Q.C.:

10 Q. When you spoke to Dr. Cook about it, what was

11 his reaction?

12 DR. ELMS:

13 A. He appreciated letting me know. I mean, if he

14 was going--if a patient was going to call him

15 to discuss the issue, it would be important

16 for him to know what the issue was, so he was

17 appreciative that I had brought it to his

18 attention.

19 COFFEY, Q.C.:

20 Q. Now had you known who Ms. Deane was before?

21 Did you know her otherwise then?

22 DR. ELMS:

23 A. Not outside. I knew who she was, by virtue of

24 her name and having gone through the medical

25 system here in terms of training, but I'd

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1 never spoken to her.

2 COFFEY, Q.C.:

3 Q. So you didn't know her in a personal way at

4 all?

5 DR. ELMS:

6 A. No.

7 COFFEY, Q.C.:

8 Q. And Doctor, did you speak then to--well, you'd

9 spoken to Dr. Rorke and Dr. Cook, I believe

10 that same day, certainly Dr. Rorke that day

11 and Dr. Cook within, if not that day,

12 certainly early the next?

13 DR. ELMS:

14 A. Yes.

15 COFFEY, Q.C.:

16 Q. Within 24 hours, Dr. Cook to tell him about

17 it, and you may have spoken to Dr. McCarthy or

18 Dr. Laing within a couple of days?

19 DR. ELMS:

20 A. Within a couple of days, yeah.

21 COFFEY, Q.C.:

22 Q. Can't really recall. Doctor, you've indicated

23 that the first time you spoke with, whether it

24 was Dr. McCarthy or Laing asked you about the

25 retesting or doing the retesting, that the

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1 invasive lobular aspect of the matter didn't
 2 come up at that time?
 3 DR. ELMS:
 4 A. At that time, that I recall.
 5 COFFEY, Q.C.:
 6 Q. Yes. But how about afterward?
 7 DR. ELMS:
 8 A. Yes, in--as I said, I recall speaking to
 9 either Dr. McCarthy or Dr. Laing subsequently
 10 and yes, then I was informed that it had been
 11 reviewed and they were somewhat surprised that
 12 a lobular had been negative.
 13 COFFEY, Q.C.:
 14 Q. They were?
 15 DR. ELMS:
 16 A. Yes, the people who did the review.
 17 COFFEY, Q.C.:
 18 Q. Okay, so they--what were you told about the
 19 review?
 20 DR. ELMS:
 21 A. That it had been seen, I believe, at the Mayo
 22 Clinic and that they had agreed that it was a
 23 lobular and that they were--they had expected
 24 that a lobular carcinoma would likely be
 25 positive.

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1 COFFEY, Q.C.:
 2 Q. Now at that time, was that news to you, at
 3 that time?
 4 DR. ELMS:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. That was new to you?
 8 DR. ELMS:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Had you passed that on--did you pass that on
 12 to Dr. Cook, do you know, at that point?
 13 DR. ELMS:
 14 A. I don't recall.
 15 COFFEY, Q.C.:
 16 Q. Having been told that, lobular invasive, it
 17 would be unusual that it would be ER negative,
 18 did that cause you to reflect upon any earlier
 19 cases that you might have had?
 20 DR. ELMS:
 21 A. No.
 22 COFFEY, Q.C.:
 23 Q. In terms of reevaluating earlier cases?
 24 DR. ELMS:
 25 A. No.

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1 COFFEY, Q.C.:
 2 Q. Did you speak to anyone else at St. Clare's or
 3 the General about this?
 4 DR. ELMS:
 5 A. Not that I recall.
 6 COFFEY, Q.C.:
 7 Q. Now Doctor, were you ever asked to reexamine
 8 Ms. Deane's case in relation to whether or not
 9 it was in fact a lobular?
 10 DR. ELMS:
 11 A. Was I ever asked to?
 12 COFFEY, Q.C.:
 13 Q. Yes.
 14 DR. ELMS:
 15 A. No, not that I recall.
 16 COFFEY, Q.C.:
 17 Q. Did you ever do so?
 18 DR. ELMS:
 19 A. At the time, yes.
 20 COFFEY, Q.C.:
 21 Q. Okay, and so when was it that you did that?
 22 DR. ELMS:
 23 A. It was at around the time that I was--within,
 24 you know, two days or three, certainly within
 25 the week, of having received the stain that

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1 was now positive.
 2 COFFEY, Q.C.:
 3 Q. The ER stain that was positive, you went back
 4 and looked then? Within a week of that, you
 5 went back and looked at her case?
 6 DR. ELMS:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. And to determine whether or not, from your
 10 perspective, it was lobular?
 11 DR. ELMS:
 12 A. Yes, yes, if I had experts at the Mayo Clinic
 13 telling me it was, then I wanted to go back
 14 and see what they were telling me.
 15 COFFEY, Q.C.:
 16 Q. And the reference to the Mayo Clinic and
 17 experts had been either Dr. McCarthy or Dr.
 18 Laing?
 19 DR. ELMS:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Certainly you hadn't called the Mayo Clinic
 23 yourself about it?
 24 DR. ELMS:
 25 A. No.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. What did you find when you reexamined it, from</p> <p>3 your perspective?</p> <p>4 DR. ELMS:</p> <p>5 A. That it had the architecture of a lobular</p> <p>6 carcinoma, that as I had noted in my</p> <p>7 microscopy there were areas that had a more</p> <p>8 ductal appearance, but that overall it looked</p> <p>9 like a lobular carcinoma.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Lobular, and you had been told that the Mayo</p> <p>12 had said it was a lobular too?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. So in effect, that was--in effect, you were</p> <p>17 confirming in your own mind what the Mayo had</p> <p>18 already confirmed you had said.</p> <p>19 DR. ELMS:</p> <p>20 A. What the Mayo had already confirmed and to see</p> <p>21 what those ductal areas were, how prominent</p> <p>22 they were, so that in future, how much would</p> <p>23 I--how much weight would I put on those kinds</p> <p>24 of cell groupings.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 fact.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Okay, and in fact, throughout all of this,</p> <p>4 you've examined now, before today, in</p> <p>5 preparing to come here today, you've examined</p> <p>6 what you have available to you about Ms.</p> <p>7 Deane's case?</p> <p>8 DR. ELMS:</p> <p>9 A. Yes.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. In terms of her pathology reports and so on?</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And other than this reference to ductal,</p> <p>16 appearance of some minor aspects of it, and</p> <p>17 it's spelled out in your report, okay -</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. - in terms of your own view of this though,</p> <p>22 documentary wise, it's always been lobular,</p> <p>23 according to the reports?</p> <p>24 DR. ELMS:</p> <p>25 A. According to the reports.</p>
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<p>1 Q. Did you ever tell anyone that this was not a</p> <p>2 lobular but a ductal cancer? Have you ever</p> <p>3 told anyone that?</p> <p>4 DR. ELMS:</p> <p>5 A. At the time?</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Yes.</p> <p>8 DR. ELMS:</p> <p>9 A. Not that I recall.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. How about since?</p> <p>12 DR. ELMS:</p> <p>13 A. I know in the course of preparing for this, I</p> <p>14 had originally remembered that I called it</p> <p>15 ductal, but I see from the report that I</p> <p>16 called it lobular.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. I'm sorry?</p> <p>19 DR. ELMS:</p> <p>20 A. In terms, in preparing for this, for to come</p> <p>21 here to address the Commission, I of course</p> <p>22 have been thinking about the case and my</p> <p>23 initial memory was that I had called it ductal</p> <p>24 on my diagnosis, but I see that I didn't.</p> <p>25 That was just a memory three years after the</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Yes.</p> <p>3 DR. ELMS:</p> <p>4 A. Not a classic lobular, but a lobular with</p> <p>5 ductal areas.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Did you tell Dr. Laing--ever speak to Dr.</p> <p>8 Laing about reexamining the slides?</p> <p>9 DR. ELMS:</p> <p>10 A. I don't recall.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. In terms of whether they were lobular or</p> <p>13 ductal?</p> <p>14 DR. ELMS:</p> <p>15 A. Oh no, I don't recall ever speaking to her</p> <p>16 about that.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. How about Dr. McCarthy?</p> <p>19 DR. ELMS:</p> <p>20 A. Again, I don't recall speaking to them about</p> <p>21 that.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Doctor, if we could look, please, at Exhibit</p> <p>24 C-0167? Now Doctor, this is a discharge</p> <p>25 summary for Ms. Deane. It's dated--the</p>

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1 discharge--well, the admission date is April
2 12th, 2005. The discharge date is April 20th,
3 2005. Dr. Stewart Rorke is the attending
4 physician, and under history of present
5 illness, second paragraph says "repeat testing
6 of her ER/PR receptor status has changed the
7 status to ER/PR positive." I note she was
8 started on treatment with Tamoxifen and given
9 other treatment which is spelled out there.
10 Doctor, do you recall the actual date that you
11 called Dr. Rorke or contacted Dr. Rorke?
12 DR. ELMS:
13 A. No.
14 COFFEY, Q.C.:
15 Q. Okay. Based upon this, it would suggest, I
16 take it, it was some--certainly on or before
17 April 20th.
18 DR. ELMS:
19 A. Definitely, yes.
20 COFFEY, Q.C.:
21 Q. Yes, sometime. Now when you--on the retest in
22 2005, I take it the ER and PR were both
23 positive?
24 DR. ELMS:
25 A. As I remember. I would have to see my

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1 addendum.
2 COFFEY, Q.C.:
3 Q. Sure, and I'll be showing you that just now
4 momentarily. Well, I'll do that now. Exhibit
5 C-0156, please, page one. That's the same
6 surgical number there, Doctor, and the
7 addendum number three entered May 31st, '05 at
8 15:28 hours. It reads "immunohistochemical
9 staining for ER and PR has been repeated on
10 this tissue using Ventana automated system.
11 Stains for both receptors are positive" and
12 it's signed out yourself the same day.
13 DR. ELMS:
14 A. Yes.
15 COFFEY, Q.C.:
16 Q. Doctor, can you tell us, please, why it wasn't
17 until May 31st that this was entered?
18 DR. ELMS:
19 A. I'm not exactly sure as to the reason. I had-
20 -I knew that Doctor--that the clinicians had
21 the information about Ms. Deane and that they
22 were working on it, but as to the reason why
23 it took so long to get that done, I don't
24 recall.
25 COFFEY, Q.C.:

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1 Q. Exhibit C-0168, please. Doctor, do you
2 recall--the percentages are not there on that
3 one.
4 DR. ELMS:
5 A. No.
6 COFFEY, Q.C.:
7 Q. Notice that?
8 DR. ELMS:
9 A. Yeah.
10 COFFEY, Q.C.:
11 Q. Do you recall roughly what the percentages
12 were?
13 DR. ELMS:
14 A. No, not at the time.
15 COFFEY, Q.C.:
16 Q. Were they strongly positive, do you know?
17 DR. ELMS:
18 A. Again, I don't recall. If I called it
19 positive, I wouldn't have been questioning in
20 my own mind whether or not to call it
21 positive.
22 COFFEY, Q.C.:
23 Q. Are you able to tell us why you didn't have
24 the percentages there?
25 DR. ELMS:

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1 A. No, not at the time.
2 COFFEY, Q.C.:
3 Q. Because your practice had been, for some
4 period of time, reporting -
5 DR. ELMS:
6 A. Had been, as a general rule, yes, to report
7 percentages.
8 COFFEY, Q.C.:
9 Q. Doctor, this is--again, this is for Ms. Deane
10 and it's a progress note of May 3rd, 2005,
11 medical oncology clinic. There's part of it--
12 now normally you wouldn't see these progress
13 notes, I take it, in your practice?
14 DR. ELMS:
15 A. No.
16 COFFEY, Q.C.:
17 Q. And here, in the second paragraph, I'm just
18 going to read you a portion of it and then ask
19 you a question about it. Dr. Laing has
20 written "when I had sent an e-mail to Dr.
21 Clifford Hudis in the United States asking him
22 if he had any trials that Peggy might be
23 eligible for, he commented that it would be
24 unusual for a lobular carcinoma to be ER/PR
25 negative. For this reason, I had asked for

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1 her pathology to be reviewed and
 2 interestingly, it came back saying it was a
 3 ductal cancer, but when they did stain her for
 4 ER/PR, it was positive for both. Because of
 5 this, we started Peggy on Tamoxifen as she
 6 still had evidence of an estradiol at a level
 7 which would put her in a pre-menopausal range"
 8 and it goes on from there. "She has been
 9 tolerating the Tamoxifen well with no
 10 difficulties." This is dictated May 3rd, 2005
 11 and typed May 13th.

12 Now Doctor, did you ever tell, that you
 13 can recall, anyone that this was a ductal
 14 cancer?

15 DR. ELMS:
 16 A. No.

17 COFFEY, Q.C.:
 18 Q. Have you ever become aware that, at least in
 19 St. John's, that it has been determined to be
 20 a ductal cancer?

21 DR. ELMS:
 22 A. No.

23 COFFEY, Q.C.:
 24 Q. Okay. Now Doctor, having spoken with Dr.
 25 Rorke and then Dr. Cook and one or perhaps

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1 both of Doctors McCarthy and Laing in the
 2 aftermath, immediate aftermath of the positive
 3 results, did you have any further involvement
 4 with Ms. Deane's case?

5 DR. ELMS:
 6 A. Not that I recall, no.

7 COFFEY, Q.C.:
 8 Q. I take it in May, we've gone through that, you
 9 dictated the Meditec addendum three.

10 DR. ELMS:
 11 A. Yes.

12 COFFEY, Q.C.:
 13 Q. But other than that?

14 DR. ELMS:
 15 A. Not that I recall.

16 COFFEY, Q.C.:
 17 Q. Okay, and in relation to this whole ER/PR
 18 matter that brings us here now, you'd first
 19 become aware of this change for Ms. Deane in
 20 April of '05.

21 DR. ELMS:
 22 A. Um-hm.

23 COFFEY, Q.C.:
 24 Q. When did you next become aware of
 25 investigations going on into ER/PR?

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1 DR. ELMS:
 2 A. It was over the course of the following weeks
 3 subsequent to that. My understanding was that
 4 one of the oncologists remembered a small
 5 number of other cases that they had been
 6 concerned about and that these cases were
 7 looked into and then that other cases were
 8 being looked into and the situation developed
 9 over a matter of weeks, but I wasn't directly
 10 involved with any of those.

11 COFFEY, Q.C.:
 12 Q. And how were you made aware that even that was
 13 going on?

14 DR. ELMS:
 15 A. Within the department it was, it became known.

16 COFFEY, Q.C.:
 17 Q. Because Dr. Cook, who was the clinical chief
 18 and site chief, was within the small, the same
 19 area of the building as you were anyway?

20 DR. ELMS:
 21 A. Yes.

22 COFFEY, Q.C.:
 23 Q. And what then happened, Doctor, in terms of--
 24 at least as best you can recall, in terms of
 25 what you knew about what was going on?

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1 DR. ELMS:
 2 A. I knew that Dr. Cook was looking into the
 3 matter, that other cases were being found that
 4 had originally been called negative and were
 5 now being called positive, and then I became
 6 aware that it had been decided to stop testing
 7 and that a more formal review would be done.

8 COFFEY, Q.C.:
 9 Q. Doctor, in terms of Ms. Deane's case, did you
 10 look at the original ER/PR slides?

11 DR. ELMS:
 12 A. At the time, yes.

13 COFFEY, Q.C.:
 14 Q. And do you recall how they appeared at the
 15 time?

16 DR. ELMS:
 17 A. No, I don't recall now. I know they were
 18 negative.

19 COFFEY, Q.C.:
 20 Q. Negative, and when you looked, at the time
 21 when you reexamined, got the positive results
 22 back, you would have looked at the original
 23 slides?

24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And you do recall now, looking back on it,

3 that it confirmed for you that they were

4 negative, the slides were negative?

5 DR. ELMS:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. It wasn't kind of like "I didn't see

9 something." You confirmed it was -

10 DR. ELMS:

11 A. Yes.

12 COFFEY, Q.C.:

13 Q. - "what I saw as a negative originally, I

14 still see as negative."

15 DR. ELMS:

16 A. I still see as negative.

17 COFFEY, Q.C.:

18 Q. Do you know whether--did you make any

19 observation as to whether or not there was any

20 internal control tissue?

21 DR. ELMS:

22 A. Not at the time.

23 COFFEY, Q.C.:

24 Q. Doctor, then could you take the Commissioner

25 then through the ER/PR matter then as it

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1 developed? We're into the middle of 2005.

2 You understand there's a more formal review,

3 as you put it, going on.

4 DR. ELMS:

5 A. Well, I was only peripherally aware of what

6 was happening. I knew that Dr. Cook and lab

7 management were reviewing cases and that

8 originally there were a couple of cases that

9 had been identified by a particular oncologist

10 as something that they'd always thought was

11 kind of puzzling, was the way I understood it,

12 and that when those two cases were looked

13 into, then other cases came to light and over

14 the course of a couple of weeks, the situation

15 developed and I'm not sure as to how or when

16 the decision was made to formalize the process

17 or what formalities that entailed.

18 COFFEY, Q.C.:

19 Q. And then, I take it, you understood that there

20 was a full scale review going on.

21 DR. ELMS:

22 A. Yes.

23 COFFEY, Q.C.:

24 Q. Or some kind of a large review going on, and

25 we understand that in the summer of 2005, the

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1 middle of the summer, the ER/PR testing was

2 suspended locally?

3 DR. ELMS:

4 A. Yes.

5 COFFEY, Q.C.:

6 Q. Doctor, just look--how did you become aware

7 they were suspended locally? Who made you

8 aware of that?

9 DR. ELMS:

10 A. I don't recall specifically. It may have been

11 Dr. Cook.

12 COFFEY, Q.C.:

13 Q. Look at Exhibit C-0156, please. Doctor, here

14 this is this addendum number three for Ms.

15 Deane. You do conclude here by saying "using

16 Ventana automated system."

17 DR. ELMS:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. Why the reference to that?

21 DR. ELMS:

22 A. I'm not sure. That wasn't a part of my usual

23 reporting at that time. I can't say.

24 COFFEY, Q.C.:

25 Q. At the time, when this first happened, you got

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1 the positive slides in front of you and the

2 earlier ones were negative, did you make any

3 inquiries or conduct any investigations as to

4 how that could have happened?

5 DR. ELMS:

6 A. No, not at the time.

7 COFFEY, Q.C.:

8 Q. And how about afterward?

9 DR. ELMS:

10 A. No, because very shortly there afterward, it

11 became obvious that the laboratory

12 administration was looking into the issue.

13 COFFEY, Q.C.:

14 Q. Did you ever attribute the change yourself to

15 the changeover using from one--from the DAKO

16 to the Ventana system?

17 DR. ELMS:

18 A. No.

19 COFFEY, Q.C.:

20 Q. You never, in your mind?

21 DR. ELMS:

22 A. No.

23 COFFEY, Q.C.:

24 Q. What then happened, Doctor? The testing was

25 suspended locally. What next, in terms of

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<p>1 your recollection now, looking back on it, as 2 a staff pathologist? 3 DR. ELMS: 4 A. I remember that there were meetings and there 5 was a panel set up and a procedure started to 6 investigate these cases to decide how far back 7 to look and to look at disclosing to the 8 patients what had happened. 9 COFFEY, Q.C.: 10 Q. Did you have any input into any of that? 11 DR. ELMS: 12 A. No. 13 COFFEY, Q.C.: 14 Q. You were just kind of aware generally? 15 DR. ELMS: 16 A. I was aware that it was going on. 17 COFFEY, Q.C.: 18 Q. Were you ever formally made aware or in a 19 semiformal way made aware of it, in terms of, 20 "look, we're having a meeting. Doctor, would 21 you like to come--we expect everybody to be 22 there and we'll tell them kind of the status, 23 updates from time to time"? 24 DR. ELMS: 25 A. I believe there were, there was a meeting, but</p>	<p>1 A. No. 2 COFFEY, Q.C.: 3 Q. How about Ms. Wegrynowski? 4 DR. ELMS: 5 A. No. 6 COFFEY, Q.C.: 7 Q. What was your understanding as to what the 8 purpose of their investigations were? 9 DR. ELMS: 10 A. That they were looking at the running of our 11 lab as a means of trying to find out what had 12 happened. 13 COFFEY, Q.C.: 14 Q. Now we've heard from Dr. Carter, who was a 15 colleague of yours at St. Clare's. 16 DR. ELMS: 17 A. Um-hm. 18 COFFEY, Q.C.: 19 Q. At this point in time, in 2005. And she's 20 told the Commissioner about investigation she 21 conducted in the summer of 2005 into this 22 matter. 23 DR. ELMS: 24 A. Um-hm. 25 COFFEY, Q.C.:</p>
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<p>1 I don't recall exactly, but I believe there 2 was a meeting in which we were informed. 3 COFFEY, Q.C.: 4 Q. Doctor, did you become aware that the 5 retesting was going on at Mount Sinai? 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. How about any outside consultants or experts 10 coming in, did you become aware of that? 11 DR. ELMS: 12 A. I knew that Dr. Banerjee was coming to review 13 the lab. 14 COFFEY, Q.C.: 15 Q. And how about, well as it turns out, it's 16 Trish Wegrynowski. 17 DR. ELMS: 18 A. Trish Wegrynowski as well, yes. 19 COFFEY, Q.C.: 20 Q. You became aware that both of them were - 21 DR. ELMS: 22 A. Both of them were coming, yes. 23 COFFEY, Q.C.: 24 Q. Had you known Dr. Banerjee before? 25 DR. ELMS:</p>	<p>1 Q. Were you aware that she was doing that? 2 DR. ELMS: 3 A. No. 4 COFFEY, Q.C.: 5 Q. So if you weren't aware she was doing it, I 6 take it you weren't aware that she 7 discontinued doing it? 8 DR. ELMS: 9 A. No, I wasn't. 10 COFFEY, Q.C.: 11 Q. Doctor, when did you first become aware that 12 Dr. Carter had in fact begun to undertake 13 investigation? 14 DR. ELMS: 15 A. Sometime during the course of that or just 16 after her finishing it, but it was a very 17 informal understanding. I was peripheral to 18 the whole process. I wasn't involved in 19 looking into the lab and that nature. So what 20 I found out, I would have found out from 21 discussions, informal talks in the corridor. 22 COFFEY, Q.C.: 23 Q. Now were you aware that Dr. Banerjee, were you 24 aware when he was in St. John's? 25 DR. ELMS:</p>

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<p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Did you have any interaction with him</p> <p>4 yourself?</p> <p>5 DR. ELMS:</p> <p>6 A. I don't recall speaking to him.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. How about Ms. Wegrynowski?</p> <p>9 DR. ELMS:</p> <p>10 A. No, I didn't speak with her.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. The results of their investigations, when did</p> <p>13 you first become aware of those?</p> <p>14 DR. ELMS:</p> <p>15 A. When they were received, I was aware that they</p> <p>16 had received a document.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. You were aware. When did you first become</p> <p>19 aware of the contents?</p> <p>20 DR. ELMS:</p> <p>21 A. Subsequent to my taking up my position as</p> <p>22 medical director.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Okay, which would be in 2006?</p> <p>25 DR. ELMS:</p>	<p>1 form, page 1, it's for SS1044-03, it's</p> <p>2 February 17th, 2003. It's for yourself, Dr.</p> <p>3 Elms. 1-E is the block. ER/PR there. And</p> <p>4 completed, February 21, '03 by Ms. Welsh. On</p> <p>5 the second page you'll see that that's the</p> <p>6 surgical number?</p> <p>7 DR. ELMS:</p> <p>8 A. Um-hm.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. '03, SS1044. And go to the next page,</p> <p>11 actually, the fourth in the exhibit. Addendum</p> <p>12 No. 1 is you, on appears to be March 4th, '03</p> <p>13 reporting in Addendum 1, immunohistochemical</p> <p>14 staining for estrogen and progesterone</p> <p>15 receptors is negative?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And then if we look at the page before, which</p> <p>20 is Addendum No. 2, it's March 26, 2003 it's</p> <p>21 entered. And it says, you've written, "I have</p> <p>22 received a request from Dr. Kara Laing to</p> <p>23 review this case to clarify lymph node status</p> <p>24 and ER/PR status." And you go on to speak</p> <p>25 about your reexamination. But on the top of</p>
<p>Page 162</p> <p>1 A. Which would have been in 2006.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. So before that -</p> <p>4 DR. ELMS:</p> <p>5 A. So it was sometime after May of 2006.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. So in the intervening time period, you weren't</p> <p>8 aware of -</p> <p>9 DR. ELMS:</p> <p>10 A. No.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. - weren't told what Dr. Banerjee had found or</p> <p>13 Ms. Wegrynowski had found?</p> <p>14 DR. ELMS:</p> <p>15 A. No.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Just one moment, please, Commissioner.</p> <p>18 Doctor, there were a couple--before I go on</p> <p>19 then to your time as assistant director and</p> <p>20 then director of IHC, there are a couple of</p> <p>21 matters that I do wish to look at. If we</p> <p>22 could look at, please, Exhibit--and this is</p> <p>23 going back to 2003, C-0226 please?</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. ... Doctor, this is a immunoperoxidase request</p>	<p>Page 164</p> <p>1 the fourth page of the exhibit, said, "Further</p> <p>2 estrogen and progesterone receptors have been</p> <p>3 reviewed in both cases." And including</p> <p>4 SS1044-03. And you note in the earlier case,</p> <p>5 SS1103 ER/PR are both weakly positive and the</p> <p>6 later case, 1044-03, ER and PR are both</p> <p>7 negative. "It's worth noting that the areas</p> <p>8 of DCIS in 1044-03 are positive for estrogen</p> <p>9 receptors. Overall, given that the metastatic</p> <p>10 lesion is weakly ER/PR positive, this</p> <p>11 interpreted as the tumour having ER/PR</p> <p>12 receptor positivity. Discrepancy on the later</p> <p>13 case is possibly on the basis of weak presence</p> <p>14 of estrogen and progesterone receptors overall</p> <p>15 in the tumour with the possible existence of</p> <p>16 hormone receptor negative clone within the</p> <p>17 slide tested in the latter case." Doctor, I</p> <p>18 take it this is one of those cases where</p> <p>19 you're requested by an oncologist to review</p> <p>20 the ER/PR status?</p> <p>21 DR. ELMS:</p> <p>22 A. Yes.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And this again is just before the suspension</p> <p>25 of--well, the April 4th memo -</p>

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<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. - of 2003 of Dr. Ejeckam? I appreciate here 5 you were finally reporting this as ER/PR 6 receptor positivity? 7 DR. ELMS: 8 A. Um-hm. 9 COFFEY, Q.C.: 10 Q. I think is your final conclusion here. Do you 11 recall this case? 12 DR. ELMS: 13 A. Not specifically, but I have had occasion to 14 go over this report. 15 COFFEY, Q.C.: 16 Q. Okay. And do you recall why it was that Dr. 17 Laing requested you to review it? 18 DR. ELMS: 19 A. This case, this patient had originally had a 20 biopsy of an axillary lymph node which showed 21 a metastatic carcinoma and that had been 22 originally reported as weakly positive. Then 23 she proceeded to have a definitive procedure 24 done on that lesion in her breast, so it was 25 removed, and when that was stained for</p>	<p>1 that over the course of this time, evolution 2 being what it is, DNA damage will continue to 3 occur in the daughters so that you, over time, 4 in any tumour, can get a situation in which a 5 more aggressive or a less well differentiated 6 clone will occur and that clone may well then 7 go on to multiply and to dominate the tumour. 8 So it could be a case in this instance that 9 the tumour was originally ER positive but that 10 a more aggressive or a different, anyway, ER 11 negative clone arose and then dominated the 12 original tumour after it had already 13 metastasized to the lymph node. Within 14 tumours we will see that, as well. That's 15 part of the reason I think why you will see a 16 breast tumour that is not 100 percent, some of 17 those cells simply do not have the receptor 18 there of a different Clone. 19 THE COMMISSIONER: 20 Q. Dr. Elms, just to make sure I understood that, 21 so the explanation is that in the process of 22 the cells changing, one should not assume that 23 the--all of the cancer which results in the 24 end has precisely the same structure because 25 the mutating cells can mutate to something</p>
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<p>1 estrogen and progesterone receptors, that was 2 negative. So that prompted Dr. Laing to ask 3 for a review as to why these two pieces of 4 tissue from the patient should have a 5 different result. 6 COFFEY, Q.C.: 7 Q. In fact, probably from the same tumour, in 8 fact? 9 DR. ELMS: 10 A. From the same tumour, yes, one would assume, 11 yes. 12 COFFEY, Q.C.: 13 Q. Sure. And the explanation was what, in 14 layman's terms? 15 DR. ELMS: 16 A. In layman's terms, when a particular tissue 17 becomes malignant, there are several changes 18 that occur to the DNA, the governing material, 19 if you will, of that cell that allow it to be 20 malignant, so that the development of 21 malignancy isn't a single hit event. And when 22 a cell become malignant, all of its daughter 23 cells, so to speak, as it divides and then as 24 they divide will all have the same appearance 25 as the original cell. Now, you can appreciate</p>	<p>1 different? 2 DR. ELMS: 3 A. That's correct. 4 THE COMMISSIONER: 5 Q. Is that sum and substance of it? 6 DR. ELMS: 7 A. Yes. 8 THE COMMISSIONER: 9 Q. Okay. So you will get, within a massive 10 cancer, perhaps, conflicting results on a test 11 which is designed to look for a specific thing 12 like ER/PR because some of those cells, in 13 fact, will have it and some won't, some having 14 mutated, depending on which was first? 15 DR. ELMS: 16 A. Yes. 17 THE COMMISSIONER: 18 Q. Okay, thank you. 19 COFFEY, Q.C.: 20 Q. Did you discuss this case with anyone, do you 21 recall, other than perhaps Dr.--obviously you 22 communicated with Dr. Laing through Meditech, 23 certainly? 24 DR. ELMS: 25 A. Yes.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. But did you discuss it with any pathologists,</p> <p>3 do you know?</p> <p>4 DR. ELMS:</p> <p>5 A. Not that I recall.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And the fact that you were advised the next</p> <p>8 month, in April of 2003, that the ER/PR stains</p> <p>9 were thought to erratic and so on and so</p> <p>10 forth? You remember we looked at the memo?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Dr. Ejeckam's memo. You didn't connect the</p> <p>15 two, possibly?</p> <p>16 DR. ELMS:</p> <p>17 A. I didn't connect the two.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. I'm not saying they're necessarily connected</p> <p>20 at all, but -</p> <p>21 DR. ELMS:</p> <p>22 A. No, I didn't -</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. - but you didn't at the time?</p> <p>25 DR. ELMS:</p>	<p>1 say, you conclude that page by saying, "To</p> <p>2 that end, immunohistochemical staining will be</p> <p>3 performed and an addendum issued once these</p> <p>4 studies have been received."</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And this was under your original report?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. I take it, you can look back, the first copy?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Okay. And then we go to the fourth page of</p> <p>17 the exhibit, this case is originally signed</p> <p>18 out July 25th, '02. See that?</p> <p>19 DR. ELMS:</p> <p>20 A. Yes.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Signature on file. And then there are the</p> <p>23 various addendums. And this is one of the</p> <p>24 reasons I was asking you about the addendums</p> <p>25 is here they're at the end, you'll see?</p>
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<p>1 A. No.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. If we could, please, Exhibit P-2173? Now,</p> <p>4 Doctor, we saw this--I apologize. Page 56.</p> <p>5 Doctor, we looked at this earlier today, this</p> <p>6 is this May 23rd, 2003 form, immunoperoxidase</p> <p>7 request form, one referring to repeat ER/PR</p> <p>8 requested by Dr. Zaidi. And if we could bring</p> <p>9 up, please, Exhibit C-0174? That surgical</p> <p>10 number on that form, Doctor, was SS5231-02.</p> <p>11 And if we look here at page 1 of C-0174,</p> <p>12 you'll see that this is the pathology report</p> <p>13 for that same surgical number?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes. This is--yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Yes, you can flip back if you like, but that's</p> <p>18 the one where you hand wrote, "Requested by</p> <p>19 Dr. Zaidi."</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Repeat. And here, this particular case, if we</p> <p>24 look through the third page at the comment at</p> <p>25 the bottom, you have a comment and then you</p>	<p>1 DR. ELMS:</p> <p>2 A. Yes.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. At least the way this one is printed out.</p> <p>5 Addendum No. 1 is July 31st, '02. And you</p> <p>6 refer to immunohistochemical staining for CK7.</p> <p>7 And then addendum No. 2, August 29th, 2002,</p> <p>8 "Immunohistochemical staining for progesterone</p> <p>9 receptors is positive in approximately 15</p> <p>10 percent of lesional cells. Immunochemical</p> <p>11 staining for estrogen receptors is negative."</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And it's signed out by yourself, August 29th,</p> <p>16 '02. And then addendum No. 3, which is</p> <p>17 entered June 11th, '03 and signed out by</p> <p>18 yourself the same day. It says, "At the</p> <p>19 request of Dr. Zaidi immunohistochemical</p> <p>20 staining for estrogen and progesterone</p> <p>21 receptors has been repeated. Estrogen</p> <p>22 receptors show faint positivity in</p> <p>23 approximately 10 to 15 percent of lesional</p> <p>24 cells. Progesterone receptors are</p> <p>25 unequivocally positive in approximately 75</p>

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<p>1 percent of lesional cells. So here when we 2 look at addendums 1--I'm sorry, 2 and 3, 3 estrogen is gone from negative to 10 to 15 4 percent and progesterone has gone from 15 to 5 75? See that?</p> <p>6 DR. ELMS: 7 A. Yes.</p> <p>8 COFFEY, Q.C.: 9 Q. Do you recall how it was or why it was that 10 Dr. Zaidi asked you to do the repeat?</p> <p>11 DR. ELMS: 12 A. No.</p> <p>13 COFFEY, Q.C.: 14 Q. Now, Doctor, we've heard, the Commissioner has 15 heard the word "conversion" used at times 16 here. I appreciate that that may not be a 17 precise term, perhaps more a term of art, but 18 would this be a conversion?</p> <p>19 DR. ELMS: 20 A. Yes, it would certainly be a case of if we're 21 defining conversion as a case that was 22 originally negative and is now testing 23 positive, then, yes.</p> <p>24 COFFEY, Q.C.: 25 Q. And I appreciate it goes from negative. And</p>	<p>1 might quibble about 15 to 20, 15 to 25?</p> <p>2 DR. ELMS: 3 A. Yes.</p> <p>4 COFFEY, Q.C.: 5 Q. But 15 to 75, this is a big shift?</p> <p>6 DR. ELMS: 7 A. Yes.</p> <p>8 COFFEY, Q.C.: 9 Q. And even from zero, negative or zero, to 10 to 10 15 -</p> <p>11 DR. ELMS: 12 A. Ten to fifteen.</p> <p>13 COFFEY, Q.C.: 14 Q. - that would be something that would stand 15 out, wouldn't it?</p> <p>16 DR. ELMS: 17 A. Yes.</p> <p>18 COFFEY, Q.C.: 19 Q. In your world?</p> <p>20 DR. ELMS: 21 A. Yes.</p> <p>22 COFFEY, Q.C.: 23 Q. Did you report this to anyone other than Dr. 24 Zaidi?</p> <p>25 DR. ELMS:</p>
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<p>1 in this context under addendum 2, negative 2 would be zero, I take it, at that point in 3 time?</p> <p>4 DR. ELMS: 5 A. Zero, yes.</p> <p>6 COFFEY, Q.C.: 7 Q. In August 29th, '02?</p> <p>8 DR. ELMS: 9 A. Yes.</p> <p>10 COFFEY, Q.C.: 11 Q. And would it have been zero, negative or less 12 than 10, negative?</p> <p>13 DR. ELMS: 14 A. I would say it would be zero, negative.</p> <p>15 COFFEY, Q.C.: 16 Q. Negative. And 15 percent, the PR, all the way 17 to 75?</p> <p>18 DR. ELMS: 19 A. Yes.</p> <p>20 COFFEY, Q.C.: 21 Q. And certainly that's a significant shift?</p> <p>22 DR. ELMS: 23 A. Yes.</p> <p>24 COFFEY, Q.C.: 25 Q. In your world it would be. 15, to 75, you</p>	<p>1 A. I'm not sure. I don't recall specifically.</p> <p>2 COFFEY, Q.C.: 3 Q. Do you recall, did you--so you don't recall-- 4 well, you would have spoke to Dr. Zaidi now, 5 obviously?</p> <p>6 DR. ELMS: 7 A. Um-hm.</p> <p>8 COFFEY, Q.C.: 9 Q. But how about other pathologists, including 10 Dr. Cook, for example?</p> <p>11 DR. ELMS: 12 A. I don't recall.</p> <p>13 COFFEY, Q.C.: 14 Q. Like in Ms. Deane's case where certainly you 15 spoke to the oncologist right away?</p> <p>16 DR. ELMS: 17 A. Yes.</p> <p>18 COFFEY, Q.C.: 19 Q. And then told Dr. Cook, in effect, right away?</p> <p>20 DR. ELMS: 21 A. Yes.</p> <p>22 COFFEY, Q.C.: 23 Q. You don't recall in 2003 whether or not you 24 did or didn't?</p> <p>25 DR. ELMS:</p>

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<p>1 A. No.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. If you did at the time, who would you have</p> <p>4 spoken to?</p> <p>5 DR. ELMS:</p> <p>6 A. It would have been Dr. Cook.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And to the effect to tell him what, that you'd</p> <p>9 had a -</p> <p>10 DR. ELMS:</p> <p>11 A. That I had a case like this that originally</p> <p>12 had been tested negative and was now testing</p> <p>13 positive.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Was there an incident report filed on this</p> <p>16 adverse event?</p> <p>17 DR. ELMS:</p> <p>18 A. Not that I recall.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And, Doctor, this was at a time you're</p> <p>21 reporting your June 11th, 2003, see that?</p> <p>22 DR. ELMS:</p> <p>23 A. Um-hm.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. "Entered and reported". And you had been</p>	<p>1 four-page exhibit. The immunoperoxidase</p> <p>2 request form is February 10th, 2003, it's for</p> <p>3 Dr. Vaze. And it's completed, indicated to be</p> <p>4 completed February 14, 2003 by Ken Green. If</p> <p>5 we look at the next page, I apologize, go back</p> <p>6 one. That is for surgical pathology No.</p> <p>7 SS960-03, block 1-G. Go to the second page of</p> <p>8 the exhibit is the pathology report. Again,</p> <p>9 that's the surgical pathology No. is 03-SS960.</p> <p>10 And when one goes to the fourth page of the</p> <p>11 exhibit under addendum No. 1, it's dated March</p> <p>12 17th, '03, addendum 1 entered the same day and</p> <p>13 signed off the same day. Estrogen and</p> <p>14 progesterone, immunoperoxidase method, "ER</p> <p>15 occasional positive cells less than one</p> <p>16 percent. PR 15 percent positivity. No</p> <p>17 controls available." And then addendum No. 2,</p> <p>18 entered May 28th, 2003 and signed off the same</p> <p>19 day by Dr. Vaze. "As requested," she writes,</p> <p>20 "As requested, repeat," and that's underlined</p> <p>21 "estrogen and progesterone receptors by</p> <p>22 immunoperoxidase staining. Estrogen receptors</p> <p>23 40 percent positivity. Progesterone</p> <p>24 receptors, 73 percent positivity. Controls</p> <p>25 positive." Doctor, were you made aware that--</p>
<p>Page 178</p> <p>1 requested back on May 23rd--well, that's the</p> <p>2 date of the request form, you've dated it--</p> <p>3 Exhibit P-2173, page 56. You had just gotten</p> <p>4 Dr. Ejeckam's memo in April suspending the</p> <p>5 testing and May restarting it?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And now had a case here where there had been a</p> <p>10 retest at the end of May and early June which</p> <p>11 had converted. It didn't occur to you, well,</p> <p>12 maybe I should go back in a more general way?</p> <p>13 DR. ELMS:</p> <p>14 A. Not in a more general way, no.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. If we could, one other exhibit, C-0228,</p> <p>17 please? Dr. Vaze worked where?</p> <p>18 DR. ELMS:</p> <p>19 A. Dr. Vaze.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Vaze, I'm sorry.</p> <p>22 DR. ELMS:</p> <p>23 A. She worked at St. Clare's, as well.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Worked at St. Clare's. As well, this is a</p>	<p>Page 180</p> <p>1 of this case where Dr. Vaze apparently had a</p> <p>2 conversion, as well, around the same time?</p> <p>3 DR. ELMS:</p> <p>4 A. No.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. In the context of within St. Clare's itself?</p> <p>7 DR. ELMS:</p> <p>8 A. No, I didn't, I didn't know about this case.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Doctor, if we could look, please, at Exhibit</p> <p>11 P-2076? This is a letter of April 24, 2006</p> <p>12 addressed to yourself at St. Clare's, it's</p> <p>13 from Dr. Nash Denic, copied to a number of</p> <p>14 individuals, five of whom are physicians. And</p> <p>15 Dr. Denic, it's "Re appointment of assistant</p> <p>16 director of immunohistochemistry department,</p> <p>17 St. John's hospitals, Eastern Health." Dr.</p> <p>18 Denic writes, "As per our discussion it gives</p> <p>19 me great pleasure to appoint you as Assistant</p> <p>20 Director of Immunohistochemistry Department,</p> <p>21 Laboratory Medicine, St. John's hospitals,</p> <p>22 Eastern Health. Your appointment has been</p> <p>23 endorsed by the laboratory medicine leadership</p> <p>24 team. Along with Dr. Dan Fontaine, Director</p> <p>25 of Immunohistochemistry Department you will</p>

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<p>1 take on an assumed responsibility for the 2 services provided with a goal of achieving 3 excellence in the field of 4 immunohistochemistry. Sincerely yours." I 5 take it that this is the beginning of your 6 appointment or involvement with 7 immunohistochemistry you referred to earlier? 8 DR. ELMS: 9 A. Yes. 10 COFFEY, Q.C.: 11 Q. Doctor. Doctor, do you recall how it was that 12 you came to be approached about this? 13 DR. ELMS: 14 A. Dr. Denic asked me. 15 COFFEY, Q.C.: 16 Q. Okay. And do you recall the context in which 17 that happened? 18 DR. ELMS: 19 A. I'm not sure that I was aware that it was one 20 of the recommendations from Dr. Banerjee, but 21 I do know that Dr. Denic felt that it was 22 necessary to have a medical director of 23 immunohistochemistry. 24 COFFEY, Q.C.: 25 Q. And initially that appointment letter here on</p>	<p>1 assistant director? 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. One at the General Hospital, one at St. 6 Clare's? 7 DR. ELMS: 8 A. Yes. 9 COFFEY, Q.C.: 10 Q. And there'd be administrative duties, 11 functions, necessarily? 12 DR. ELMS: 13 A. Yes. 14 COFFEY, Q.C.: 15 Q. But as well, technical and you were signing on 16 for the technical? 17 DR. ELMS: 18 A. For the most part, yes. 19 COFFEY, Q.C.: 20 Q. That summarizes it, I take it? 21 DR. ELMS: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. Doctor, had you had any training before this 25 in this particular area?</p>
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<p>1 the screen Dan Fontaine, Dr. Fontaine is going 2 to be the director and you're going to be the 3 assistant director, at least initially? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. What was the purpose of having a director and 8 assistant director? 9 DR. ELMS: 10 A. We were based at two different sites. 11 Immunohistochemistry is at Health Sciences and 12 I'm based at St. Clare's. I felt, personally, 13 that it would be advisable to have someone at 14 Health Sciences who could handles sort of day- 15 to-day issues in the running of the lab and I 16 felt it feasible, as well, to have two of us, 17 one handling the more technical issues and the 18 other handling the more administrative type of 19 issues. And I felt far more comfortable 20 handling the technological side. 21 COFFEY, Q.C.: 22 Q. And so from the outset in terms of your 23 involvement, Dr. Denic approached you about 24 it, you thought about it and said yes, you 25 understood there would be a director and an</p>	<p>1 DR. ELMS: 2 A. Other than what we've discussed earlier, no. 3 COFFEY, Q.C.: 4 Q. Okay. And what did you understand or were you 5 given to understand would happen if you took 6 this on? 7 DR. ELMS: 8 A. That I would be expected to build expertise. 9 I was quite clear that I needed some start-up 10 time to be able to familiarize myself with the 11 technology and a part of that was a two-week 12 preceptorship at PhenoPath Laboratories in 13 Seattle. 14 COFFEY, Q.C.: 15 Q. Now, Doctor, if we could, Exhibit P-0277, 16 please? Now, Doctor, this is, well, this 17 particular document is entitled 18 "Recommendations, Immunohistochemistry Service 19 spreadsheet, Dr. D. Banerjee, Trish 20 Wegrynowski." Updated April 25, '06. 21 Compiled December 16th, '05. And it's 22 updated, as indicated, April 25th, which just 23 happens to be the day after the letter is sent 24 to you. 25 DR. ELMS:</p>

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1 A. Yes.

2 COFFEY, Q.C.:

3 Q. Notifying you you're the assistant director.

4 Doctor, when you look at this, there are 30

5 recommendations. See that, spreadsheet, in

6 fact, 18 on the first, then we go on--on the

7 first page and then--I apologize. Yes, 30,

8 numbers up to 30, including the first two

9 pages. If you look at the next page of the

10 exhibit, page 3, you'll notice it's the same

11 heading except it's updated June 30th, '06?

12 DR. ELMS:

13 A. Yes.

14 COFFEY, Q.C.:

15 Q. The reference to December is gone, the top

16 right-hand side. And now page 4, continues on

17 into page 5, we're up to 52 recommendations?

18 DR. ELMS:

19 A. Yes.

20 COFFEY, Q.C.:

21 Q. Doctor, I'm going to ask you, at the time that

22 you agreed to take this on had you even see

23 the lists of these recommendations?

24 DR. ELMS:

25 A. No.

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1 COFFEY, Q.C.:

2 Q. That's the first sheet?

3 DR. ELMS:

4 A. Either sheet.

5 COFFEY, Q.C.:

6 Q. Either sheet?

7 DR. ELMS:

8 A. Um-hm.

9 COFFEY, Q.C.:

10 Q. And you had not seen Dr. Banerjee's report or

11 reports?

12 DR. ELMS:

13 A. No.

14 COFFEY, Q.C.:

15 Q. And you had not seen Trish Wegrynowski's

16 report or reports at that point?

17 DR. ELMS:

18 A. No.

19 COFFEY, Q.C.:

20 Q. Doctor, were you given to understand before

21 you agreed to take this on, given any

22 understanding about what the status of IHC

23 was?

24 DR. ELMS:

25 A. Other than the kind of general information

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1 we've already discussed, no. I knew we'd been

2 reviewed, but that was the extent of it.

3 COFFEY, Q.C.:

4 Q. When did you then first received a list of

5 recommendations?

6 DR. ELMS:

7 A. It was shortly thereafter. It would, I guess,

8 have been in June because I remember the 52

9 recommendations.

10 COFFEY, Q.C.:

11 Q. By the time, certainly by the--your

12 recollection is, look, when I really got

13 myself immersed in this, you're saying, Mr.

14 Coffey, by that point it was up to 52?

15 DR. ELMS:

16 A. By that point it was up to 52.

17 COFFEY, Q.C.:

18 Q. Yeah. And if we could look, please, at

19 Exhibit P-1754? Doctor, these are handwritten

20 notes dated June 30th, 2006. And that just

21 happens to be the--that's the same date as

22 that list of recommendations, 52 we just saw,

23 updated June 30th, '06?

24 DR. ELMS:

25 A. Yeah.

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1 COFFEY, Q.C.:

2 Q. And this is indicated to be a Friday. Present

3 are a number of individuals, Drs. Cooks,

4 Morris-Larkin, Denic, yourself, Markarla,

5 Carter, Williams and other individuals, non-

6 physicians. And it's re reimplementation of

7 ER/PR testing. And then there's some remarks

8 attributed to Nash Denic and to yourself and

9 so on and to Dr. Williams, Dr. Markarla. So,

10 Doctor, do you recall attending this meeting,

11 the June 30th?

12 DR. ELMS:

13 A. It doesn't come to my mind. I mean -

14 COFFEY, Q.C.:

15 Q. Okay, I'll look at some, I'll take you to some

16 of the notes and maybe that might help refresh

17 your memory. It indicates that, or attributes

18 to "Dr. Nash Denic gave overview of

19 immunohistochemistry. Dr. Gown, Dr. Banerjee,

20 Trish Wegrynowski. Most of recommendations

21 have been handled." It goes on from there,

22 and then to yourself it attributes--actually,

23 yes, the second remark to--or third remark

24 under Dr. Denic, "Consultants middle of pack

25 in North American practice."

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<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. Listed here. And do you remember being told 5 that? 6 DR. ELMS: 7 A. I remember it being said. I don't remember 8 exactly when. 9 COFFEY, Q.C.: 10 Q. And then attributed to yourself is the remark 11 or remarks, "Can't afford to be average. Must 12 have comparable." And it says "Pre-analytic 13 fixation, can't have specimen in formalin more 14 than 24 hours." Something "situation". 15 UNKNOWN SPEAKER: 16 Q. "Block selection." 17 DR. ELMS: 18 A. "Block selection." 19 COFFEY, Q.C.: 20 Q. "Block selection" thank you, is the second 21 thing, and then "Analytic, running out of test 22 itself, validity issue over reproducibility, 23 no global standardization" and then that is 24 continued on, "validity of antibody is issue." 25 See that there? I say continued, there's kind</p>	<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. As IHC director? 5 DR. ELMS: 6 A. Definitely. 7 COFFEY, Q.C.: 8 Q. Exhibit P-2303, please? Now, Doctor, before I 9 go into this, which is your trip to PhenoPath, 10 as the assistant director you were reporting 11 to whom? 12 DR. ELMS: 13 A. Dr. Denic. 14 COFFEY, Q.C.: 15 Q. The clinical chief? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. And then I take it as director when that 20 happened, it was the same thing? 21 DR. ELMS: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. When did you become the director? 25 DR. ELMS:</p>
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<p>1 of an arrow down here. 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. I appreciate these are not your notes. 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. And it says, "Post analytic interpretation, 10 three people will read the ER and PRs"? 11 DR. ELMS: 12 A. Yes. 13 COFFEY, Q.C.: 14 Q. And then it goes on to attribute other remarks 15 to Dr. Denic and Dr. Carter? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. Does that help you? 20 DR. ELMS: 21 A. Not really. I don't really recall the actual 22 meeting itself. 23 COFFEY, Q.C.: 24 Q. Would it be at a time early in your 25 involvement then in the -</p>	<p>1 A. It was at--there was another change in the 2 meantime. 3 COFFEY, Q.C.: 4 Q. Yes. 5 DR. ELMS: 6 A. Dr. Fontaine found that he was unable to 7 continue and Dr. Prakash Markarla was on staff 8 with us at the time and I approach Prakash to 9 see if he would fill into that role and he 10 agreed. 11 COFFEY, Q.C.: 12 Q. To the director's role? 13 DR. ELMS: 14 A. To the--yes. 15 COFFEY, Q.C.: 16 Q. On site at that - 17 DR. ELMS: 18 A. If you--we didn't see it as necessarily being 19 a subordination between the two of us. 20 COFFEY, Q.C.: 21 Q. Yes. I wanted to clarify that. Because it's 22 not--the usage of the word "director" and 23 "assistant director" here, those words - 24 DR. ELMS: 25 A. Yeah, I would say more co-director than</p>

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1 assistant director.
 2 COFFEY, Q.C.:
 3 Q. Okay.
 4 DR. ELMS:
 5 A. However, not too long after that, I'm not sure
 6 what the date of that particular letter is,
 7 but certainly by the end of 2006 Dr. Markarla
 8 has left, as well, which meant that I then
 9 became director.
 10 COFFEY, Q.C.:
 11 Q. And is there an assistant director?
 12 DR. ELMS:
 13 A. No.
 14 COFFEY, Q.C.:
 15 Q. So you not only had to take on the technical,
 16 but as well the administrative end of it?
 17 DR. ELMS:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Here, this is an e-mail from Harriet Childs to
 21 Dr. Denic, June 7th, 2006. The subject is
 22 PhenoPath visit. And after identifying
 23 herself as the preceptorship coordinator of
 24 PhenoPath Laboratories, she says you are--that
 25 would be Dr. Denic's e-mail to Dr. Gown

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1 regarding Dr. Ford Elms' visit to PhenoPath
 2 was forwarded to her for follow-up, "Based on
 3 our pathologists availability, we would
 4 recommend Dr. Elms visit for two weeks from
 5 October 23rd to November 3rd, 2006. If you
 6 are unavailable during this time period,
 7 please provide alternate dates in October."
 8 And it goes on to talk about how the expenses
 9 will be covered. Doctor, did you actually
 10 attend?
 11 DR. ELMS:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. And during the October 23rd to November 3rd?
 15 DR. ELMS:
 16 A. During that period, yes.
 17 COFFEY, Q.C.:
 18 Q. And what then was the purpose, your
 19 understanding of the purpose of you going
 20 there, what were you supposed to learn and
 21 what happened?
 22 DR. ELMS:
 23 A. To observe the running of an
 24 immunohistochemistry lab. I wanted to look at
 25 technical aspects, I also wanted to look at

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1 their means of interpretation, how they went
 2 about the process of interpreting their
 3 immunostains.
 4 COFFEY, Q.C.:
 5 Q. Doctor, why PhenoPath?
 6 DR. ELMS:
 7 A. We had had contact with Dr. Gown. Dr. Denic
 8 knew Dr. Gown and approached him and said "He
 9 will take you if you want to go."
 10 COFFEY, Q.C.:
 11 Q. Now, in that--in your world, world of
 12 pathology in North America, for example, the
 13 idea of being exposed to immunohistochemistry
 14 laboratory and being trained, as it were, to
 15 become a director or assistant director, is
 16 there any formal way of doing that that you're
 17 aware of?
 18 DR. ELMS:
 19 A. There are some very, very few post-graduate
 20 positions. The majority of such as there are
 21 are generally within the context of lymphoma.
 22 So if you're going to sub-specialize in
 23 hematopathology, there are centres in which
 24 there'll be a fairly heavy wait to
 25 immunohistochemistry, but that then is to the

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1 immunohistochemistry of lymphoma. There are a
 2 vanishingly rare number of fellowship
 3 positions that I'm aware of that's
 4 specifically looking into
 5 immunohistochemistry.
 6 COFFEY, Q.C.:
 7 Q. And again, what sort of numbers would you be
 8 talking?
 9 DR. ELMS:
 10 A. Well, I briefly--I did a very sort of
 11 superficial on-line search awhile ago and I
 12 found one in North America.
 13 COFFEY, Q.C.:
 14 Q. Okay, and where was that?
 15 DR. ELMS:
 16 A. That was in PhenoPath. There was--there may
 17 be another one in Florida, but I can't speak
 18 to that for sure.
 19 COFFEY, Q.C.:
 20 Q. And you did this search when?
 21 DR. ELMS:
 22 A. Oh, several months ago.
 23 COFFEY, Q.C.:
 24 Q. And those one or two positions in North
 25 America, Doctor, are they post--what type of

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1 post-graduate work are they?
 2 DR. ELMS:
 3 A. They would be fellowship positions.
 4 COFFEY, Q.C.:
 5 Q. Fellowship positions.
 6 DR. ELMS:
 7 A. So they would be positions you would enter
 8 into after you'd finished a residency.
 9 COFFEY, Q.C.:
 10 Q. You'd be a pathologist?
 11 DR. ELMS:
 12 A. So you'd be a practising pathologist and then
 13 -
 14 COFFEY, Q.C.:
 15 Q. And kind of like becoming a breast
 16 pathologist, a fellowship -
 17 DR. ELMS:
 18 A. Exactly.
 19 COFFEY, Q.C.:
 20 Q. - you spend a year or so or a portion of a
 21 year doing a fellowship?
 22 DR. ELMS:
 23 A. Exactly.
 24 THE COMMISSIONER:
 25 Q. Mr. Coffey, it's near to the luncheon break so

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1 wherever you can find a convenient spot.
 2 COFFEY, Q.C.:
 3 Q. Doctor, can you tell us, please, then, what it
 4 was that you--you know, how it went out there,
 5 who were you exposed to and -
 6 DR. ELMS:
 7 A. It was very productive, very informative. I
 8 would go in in the mornings and review the
 9 day's controls with the technologists and
 10 discuss issues with the running of their
 11 machines. They use a DAKO semi-automated
 12 platform, which is different from ours, but
 13 the basic idea is still the same. And
 14 PhenoPath is a referral centre, so they don't
 15 handle wet specimens; they receive tissue from
 16 other centres. Sometimes they'll receive
 17 blocks to do immunostains on themselves. And
 18 in other instances they will just receive
 19 immunostains that have been sent from
 20 somewhere else. As the referring clinician
 21 sees fit they will also send the H and E
 22 slides and the pathologists at PhenoPath are
 23 then asked to give their opinion on these
 24 particular cases. And so the cases are
 25 allotted out just as they would be in a

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1 regular pathology lab and every day they have
 2 difficult case sign-out rounds and so the
 3 pathology staff that's there will meet and
 4 discuss cases. There's generally a senior
 5 technologist in attendance.
 6 COFFEY, Q.C.:
 7 Q. During those?
 8 DR. ELMS:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Rounds. Anything else that you recall and
 12 figure that you -
 13 DR. ELMS:
 14 A. That was--there was one day of they do an
 15 academic half day quarterly and I was
 16 fortunate enough to be there for one of them.
 17 COFFEY, Q.C.:
 18 Q. So the purpose then in you going there was to
 19 be exposed to a large-scale
 20 immunohistochemistry service?
 21 DR. ELMS:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. And how that would be run?
 25 DR. ELMS:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Were you given any materials, written
 4 materials in that regard?
 5 DR. ELMS:
 6 A. Written materials, I was given some brochures
 7 about the activities that PhenoPath is doing.
 8 They're also a research lab; they develop and
 9 validate antibodies, as well, plus they're
 10 doing a great deal of research into the
 11 applications of immunohistochemistry, so I was
 12 given access to most of their publications.
 13 COFFEY, Q.C.:
 14 Q. And how about written policies and procedures?
 15 DR. ELMS:
 16 A. No.
 17 COFFEY, Q.C.:
 18 Q. You didn't have access to them?
 19 DR. ELMS:
 20 A. No, at the time.
 21 COFFEY, Q.C.:
 22 Q. Have you since asked them for them?
 23 DR. ELMS:
 24 A. Asked them for theirs, no.
 25 COFFEY, Q.C.:

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<p>1 Q. So, Doctor, then I take then for two weeks, 2 which would be, I take it, two five-day 3 periods? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. Monday to Friday, perhaps eight hours a day? 8 DR. ELMS: 9 A. Yes. 10 COFFEY, Q.C.: 11 Q. Or so, you went as an observer? 12 DR. ELMS: 13 A. Yes. 14 COFFEY, Q.C.: 15 Q. In effect, to see how their lab was operated? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. Would you have taken notes or anything on that 20 at the time? 21 DR. ELMS: 22 A. On certain, certain issues, but not to any 23 great extent. 24 COFFEY, Q.C.: 25 Q. And in terms of the aspect of their lab, we've</p>	<p>1 A. Yes. 2 COFFEY, Q.C.: 3 Q. And the processing of the slides? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. And witnessed the interpretation of them? 8 DR. ELMS: 9 A. Yes. 10 COFFEY, Q.C.: 11 Q. Thank you, Commissioner. 12 THE COMMISSIONER: 13 Q. All right, then, we'll take a luncheon break 14 and meet again at 2:05. Thank you. 15 (LUNCH BREAK) 16 THE COMMISSIONER: 17 Q. Please be seated. Mr. Coffey. 18 COFFEY, Q.C.: 19 Q. Thank you, Commissioner. Good afternoon, 20 Doctor. Doctor, when you visited PhenoPath 21 Laboratories, first of all could--in the fall 22 of 2006, where is that located? 23 DR. ELMS: 24 A. That's in Seattle, Washington. 25 COFFEY, Q.C.:</p>
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<p>1 just seen notes there, pre-analytic and 2 analytic, post-analytic? 3 DR. ELMS: 4 A. Um-hm. 5 COFFEY, Q.C.: 6 Q. What aspect of their work really would you 7 have seen, would you have seen really very 8 much of the pre-analytic at all? 9 DR. ELMS: 10 A. Not of the pre-analytic. And as a matter of 11 fact, most of the pre-analytic would have been 12 done outside of their centre, anyway. 13 COFFEY, Q.C.: 14 Q. Outside. For the reasons you just referred 15 to? 16 DR. ELMS: 17 A. Yes. 18 COFFEY, Q.C.: 19 Q. Before it became--the specimens become blocks? 20 DR. ELMS: 21 A. Yes. 22 COFFEY, Q.C.: 23 Q. So it would be the production of slides, you 24 would have seen that? 25 DR. ELMS:</p>	<p>1 Q. And were you, in fact, at the time given any 2 particular training in respect of particular 3 antibodies? 4 DR. ELMS: 5 A. No. 6 COFFEY, Q.C.: 7 Q. Okay, so it was again a more general approach? 8 DR. ELMS: 9 A. It was a more general approach. 10 COFFEY, Q.C.: 11 Q. Exhibit P-2386, please? I take it then, 12 Doctor, by the time you'd come back from 13 Seattle in the fall of 2006 that you were the 14 director? 15 DR. ELMS: 16 A. Yes. 17 COFFEY, Q.C.: 18 Q. Yes, and--of IHC. Now, this, Doctor, is a 19 memo April 17th, 2006 sent by Dr. Ejeckam. 20 And he was still in St. John's in April of 21 2006. And it's to all pathologists, 22 oncologists, pathology residents and 23 immunohistochemistry technologists, Health 24 Sciences and St. Clare's sites. It's copied 25 to a number of individuals. And this would</p>

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1 have been a week before you were appointed
2 assistant director. But it says, "The Ventana
3 Medical System will sponsor a medical session
4 on breast panel markers and role of VIAS Image
5 Analysis and grading of breast panel markers.
6 Please see attached schedule. You are all
7 encouraged to attend and hopefully have all
8 your questions answered. Yours sincerely, Dr.
9 Gershon Ejeckam, Interim Director of
10 Immunohistochemistry Laboratory." Doctor,
11 what, if anything, do you recall about this
12 VIAS system?
13 DR. ELMS:
14 A. The VIAS system is an image analyzer in which
15 you scan in the slide that you wish to analyze
16 and then the computer system basically
17 analyzes it in itself, it also draws in
18 boundaries and gives you an idea of the
19 percentage of what's considered positive. You
20 have to select the areas you want the machine
21 to analyze.
22 COFFEY, Q.C.:
23 Q. And I take it that that can be time intensive
24 at times?
25 DR. ELMS:

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1 A. Yes, it could be.
2 COFFEY, Q.C.:
3 Q. Doctor, did you, at the time in 2006, gain any
4 experience utilizing the machine?
5 DR. ELMS:
6 A. Yes, there was a session where we were shown
7 how it was used and what it could do.
8 COFFEY, Q.C.:
9 Q. Did you actually then, as it were, experiment
10 with it?
11 DR. ELMS:
12 A. Yes.
13 COFFEY, Q.C.:
14 Q. What was your reaction to it?
15 DR. ELMS:
16 A. I thought it was a very interesting piece of
17 technology.
18 COFFEY, Q.C.:
19 Q. And to call it very interesting means what?
20 DR. ELMS:
21 A. Well, I'm interested in technological things,
22 I'm something of a tech nerd, as I think a lot
23 of us are in pathology. We were looking at
24 purchasing the machine at the time and as
25 medical director of immunohistochemistry, I

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1 mean, in late 2006, it became--it fell to me
2 to make the decision.
3 COFFEY, Q.C.:
4 Q. What decision was made and why?
5 DR. ELMS:
6 A. I decided at the time that we wouldn't
7 purchase the VIAS but that we would revisit it
8 at a later date.
9 COFFEY, Q.C.:
10 Q. Has it been revisited to date?
11 DR. ELMS:
12 A. Not yet.
13 COFFEY, Q.C.:
14 Q. And why was it deferred, as it were, at that
15 point, put off -
16 DR. ELMS:
17 A. I had been provided with the names of people
18 in the United States who were using it by
19 Ventana themselves and discussed it with them
20 and they each--they all felt that while it
21 gave them the ability to produce a more
22 complete report none of the people that I
23 talked to felt that they gained any increase
24 in detection of positivity over what would
25 have been done had they been a small group of

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1 people reading all of these results.
2 Furthermore, at that time it was only being
3 used for ER/PR and HER2/neu with an eye to
4 expanding it as this kind of testing for
5 purposes of treatment becomes available. So I
6 felt at the time there were more pressing
7 issues facing us in terms of addressing issues
8 within the lab and that it would perhaps be
9 best for us to deal with those issues first,
10 deal with the recommendations in the Banerjee
11 inquiry and then revisit the issue of the
12 VIAS.
13 COFFEY, Q.C.:
14 Q. And has it gotten any further than that?
15 DR. ELMS:
16 A. Not at this point, no.
17 COFFEY, Q.C.:
18 Q. Exhibit P-1754? Now, Doctor, these are these
19 notes of June 30th, 2006, what we looked at
20 earlier today. Midway down or just past the
21 midway point on the first page there's a note,
22 "Bev has written a fixation protocol to be
23 sent out to other centres."
24 DR. ELMS:
25 A. Yes.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. Do you have any knowledge as to when that</p> <p>3 happened, if it did happen, when it happened?</p> <p>4 DR. ELMS:</p> <p>5 A. No.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And in terms of the idea of distributing a</p> <p>8 fixation protocol to other centres?</p> <p>9 DR. ELMS:</p> <p>10 A. I knew it was being done and it was being sent</p> <p>11 to other boards on the island.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Who would be responsible within your</p> <p>14 organization for distributing it?</p> <p>15 DR. ELMS:</p> <p>16 A. Dr. Carter and Dr. Denic.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Exhibit P-0076, please? And, Doctor, these</p> <p>19 are just several things, documents I'm going</p> <p>20 to take you to now, the one I just looked at</p> <p>21 and this one because I want to get some,</p> <p>22 Commissioner to get some sense of what was</p> <p>23 happening when you, in practice, took over in</p> <p>24 a practical way as the director, what you were</p> <p>25 aware of up to that point. This is a memo, I</p>	<p>1 Q. How about generally, was it discussed, do you</p> <p>2 know?</p> <p>3 DR. ELMS:</p> <p>4 A. Generally, definitely, yes, it did. I mean,</p> <p>5 the points that I'm reading in it now are</p> <p>6 things that would have been, we would have</p> <p>7 been dealing with it around that time.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Now, Doctor, as a staff pathologist in the</p> <p>10 summer of 2005, you know, what was your</p> <p>11 reaction to this overall, this whole, by then</p> <p>12 there was a mass retesting, in effect, started</p> <p>13 or planned?</p> <p>14 DR. ELMS:</p> <p>15 A. That, well, I was upset that this was going on</p> <p>16 in our lab. I was upset for what it would</p> <p>17 mean for patient care, not only for those</p> <p>18 patients that were affected, but for what it</p> <p>19 would mean for general confidence in the</p> <p>20 system. At the time I don't believe that</p> <p>21 there was much public awareness but there was</p> <p>22 also the understanding that the public was</p> <p>23 going to have to be made aware and that</p> <p>24 disclosure was necessary. So those were my</p> <p>25 biggest concerns.</p>
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<p>1 should point out to you or show you, Doctor,</p> <p>2 that on the second page the space for Doctors</p> <p>3 Cook and Beverley Carter's signature, but we</p> <p>4 don't have a signed copy, if there is one.</p> <p>5 It's dated July 28th, 2005, it's to all</p> <p>6 pathologists and pathology residents in the</p> <p>7 Department of Pathology, St. John's hospitals,</p> <p>8 Eastern Health. It's from Doctors Cook and</p> <p>9 Carter. It's "Re optimal assessment and</p> <p>10 reporting of hormone receptor status in</p> <p>11 infiltrating carcinoma." And it begins by</p> <p>12 saying, "When ordering and reporting ER/PR</p> <p>13 status on infiltrating carcinoma of the</p> <p>14 breast," and it goes one, two, three, four,</p> <p>15 five, six, seven, eight through nine. And</p> <p>16 I'll just take you to the first couple.</p> <p>17 "Select a block that contains infiltrating</p> <p>18 carcinoma and normal and/or benign breast</p> <p>19 epithelium. (2) When reporting always check</p> <p>20 internal and external controls." And it goes</p> <p>21 on from there in a fairly detailed form. Do</p> <p>22 you recall seeing this in the summer of 2005?</p> <p>23 DR. ELMS:</p> <p>24 A. Not specifically, no.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Doctor, then as a staff pathologist, and I</p> <p>3 appreciate it was in April of 2006,</p> <p>4 effectively eight or nine--almost actually a</p> <p>5 year after you'd first spoken about Ms.</p> <p>6 Deane's case, that you became assistant</p> <p>7 director of IHC. But before you became</p> <p>8 assistant director how informed were you kept</p> <p>9 as to what was going on in terms of the</p> <p>10 investigation?</p> <p>11 DR. ELMS:</p> <p>12 A. I knew that it was going on, I knew that over</p> <p>13 the course of weeks to months after the</p> <p>14 initial case that the review had been extended</p> <p>15 on at least two occasions, if not more, to</p> <p>16 cover a certain amount of time. And I was</p> <p>17 perfectly aware that the lab was being</p> <p>18 reviewed, these types of things, and that</p> <p>19 there were meetings ongoing to discuss what</p> <p>20 the impact would be for individual patients</p> <p>21 and to review individual patient cases and</p> <p>22 then contact them.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. In terms of how about as a pathologist, as a</p> <p>25 member of the staff, were you in a periodic</p>

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1 way or any routine fashion, kept apprised of
 2 what was going on? In any systematic way?
 3 DR. ELMS:
 4 A. Not in any systematic way.
 5 COFFEY, Q.C.:
 6 Q. Looking back on that now, you know, if someone
 7 was to consult you about it, if someone else
 8 had a problem elsewhere and was to consult you
 9 about it, do you think that that sort of
 10 approach-- would you advocate that sort of
 11 approach or would you advocate the
 12 pathologists being kept apprised from time to
 13 time?
 14 DR. ELMS:
 15 A. Yes, I would. I would think that as a
 16 situation like this developed, that there
 17 should be a specific group of people who are
 18 dealing with the issue, and who would, as
 19 necessary, apprise the staff pathologist as to
 20 any impact it might have on their current
 21 practise. There would come a point in which I
 22 would think people should at least be made
 23 aware of how far it impacted their practise,
 24 how many of the cases were actually theirs,
 25 but to--I would think it would be more

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1 appropriate to have a smaller group of people
 2 who were dealing with these issues.
 3 COFFEY, Q.C.:
 4 Q. And actually to manage the issue.
 5 DR. ELMS:
 6 A. To manage the issue.
 7 COFFEY, Q.C.:
 8 Q. Dealing with it, but from time to time keep
 9 people apprised of it?
 10 DR. ELMS:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. As to what they found. Doctor, on that latter
 14 point, the one about being told what the
 15 impact was for your own patients, have you
 16 ever been told that?
 17 DR. ELMS:
 18 A. Yes, yes.
 19 COFFEY, Q.C.:
 20 Q. When did that occur?
 21 DR. ELMS:
 22 A. It was well into it because we needed to know
 23 how many were--I mean, the retesting had to be
 24 done before we could know how many of our
 25 cases were involved with this.

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1 COFFEY, Q.C.:
 2 Q. Oh, yes.
 3 DR. ELMS:
 4 A. So it was well into the process of retesting.
 5 COFFEY, Q.C.:
 6 Q. Do you recall when?
 7 DR. ELMS:
 8 A. No, not specifically.
 9 COFFEY, Q.C.:
 10 Q. At the time the inquiry was announced in May
 11 of 2007, had you--at that point, did you know
 12 how many of your patients were impacted?
 13 DR. ELMS:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. You had been told before that?
 17 DR. ELMS:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Were you told in your capacity or did you
 21 learn in your capacity as the Director of
 22 Immunohistochemistry, or as a pathologist
 23 generally?
 24 DR. ELMS:
 25 A. As a pathologist.

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1 COFFEY, Q.C.:
 2 Q. General staff pathologist.
 3 DR. ELMS:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. Do you recall who informed you and how you
 7 were informed?
 8 DR. ELMS:
 9 A. Dr. Denic.
 10 COFFEY, Q.C.:
 11 Q. Was it you individually or a group and you
 12 could ask him?
 13 DR. ELMS:
 14 A. It was me individually.
 15 COFFEY, Q.C.:
 16 Q. Did you approach him or him --
 17 DR. ELMS:
 18 A. It was in the context of a conversation we
 19 were having and we were talking about how
 20 extensive it was, and he said, well, you know,
 21 here are your numbers.
 22 COFFEY, Q.C.:
 23 Q. Okay. You did have some cases that did
 24 convert?
 25 DR. ELMS:

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<p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Doctor, I appreciate now, of course--I gather,</p> <p>4 as the Director, you've become much more aware</p> <p>5 of immunohistochemistry as a field?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Looking back on it, from your perspective, are</p> <p>10 you able to attribute any reason or reasons as</p> <p>11 to why there might have been conversions in</p> <p>12 individual cases that you were involved in?</p> <p>13 DR. ELMS:</p> <p>14 A. I have felt that individual errors at a given</p> <p>15 time, or individual conversions at a given</p> <p>16 time, could be based on a number of issues,</p> <p>17 and that it probably wasn't a single issue</p> <p>18 overriding.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. For example, examples such as what sorts of</p> <p>21 things?</p> <p>22 DR. ELMS:</p> <p>23 A. Such as fixation, for instance, and antigen</p> <p>24 retrieval. There may have been issues with</p> <p>25 temperatures, with ph's, and many of these</p>	<p>1 Q. And that would be from the technologist end, I</p> <p>2 take it, in terms of the processing of the</p> <p>3 slides?</p> <p>4 DR. ELMS:</p> <p>5 A. In terms of the processing, yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. So is that answer then to the effect that, no,</p> <p>8 you don't think it would be possible, in fact,</p> <p>9 now, in at least an overall manner to do so?</p> <p>10 DR. ELMS:</p> <p>11 A. I think it would be a very big job. It would</p> <p>12 require a review of all those cases, and I</p> <p>13 think in some instances we may not be able to</p> <p>14 tell.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. If, for example, it was an antigen retrieval</p> <p>17 problem or issue in a particular case?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. As opposed to a fixation issue, as opposed to</p> <p>22 both of them?</p> <p>23 DR. ELMS:</p> <p>24 A. Or a temperature issue, or a length of time</p> <p>25 with the antibody on the--on the tissue</p>
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<p>1 tests. ER isn't as susceptible as some, but</p> <p>2 many of these tests are quite sensitive to</p> <p>3 minor changes in their environment.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And for any one patient's circumstances, it's</p> <p>6 your view that there might be one or more of</p> <p>7 those factors came into play in that</p> <p>8 individual patient's case?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Doctor, have you given any thought to whether</p> <p>13 or not it's possible to actually ascertain at</p> <p>14 this point in time for any one case what</p> <p>15 factor or factors might have played a part?</p> <p>16 DR. ELMS:</p> <p>17 A. I'm not sure at this point that it might be</p> <p>18 specifically. We can know the actual quality</p> <p>19 of the slides themselves, but my</p> <p>20 understanding, not having gone back and</p> <p>21 looked, my understanding is that the</p> <p>22 documentation isn't necessarily always there</p> <p>23 as to the exact path of the material through</p> <p>24 the laboratory.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 itself.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Doctor, while Exhibit P-0076 is on the screen</p> <p>4 there in front of you, I appreciate this was -</p> <p>5 is dated, anyway, July 28th, 2005. Doctor,</p> <p>6 knowing what you do now, would a memo such as</p> <p>7 this have been of benefit to have had back in-</p> <p>8 -well, in fact, in your residency days?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Or anything if it developed over time,</p> <p>13 something -- one of these arose afterward.</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. It's certainly a detailed memo as to what to</p> <p>18 look out for.</p> <p>19 DR. ELMS:</p> <p>20 A. Yes.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. In your experience, Doctor, and your training</p> <p>23 in the late 90s, and then practising in the</p> <p>24 2000's here in St. John's, did you ever</p> <p>25 receive any sort of memo like this for any</p>

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1 other stain?
 2 DR. ELMS:
 3 A. Any other stain, no.
 4 COFFEY, Q.C.:
 5 Q. How about since then? I'm not suggesting you
 6 even did receive this one, but--like, this
 7 kind of detailed memo about a particular stain
 8 or stains?
 9 DR. ELMS:
 10 A. No, no, not that I recall.
 11 COFFEY, Q.C.:
 12 Q. Do you have any thoughts as to whether or not
 13 it might be of benefit to a pathologist?
 14 DR. ELMS:
 15 A. For the majority of our stains, probably not,
 16 because as I say, the majority of our stains
 17 are investigative and are used in the
 18 diagnostic process and are used as part of a
 19 panel. However, estrogen receptor was the
 20 first, HER2/neu was next, and now we're
 21 gradually getting more and more antibodies
 22 developed as single point tests used in the
 23 guiding of treatment, and that puts a very
 24 different impact on what it is you're doing
 25 with your antibodies. So in that instance,

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1 yes, that would certainly be of value.
 2 COFFEY, Q.C.:
 3 Q. Right now with the resources that you have
 4 available to you locally, are there sufficient
 5 resources to actually then produce such for
 6 those sorts of stains, those stains that fall
 7 into that category you just described? Do you
 8 have the resources available to you to have
 9 someone on the staff there produce such a
 10 memo?
 11 DR. ELMS:
 12 A. Such a memo?
 13 COFFEY, Q.C.:
 14 Q. Like, an instructive memo?
 15 DR. ELMS:
 16 A. Not really. Administrative support is not
 17 prominent, with the result that the production
 18 of such a memo would--it would require me to
 19 find someone, which is usually the case.
 20 COFFEY, Q.C.:
 21 Q. And, I take it as well, either you would have
 22 to prepare the memo yourself or deputize or
 23 could you haul some other pathologist into
 24 doing it?
 25 DR. ELMS:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Researching it and doing it?
 4 DR. ELMS:
 5 A. I could do that. I would end up typing it up
 6 myself.
 7 COFFEY, Q.C.:
 8 Q. But it is something that--I take it your time
 9 might be better spent doing other things than
 10 typing up a memo?
 11 DR. ELMS:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Exhibit P-2467, please. Doctor, as you're
 15 going to see now, this is an e-mail from
 16 Heather Predham to Pam Elliott and Patricia
 17 Pilgrim. The subject is ER/PR, the date is
 18 November 19th, 2006, and she begins by saying,
 19 "I met with Bev Carter, Ford Elms, Don Cook,
 20 Nash Denic, and Susan Bonnell, on Friday
 21 afternoon. We reviewed the presentation from
 22 Monday, and it's very good and comprehensive.
 23 As always, Bev's comments in the meeting were
 24 a bit alarmist in nature, but she is only
 25 speaking about ER testing at the

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1 presentation", and they go on here to talk
 2 about the summary document of the reviewer's
 3 recommendations and the lab's actions, and it
 4 hadn't been updated since June of 2006, that
 5 would be. Doctor, I take it that you were
 6 involved in this meeting and the preparation
 7 for these November 2006 presentations to the
 8 executive and to the medical staff?
 9 DR. ELMS:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. What was the nature of your involvement?
 13 DR. ELMS:
 14 A. I was there to explain the science behind
 15 immunohistochemistry, how the test was carried
 16 out.
 17 COFFEY, Q.C.:
 18 Q. And who had asked you to do that?
 19 DR. ELMS:
 20 A. I believe it was Dr. Denic.
 21 COFFEY, Q.C.:
 22 Q. I'm sorry, Doctor --
 23 DR. ELMS:
 24 A. Denic.
 25 COFFEY, Q.C.:

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1 Q. Denic. The idea--from your perspective--"Bev
 2 Carter's comments in the meeting, a bit
 3 alarmist". From your perspective, had you
 4 found Bev Carter to be alarmist, at least that
 5 you would conclude that she was alarmist?
 6 DR. ELMS:
 7 A. No.
 8 COFFEY, Q.C.:
 9 Q. Did anyone ever express to you that she was
 10 alarmist, that you recall?
 11 DR. ELMS:
 12 A. Not that I recall.
 13 COFFEY, Q.C.:
 14 Q. If we could look, please, at Exhibit P-1425.
 15 Doctor, this is, I believe, a PowerPoint
 16 presentation. It goes on for quite a number of
 17 pages, but the first of them is--the first
 18 slide is immunohistochemistry, Dr. Ford Elms,
 19 and then it goes on from there,
 20 immunohistochemistry microscopy requires
 21 cellular constituents be made visible, and it
 22 goes on from there. This, I take it, is your
 23 slide presentation?
 24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Or at least a portion of it, and the purpose
 3 of this slide presentation was what?
 4 DR. ELMS:
 5 A. It was to inform the clinicians--this was just
 6 before the announcement was made that there
 7 had been the problem in our lab, and the
 8 purpose of this was to inform the clinicians -
 9 well, to give them a background as to the
 10 technology, to inform them what had gone on,
 11 what measures had been taken up until that
 12 point, and to update their knowledge or
 13 refresh their knowledge on the issues of ER/PR
 14 testing.
 15 COFFEY, Q.C.:
 16 Q. And then from your perspective, this was
 17 geared to what, what sort of an audience?
 18 DR. ELMS:
 19 A. It was geared to the clinicians, the surgeons,
 20 and the oncologists who had been dealing with
 21 breast cancer patients.
 22 COFFEY, Q.C.:
 23 Q. Did you participate in the presentation?
 24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Did you make a presentation to anyone else?
 3 DR. ELMS:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. How about the executive?
 7 DR. ELMS:
 8 A. No, there was a meeting the following day, but
 9 I didn't attend that meeting.
 10 COFFEY, Q.C.:
 11 Q. Do you know if your part of the presentation
 12 was given to the administration?
 13 DR. ELMS:
 14 A. I don't know.
 15 COFFEY, Q.C.:
 16 Q. Doctor, I'm here leafing through it, and we're
 17 at page 28 of the exhibit. It says, "In
 18 summary", and then it goes on. Page 29 of the
 19 exhibit is "Pitfalls in ER testing" by Dr. Bev
 20 Carter.
 21 DR. ELMS:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. Doctor, the information, for example,
 25 contained here in pages one through 28 of this

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1 exhibit --
 2 DR. ELMS:
 3 A. Uh-hm.
 4 COFFEY, Q.C.:
 5 Q. Prior to becoming assistant director, had you
 6 been aware of that, those sorts of things?
 7 DR. ELMS:
 8 A. Somewhat more generally, more superficially
 9 than that.
 10 COFFEY, Q.C.:
 11 Q. Okay. So I'll ask you then in terms of--when
 12 had you emersed yourself or began to really
 13 immerse yourself in this, and what process did
 14 you use?
 15 DR. ELMS:
 16 A. It was in May of 2006. When I was asked to
 17 take over the running of the lab, as I said,
 18 my first task was to educate myself to get
 19 myself up and running. I read textbooks and
 20 and reviewed the literature, and then went
 21 into phenopath.
 22 COFFEY, Q.C.:
 23 Q. When you read textbooks, they would be
 24 textbooks on what?
 25 DR. ELMS:

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<p>1 A. On immunohistochemistry, as a sub-area of 2 pathology. 3 COFFEY, Q.C.: 4 Q. Do you recall any particular text you read? 5 DR. ELMS: 6 A. Dabbs was the most prominent one. 7 COFFEY, Q.C.: 8 Q. That would be David Dabbs? 9 DR. ELMS: 10 A. David Dabbs. 11 COFFEY, Q.C.: 12 Q. And his textbook deals with 13 immunohistochemistry generally, not just 14 breast? 15 DR. ELMS: 16 A. Yeah, yes, that's correct. 17 COFFEY, Q.C.: 18 Q. All the different aspects of IHC? 19 DR. ELMS: 20 A. Yes. 21 COFFEY, Q.C.: 22 Q. At least there are quite a number of them 23 spelled out in the text. 24 DR. ELMS: 25 A. Yes.</p>	<p>1 A. June of this year, I believe. 2 COFFEY, Q.C.: 3 Q. So June of 2008? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. The media, you just alluded to the fact that 8 in -- just before this went public, which 9 would have been the December 11, 2006, media, 10 technical media briefing, you weren't involved 11 in that, I take it? 12 DR. ELMS: 13 A. No. 14 COFFEY, Q.C.: 15 Q. If we could look, please, at Exhibit P-1602. 16 I apologize, P-2108. Doctor, these are the 17 Minutes of an Executive Management meeting 18 held November 21st, 2006, in Conference Room C 19 of the corporate office in St. John's. 20 Present are a number of the executive, they're 21 spelled out there. Guests for the ER/PR 22 presentation, you're listed fifth down. 23 DR. ELMS: 24 A. Uh-hm. 25 COFFEY, Q.C.:</p>
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<p>1 COFFEY, Q.C.: 2 Q. Doctor, when you gave your presentation in 3 November of 2006 to your colleagues, do you 4 recall being questioned or asked questions? 5 DR. ELMS: 6 A. I may have been asked a couple, but I think 7 most of the questions were directed at Dr. 8 Carter, Dr. Denic, and Dr. Cook. 9 COFFEY, Q.C.: 10 Q. Have you ever--have you provided any other 11 presentations other than that one? 12 DR. ELMS: 13 A. You mean, in general? 14 COFFEY, Q.C.: 15 Q. Yes. 16 DR. ELMS: 17 A. I provided a presentation to the media that 18 was associated with this inquiry at their 19 request just to--again, it was a very similar 20 presentation, to inform them of the nature of 21 the test and what the technology was they were 22 hearing. 23 COFFEY, Q.C.: 24 Q. Do you recall when that was? 25 DR. ELMS:</p>	<p>1 Q. As being from Laboratory Medicine, and then 2 the actual presentations themselves are 3 indicated to be presentation ER/PR, Dr. 4 Denic's presentation, and Dr. Kara Laing's 5 presentation is referred to below that. 6 DR. ELMS: 7 A. Uh-hm. 8 COFFEY, Q.C.: 9 Q. So I take it that you did not actually give a 10 presentation? 11 DR. ELMS: 12 A. No, I don't recall this. Is this on the day 13 after the previous presentation? 14 COFFEY, Q.C.: 15 Q. Yes. 16 DR. ELMS: 17 A. No, I wasn't -- 18 COFFEY, Q.C.: 19 Q. Day after or day before, depending on--day 20 after. 21 DR. ELMS: 22 A. Day after. No, I didn't -- 23 COFFEY, Q.C.: 24 Q. You certainly don't recall. 25 DR. ELMS:</p>

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<p>1 A. No.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. If you were there, you don't have any</p> <p>4 recollection of it at all.</p> <p>5 DR. ELMS:</p> <p>6 A. No.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Doctor, by this point in time, anyway, by the</p> <p>9 time you briefed your colleagues in November,</p> <p>10 2006, clinicians, did you have any</p> <p>11 understanding by that point as to what the</p> <p>12 cause or causes of the problem had been?</p> <p>13 DR. ELMS:</p> <p>14 A. I knew that there had been identified issues</p> <p>15 of fixation, but other than that, I wasn't</p> <p>16 aware of -- I'm trying to remember when it was</p> <p>17 I got the recommendations from the Banerjee</p> <p>18 inquiry. I knew what was on those</p> <p>19 recommendations.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. But other than the recommendations, how about</p> <p>22 the reports themselves?</p> <p>23 DR. ELMS:</p> <p>24 A. I had been shown portions of the reports.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 background, incident problem case, review of</p> <p>2 cases, literature review of Dako vs. Ventana</p> <p>3 immunostainer performance, literature review</p> <p>4 about the effects of formalin fixation on ER</p> <p>5 immunostaining, choice of antibody,</p> <p>6 interlaboratory variability, conclusions about</p> <p>7 the reason for test failure, and then other</p> <p>8 system flaws observed, and recommendations. Do</p> <p>9 you recall what portions of this you were</p> <p>10 shown?</p> <p>11 DR. ELMS:</p> <p>12 A. If you'll go back up --</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Sure.</p> <p>15 DR. ELMS:</p> <p>16 A. The issue of choice of antibody was one. If</p> <p>17 we can come back down.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Sure, choice of antibody which is there on</p> <p>20 page four, yes.</p> <p>21 DR. ELMS:</p> <p>22 A. Choice of antibody, and the issue of fixation,</p> <p>23 and I believe we went through the conclusions</p> <p>24 about reasons for test failure and other</p> <p>25 reasons.</p>
<p>Page 234</p> <p>1 Q. Do you recall when that was and by whom?</p> <p>2 DR. ELMS:</p> <p>3 A. It was by Dr. Denic and it was sometime over</p> <p>4 the course of that fall.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. The fall of 2006?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Before the actual presentation to your</p> <p>11 colleagues?</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. The slide show?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. P-0046, please. Doctor, this is the cover</p> <p>20 letter of October 17, 2005, for Dr. Banerjee's</p> <p>21 first report.</p> <p>22 DR. ELMS:</p> <p>23 A. Uh-hm.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. October 17th, 2005, and then the headings are</p>	<p>Page 236</p> <p>1 COFFEY, Q.C.:</p> <p>2 Q. It would be the choice of antibody, SP1 vs.</p> <p>3 ID5, and conclusions about the reasons for</p> <p>4 test failure, and it's numbered 1 to 4, and</p> <p>5 then 6 and 7.</p> <p>6 DR. ELMS:</p> <p>7 A. Uh-hm.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And other system flaws observed, 1 through 7.</p> <p>10 DR. ELMS:</p> <p>11 A. Yes, and they were--I considered those to be a</p> <p>12 part of the recommendations, the spreadsheet</p> <p>13 that I had.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Sure. So, Doctor, when you became aware and</p> <p>16 were exposed to these in the fall of 2006,</p> <p>17 those portions of Dr. Banerjee's report, I</p> <p>18 take it your conclusion was that it certainly</p> <p>19 wasn't the Dako System or the Ventana System</p> <p>20 per se?</p> <p>21 DR. ELMS:</p> <p>22 A. Certainly.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And you had no reason to believe, as you</p> <p>25 pointed out earlier today, that it was ever</p>

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<p>1 that yourself?</p> <p>2 DR. ELMS:</p> <p>3 A. No, no.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And this would just confirm for you it wasn't?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. In fact, the laboratory you visited in</p> <p>10 Seattle, Dr. Gown's used the Dako autostainer?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. The problems with tissue fixation, he refers</p> <p>15 here to inadequate attention being paid by</p> <p>16 grossing pathologists to the thickness of</p> <p>17 tissue slices?</p> <p>18 DR. ELMS:</p> <p>19 A. Uh-hm.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Quality and adequacy of fixation, and there's</p> <p>22 no standardized fixation protocol. Doctor, the</p> <p>23 idea of thickness of tissue slices, and</p> <p>24 quality and adequacy of fixation, when you</p> <p>25 first saw this report, was that the first time</p>	<p>1 point when you were first shown portions of</p> <p>2 this report by Dr. Denic, it would have been</p> <p>3 in the context of someone making a comment</p> <p>4 generally?</p> <p>5 DR. ELMS:</p> <p>6 A. Yes.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. As opposed to in a more formal way.</p> <p>9 DR. ELMS:</p> <p>10 A. And there were very few comments made. I</p> <p>11 don't recall informal comments being made on</p> <p>12 what was in the document.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And inadequate or no attention is being paid</p> <p>15 by the reporting pathologist to the status of</p> <p>16 internal controls, inappropriately exclusive</p> <p>17 reliance on external positive controls. Now,</p> <p>18 Doctor, from your perspective again looking</p> <p>19 back on your own practise, had that been a--</p> <p>20 had you fallen into that category?</p> <p>21 DR. ELMS:</p> <p>22 A. In the period of the review, yes.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And Doctor, we did look at that handwritten</p> <p>25 note that we saw there earlier today. I'll</p>
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<p>1 that you became aware that the thickness, for</p> <p>2 example, of the tissue slices was a concern?</p> <p>3 DR. ELMS:</p> <p>4 A. Was it a concern in this instance, or was it</p> <p>5 something to be paid attention to when you're</p> <p>6 grossing a case?</p> <p>7 DR. ELMS:</p> <p>8 A. Well, both, actually.</p> <p>9 DR. ELMS:</p> <p>10 A. No. Issues of tissue thickness was something</p> <p>11 I was made aware of during my residency.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Which is for the cassettes, I take it?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. But how about in relation in particular to</p> <p>18 ER/PR?</p> <p>19 DR. ELMS:</p> <p>20 A. In relation to ER/PR, I don't recall if that</p> <p>21 was the first time. I'm certainly aware of it</p> <p>22 now, but if that was the first time that I was</p> <p>23 made aware of it, I can't say.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And if you were made aware of it before this</p>	<p>1 just -</p> <p>2 DR. ELMS:</p> <p>3 A. Yes, I remember the one.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Remember that, take you there. Anyway, it's</p> <p>6 the one dealing with non-neoplastic -</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. - cells and them not being stained, which in</p> <p>11 effect is internal controls.</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And that was back in 2001?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Are you able, and upon reflecting upon it, are</p> <p>20 you able to -</p> <p>21 DR. ELMS:</p> <p>22 A. No.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. - help the Commissioner in that regard, as to</p> <p>25 why that would have been on your mind at that</p>

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<p>1 particular point in 2001?</p> <p>2 DR. ELMS:</p> <p>3 A. I'm not sure why at that time I felt obliged</p> <p>4 to make a comment on a form. In any event,</p> <p>5 it's not a common thing for me to do.</p> <p>6 Sometimes, if I'm say--you know, I want to say</p> <p>7 "there's holes in this piece, do another one,"</p> <p>8 but I'm not sure why I wrote that.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. It was in the context of you asking that it be</p> <p>11 repeated.</p> <p>12 DR. ELMS:</p> <p>13 A. That it be repeated, yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And you were explaining why, because the</p> <p>16 internal controls didn't stain.</p> <p>17 DR. ELMS:</p> <p>18 A. Yes. What I can say is that it was a reason</p> <p>19 why I wanted it done. It certainly wasn't</p> <p>20 that I was paying attention any more to</p> <p>21 internal controls than--like I said, I'm not</p> <p>22 sure why it was I wrote that comment.</p> <p>23 THE COMMISSIONER:</p> <p>24 Q. Dr. Elms, doesn't the comment indicate that in</p> <p>25 the context of an ER/PR test, you are saying</p>	<p>1 looking for internal controls?</p> <p>2 DR. ELMS:</p> <p>3 A. At that point, I wasn't.</p> <p>4 THE COMMISSIONER:</p> <p>5 Q. So for a reason that you don't know, or you</p> <p>6 now can't remember, when ordering a retest,</p> <p>7 you indicated the absence of the appropriate</p> <p>8 result on internal control?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 THE COMMISSIONER:</p> <p>12 Q. Although you don't normally look for it. It's</p> <p>13 an odd sequence.</p> <p>14 DR. ELMS:</p> <p>15 A. I appreciate that. As I say, I'm not sure</p> <p>16 what I was looking at at the time in that</p> <p>17 particular case. I know in those days,</p> <p>18 absence of an internal control would not have</p> <p>19 triggered me to -</p> <p>20 THE COMMISSIONER:</p> <p>21 Q. To order a repeat.</p> <p>22 DR. ELMS:</p> <p>23 A. - to reorder the test. So I'm not sure as to</p> <p>24 why I put that there. I'm assuming I ordered</p> <p>25 the test for another reason.</p>
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<p>1 the absence of the appropriate response on the</p> <p>2 internal control has caused you to want that</p> <p>3 repeated?</p> <p>4 DR. ELMS:</p> <p>5 A. I'm not sure that that's the case in this</p> <p>6 instance. I know that I made that comment,</p> <p>7 but I'm not sure why it was that I ordered</p> <p>8 that test.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Can you think of any other reason why?</p> <p>11 DR. ELMS:</p> <p>12 A. No.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Other than the one the Commissioner has -</p> <p>15 DR. ELMS:</p> <p>16 A. No, I've thought about it. It certainly at</p> <p>17 that time would not have spurred me to reorder</p> <p>18 the test. It would have been almost as an</p> <p>19 add-on to say "I want this repeated, and</p> <p>20 besides, this is the case in this instance."</p> <p>21 I'm not sure what other issues there were in</p> <p>22 that case.</p> <p>23 THE COMMISSIONER:</p> <p>24 Q. But did I misunderstand you? I had understood</p> <p>25 you to say that at that point, you were not</p>	<p>1 THE COMMISSIONER:</p> <p>2 Q. Okay, which you didn't put on the form.</p> <p>3 DR. ELMS:</p> <p>4 A. That wasn't there, yes. I'm not sure why.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Doctor, in doing a presentation for your</p> <p>7 colleagues in November of 2006, for the</p> <p>8 clinicians, I take it the presentation, you</p> <p>9 have understood, would have gone to</p> <p>10 pathologists as well? I mean, there would</p> <p>11 have been medical staff generally there?</p> <p>12 DR. ELMS:</p> <p>13 A. Yes, yes, I would have expected pathologists</p> <p>14 to have been in the room.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Doctor, were you ever asked for your input or</p> <p>17 did you ever give any input as to, from your</p> <p>18 perspective, what should or shouldn't be</p> <p>19 talked about or could or couldn't be talked</p> <p>20 about, in the sense of, for example, the</p> <p>21 reasons for test failure, to quote Dr.</p> <p>22 Banerjee?</p> <p>23 DR. ELMS:</p> <p>24 A. I understood that at the time we were treating</p> <p>25 the Banerjee report as a protected document</p>

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1 and that as a result of that, that was not
 2 something to be addressed. I don't recall if
 3 I was formally told that. I do know that when
 4 I was first introduced to the Banerjee report,
 5 I was told that it was a confidential
 6 document.
 7 COFFEY, Q.C.:
 8 Q. To which you were provided some access?
 9 DR. ELMS:
 10 A. Some access.
 11 COFFEY, Q.C.:
 12 Q. And were given a copy?
 13 DR. ELMS:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. How about Trish Wegrynowski's reports?
 17 DR. ELMS:
 18 A. Very similar. I mean, the spreadsheet which I
 19 was provided was a summary of both of them and
 20 again, there were portions of the report. As
 21 I needed clarification, I felt, on the
 22 spreadsheet material, there was portions that
 23 I was read.
 24 COFFEY, Q.C.:
 25 Q. Of Ms. Wegrynowski's report?

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1 DR. ELMS:
 2 A. Ms. Wegrynowski's report, yes.
 3 COFFEY, Q.C.:
 4 Q. And that would be of both the original and
 5 subsequent reports in both cases, do you
 6 think?
 7 DR. ELMS:
 8 A. Yes, I believe so.
 9 COFFEY, Q.C.:
 10 Q. By the fall of '06, both reports had been in
 11 at least for five or six months?
 12 DR. ELMS:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. The second report from each?
 16 DR. ELMS:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. Doctor, again, as the then director, in the
 20 fall of 2006, and preparing to talk to your
 21 colleagues about this matter, did the
 22 inability to actually kind of talk frankly
 23 about what was in those reports, openly,
 24 frankly about what was in them? Would that,
 25 in any way, inhibit or did it in any way

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1 inhibit your ability or the discussion
 2 generally?
 3 DR. ELMS:
 4 A. No, not my ability. I was talking about how
 5 the test is done.
 6 COFFEY, Q.C.:
 7 Q. Okay, as a theoretical structure?
 8 DR. ELMS:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. How about--but you would have sat through the
 12 presentations of others, Dr. Carter, Dr.
 13 Denic's -
 14 DR. ELMS:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Dr. Howell's presentations?
 18 DR. ELMS:
 19 A. Yes.
 20 COFFEY, Q.C.:
 21 Q. As a staff pathologist at the time, was there
 22 talk amongst the staff pathologists in St.
 23 John's about what happened here, why did it
 24 happen? Like I'm trying to get for the
 25 Commissioner some sense of, you know, as the

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1 people actually doing the work, how they felt
 2 about it.
 3 DR. ELMS:
 4 A. I think what was felt was that there was a
 5 group of people that was looking into this and
 6 that would identify the problems and fix them.
 7 People were wondering. People had their own
 8 speculations as to what might have gone wrong.
 9 But that was the level of the discussion.
 10 COFFEY, Q.C.:
 11 Q. If we could look, please, at Exhibit P-1602?
 12 Now Doctor, here, this is a document, it's
 13 undated, the source was Terry Gulliver. It's
 14 entitled "major changes improvements for the
 15 IHC lab." Technology is there. Training is
 16 there. You're referenced in the last bullet
 17 of the training, planning to send you to Dr.
 18 Gown's lab for training. Staffing has
 19 approval for four pathologist assistants. I
 20 take it that that, the idea of pathologist
 21 assistants, we understand, we've heard here at
 22 the Commission, that that had been going on
 23 for years, had been talked about.
 24 DR. ELMS:
 25 A. Had been talked about, yes.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. Talked about. From your perspective, had you</p> <p>3 been in favour of it or against it?</p> <p>4 DR. ELMS:</p> <p>5 A. Very much in favour of it.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. What was your understanding, if any, as to why</p> <p>8 it hadn't happened before this?</p> <p>9 DR. ELMS:</p> <p>10 A. My understanding was that it was an issue of</p> <p>11 funding.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Approval for one QA tech. Had there been any</p> <p>14 QA techs before this?</p> <p>15 DR. ELMS:</p> <p>16 A. Not that I was aware of.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Approval for Dr. Carter part time QA</p> <p>19 pathologist. Had there been any full or part-</p> <p>20 time QA pathologist before this?</p> <p>21 DR. ELMS:</p> <p>22 A. At times during the course of my training and</p> <p>23 my employment there, yes, there had been. Dr.</p> <p>24 Miriam Griffin at St. Clare's was one who I</p> <p>25 remember who was doing QA.</p>	<p>1 individual pathologists and we assess them and</p> <p>2 submit them back as a proficiency test.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Had that ever involved IHC testing, do you</p> <p>5 know?</p> <p>6 DR. ELMS:</p> <p>7 A. It would depend on the cases. We're given a</p> <p>8 certain number of cases and in some instances,</p> <p>9 there may be an IHC, but it's not a prominent</p> <p>10 feature of the modules that we were using.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. From CAP?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. How about then enrolled in the UK, that would</p> <p>17 be NEQAS?</p> <p>18 DR. ELMS:</p> <p>19 A. That would be NEQAS.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And this was new, I take it?</p> <p>22 DR. ELMS:</p> <p>23 A. This was new.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Go back, please, to Exhibit P-2108? Page two,</p>
Page 250	Page 252
<p>1 COFFEY, Q.C.:</p> <p>2 Q. And do you recall what time period that was?</p> <p>3 DR. ELMS:</p> <p>4 A. That would have been '96 up until she left in,</p> <p>5 I believe, 1999.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And after she left?</p> <p>8 DR. ELMS:</p> <p>9 A. I'm not sure that anyone was doing it then.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. And to your knowledge, was anyone doing it at</p> <p>12 the General Hospital, that you were aware of?</p> <p>13 DR. ELMS:</p> <p>14 A. Not to my knowledge.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Now it refers to enrolled in CAP, College of</p> <p>17 American Pathologists?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Had that been going on before?</p> <p>22 DR. ELMS:</p> <p>23 A. Yes, we had had--we get quarterly reviews in</p> <p>24 which we're send slides and photographs of</p> <p>25 slides with cases that are circulated to the</p>	<p>1 Doctor, this is minutes of executive</p> <p>2 management meeting of November 21/06. The</p> <p>3 second page, it's noted here "quality and risk</p> <p>4 management are confident that the appropriate</p> <p>5 processes are in place. Heather Predham</p> <p>6 advised that there are some recommendations</p> <p>7 from the review that have yet to be</p> <p>8 implemented. It is important to ensure the</p> <p>9 quality assurance monitoring processes are in</p> <p>10 place and can be sustained and monitored into</p> <p>11 the future. Documentation is of paramount</p> <p>12 importance and must be monitored and</p> <p>13 reviewed." And then it concludes by saying,</p> <p>14 "the director and clinical chief are directly</p> <p>15 accountable for the laboratory," and "Dr.</p> <p>16 Howell agreed to develop a proposal re: the</p> <p>17 leadership component for further discussion at</p> <p>18 executive." Now the director in this context</p> <p>19 would be?</p> <p>20 DR. ELMS:</p> <p>21 A. That would be the laboratory director.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Mr. Gulliver?</p> <p>24 DR. ELMS:</p> <p>25 A. Yes.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And not yourself as IHC?</p> <p>3 DR. ELMS:</p> <p>4 A. Not myself.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. The reference to "documentation is of</p> <p>7 paramount importance and must be monitored and</p> <p>8 reviewed," what was the state, in November of</p> <p>9 2006, of the development of documentation in</p> <p>10 the lab or the labs in St. John's?</p> <p>11 DR. ELMS:</p> <p>12 A. The state, it was being developed. We were,</p> <p>13 at that point, I believe there was</p> <p>14 documentation ongoing on the machinery, the</p> <p>15 maintenance of the machinery, the various</p> <p>16 temperatures and pH's, and we were also</p> <p>17 retaining documents of our proficiency testing</p> <p>18 and these types of things.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Compared to, for example, what exists today?</p> <p>21 DR. ELMS:</p> <p>22 A. It was in the process of being developed. It</p> <p>23 wasn't as extensive as now.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And was this the beginning of it then in the</p>	<p>1 the MAC in relation to this?</p> <p>2 DR. ELMS:</p> <p>3 A. No.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Have you ever been asked to?</p> <p>6 DR. ELMS:</p> <p>7 A. No.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. That's up to the day today?</p> <p>10 DR. ELMS:</p> <p>11 A. Up to today.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Would you be prepared to address them, if they</p> <p>14 asked?</p> <p>15 DR. ELMS:</p> <p>16 A. If they asked, yes.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. I take it, in the course of your presentation</p> <p>19 to your colleagues in November 2006 that some</p> <p>20 people in the audience were probably members</p> <p>21 of the MAC itself?</p> <p>22 DR. ELMS:</p> <p>23 A. Yes, I would assume, yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. As is Dr. Denic?</p>
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<p>1 fall of 2006?</p> <p>2 DR. ELMS:</p> <p>3 A. It had been ongoing that it had been</p> <p>4 developed, so that when I came to this and</p> <p>5 began inquiring, some of it was already being</p> <p>6 done.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Who had done the initial work?</p> <p>9 DR. ELMS:</p> <p>10 A. Mr. Gulliver and Mr. Dyer, I had assumed.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Doctor, here, as well, in this particular</p> <p>13 page, there's a reference in the third last</p> <p>14 bullet to "the organization needs to establish</p> <p>15 a date when it will return to 'testing mode'</p> <p>16 and returning to testing mode requires the</p> <p>17 confidence," it should be, I suppose, "of the</p> <p>18 oncologists and medical staff." Then there's</p> <p>19 reference to extending the ER/PR testing at</p> <p>20 Mount Sinai for another month, and then "the</p> <p>21 MAC is a key group that confidence will need</p> <p>22 to be restored," or the confidence of which, I</p> <p>23 presume it means, will need to be restored.</p> <p>24 Now the MAC, as the director of</p> <p>25 immunohistochemistry, have you ever addressed</p>	<p>1 DR. ELMS:</p> <p>2 A. Yes.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Exhibit P-2175, page seven, please. This is a</p> <p>5 document, page seven of it is entitled</p> <p>6 "immunohistochemistry laboratory management</p> <p>7 and staff." It lists a number of laboratory</p> <p>8 medicine program leadership, Dr. Denic, Mr.</p> <p>9 Gulliver and Ms. Wade. Pathology division</p> <p>10 leadership, Dr. Morris-Larkin, Mr. Barry Dyer</p> <p>11 and Ms. Catherine Parnell, and then the</p> <p>12 immunohistochemistry section, technical staff,</p> <p>13 are yourself as clinical director</p> <p>14 immunohistochemistry and at the time, Mr.</p> <p>15 Green, Mr. Simms, Ms. Rowe and Ms. Voisey.</p> <p>16 Doctor, who are the current staff of the</p> <p>17 immunohistochemistry section?</p> <p>18 DR. ELMS:</p> <p>19 A. There's myself, Mr. Ken Green, Ms. Kim Voisey,</p> <p>20 Ms. Jane Gamberg and we have another</p> <p>21 technologist just starting now, Mr. Lloyd</p> <p>22 Mushreau.</p> <p>23 THE COMMISSIONER:</p> <p>24 Q. I'm sorry, what was that last name?</p> <p>25 DR. ELMS:</p>

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<p>1 A. Lloyd Mushreau. 2 THE COMMISSIONER: 3 Q. Mushreau? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. Could you spell that, please? 8 DR. ELMS: 9 A. Not sure exactly how. I believe it ends in R- 10 E-A-U, M-U-S-H-R-E-A-U. 11 COFFEY, Q.C.: 12 Q. Doctor, what, if any, training did the 13 technologists receive? 14 DR. ELMS: 15 A. They had gone to--I know Mr. Green and Mr. 16 Simms did some training at Ventana. They had 17 also gone off to Jewish General. Ms. Rowe and 18 Ms. Voisey had also done likewise. Mr. 19 Mushreau has not been sent off, but we are 20 undertaking his training within the 21 laboratory. 22 COFFEY, Q.C.: 23 Q. Who would be doing the training? 24 DR. ELMS: 25 A. That would be myself and Mr. Green.</p>	<p>1 be trained? 2 DR. ELMS: 3 A. We are in the process of developing a syllabus 4 now for Mr. Mushreau and for future. I would 5 not see us as being the sole trainers of our 6 technologists all the same. I would like to 7 see a continuance of this training outside of 8 our department. 9 COFFEY, Q.C.: 10 Q. Have there inquiries been made of other 11 bodies, educational bodies or other 12 institutions? 13 DR. ELMS: 14 A. We have subscribed to a series of online 15 seminars by CSMLS or rather, I should say, 16 MSH, and these are quite valuable actually for 17 our technologists. 18 COFFEY, Q.C.: 19 Q. Who is responsible, in an administrative 20 sense, for their training? 21 DR. ELMS: 22 A. The laboratory director. 23 COFFEY, Q.C.: 24 Q. That would be Mr. - 25 DR. ELMS:</p>
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<p>1 COFFEY, Q.C.: 2 Q. And you say, I'm sorry, the middle two, Ms. 3 Rowe and Ms. Voisey? 4 DR. ELMS: 5 A. Ms. Voisey, they also went away for seminars. 6 COFFEY, Q.C.: 7 Q. With whom? 8 DR. ELMS: 9 A. I'm not sure. I believe it was with Ventana, 10 but I'm not 100 percent sure of that. 11 COFFEY, Q.C.: 12 Q. Have they been to Montreal, Jewish General? 13 DR. ELMS: 14 A. I don't know. 15 COFFEY, Q.C.: 16 Q. Okay. Is there any particular certification 17 that technologists receive as IHC 18 technologists? 19 DR. ELMS: 20 A. Not that I'm aware of. They do training and 21 the training itself, the individual seminars 22 are documented. 23 COFFEY, Q.C.: 24 Q. Yes, and so in terms of that, is there a 25 syllabus for them or a plan for how they're to</p>	<p>1 A. So Mr. Dyer and Mr. Gulliver. 2 COFFEY, Q.C.: 3 Q. I take it you're consulted about it? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. In your capacity as--you wouldn't see yourself 8 as responsible for it, but you would be 9 consulted about it? 10 DR. ELMS: 11 A. Consulted about it. 12 COFFEY, Q.C.: 13 Q. Have input. 14 DR. ELMS: 15 A. Yes. 16 COFFEY, Q.C.: 17 Q. Exhibit P-2112. Doctor, this is a division of 18 anatomic pathology meeting, January 10th, 19 2007. Present are yourself and a number of 20 other pathologists listed there. The new 21 business begins with subspecialty task groups, 22 paragraph Roman numeral two, paragraph one. 23 "These groups were explained by Dr. Nash 24 Denic. So far the two most urgent groups, 25 breast and genitourinary have met. The breast</p>

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<p>1 group has their mandate and terms of reference 2 done. The terms of reference have been passed 3 to all pathologists for their information." 4 Doctor, what do you recall this was about, 5 this subspecialty task group? 6 DR. ELMS: 7 A. This was in response to recommendations from 8 the Banerjee review or Dr. Banerjee and Ms. 9 Wegrynowski's review. The issue of 10 subspecialty sign out in pathology is coming 11 more to the fore within the field of pathology 12 in any event and we decided that in response 13 to these recommendations, we should attempt, 14 as best we can, to set up subspecialty groups 15 and breast, of course, was quite important, 16 because breast is one of the few areas up 17 until now where we have a single test that 18 determines treatment. Genitourinary was 19 another one that was seen as priority. 20 COFFEY, Q.C.: 21 Q. And in a general way, where does it stand 22 right now? 23 DR. ELMS: 24 A. We still have our genitourinary group. Our 25 numbers have dwindled to the point where we</p>	<p>1 group had been made of Dr. Cook, Dr. Carter - 2 DR. ELMS: 3 A. And Dr. Naghibi. 4 COFFEY, Q.C.: 5 Q. And Dr. Carter just left? 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. Dr. Cook is off on leave? 10 DR. ELMS: 11 A. Yes. Dr. Naghibi was the first. She left 12 over a year ago, and which reduced the group 13 down to two, and then Dr. Carter went--Dr. 14 Cook went on leave, bringing the group down to 15 one, and then when Dr. Carter resigned, we had 16 no one. 17 COFFEY, Q.C.: 18 Q. Doctor, do you know if any particular funding 19 was spent for training for the people in that 20 group, that you're aware of? 21 DR. ELMS: 22 A. Not that I'm aware of. 23 COFFEY, Q.C.: 24 Q. Now this next paragraph refers to resident 25 teaching and sign out. Won't take you through</p>
<p>Page 262</p> <p>1 haven't been able to maintain groups and the 2 most obvious is our breast group. 3 COFFEY, Q.C.: 4 Q. And this group would be, I take it, of 5 pathologists, I take it, in this context? 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. The third paragraph refers to Dr. Denic having 10 spoken to Dr. Howell to try to get funding for 11 training in these subspecialties. I 12 appreciate this was January of '07 and it is 13 now September of '08. What's the situation 14 been with respect to, for example, funding for 15 training for subspecialties? 16 DR. ELMS: 17 A. I know, Dr. Afrouzian went for a short period 18 to Calgary. We also have a resident who is 19 interested in doing a subspecialty fellowship 20 and I know arrangements are--people are 21 attempting to make arrangements for him to 22 have funding. I'm not sure if they've been 23 successful as yet. 24 COFFEY, Q.C.: 25 Q. For example, in terms of a breast group, the</p>	<p>Page 264</p> <p>1 that in detail, but as it is here, as part of 2 the exhibit, are there problems with resident 3 teaching, because of the staffing levels? 4 DR. ELMS: 5 A. I know it can be difficult to fulfil 6 responsibilities in terms of teaching at 7 rounds in this type of area. I'm not aware 8 that there's a problem with RHADIP and 9 residents are still assigned to individual 10 pathologists for the sign--assigned to 11 individual pathologists for the signing out of 12 cases, so that they still get cases to assess 13 and then review with an attending physician 14 prior to sign out. 15 COFFEY, Q.C.: 16 Q. Now there is a reference in this paragraph to 17 cases being sent to Dynacare. 18 DR. ELMS: 19 A. Yes. 20 COFFEY, Q.C.: 21 Q. What's the current situation? 22 DR. ELMS: 23 A. That's still going on. 24 COFFEY, Q.C.: 25 Q. I take it does it vary from time, month to</p>

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<p>1 month or time to time?</p> <p>2 DR. ELMS:</p> <p>3 A. It varies from month to month, depending on</p> <p>4 the numbers, but our numbers have been very</p> <p>5 low since the beginning of May.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Numbers being sent?</p> <p>8 DR. ELMS:</p> <p>9 A. Numbers of pathologists.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Yes, okay. So you would expect the volume</p> <p>12 going to Dynacare has been higher in the past</p> <p>13 four months?</p> <p>14 DR. ELMS:</p> <p>15 A. In the past four months, yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Is there any particular cases that are sent?</p> <p>18 DR. ELMS:</p> <p>19 A. I know the cases are triaged at Health</p> <p>20 Sciences prior to being assigned, so that the</p> <p>21 material all comes in and then at the Health</p> <p>22 Sciences, a decision is made. I believe Dr.</p> <p>23 Morris-Larkin has a list of the cases she</p> <p>24 sends, but I'm not sure what the content of</p> <p>25 that list is.</p>	<p>1 Q. Doctor, on the bottom of the third page of</p> <p>2 Exhibit P-2112, under the heading "seven</p> <p>3 quality management program" it says "quality</p> <p>4 management is in the process of creating a</p> <p>5 book of policy and procedures for pathology."</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. I take it this is January 2007. So that was</p> <p>10 then ongoing?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes, ongoing.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. Has progress been made in that regard?</p> <p>15 DR. ELMS:</p> <p>16 A. Yes, yes, we have developed policies and as we</p> <p>17 know, it's a continually growing document.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. The next page, page four, under the conclusion</p> <p>20 at paragraph seven, it says "Dr. Ford Elms is</p> <p>21 the new director of immunohistochemistry. He</p> <p>22 will work on validation of</p> <p>23 estrogen/progesterone and HER2/neu staining.</p> <p>24 The next stains to be looked at are CD20 and</p> <p>25 CD117 for prostate." So as of January 2007, I</p>
<p style="text-align: right;">Page 266</p> <p>1 COFFEY, Q.C.:</p> <p>2 Q. Doctor, we've heard reference to a breast</p> <p>3 pathologist, a new breast pathologist. What's</p> <p>4 the person's name?</p> <p>5 DR. ELMS:</p> <p>6 A. That's Dr. Nikita MaKretzov. He is just</p> <p>7 returned from Great Britain. His background</p> <p>8 is in breast research and he has taken over,</p> <p>9 at this point, reading the breast cases and he</p> <p>10 has agreed to be a core of the reconstituted</p> <p>11 breast group, when we get back to having that</p> <p>12 done and reinstating breast testing.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And has he started here in St. John's?</p> <p>15 DR. ELMS:</p> <p>16 A. Yes.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. When was that?</p> <p>19 DR. ELMS:</p> <p>20 A. In July.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Of this year?</p> <p>23 DR. ELMS:</p> <p>24 A. Of this year.</p> <p>25 COFFEY, Q.C.:</p>	<p style="text-align: right;">Page 268</p> <p>1 don't know if you were really new new then,</p> <p>2 but you had become director in the fall of</p> <p>3 2006. "Working on validation of estrogen and</p> <p>4 progesterone and HER2/neu staining." Did you</p> <p>5 do so?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And what did that involve?</p> <p>10 DR. ELMS:</p> <p>11 A. The first part of the process is to determine</p> <p>12 basically what your recipe is, what your</p> <p>13 protocol for the carrying out of the test is.</p> <p>14 In that instance, we would--we take a breast,</p> <p>15 a piece of breast tissue with known staining</p> <p>16 qualities and every antibody comes with</p> <p>17 manufacturer's recommendations as to how you</p> <p>18 do the test, but that can only ever be a</p> <p>19 recommendation. Immunohistochemistry requires</p> <p>20 that you know what you're doing in your own</p> <p>21 lab. So we would take, as a start, and this</p> <p>22 was something I read in several areas really.</p> <p>23 You take as a start the variables that you can</p> <p>24 manipulate. We, on our machine, can</p> <p>25 manipulate the antibody incubation time, which</p>

<p style="text-align: right;">Page 269</p> <p>1 is the time the antibody is exposed to the 2 tissue, and we can manipulate the antigen 3 retrieval, both in terms of the type of 4 antigen retrieval used and the duration. The 5 easiest and well, the most easily manipulable 6 is the antibody incubation time. We get an 7 antibody that has a recommended incubation 8 time and we will run five slides going down 9 and above at two-minute intervals. We would 10 then assess those slides and based on the 11 results of that, decide where we go from 12 there. We may well find an acceptable 13 protocol then. We may need to alter our 14 incubation time further. We may need to 15 introduce or change in some fashion or take 16 away our antigen retrieval and this applies to 17 any antibody. Once that process has been done 18 and we know what our protocol is, we then need 19 to run a series of slides, again of known 20 result, so that we can show that we can 21 reliably reproduce them. So that process 22 needed to go on for estrogen and progesterone 23 and then subsequent to that, we started the 24 validation of HER2/neu. 25 COFFEY, Q.C.:</p>	<p style="text-align: right;">Page 271</p> <p>1 optimum? 2 DR. ELMS: 3 A. Myself and Mr. Green. 4 COFFEY, Q.C.: 5 Q. And this would be for ER/PR? 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. Do you have any particular training in that 10 regard yourself? 11 DR. ELMS: 12 A. Other than what I picked up in the course of 13 my self education and my perceptorship, no. 14 COFFEY, Q.C.: 15 Q. Now in terms of control tissue, I take it then 16 when you were looking at these slides trying 17 to determine which was the optimum recipe, as 18 it were, to use that word, how would you have 19 picked the blocks? What criteria would be 20 used to pick those and then to know what you 21 were actually looking for, what the block 22 should look like? 23 DR. ELMS: 24 A. I would have to search back through the 25 records to identify blocks and they would</p>
<p style="text-align: right;">Page 270</p> <p>1 Q. So the estrogen and progesterone, when was 2 that done, the validation? 3 DR. ELMS: 4 A. That was done late January, early February of 5 2007. 6 COFFEY, Q.C.: 7 Q. And were records kept of that? 8 DR. ELMS: 9 A. Yes. 10 COFFEY, Q.C.: 11 Q. And do they still exist? 12 DR. ELMS: 13 A. Yes. 14 COFFEY, Q.C.: 15 Q. And when you say records, I take it that would 16 be the actual slides? 17 DR. ELMS: 18 A. The slides and the run sheets. 19 COFFEY, Q.C.: 20 Q. That produce those particular slides? 21 DR. ELMS: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. Doctor, who would have examined the slides 25 themselves, as to determining which was the</p>	<p style="text-align: right;">Page 272</p> <p>1 already have been stained for estrogen, and so 2 I would know what the original result was, and 3 then, I would have to pull the case numbers 4 and look at the slides and examine them and 5 then select an appropriate block and it's not 6 sufficient to use one block from one case. 7 You need to get one block from many cases. 8 COFFEY, Q.C.: 9 Q. Yes, and how--I take it then, how would you 10 know then what the slide should look like? 11 DR. ELMS: 12 A. They had been tested previously. We used 13 slides that had been tested at Mount Sinai. 14 COFFEY, Q.C.: 15 Q. I'm sorry, you used? 16 DR. ELMS: 17 A. We used tissue that had been tested at Mount 18 Sinai. 19 COFFEY, Q.C.: 20 Q. Okay, the blocks that had ended up at Mount 21 Sinai? 22 DR. ELMS: 23 A. The cases that had ended up at Mount Sinai. 24 COFFEY, Q.C.: 25 Q. Cases, and so some of those cases, you would</p>

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<p>1 at least have Mount Sinai's results?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. The block that they had tested.</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Would you have the actual slides themselves?</p> <p>10 DR. ELMS:</p> <p>11 A. No.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. You would have a report on a block, on a slide</p> <p>14 on a block done at Mount Sinai?</p> <p>15 DR. ELMS:</p> <p>16 A. Yes.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And then you would utilize the same case, a</p> <p>19 case, that case, and pick another suitable</p> <p>20 block?</p> <p>21 DR. ELMS:</p> <p>22 A. Yes.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Create your own slide?</p> <p>25 DR. ELMS:</p>	<p>1 staining? Is there other extraneous staining?</p> <p>2 And if that is the case, as sometimes happens,</p> <p>3 then you need to do something to deal with</p> <p>4 that. It may be biotin staining, in which</p> <p>5 you'd need the block, overall now not</p> <p>6 necessarily just with ER. You'd need to know</p> <p>7 if you need to block it with biotin for</p> <p>8 instance. You may have to turn up or turn</p> <p>9 down your antigen retrieval. You may have to</p> <p>10 alter the antibody incubation time, depending</p> <p>11 on what you see.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And what you see, I take it, is you have to</p> <p>14 have some idea first of all of what perhaps I</p> <p>15 should be seeing?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Anticipate I should be seeing.</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. And what you should be seeing in this</p> <p>24 particular instance, in the early 2007, was a</p> <p>25 function of what Mount Sinai had reported</p>
<p>Page 274</p> <p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Or slides, series of slides?</p> <p>4 DR. ELMS:</p> <p>5 A. Series of slides, yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And using different antigen retrieval times</p> <p>8 and so on, as you've described?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Different recipes as it were?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And would look at the slides and determine--</p> <p>17 how would you determine which was the best</p> <p>18 recipe?</p> <p>19 DR. ELMS:</p> <p>20 A. Well, if you know, for instance, that you have</p> <p>21 40 percent intense staining in your case, you</p> <p>22 would--I would look at that first. Then I</p> <p>23 need to--it's not a matter merely of saying do</p> <p>24 I get positive or negative. I also need to</p> <p>25 know specificity. Is there background</p>	<p>Page 276</p> <p>1 these cases as?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 THE COMMISSIONER:</p> <p>5 Q. Dr. Elms, is this whole process like a house</p> <p>6 of cards, it all depends on the validity of</p> <p>7 what was done before?</p> <p>8 DR. ELMS:</p> <p>9 A. Yes, I would say. Yes, I mean, we -</p> <p>10 THE COMMISSIONER:</p> <p>11 Q. It seems to me the descriptions I get are we</p> <p>12 use known quantities for the purpose of</p> <p>13 determining what we use now.</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 THE COMMISSIONER:</p> <p>17 Q. But you must go on the assumption that the</p> <p>18 known quantities in fact are valid?</p> <p>19 DR. ELMS:</p> <p>20 A. Yes.</p> <p>21 THE COMMISSIONER:</p> <p>22 Q. And Dr. Khalifa comes in and describes how he</p> <p>23 set this up originally and he goes back to the</p> <p>24 results that they would have gotten in terms</p> <p>25 of his use of certain criteria, when they were</p>

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<p>1 using the old bioassay method.</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 THE COMMISSIONER:</p> <p>5 Q. So it seems like it's all built on the</p> <p>6 assumption that at every step along the way,</p> <p>7 things were done properly.</p> <p>8 DR. ELMS:</p> <p>9 A. That's correct. The issue of standardization</p> <p>10 in immunohistochemistry worldwide has been</p> <p>11 debated and looked at for years. In Great</p> <p>12 Britain, they've been working for at least ten</p> <p>13 years on that. One of the problems, and we</p> <p>14 keep saying there's no gold standard. One of</p> <p>15 the problems is that it's not like a blood</p> <p>16 test. If you, for instance, want to have a</p> <p>17 standardized glucose test, you can take blood</p> <p>18 samples from 1,000 or 2,000 or whatever</p> <p>19 people, pool them all and then that can be</p> <p>20 used as your standard across the country. You</p> <p>21 can't do that with a small portion of tissue.</p> <p>22 Various techniques have been discussed as to</p> <p>23 how to do it. What seems to be most up and</p> <p>24 coming now is the issue of tissue micro rays,</p> <p>25 which is a methodology that's being used in</p>	<p>1 there is some information available in</p> <p>2 textbooks. There is not a specific standard</p> <p>3 procedure for doing this. Every lab has</p> <p>4 manifestations anyway of the basic principles.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. But there's no one template, I take it?</p> <p>7 DR. ELMS:</p> <p>8 A. There's no one absolute template, no.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Now Doctor, the kind of outline then for the</p> <p>11 recipe was gotten from where? I use the word</p> <p>12 "recipe".</p> <p>13 DR. ELMS:</p> <p>14 A. The outline comes with the antibody itself.</p> <p>15 When we receive the antibody from the vendor,</p> <p>16 they have recommendations as to how to perform</p> <p>17 the test.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And this antibody at the time was being</p> <p>20 provided by whom? Who was the manufacturer?</p> <p>21 DR. ELMS:</p> <p>22 A. We have several manufacturers. We got some</p> <p>23 from Ventana. We use some--most of the ones</p> <p>24 are from Ventana, but some are from Celmarque,</p> <p>25 some are from DAKO, and some are produced by</p>
<p>Page 278</p> <p>1 B.C., and in that, you have very small</p> <p>2 portions of tissue, numerous portions of</p> <p>3 tissue mounted on the same slide, and that is</p> <p>4 where the B.C. group is going. But the issue</p> <p>5 of how you standardize immunohistochemistry is</p> <p>6 still being discussed and worked on.</p> <p>7 THE COMMISSIONER:</p> <p>8 Q. Okay.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Doctor, I take it then, in doing this, going</p> <p>11 through this validation process for ER and PR</p> <p>12 in early 2007, had you ever been through such</p> <p>13 a validation process before yourself?</p> <p>14 DR. ELMS:</p> <p>15 A. No.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. So this was your first time out?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And the approach to be utilized you obtained</p> <p>22 from where?</p> <p>23 DR. ELMS:</p> <p>24 A. I received--I read some documents from Dr.</p> <p>25 Gown's lab and also from a lab in Dallas, and</p>	<p>Page 280</p> <p>1 other organizations but sold, by other</p> <p>2 companies but sold through Ventana as well.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. The ER and PR at the time, beginning of 2007?</p> <p>5 DR. ELMS:</p> <p>6 A. At the time, they were Ventana antibodies.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. They come, I take it, prediluted?</p> <p>9 DR. ELMS:</p> <p>10 A. Prediluted.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. At that point, do you recall what they were at</p> <p>13 the time?</p> <p>14 DR. ELMS:</p> <p>15 A. Our ER antibody at the time was 6F11 or 4B5.</p> <p>16 I keep getting confused between that and the--</p> <p>17 there was an awful lot of HER2/neu testing at</p> <p>18 the same time, and I don't recall the name of</p> <p>19 what was then our PR antibody. We changed it</p> <p>20 quite a while ago.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. So in effect, you were getting the antibody--</p> <p>23 you had a Ventana machine?</p> <p>24 DR. ELMS:</p> <p>25 A. Yes.</p>

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. You had Ventana supplied antibodies?</p> <p>3 DR. ELMS:</p> <p>4 A. Yes.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. They supplied the formula?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Recipe, as it were?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. The approach protocol, and you then</p> <p>15 experimented with that, within certain limits?</p> <p>16 DR. ELMS:</p> <p>17 A. Yes.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. To get what you thought was an optimum result?</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. Based upon a report for that particular</p> <p>24 patient?</p> <p>25 DR. ELMS:</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Any particular reason she was listed here at</p> <p>3 the time, that you're aware?</p> <p>4 DR. ELMS:</p> <p>5 A. I'm not sure.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. And he informs Dr. Carter that "after a period</p> <p>8 of 18 months, we are reinstating IHC testing</p> <p>9 for ER/PR and HER2/neu. I was given assurance</p> <p>10 by the director of immunohistochemistry</p> <p>11 department, Dr. Ford Elms, that the</p> <p>12 immunohistochemistry service has met all the</p> <p>13 requirements to continue aforementioned tests.</p> <p>14 The reporting of ER/PR and HER2/neu should</p> <p>15 come into effect immediately, according to the</p> <p>16 approved (standardized) protocols." Now</p> <p>17 Doctor, these approved standardized protocols,</p> <p>18 approved by whom?</p> <p>19 DR. ELMS:</p> <p>20 A. Me.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And standardized?</p> <p>23 DR. ELMS:</p> <p>24 A. He's referring to the validation process.</p> <p>25 COFFEY, Q.C.:</p>
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<p>1 A. For that particular patient.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. That you had received from Mount Sinai?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Exhibit P-2114. Now this is February 8th,</p> <p>8 2007. It's a letter to Dr. Carter as leader</p> <p>9 of the breast pathology subspecialty task</p> <p>10 group. It's re: ER/PR and HER2/neu reporting.</p> <p>11 It's from Dr.--just on the second page,</p> <p>12 Doctor, it's from Dr. Denic.</p> <p>13 DR. ELMS:</p> <p>14 A. Um-hm.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. It's copied to a number of individuals,</p> <p>17 including yourself, and who is the third</p> <p>18 doctor?</p> <p>19 DR. ELMS:</p> <p>20 A. Dr. Afrouzian, Dr. Marjan Afrouzian.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And who is that in this context?</p> <p>23 DR. ELMS:</p> <p>24 A. She's one of our staff pathologists at St.</p> <p>25 Clare's.</p>	<p>1 Q. And it's ER and PR and we do understand that</p> <p>2 it did start then in February of 2007.</p> <p>3 DR. ELMS:</p> <p>4 A. Yes.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. How about the HER2/neu?</p> <p>7 DR. ELMS:</p> <p>8 A. No.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And why is that?</p> <p>11 DR. ELMS:</p> <p>12 A. HER2/neu is a very delicate antibody, is</p> <p>13 probably the best, but I hesitate to use the</p> <p>14 word "sensitive" because that has specific</p> <p>15 meaning. HER2/neu is quite susceptible to a</p> <p>16 number of small variations in environment. It</p> <p>17 remains as yet one of the--well, remains the</p> <p>18 only antibody for which we have formal</p> <p>19 recommendations as to how you validate it and</p> <p>20 control it, and those recommendations became</p> <p>21 law in the United States in February, but</p> <p>22 they're still recommendations in this country.</p> <p>23 It requires -</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Recommendations by whom?</p>

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<p>1 DR. ELMS: 2 A. They were put out originally by the CAP ASCO, 3 the College of American Pathologists and 4 American Society of Clinical Oncologists and 5 then adopted by the Canadian working group in 6 Toronto, and they make specific 7 recommendations as to fixation, time and 8 fixation, how many cases need to be done in 9 order to validate the case. They recommend a 10 minimum number of cases that should be read a 11 year, and how controls should be done as the 12 tests are made, and they're quite stringent. 13 As I say, it's the only antibody for which we 14 have any kind of recommendation specific as to 15 how to validate and control them.</p> <p>16 COFFEY, Q.C.: 17 Q. As to how to validate?</p> <p>18 DR. ELMS: 19 A. As to how to validate them.</p> <p>20 COFFEY, Q.C.: 21 Q. Period?</p> <p>22 DR. ELMS: 23 A. Period.</p> <p>24 COFFEY, Q.C.: 25 Q. And you, I take it, in Canada, there are still</p>	<p>1 and they're considered zero. Three plus 2 staining also has a specific--as does two 3 plus, of course, has specific definitions, and 4 a three plus is a three. But a two plus is 5 considered equivocal and must then reflex to 6 FISH, which is a different technology. 7 There's another kind of equivocal and that is 8 you have to run two antibodies on HER2/neu, 9 not just one. You use a sensitive one and a 10 specific one. The other kind of equivocal is 11 if there is a discrepancy between your 12 sensitive and your specific and that also has 13 to reflex to FISH. We don't have access to 14 FISH in our lab and most of our equivocals are 15 of the latter kind, where there's a 16 discrepancy between the two antibodies, and so 17 as a result of that, until I was able to get a 18 good equivocal control, I wasn't comfortable 19 turning on the testing of HER2/neu. We were 20 getting it done at Mount Sinai and I felt it 21 would be best for us to continue with that 22 until such time as we had adequate controls.</p> <p>23 COFFEY, Q.C.: 24 Q. You say adequate controls, why weren't you 25 able to get adequate controls?</p>
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<p>1 a number of IHC stains available, commercially 2 available is what, pushing 200?</p> <p>3 DR. ELMS: 4 A. Pushing 200.</p> <p>5 COFFEY, Q.C.: 6 Q. And this is the only--HER2/neu is the only 7 one?</p> <p>8 DR. ELMS: 9 A. Yes, and we had significant problems with 10 validating them with regards to background 11 staining and we tried several--two antibodies 12 at least before we arrived at SP3 and we were 13 able to validate that. I had it validated, 14 reviewed the material with Dr. Carter. She 15 felt the stain was too weak, so we went back 16 and revalidated at a more intense level, and 17 in discussions with laboratory technologists, 18 chief technologists in other labs, the 19 recommendations are that you have a positive 20 control and a negative control, but when you 21 discuss this with other technologists, what 22 you always hear is that "yes, but it's your 23 equivocals that are the problem." HER2 is 24 graded on a scale of zero to three. Zero and 25 one plus staining have specific definitions</p>	<p>1 DR. ELMS: 2 A. Because most of our equivocals are not of the 3 two plus equivocal. They're of the discrepant 4 equivocal.</p> <p>5 COFFEY, Q.C.: 6 Q. And are you aware of why that would be so?</p> <p>7 DR. ELMS: 8 A. Other than just that it--I know that that's a 9 problem across the board. I've been talking 10 to various people in various other hospitals 11 and they have a similar problem. Not quite as 12 acute as ours, but they do have a problem.</p> <p>13 COFFEY, Q.C.: 14 Q. And this sort of problem can be caused by 15 what?</p> <p>16 DR. ELMS: 17 A. Well, it's just the rarity of two plus stains. 18 It's not that there's something wrong with 19 your test. It's that the equivocal HER2's can 20 be difficult to find within your community.</p> <p>21 COFFEY, Q.C.: 22 Q. I was thinking about the contradictory results 23 between the two different stains.</p> <p>24 DR. ELMS: 25 A. On the contradictory, that has to do with the</p>

<p style="text-align: right;">Page 289</p> <p>1 nature of the stains themselves. We run two 2 antibodies. One is a polyclonal and the other 3 is a monoclonal. A polyclonal antibody is 4 more sensitive, which is to say it'll pick up 5 more--it will stain more things. It will rule 6 out more false negatives, so to speak. A 7 sensitive will stain--or a specific stain 8 rather, will stain less frequently, but it 9 will be more specific to the--if it's there, 10 you're more sure that it's there. So 11 basically a sensitive stain rules out the 12 false negatives and the positive--or a 13 specific rules out the false negatives. So 14 that if you have a very sensitive stain, it is 15 possible in your staining that you're getting 16 staining that may well be specific to the area 17 where you expect to see it, but it's not 100 18 percent sure that it's actually staining the 19 antibody you're looking for. That is more of 20 an acute situation with HER2. So you then do 21 your monoclonal and then if your monoclonal as 22 well stains, then you can be reasonably sure. 23 If you do have a discrepancy between them, 24 that may be an equivocal that you need to go 25 to FISH for, and then when your FISH result</p>	<p style="text-align: right;">Page 291</p> <p>1 anyway. 2 DR. ELMS: 3 A. Yes. 4 COFFEY, Q.C.: 5 Q. And continued to be. The ER/PR testing, why 6 not just leave it to Mount Sinai, because I 7 gather since May of this year, since Dr. 8 Carter announced that she was going, that 9 ER/PR testing in St. John's was suspended? 10 DR. ELMS: 11 A. Yes. 12 COFFEY, Q.C.: 13 Q. Well, first of all I'll ask you, why was that? 14 DR. ELMS: 15 A. Why was it suspended? 16 DR. ELMS: 17 A. Because we no longer had a breast 18 subspecialty group that would be able to, as 19 a small group, would be able to sign out all 20 of our breast cases. 21 COFFEY, Q.C.: 22 Q. And I take it that arrangements were made with 23 Mount Sinai for them to then, at least for a 24 period of time, continue to do or do ER/PR? 25 DR. ELMS:</p>
<p style="text-align: right;">Page 290</p> <p>1 comes back, it's of a different nature. 2 COFFEY, Q.C.: 3 Q. But you indicated discrepancy is more common 4 here, you've noticed? 5 DR. ELMS: 6 A. I wouldn't say that it is more common here, 7 but it is common that, I mean, every 8 technologist that you talk to will tell you 9 that true equivocal HER2s are rare. You can 10 buy cell line controls which are produced 11 bodies of cells, produced within a lab, and 12 that are optimized to show particular levels 13 of staining. We could use those as controls 14 but they are not optimal controls by virtue of 15 the fact that they're not tissue from your own 16 lab that have been through your own particular 17 processes, and the general wisdom in 18 immunohistochemistry is that the better 19 control is always the control that's been 20 subject to what you would expect all of your 21 tissue to be subject to in your lab. 22 COFFEY, Q.C.: 23 Q. Doctor, while we're on the idea of, well, some 24 of the testing, HER2/neu testing is being done 25 at Mount Sinai, had been up to this point,</p>	<p style="text-align: right;">Page 292</p> <p>1 A. Yes. 2 COFFEY, Q.C.: 3 Q. And the HER2/neu they were doing anyway? 4 DR. ELMS: 5 A. Yes. 6 COFFEY, Q.C.: 7 Q. Doctor, why not just simply have Mount Sinai 8 do the ER/PR or their equivalent, Mount Sinai 9 or another laboratory? 10 DR. ELMS: 11 A. Well, within the organization I think it was 12 felt that, I mean, it's important to provide 13 services for patients and this, has now become 14 a pretty standard service in the treatment of 15 breast cancer patients and we should be 16 offering it. So that was the idea, that if 17 we're going to be running an 18 immunohistochemistry lab and if we're going to 19 be treating breast cancer patients, we feel a 20 need to provide the service of ER/PR testing. 21 COFFEY, Q.C.: 22 Q. Are there any other ramifications of not 23 providing it? 24 DR. ELMS: 25 A. Well, we would be relying on an external lab.</p>

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<p>1 Cost factors would certainly be involved, time 2 factors, as well, and you're relying on a lab, 3 you're not doing the test yourself, you're 4 relying on someone else's results. 5 COFFEY, Q.C.: 6 Q. Would it have any affect on accreditation? 7 DR. ELMS: 8 A. I'm not sure at this Time. 9 COMMISSIONER: 10 Q. Mr. Coffey, wherever you can find a convenient 11 spot, we'll take the afternoon break. 12 COFFEY, Q.C.: 13 Q. Doctor, just looking to the next page of this 14 February 8th letter it says, Dr. Denic 15 concludes by saying "I also expect that your 16 group should monitor and take an active role 17 in QA of these tests with certain number of 18 cases as decided by this group to be sent to 19 an outside institution such as Mount Sinai for 20 validation." I take it this is a kind of a 21 random sampling, as it were? 22 DR. ELMS: 23 A. Um-hm. 24 COFFEY, Q.C.: 25 Q. Have them checked?</p>	<p>1 COFFEY, Q.C.: 2 Q. Of the ER/PR cases? 3 DR. ELMS: 4 A. Yes, were discrepant. 5 COFFEY, Q.C.: 6 Q. Were discrepant. And discrepant in this 7 context would be defined as what? 8 DR. ELMS: 9 A. We called it positive, they called it 10 negative; we called it negative, they called 11 it positive. 12 COFFEY, Q.C.: 13 Q. And in this context calling it positive means 14 what in this context? 15 DR. ELMS: 16 A. That we reported positivity in ten percent--it 17 was never an issue that you had debate over 18 whether they called it 12 and we called it 19 eight. 20 COFFEY, Q.C.: 21 Q. Okay, so what I'm getting at is positivity 22 defined here in a clinical oncology sense is 23 ten percent or was it positivity, they called 24 it zero, Mount Sinai did, and St. John's 25 called it, I don't know, 10, 20, 30?</p>
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<p>1 DR. ELMS: 2 A. Yes. 3 COFFEY, Q.C.: 4 Q. Was that done? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. And what were the results? 9 DR. ELMS: 10 A. We had good correlation. I kept--the logbook 11 was maintained by Dr. Carter and I kept in 12 close contact with her and she never felt 13 there was any significant issues. 14 COFFEY, Q.C.: 15 Q. So what does that, in fact, mean? 16 DR. ELMS: 17 A. Well, I believe that our correlation was three 18 to four percent discrepancy between us and 19 Mount Sinai. 20 COFFEY, Q.C.: 21 Q. Three to four percent in the sense of, like, 22 40 to 45, is that--or three to four - 23 DR. ELMS: 24 A. Oh, no, no. What I'm saying is of the cases 25 that were sent, three to four percent -</p>	<p>1 DR. ELMS: 2 A. Or vice versa. 3 COFFEY, Q.C.: 4 Q. Or vice versa? 5 DR. ELMS: 6 A. Yes. 7 COFFEY, Q.C.: 8 Q. That's the discrepancy you're talking about 9 here? 10 DR. ELMS: 11 A. Yes. 12 COFFEY, Q.C.: 13 Q. For the discrepant cases were there any 14 inquiries made as to why they were discrepant? 15 DR. ELMS: 16 A. We reviewed the material, we reviewed the 17 cases and reviewed back through the 18 documentation of the quality initiatives or 19 quality management material that was looked 20 at. But three to four percent is not outside 21 of what one would expect as a discrepancy 22 between labs. 23 COFFEY, Q.C.: 24 Q. What would, in that regard, what would one 25 expect?</p>

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1 DR. ELMS:
 2 A. Three to five.
 3 COFFEY, Q.C.:
 4 Q. Three to five percent?
 5 DR. ELMS:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And that figure comes from where?
 9 DR. ELMS:
 10 A. Various quoted sources.
 11 COFFEY, Q.C.:
 12 Q. I'm sorry, various?
 13 DR. ELMS:
 14 A. Various quoted sources. You can find it in
 15 textbooks.
 16 COFFEY, Q.C.:
 17 Q. Thank you, Commissioner, break.
 18 COMMISSIONER:
 19 Q. All right, we'll take the afternoon break.
 20 (RECESS)
 21 COMMISSIONER:
 22 Q. Please be seated. Mr. Coffey.
 23 COFFEY, Q.C.:
 24 Q. Thank you, Commissioner. Now, Registrar,
 25 Exhibit P-2114, please? This is a letter of

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1 February 8th, 2007 from Dr. Denic to Dr.
 2 Carter, copied to yourself, Doctor. Doctor,
 3 so I take it then what's reflected here in the
 4 first paragraph is that you had assured Dr.
 5 Denic that the requirements to begin, at
 6 least, ER and PR reporting in the sense of at
 7 least producing the slides here in St. John's,
 8 you were satisfied that it was appropriate?
 9 DR. ELMS:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. It could be done?
 13 DR. ELMS:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Appropriately and safely?
 17 DR. ELMS:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Doctor, did anyone check your work in that
 21 regard?
 22 DR. ELMS:
 23 A. No.
 24 COFFEY, Q.C.:
 25 Q. To your knowledge had ER and PR stains ever

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1 been validated before that in St. John's, to
 2 your knowledge?
 3 DR. ELMS:
 4 A. Not to my knowledge.
 5 COFFEY, Q.C.:
 6 Q. How about any other IHC stain?
 7 DR. ELMS:
 8 A. No, to my knowledge.
 9 COFFEY, Q.C.:
 10 Q. Doctor, just before we broke you indicated
 11 that there was on these cases that were
 12 referred out for QA to Mount Sinai, they would
 13 be ER/PR cases, some of them?
 14 DR. ELMS:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Approximately how many would that involve?
 18 DR. ELMS:
 19 A. I don't remember the exact number. I know we
 20 were sending approximately 20 percent.
 21 COFFEY, Q.C.:
 22 Q. Okay. And so and it was about a four percent
 23 discrepancy?
 24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Well, our of 100 cases that would be four or
 3 about one in 25?
 4 DR. ELMS:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. In effect. Doctor, in those instances where
 8 that happened and what, if anything, was done
 9 then in terms of for that particular patient?
 10 DR. ELMS:
 11 A. We'd review the case. But that level of
 12 disagreement between labs is not unacceptable,
 13 that's what we would understand. So we would
 14 review the case, we would see if we agreed,
 15 and then decide from there. But it wouldn't
 16 necessarily treat--trigger a retest elsewhere
 17 that that--that's within the working
 18 parameters.
 19 COFFEY, Q.C.:
 20 Q. From lab to lab?
 21 DR. ELMS:
 22 A. From lab to lab.
 23 COFFEY, Q.C.:
 24 Q. Involving inter-lab variability, I take it?
 25 DR. ELMS:

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<p>1 A. Yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Sort of that phrase?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Doctor, but for the individual patient, I take</p> <p>8 it, if St. John's reviewed its--the material</p> <p>9 it had for that particular patient, that there</p> <p>10 was discordant result with Mount Sinai in the</p> <p>11 current cases?</p> <p>12 DR. ELMS:</p> <p>13 A. Um-hm.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And the local result, if you were satisfied</p> <p>16 that, yeah, we'll go, we'll accept Mount</p> <p>17 Sinai's, I take it the patients' oncologists</p> <p>18 would be told accordingly or do I have that</p> <p>19 right or wrong?</p> <p>20 DR. ELMS:</p> <p>21 A. We weren't doing these retests from a point of</p> <p>22 view of clinical treatment, we were doing this</p> <p>23 from a point of view of quality assurance, to</p> <p>24 monitor our results in correlation to someone</p> <p>25 else's. So it's not to say that if we say</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. Would you communicate that to Mount Sinai or -</p> <p>3 DR. ELMS:</p> <p>4 A. No.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Okay. How about if you looked at your case</p> <p>7 and it had been reported already?</p> <p>8 DR. ELMS:</p> <p>9 A. Um-hm.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. To the patient, the patients' oncologist and</p> <p>12 upon reconsideration you thought, no, Mount</p> <p>13 Sinai had got this--you know, this result was</p> <p>14 probably not appropriate or wrong internal</p> <p>15 result, what would happen then for that</p> <p>16 patient?</p> <p>17 DR. ELMS:</p> <p>18 A. It would depend on what we're talking about in</p> <p>19 terms of our result not being appropriate. As</p> <p>20 I say, we're doing this -- we're not doing</p> <p>21 this to identify specific problems with an</p> <p>22 individual case. We're doing this to see what</p> <p>23 our trends are over time, but if you would</p> <p>24 look back and see -- for instance, if we</p> <p>25 looked back and saw that our slide had been</p>
<p>Page 302</p> <p>1 positive and Mount Sinai says negative, that</p> <p>2 we or Mount Sinai are necessarily wrong, it's</p> <p>3 to be sure that we are within that same</p> <p>4 parameters of concordance with other labs.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. And on that point, like, the idea of random</p> <p>7 testing for QA purposes, which is what you're</p> <p>8 describing here, as within medicine does that</p> <p>9 involve clinical, potentially clinical</p> <p>10 ramifications for the patients or how does</p> <p>11 that work?</p> <p>12 DR. ELMS:</p> <p>13 A. I not understanding -</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Well, for example, if you look at a case and</p> <p>16 you say, well, say, one in 25 you have a</p> <p>17 different result?</p> <p>18 DR. ELMS:</p> <p>19 A. Um-hm.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. And you look at it and you think, well, no,</p> <p>22 our result, we're satisfied our result is</p> <p>23 appropriate?</p> <p>24 DR. ELMS:</p> <p>25 A. Um-hm.</p>	<p>Page 304</p> <p>1 misinterpreted or that there was an obvious</p> <p>2 issue with the staining, then you would have</p> <p>3 to be concerned about that particular case.</p> <p>4 I'm not aware that that happened in this</p> <p>5 instance.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. But those sorts of factors, you look back on</p> <p>8 your original slides and it was obvious to you</p> <p>9 that it was inappropriately reported?</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Interpreted?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. Well, then --</p> <p>18 DR. ELMS:</p> <p>19 A. You'd have an obligation to repeat the test. I</p> <p>20 don't think that I would necessarily go on</p> <p>21 Mount Sinai's result as it stood. I would</p> <p>22 repeat the test myself and then make a</p> <p>23 decision.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. And I take it then, does this generally</p>

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<p>1 describe the approach to QA processes? 2 DR. ELMS: 3 A. Yes, that's the way I -- 4 COFFEY, Q.C.: 5 Q. They're not done for clinical purposes per se 6 for individual patients. 7 DR. ELMS: 8 A. Yes. 9 COFFEY, Q.C.: 10 Q. It might be, though, that a patient is 11 clinically affected by it depending upon the 12 reasons upon investigation as to why there's a 13 discrepancy? 14 DR. ELMS: 15 A. Possibly, possibly. 16 COFFEY, Q.C.: 17 Q. Exhibit P-1114. I apologize, Exhibit P-2304 18 first. Doctor, these are minutes of a 19 Laboratory Medicine Program meeting of April 20 10th, 2007. Dr. Howell, Denic, and Mr. 21 Gulliver are present. On page two, paragraph 22 five, ER/PR HER2 receptors, it says, "Dr. 23 Denic gave an update on ER/PR, and informed 24 the lab has reinstated testing and it is going 25 well. Dr. Denic also informed that we are</p>	<p>1 the approval of new antibodies, with the 2 recommendation of antibody panels, with the 3 interpretation of difficult cases. 4 COFFEY, Q.C.: 5 Q. In contra-distinction to? 6 DR. ELMS: 7 A. In contra-distinction to issues like staffing, 8 payroll, maintenance of the machines, these 9 types of things. 10 COFFEY, Q.C.: 11 Q. And who had that responsibility? 12 DR. ELMS: 13 A. Mr. Gulliver and Mr. Dyer. 14 COFFEY, Q.C.: 15 Q. Is that really any different than it had been 16 before? 17 DR. ELMS: 18 A. No, no. 19 COFFEY, Q.C.: 20 Q. Before, in the sense of before 2005? 21 DR. ELMS: 22 A. I can't speak to what happened before 2005. 23 COFFEY, Q.C.: 24 Q. Sure, but as a pathologist looking back on it 25 now, is it really any different for the --</p>
<p>Page 306</p> <p>1 doing comparison testing with Mount Sinai in 2 regards to HER2 testing. Terry will arrange a 3 meeting with Dr. Denic, Dr. Elms, and Barry 4 Dyer, to review roles and responsibilities for 5 the immunohistochemistry lab". Doctor, do you 6 know if such a meeting occurred? 7 DR. ELMS: 8 A. Yes, we did. 9 COFFEY, Q.C.: 10 Q. Do you recall when that was and who was there? 11 DR. ELMS: 12 A. I'm not sure. I remember a meeting with 13 myself, Dr. Dyer, and Mr. Gulliver, and Dr. 14 Denic. 15 COFFEY, Q.C.: 16 Q. And it was about the roles and 17 responsibilities for the IHC lab? 18 DR. ELMS: 19 A. Yes. 20 COFFEY, Q.C.: 21 Q. And what was the outcome of that? 22 DR. ELMS: 23 A. My understanding was that I was to be more 24 concerned with the medical/clinical aspects of 25 the running of the lab, that is to say with</p>	<p>Page 308</p> <p>1 whoever the pathologist, with their individual 2 case, they'd be responsible for reporting and 3 interpretation of a difficult case, and 4 staffing, and IHC, and machinery and so on was 5 the -- 6 DR. ELMS: 7 A. Yes. 8 COFFEY, Q.C.: 9 Q. -- technologist problem. 10 DR. ELMS: 11 A. Yes. Individual pathologists, of course, were 12 still to be responsible for reporting their 13 own immuno. 14 COFFEY, Q.C.: 15 Q. As the Director then, you were responsible for 16 exactly what? 17 DR. ELMS: 18 A. For the approval of new antibodies, the 19 retirement of old antibodies, the 20 recommendation of panels for investigation. 21 COFFEY, Q.C.: 22 Q. Could you just explain that to the 23 Commissioner? 24 DR. ELMS: 25 A. Well, for instance, if you are investigating a</p>

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1 biopsy of prostate and you're looking for
 2 prostate carcinoma, there are specific stains
 3 that you would do.
 4 COFFEY, Q.C.:
 5 Q. That would be a panel of stain?
 6 DR. ELMS:
 7 A. That would be a panel of stains, and you
 8 wouldn't only do just the one, to rely on the
 9 one. So you could recommend not just -- most
 10 pathologists would sort of have an idea what
 11 their stains were going to be. However, as
 12 new antibodies come on line to be introduced
 13 into a panel, as new understandings of how to
 14 approach diagnosis come about, it would be up
 15 to me to recommend that to my colleagues.
 16 COFFEY, Q.C.:
 17 Q. In your role as --
 18 COMMISSIONER:
 19 Q. If you made no recommendations to the panel
 20 for a particular type of cancer, is that an
 21 indication of what's being offered in the lab?
 22 DR. ELMS:
 23 A. Yes.
 24 COMMISSIONER:
 25 Q. Which you were in before that?

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1 DR. ELMS:
 2 A. Yes.
 3 COMMISSIONER:
 4 Q. Or would a particular pathologist who might
 5 like -- or find informative another test which
 6 you did not include, could they get that done
 7 within the lab, or would it not be offered?
 8 DR. ELMS:
 9 A. If we offered it within the lab, yes, they
 10 could get it done even if it wasn't something
 11 I might have recommended. If it was to be
 12 outside, we would have to make recommendations
 13 to -- make arrangements to have it done.
 14 COMMISSIONER:
 15 Q. Uh-hm, but they're free to do that?
 16 DR. ELMS:
 17 A. Oh, yes.
 18 COFFEY, Q.C.:
 19 Q. Doctor, were there any problems then
 20 encountered in re-instituting ER/PR?
 21 DR. ELMS:
 22 A. No, no, we were able to get it validated and
 23 on line.
 24 COFFEY, Q.C.:
 25 Q. Doctor, what about the other regions within

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1 the province, the other health authorities,
 2 were they invited to participate with St.
 3 John's?
 4 DR. ELMS:
 5 A. The initial -- it was initially offered just
 6 within Eastern Health, and subsequent to that,
 7 I believe some medical directors have felt
 8 that they were quite satisfied with the
 9 service they were being provided with Mount
 10 Sinai and they continued with that.
 11 COFFEY, Q.C.:
 12 Q. And to this day, how has that worked, has it
 13 changed in any way?
 14 DR. ELMS:
 15 A. I believe Corner Brook is still sending their
 16 ER/PR to Mount Sinai.
 17 COFFEY, Q.C.:
 18 Q. What I'm asking about really is in terms of
 19 their involvement with St. John's. Have they
 20 been approached since to --
 21 DR. ELMS:
 22 A. I don't know if they've been approached since.
 23 COFFEY, Q.C.:
 24 Q. Certainly not by you anyway?
 25 DR. ELMS:

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1 A. No.
 2 COFFEY, Q.C.:
 3 Q. Have you discussed with any of the
 4 pathologists in the other regions as to their
 5 views on this?
 6 DR. ELMS:
 7 A. Their views on having testing done -- I had
 8 early on in this process discussions with Dr.
 9 Neil in Corner Brook, and as I said, he was
 10 quite satisfied with the service they were
 11 getting, and at that time had no intent to
 12 change from Mount Sinai back to Eastern
 13 Health.
 14 COFFEY, Q.C.:
 15 Q. Did he express any concerns about utilizing
 16 St. John's?
 17 DR. ELMS:
 18 A. Just given what had happened, he preferred to
 19 stay with Mount Sinai in the interim.
 20 COFFEY, Q.C.:
 21 Q. Exhibit P-0050, please. Doctor, this is one
 22 of those spreadsheets. This one is dated April
 23 26th, 2007, recommendations. See that?
 24 DR. ELMS:
 25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. And it's 0052. It's updated April 26/07.

3 Doctor, do you recall how it was that this

4 came to be produced at that date?

5 DR. ELMS:

6 A. That this came to be produced at that date?

7 COFFEY, Q.C.:

8 Q. Yes.

9 DR. ELMS:

10 A. We had -- I had been suing this as my template

11 for measures that I wanted to take in the lab,

12 so it was updated to sort of keep it up to

13 date as to what had been actually done, what

14 was ongoing, what had yet to be done.

15 COFFEY, Q.C.:

16 Q. Okay. Was it updated at your request?

17 DR. ELMS:

18 A. No.

19 COFFEY, Q.C.:

20 Q. It wasn't.

21 DR. ELMS:

22 A. No.

23 COFFEY, Q.C.:

24 Q. Doctor, we understand that ER/PR matter became

25 a matter of a large public issue in May of

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1 2007?

2 DR. ELMS:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. You would be aware of that. Had you been

6 aware of the media briefing in December of

7 '06?

8 DR. ELMS:

9 A. Yes, yes.

10 COFFEY, Q.C.:

11 Q. Had you been asked for any input into it

12 yourself?

13 DR. ELMS:

14 A. No, no, I wasn't in town at that point.

15 COFFEY, Q.C.:

16 Q. And then when this became an issue in May of

17 2007, how did you become aware of it, that it

18 was an issue in the way it became?

19 DR. ELMS:

20 A. I knew that it was going to be announced, and,

21 I mean, I knew that it had been an issue, I

22 knew that there had been -- up until that

23 point, that the issue had been looked into and

24 that retesting had been done.

25 COFFEY, Q.C.:

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1 Q. You're thinking of December of '06. I'm

2 thinking about May of '07 when it became a big

3 controversy in the province, not so much the

4 press conference, as it was talked about in

5 the media, it was talked about in the House of

6 Assembly.

7 DR. ELMS:

8 A. Well, I think -- what question are you asking?

9 COFFEY, Q.C.:

10 Q. I'm asking you at the time were you aware that

11 there was a blow up, as it were, at the time?

12 DR. ELMS:

13 A. I knew that it would become an issue. I mean,

14 obviously, this is something that was going to

15 cause a great deal of concern to a large

16 number of people. So it wasn't surprising to

17 me.

18 COFFEY, Q.C.:

19 Q. Exhibit P-0114. Doctor, this is a document

20 that's typed. It says, "Feedback from

21 immunohistochemistry technologists", dated May

22 29th, 2007. The first bullet is, "Expressed

23 concerns related to coordination of quality

24 assurance activities for entire

25 immunohistochemical service. Vast majority of

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1 IHC SOP's not signed off. ER/PR had been

2 completed. No knowledge or feedback re;

3 external proficiency testing, no knowledge of

4 overall action plan or status of same,

5 recommended training for technologists to read

6 controls has not occurred. Overall feeling

7 that QA activities for ER/PR are in place, but

8 not for the remaining IHC service", and then

9 there's another bullet, "Expressed concerns

10 regarding communication; requests for project

11 type work are coming from numerous sources,

12 i.e. clinical chief, IHC chief, without

13 explanation or knowledge of manager, requests

14 for documentation are coming in without

15 knowledge of manager, ER/PR retesting

16 restarted without knowledge of manager,

17 manager informed by technologists after the

18 fact". Now, Doctor, first of all, were you

19 aware that feedback was being sought from

20 immunohistochemistry technologists in late May

21 of '07?

22 DR. ELMS:

23 A. No.

24 COFFEY, Q.C.:

25 Q. Were you made aware of what's referred to

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<p>1 here?</p> <p>2 DR. ELMS:</p> <p>3 A. No.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. When did you first become aware that at least</p> <p>6 in May of 2007 this reports that these are the</p> <p>7 technologists concerns?</p> <p>8 DR. ELMS:</p> <p>9 A. During the course of the inquiry.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Okay, at some point in the --</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. In the interviews or at some point in time,</p> <p>16 anyway, you became aware of this?</p> <p>17 DR. ELMS:</p> <p>18 A. Yes.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. Doctor, can I ask you then, from your</p> <p>21 perspective as the Director of</p> <p>22 Immunohistochemistry, whose responsibility at</p> <p>23 least as of May, 2007, up to that point, had</p> <p>24 it been to deal with the technologists in this</p> <p>25 regard?</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. You've generally been carrying your share of</p> <p>3 the full time equivalent load?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. As a staff pathologist and also doing this</p> <p>8 daily visit to the IHC part of the lab?</p> <p>9 DR. ELMS:</p> <p>10 A. Yes, and since May it's become far more acute.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. May of this year?</p> <p>13 DR. ELMS:</p> <p>14 A. Of this year.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. And I take it that's because of the shortage</p> <p>17 of pathologists?</p> <p>18 DR. ELMS:</p> <p>19 A. Yes.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Doctor, since becoming aware of this document</p> <p>22 and the things referred to in it since the</p> <p>23 inquiry process started, have you made any</p> <p>24 inquiries to ascertain whether these have been</p> <p>25 addressed?</p>
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<p>1 DR. ELMS:</p> <p>2 A. Mr. Gulliver and Mr. Dyer.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. Did any of the technologists ever complain to</p> <p>5 you about the matter --</p> <p>6 DR. ELMS:</p> <p>7 A. No.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. These matters?</p> <p>10 DR. ELMS:</p> <p>11 A. No.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And in that regard, Doctor, how much time as</p> <p>14 the Director do you get to spend in the</p> <p>15 General Hospital in the IHC part of the lab?</p> <p>16 DR. ELMS:</p> <p>17 A. I spend roughly two hours a day.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And what, if any, adjustments are made in the</p> <p>20 rest of your pathology workload to allow that?</p> <p>21 DR. ELMS:</p> <p>22 A. As Dr. Denic has been able to do so, I have</p> <p>23 had my workload reduced, but that has not</p> <p>24 always been -- for the most part, that hasn't</p> <p>25 been possible.</p>	<p>1 DR. ELMS:</p> <p>2 A. Yes.</p> <p>3 COFFEY, Q.C.:</p> <p>4 Q. And what have you found?</p> <p>5 DR. ELMS:</p> <p>6 A. Some of them have. We have consolidated our</p> <p>7 process of reviewing our external proficiency</p> <p>8 testing, and we always discussed them as they</p> <p>9 came in, but now we discuss the actual results</p> <p>10 in tabulated form. "The recommended training</p> <p>11 for technologists to read controls" has been</p> <p>12 ongoing. That's part of what I go to the</p> <p>13 Health Sciences every day for, actually, is to</p> <p>14 read the controls with the technologists prior</p> <p>15 to release of the cases, and again, as I say,</p> <p>16 now in the fall I'll be formalizing that more</p> <p>17 with a series of lectures. "The overall</p> <p>18 feeling that QA activities for ER/PR are in</p> <p>19 place, but not for the remaining IHC service",</p> <p>20 we are developing our control bank and my</p> <p>21 understanding is that the total quality</p> <p>22 initiatives is -- that that may be a feeling,</p> <p>23 but it's not necessarily a reality, promoting</p> <p>24 QA activities for IHC. "Request for project</p> <p>25 type work coming from numerous sources", I'm</p>

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<p>1 assuming that refers to validations and the 2 running of the lab. That has certainly been 3 tightened up. "Request for documentation 4 coming in without knowledge of the manager", 5 I'm not sure what that refers to. I mean, 6 what kind of documentation we're talking 7 about. 8 COFFEY, Q.C.: 9 Q. And the ER/PR retesting? 10 DR. ELMS: 11 A. The ER/PR retesting was started. I informed 12 my supervisor, Dr. Denic at the time, that we 13 were ready to restart. 14 COFFEY, Q.C.: 15 Q. And if Mr. Dyer didn't know, then you had 16 anticipated, I take it, Dr. Denic would pass 17 that on? 18 DR. ELMS: 19 A. I had anticipated he would pass that on. 20 COFFEY, Q.C.: 21 Q. Doctor, in terms of QA activities for ER and 22 PR, I take it they are in place from your 23 perspective? 24 DR. ELMS: 25 A. Yes.</p>	<p>1 activities, I'm not exactly sure what QA is 2 doing, but we need to -- that's an area where 3 we're still working. 4 COFFEY, Q.C.: 5 Q. So from your perspective in terms of the 6 ER/PR, you've described those? 7 DR. ELMS: 8 A. Yes. 9 COFFEY, Q.C.: 10 Q. For the other stains, are there any other 11 stains? 12 DR. ELMS: 13 A. The other stains are in development. 14 COFFEY, Q.C.: 15 Q. That's in development process? 16 DR. ELMS: 17 A. Yes. As I said, we still haven't been sending 18 out a proportion of our other stains, and we 19 are also involved in -- as I said, we're also 20 involved in proficiency testing, and that 21 proficiency testing program, they don't only 22 relate to ER/PR and HER2. CIQC so far has -- 23 we have done -- we do several other spot check 24 stains with our NEQAS, and our CAP, and the 25 QMPLS programs.</p>
<p>Page 322</p> <p>1 COFFEY, Q.C.: 2 Q. And they are what? 3 DR. ELMS: 4 A. Pardon? 5 COFFEY, Q.C.: 6 Q. They are what? 7 DR. ELMS: 8 A. Again the usual monitoring of our machines, 9 the retesting, the performance of our 10 controls, and the retesting we just referred 11 to earlier. 12 COFFEY, Q.C.: 13 Q. Retesting at Mount Sinai? 14 DR. ELMS: 15 A. Yeah, the sending away of a larger percentage 16 than recommended, actually, of cases for 17 retesting. 18 COFFEY, Q.C.: 19 Q. And how about other stains? 20 DR. ELMS: 21 A. That work is ongoing. We have had to build up 22 a control bank and we are still building that 23 up. We do provide a control with every slide, 24 and as I say, the slides are reviewed by 25 myself before they go out, and the remaining</p>	<p>Page 324</p> <p>1 COFFEY, Q.C.: 2 Q. And how about validation of all these other 3 stains? 4 DR. ELMS: 5 A. The validation is an ongoing process as well. 6 We're working on validating them now. 7 COFFEY, Q.C.: 8 Q. Is there any particular master list, like, how 9 many are you through, how many have you got to 10 go, and I appreciate there will always be new 11 stains? 12 DR. ELMS: 13 A. We should have -- we do have a list of our 14 signed off protocols. 15 COFFEY, Q.C.: 16 Q. For individual stains? 17 DR. ELMS: 18 A. For individual stains. 19 COFFEY, Q.C.: 20 Q. Can you give us a ballpark figure as to how 21 many have been validated? 22 DR. ELMS: 23 A. Ten to fifteen. That's very ballpark. 24 COFFEY, Q.C.: 25 Q. And I appreciate it's a ballpark figure, but</p>

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<p>1 ER and PR, the two of those --</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. And they were the first two?</p> <p>6 DR. ELMS:</p> <p>7 A. Yes.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Exhibit P-2130, please. Actually, I'm sorry,</p> <p>10 2272. Doctor, this is -- the first page is a</p> <p>11 fax coversheet to Paul Neil, but attached to</p> <p>12 it is an e-mail from Dr. Nash Denic, with a</p> <p>13 memorandum below it of May 31st, 2007, to</p> <p>14 pathologists in Newfoundland and Labrador.</p> <p>15 It's from him and Dr. Carter. He refers to --</p> <p>16 it says, "Please find enclosed a number of</p> <p>17 evidence-based policies in current use at the</p> <p>18 St. John's hospitals of Eastern Health", and</p> <p>19 it goes on from there. He continues on at the</p> <p>20 second page, page 2 of 3 of this, saying, "I'm</p> <p>21 inviting all lab directors to pay us a visit</p> <p>22 and view the IHC lab", and he goes on to talk</p> <p>23 about that, and suggestions can be forwarded</p> <p>24 to him and/or Dr. Ford Elms. Doctor, to your</p> <p>25 knowledge, did any of your colleagues across</p>	<p>1 IHC?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes, I mean, we discuss it informally. I have</p> <p>4 not had any formal request or concerns about</p> <p>5 particular issues.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. Here at the top of this second page at the e-</p> <p>8 mail he says, "At this visit you can get</p> <p>9 familiarized with issues and recommendations</p> <p>10 by external reviewers and the accomplishments</p> <p>11 of the IHC lab pertaining to ER/PR testing and</p> <p>12 reporting". So the issues and recommendations</p> <p>13 by external reviewers, have you ever been</p> <p>14 asked by any of your colleagues across the</p> <p>15 province as to what they were?</p> <p>16 DR. ELMS:</p> <p>17 A. No.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. For example, the issues?</p> <p>20 DR. ELMS:</p> <p>21 A. No.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. This particular exhibit, fourth page of it,</p> <p>24 and this was faxed out to Dr. Neil as</p> <p>25 apparently this had been missed and the e-mail</p>
<p>1 the province take you up on this offer?</p> <p>2 DR. ELMS:</p> <p>3 A. No.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. They haven't been to visit the lab, at least</p> <p>6 that you're aware of?</p> <p>7 DR. ELMS:</p> <p>8 A. Not that I'm aware of.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Have you been consulted by any of your</p> <p>11 colleagues across the province about this?</p> <p>12 DR. ELMS:</p> <p>13 A. About?</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. IHC service, and generally what the status is?</p> <p>16 DR. ELMS:</p> <p>17 A. Not in general. I have been consulted about</p> <p>18 particular cases, but not IHC in general.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. How about your colleagues in St. John's?</p> <p>21 Particular cases, I take it, but --</p> <p>22 DR. ELMS:</p> <p>23 A. Again particular cases.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. How about in terms of the lab service overall,</p>	<p>1 sent out to him, he's told us. This particular</p> <p>2 one, breast needle core biopsy standardized</p> <p>3 reporting, there's this one, and there were a</p> <p>4 number of others went out at that time. Were</p> <p>5 you aware that these were being sent out in</p> <p>6 May of 2007?</p> <p>7 DR. ELMS:</p> <p>8 A. I'd need to see the --</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Sure.</p> <p>11 DR. ELMS:</p> <p>12 A. I know that they were -- that our fixation</p> <p>13 policy was being sent out, but I'm not sure --</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Okay, that's -- so you were aware that that</p> <p>16 was -- made aware that was going out?</p> <p>17 DR. ELMS:</p> <p>18 A. Yes.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And your understanding of the purpose in doing</p> <p>21 so was what?</p> <p>22 DR. ELMS:</p> <p>23 A. Was to bring greater standardization to the</p> <p>24 process across the province.</p> <p>25 COFFEY, Q.C.:</p>

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1 Q. In terms of that fixation policy, I take it
 2 that wasn't limited to ER and PR breast
 3 tissue?
 4 DR. ELMS:
 5 A. No, that was limited to -- that was how to fix
 6 tissue.
 7 COFFEY, Q.C.:
 8 Q. Period?
 9 DR. ELMS:
 10 A. Period.
 11 COFFEY, Q.C.:
 12 Q. And fixation of tissue, period, as it were,
 13 could influence all these other stains
 14 potentially?
 15 DR. ELMS:
 16 A. Potentially.
 17 COFFEY, Q.C.:
 18 Q. So it was felt important at the time to have
 19 that distributed?
 20 DR. ELMS:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. Province-wide, because all the other -- even
 24 if ER/PR was being done elsewhere at Mount
 25 Sinai, all the other IHC stains were being

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1 done in St. John's?
 2 DR. ELMS:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. With the exception of HER2/neu?
 6 DR. ELMS:
 7 A. Yes.
 8 COFFEY, Q.C.:
 9 Q. Exhibit P-2130, please. Thank you. Doctor,
 10 these are minutes of a joint laboratory
 11 medicine discipline and program meeting of
 12 September 13, 2007, and there are a number of
 13 individuals present, including yourself. Dr.
 14 Denic, in the first paragraph, stated that the
 15 goal is to have monthly meetings, and he
 16 passed out a schedule for these meetings, and
 17 do you recall what this was about, Doctor, in
 18 terms of your involvement, not this particular
 19 meeting so much as the purpose of this group?
 20 DR. ELMS:
 21 A. This is a meeting of our discipline, the
 22 laboratory medicine discipline, just for us to
 23 get together to discuss, as a body, the issues
 24 going on within the lab.
 25 COFFEY, Q.C.:

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1 Q. And have these meetings continued?
 2 DR. ELMS:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. And how frequently do they?
 6 DR. ELMS:
 7 A. Not monthly, unfortunately, especially most
 8 recently, but we do have these meetings, and
 9 Dr. Denic convenes them as we can have them.
 10 COFFEY, Q.C.:
 11 Q. Sure. Subspecialty task groups, paragraph
 12 seven, says, "It is expected from the members
 13 of subspecialty groups to start working on
 14 terms of reference for each group, which will
 15 be presented at the next meeting. In the
 16 future, all pathologists will be involved in
 17 QA/QC of the surgical pathology reports. A
 18 letter in this regard was passed out to the
 19 pathologists". Doctor, talking about
 20 subspecialties, would IHC be considered a
 21 subspecialty?
 22 DR. ELMS:
 23 A. Not in this context.
 24 COFFEY, Q.C.:
 25 Q. In this context.

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1 DR. ELMS:
 2 A. No.
 3 COFFEY, Q.C.:
 4 Q. Exhibit P-2306. This is a joint laboratory
 5 medicine discipline and program meeting of
 6 October 11, 2007, and you're present.
 7 Paragraph eight reads, "IHC report. Dr. F.
 8 Elms reported that ER/PR and HER2/neu testing
 9 has been validated for new antibodies being
 10 used for testing at present, SP3 and AO485.
 11 Soon this test will be conducted on site.
 12 Prostate related antibodies are next to be
 13 validated". Doctor, we spoke earlier about ER
 14 and PR being validated, and I take it that
 15 that was the validation that had occurred
 16 early in '07?
 17 DR. ELMS:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. The HER2/neu testing, had that, in fact, from
 21 your perspective, been validated locally?
 22 DR. ELMS:
 23 A. Yes, it had been validated by that point.
 24 COFFEY, Q.C.:
 25 Q. And these two new antibodies, they relate to

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1 what?
 2 DR. ELMS:
 3 A. They are the HER2/neu antibodies. The SP3 is
 4 the monoclonal, the specific one, and the
 5 AO485 is the polyclonal.
 6 COFFEY, Q.C.:
 7 Q. And HER2/neu did not start here again?
 8 DR. ELMS:
 9 A. No.
 10 COFFEY, Q.C.:
 11 Q. For the reasons you've enunciated earlier?
 12 DR. ELMS:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Exhibit P-0051, please. Doctor, this is a
 16 report from QMPLS. It's on site consultation
 17 report for Newfoundland, date and time of on
 18 site consultation is December 7, 2007, and the
 19 name of the laboratory is the immunopathology
 20 laboratory at Eastern Health.
 21 COFFEY, Q.C.:
 22 Q. Uh-hm, yes.
 23 COFFEY, Q.C.:
 24 Q. Doctor, you would have received a copy of
 25 this?

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1 DR. ELMS:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. Can you tell us, please, or give us your
 5 observations in relation to this? Do you
 6 recall when you received it and what your
 7 observations were?
 8 DR. ELMS:
 9 A. I received it early in January, I believe it
 10 was, of this year, and I received a copy
 11 through Dr. Denic. It was quite valuable, it
 12 was actually quite reassuring that we had --
 13 we had come a good way with regard to this. It
 14 was very heartening for our technologists as
 15 well that they had -- that all of us together
 16 had worked to bring the lab up to the position
 17 that it was. They felt that -- QMPLS felt that
 18 we were certainly in the middle of the pack,
 19 and made some very, very good comments about
 20 our status, and some good recommendations as
 21 to how to proceed, most of which we were
 22 already in the process of bringing on.
 23 COFFEY, Q.C.:
 24 Q. Now having read this, how about in terms of
 25 distance to go to things to do?

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1 DR. ELMS:
 2 A. We still need to -- we still needed to work on
 3 our SOP's, we still needed to work on our --
 4 to tighten up our control procedures, and we
 5 certainly need to work on communication within
 6 our department.
 7 COFFEY, Q.C.:
 8 Q. Deal with the last first, communications
 9 within the department --
 10 DR. ELMS:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. What did --
 14 DR. ELMS:
 15 A. Well, for me that meant communication between
 16 myself and the technological management of the
 17 lab, Mr. Dyer and Mr. Gulliver.
 18 COFFEY, Q.C.:
 19 Q. And what, if anything, have you done in that
 20 regard?
 21 DR. ELMS:
 22 A. We have -- we've worked at being more -- we
 23 still haven't formalized meetings and this
 24 type of thing, added to which Mr. Dyer has
 25 been off for several months, but we are in

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1 close communication.
 2 COFFEY, Q.C.:
 3 Q. Communication -- I'm sorry, the other two
 4 were?
 5 DR. ELMS:
 6 A. We need to -- we're working still on
 7 tightening up our control procedures.
 8 COFFEY, Q.C.:
 9 Q. And what does that mean, tightening up
 10 controls?
 11 DR. ELMS:
 12 A. Well, what I mean by that is we're working at
 13 developing a control bank because that was the
 14 recommendation made earlier, and dealing with
 15 some of the logistics of how we run our
 16 controls. We have -- also as I said, we're
 17 tightening up our documentation and our SOP's
 18 specifically, which is an ongoing process,
 19 anyway.
 20 COFFEY, Q.C.:
 21 Q. QMPLS were in St. John's in early December of
 22 2007, December 7th, in particular. The actual
 23 number of SOP's that have been signed off were
 24 very few, I take it?
 25 DR. ELMS:

<p style="text-align: right;">Page 337</p> <p>1 A. There were very few at that point, yes.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Very few at that point, and some of them at</p> <p>4 the time existed in draft form?</p> <p>5 DR. ELMS:</p> <p>6 A. In draft form.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. The bulk of them had been prepared or created</p> <p>9 when?</p> <p>10 DR. ELMS:</p> <p>11 A. Last fall around -- between September and</p> <p>12 November of 2007.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And you had become aware that QMPLS was coming</p> <p>15 when, when did you first become aware that</p> <p>16 they were --</p> <p>17 DR. ELMS:</p> <p>18 A. Again the course of -- when Dr. Denic arranged</p> <p>19 it, he had contacted me and let me know.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Has any list of recommendations been made,</p> <p>22 like a spreadsheet list made in relation to</p> <p>23 this report?</p> <p>24 DR. ELMS:</p> <p>25 A. Not in relation to that report.</p>	<p style="text-align: right;">Page 339</p> <p>1 outside centres. We've already begun this</p> <p>2 process for breast tissue. As you are aware,</p> <p>3 we are working on a system of controls to be</p> <p>4 done and held in our lab for review". Signed,</p> <p>5 Ford Elms. Now, Doctor, was there any further</p> <p>6 detailed analysis?</p> <p>7 DR. ELMS:</p> <p>8 A. I did discuss the report with Dr. Denic in</p> <p>9 detail.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. Was it ever reduced to writing, any further</p> <p>12 analysis?</p> <p>13 DR. ELMS:</p> <p>14 A. No.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. To your knowledge, has there been by you or</p> <p>17 anyone else?</p> <p>18 DR. ELMS:</p> <p>19 A. No.</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. Do you know how far along you are in terms of</p> <p>22 implementing the recommendations that are in</p> <p>23 the report?</p> <p>24 DR. ELMS:</p> <p>25 A. We have -- as I mentioned in that letter, we</p>
<p style="text-align: right;">Page 338</p> <p>1 COFFEY, Q.C.:</p> <p>2 Q. Any reason why not?</p> <p>3 DR. ELMS:</p> <p>4 A. Largely as a result of time and ability to do</p> <p>5 so.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. If you could look, please, at Exhibit P-2305.</p> <p>8 This is an e-mail -- it's actually several e-</p> <p>9 mails, but there's one of January 14th, 2008,</p> <p>10 at the bottom of the page there to Dr. Denic</p> <p>11 from Brenda Todd at QMPLS, advising Dr. Denic</p> <p>12 that the report is attached, the report we</p> <p>13 just looked at, and then Dr. Denic on January</p> <p>14 15th forwarded it to a number of individuals,</p> <p>15 including yourself, and then on January 15th</p> <p>16 at 12:49 p.m., you wrote to Dr. Denic as</p> <p>17 follows, "I've read the report and will make a</p> <p>18 more detailed analysis and comments on it</p> <p>19 shortly. At this time, I note some very</p> <p>20 helpful recommendations as to how we can fine</p> <p>21 tune our documentation of times and fixation,</p> <p>22 et cetera. Further, they suggest we use</p> <p>23 controls of varying fixation times for at</p> <p>24 least specimens reflect varying times tissue</p> <p>25 spends in formalin when it is referred in from</p>	<p style="text-align: right;">Page 340</p> <p>1 have worked at developing control tissues for</p> <p>2 breast tissue based on different times and</p> <p>3 fixation in formalin, and we are still working</p> <p>4 on a control bank. We're coming along very</p> <p>5 well now with that. One of the great benefits</p> <p>6 of that is that we have hired Ms. Gamberg, who</p> <p>7 has looked after a lot of those issues.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. She was retained or brought in when?</p> <p>10 DR. ELMS:</p> <p>11 A. I believe it was February or March of this</p> <p>12 year.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. How about any other recommendations there, and</p> <p>15 there are a number of them?</p> <p>16 DR. ELMS:</p> <p>17 A. I'd have to look down through them to --</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. And I appreciate that, and we can go through</p> <p>20 it kind of line for line, or paragraph to</p> <p>21 paragraph, sorry, and at times line for line.</p> <p>22 DR. ELMS:</p> <p>23 A. Yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. But in terms of systematically going through</p>

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1 and, as it were, extracting a recommendation,
 2 what could be said to be a recommendation and
 3 putting it kind of number one, number two,
 4 number three, listing out however many there
 5 are --
 6 DR. ELMS:
 7 A. We haven't systematically done that, no.
 8 COFFEY, Q.C.:
 9 Q. I'll just pick one, as an example, page four -
 10 if we could go back, please, to P-0051, page
 11 four, under "Documentation/recording keeping",
 12 and "we recommend that Ventana data backups be
 13 performed on a daily or weekly basis to
 14 protect the integrity of the Ventana System
 15 information. Please see Section 9.0 for
 16 quality control recommendations". Do you know,
 17 for example, if data backups --
 18 DR. ELMS:
 19 A. That one hasn't been done. To do that wipes
 20 the material off the machine and we found that
 21 that wasn't feasible for us. We're still
 22 doing our six month backups.
 23 COFFEY, Q.C.:
 24 Q. I take it that's using a zip drive?
 25 DR. ELMS:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Is there any reason that couldn't be done
 4 using a zip drive daily?
 5 DR. ELMS:
 6 A. As I say, it takes the information off the
 7 machine from a day-to-day basis, so it makes
 8 it more difficult for us to be able to compare
 9 from day to day.
 10 COFFEY, Q.C.:
 11 Q. So in making a backup, you take all --
 12 DR. ELMS:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. The process takes the information off the
 16 Ventana computer?
 17 DR. ELMS:
 18 A. Yes, that's what I've been advised by my tech
 19 staff.
 20 COFFEY, Q.C.:
 21 Q. Doctor, do you think it might be worthwhile to
 22 actually have someone make a listing of all
 23 what could be made recommendations?
 24 DR. ELMS:
 25 A. Definitely.

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1 COFFEY, Q.C.:
 2 Q. And then you could kind of check them off or
 3 at least make a note as to where -
 4 DR. ELMS:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. - as a group you are. Exhibit P-2157? This
 8 is a large document, yes. Sorry. Thank you,
 9 Registrar. Doctor, this is a document,
 10 "Pathology Policies and Procedures Manual,
 11 Table of Contents." The first page here is
 12 "Pathology policies," and there are a list of
 13 them there. There's seven, I think, here on
 14 this page. And then the pathology procedures
 15 begin at page 2 of the document. And the
 16 table of contents continues on the third page
 17 and so on. Doctor, I'm going to take you
 18 through to, if I could, please, page 201?
 19 Doctor, this particular one is entitled
 20 "Pathology Procedure" the second is "Anatomic
 21 Pathology/Immunohistochemistry" and there's a
 22 number associated with it titled
 23 "Immunohistochemistry Stain Process Flow
 24 Chart." Issuing authority is yourself?
 25 DR. ELMS:

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1 A. Um-hm.
 2 COFFEY, Q.C.:
 3 Q. And the signature is March 17th, 2008. The
 4 author is Ken Green and the issue date is
 5 March 19th, 2008 and date effective, March
 6 19th, 2008. And there's a space for revision
 7 dates?
 8 DR. ELMS:
 9 A. Yeah.
 10 COFFEY, Q.C.:
 11 Q. And, Doctor, if you can just--the next page is
 12 noted to be left blank intentionally. And
 13 then page 203 of the exhibit is titled
 14 "Ancillary Products, Records" and again, its
 15 issuing authority is yourself. And then as we
 16 go through, on page 205 again there's another
 17 entitled "Ordering Class Slides" and issuing
 18 authority is yourself. The author is Ken
 19 Green. I could take you through a number of
 20 them here. I just collected them here at the
 21 end of the book that's there in front of you.
 22 Doctor, how is it that you--how is it
 23 determined that you are the issuing authority
 24 and Mr. Green is the author and what process
 25 is utilized for this?

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<p>1 DR. ELMS: 2 A. When it became--well, when I was told I was 3 required to write the SOPs, there's a 4 significant number of SOPs that relate to the 5 technological running of the test, the running 6 of the machines, this type of thing. Mr. 7 Green is my lead tech and he has been an 8 invaluable aid in this. He actually compiled 9 most of the SOPs, especially the ones to do 10 with the technological aspects. We were then-- 11 these were written out in rough form by hand. 12 We then submitted them to Ms. Wade, who passed 13 them on to Quality Assurance. And I guess my 14 name is there as issuing authority because I'm 15 the medical director of immunohistochemistry.</p> <p>16 COFFEY, Q.C.: 17 Q. So you would perhaps see them in draft form?</p> <p>18 DR. ELMS: 19 A. Yes.</p> <p>20 COFFEY, Q.C.: 21 Q. Handwritten form and get a typed version and 22 say, okay, I'm satisfied with that and signify 23 that and -</p> <p>24 DR. ELMS: 25 A. Yes.</p>	<p>1 of time and it's quite conceivable that they 2 were submitted to QA all at the same time.</p> <p>3 COFFEY, Q.C.: 4 Q. And, Doctor, currently, I take it, and we 5 referred to this earlier, that ER and PR 6 reporting is not going on in St. John's?</p> <p>7 DR. ELMS: 8 A. Not since the beginning of May.</p> <p>9 COFFEY, Q.C.: 10 Q. Not since the beginning--since May of 2008?</p> <p>11 DR. ELMS: 12 A. Of 2008.</p> <p>13 COFFEY, Q.C.: 14 Q. What is the plan right now?</p> <p>15 DR. ELMS: 16 A. The plan is to return to ER/PR testing when 17 the situation permits. That would require 18 reconstituting our breast group, so we would 19 need to find--Dr. Makretzov has agreed to be 20 the core. We would need to find another two 21 people, at most, to function as a breast 22 group. It will also require revalidation of 23 the antibody.</p> <p>24 COFFEY, Q.C.: 25 Q. And why is that?</p>
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<p>1 COFFEY, Q.C.: 2 Q. - and then it would be approved?</p> <p>3 DR. ELMS: 4 A. Yes.</p> <p>5 COFFEY, Q.C.: 6 Q. And issued. And if we look, in fact, this 7 particular one is March 17th, 2008. And then 8 page 203, it's issued and you're the issuing 9 authority, March 17th, 2008. Page 205, same 10 thing, different pathology procedure. Page 11 207, same thing, you're the issuing authority, 12 March 17th and it's a different title or 13 aspect of the matter. And we go on through, 14 there's another one at page 209 of the exhibit 15 issued by yourself March 17, 2008. And page 16 211 of the exhibit the same thing. There are 17 quite a number of them.</p> <p>18 DR. ELMS: 19 A. Yes.</p> <p>20 COFFEY, Q.C.: 21 Q. March 17, 2008. Is there any particular 22 reason why it was March 17, 2008 that a group 23 of them got issued?</p> <p>24 DR. ELMS: 25 A. Mr. Green was compiling them over the course</p>	<p>1 DR. ELMS: 2 A. Because over time antibody specificity can 3 drift. If you're running daily controls and 4 you're reading daily controls, you can pick it 5 up before it becomes significant, so you can 6 see, for instance, your stain weakening if 7 you're seeing the same control tissue every 8 day. We have not been doing that now since 9 May, so therefore I would need to--I wouldn't 10 be comfortable without going back and 11 revalidating it because I don't know what 12 drift may or may not have occurred in the 13 course of that time.</p> <p>14 COFFEY, Q.C.: 15 Q. And what would cause such drift or could cause 16 such drift?</p> <p>17 DR. ELMS: 18 A. It has to do with degradation of the antibody 19 over time. It's a protein product and it 20 would gradually break down.</p> <p>21 COFFEY, Q.C.: 22 Q. Okay, the actual--the chemical?</p> <p>23 DR. ELMS: 24 A. Yeah.</p> <p>25 COFFEY, Q.C.:</p>

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<p>1 Q. Or chemicals in the liquid form?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Exhibit P-1840? How long, Doctor, would</p> <p>6 validation take?</p> <p>7 DR. ELMS:</p> <p>8 A. Revalidation of this nature might take me a</p> <p>9 week.</p> <p>10 COFFEY, Q.C.:</p> <p>11 Q. And, Doctor, this is a letter of April 14th,</p> <p>12 2008, it's addressed to myself as Commission</p> <p>13 co-counsel. It's from Dr. Mullen, Brendan</p> <p>14 Mullen. And he had examined a number of</p> <p>15 individual original slides, ER/PR slides.</p> <p>16 Have you seen this? Take your time, Doctor,</p> <p>17 I'll just bring it back up and just -</p> <p>18 DR. ELMS:</p> <p>19 A. I believe this was entered into evidence</p> <p>20 previous in the Inquiry?</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. Yes, oh, yes.</p> <p>23 DR. ELMS:</p> <p>24 A. So I would--I saw it over the course of that.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 any thoughts or observations on this, what Dr.</p> <p>2 Mullen reported as, at least in his view in</p> <p>3 terms of looking at these 539 cases that go</p> <p>4 back to the--there are a portion of the case</p> <p>5 during the time period?</p> <p>6 DR. ELMS:</p> <p>7 A. I'm not sure -</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Did you have any thought at the time in terms</p> <p>10 of, well, did you take any issue with</p> <p>11 anything?</p> <p>12 DR. ELMS:</p> <p>13 A. Did I take issue with anything?</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. Yes.</p> <p>16 DR. ELMS:</p> <p>17 A. I certainly didn't--I wasn't aware that to say</p> <p>18 that the overwhelming majority of issue was to</p> <p>19 do with anything specific. As I say, I had</p> <p>20 seen my own cases, but I was looking at the</p> <p>21 results of someone who had looked at, you</p> <p>22 know, the majority of the cases across the--</p> <p>23 across our organization.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. The fact that, for example, internal controls</p>
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<p>1 Q. And at the bottom of the first page he says,</p> <p>2 "To summarize my observations, the</p> <p>3 overwhelming majority of cases had one or more</p> <p>4 of the following problems: (1) Poor fixation</p> <p>5 or processing resulting in incomplete tissue</p> <p>6 sections; loss of the internal structure of</p> <p>7 the nucleus; and staining restricted to the</p> <p>8 periphery of the slide." And he goes on from</p> <p>9 there, talks about exploding sections and so</p> <p>10 on. Her refers to hollow nuclei as the second</p> <p>11 issue and the third issue, staining restricted</p> <p>12 to the periphery. He in paragraph 2 refers to</p> <p>13 the absence of internal controls, that would</p> <p>14 be for any particular slide or slides. And</p> <p>15 negative internal controls where the tissue</p> <p>16 was, normal tissue was present but not</p> <p>17 stained, or stained very weakly. And stain</p> <p>18 deposit obscuring morphology and external</p> <p>19 controls and them being inconsistent both</p> <p>20 between slides and within slides, some had</p> <p>21 barely stained. And then discrepancy between</p> <p>22 internal and external controls, and he found</p> <p>23 that only in one or two--of the--two of the</p> <p>24 539 cases he had reviewed. Now, Doctor, when</p> <p>25 you had a chance to review this, did you have</p>	<p>1 might be there but not stained, be negative,</p> <p>2 in your own individual case for a period of</p> <p>3 time you had not been even aware to have</p> <p>4 internal controls?</p> <p>5 DR. ELMS:</p> <p>6 A. Exactly, exactly.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. So that wouldn't be--if they weren't stained,</p> <p>9 you wouldn't be surprised by it?</p> <p>10 DR. ELMS:</p> <p>11 A. No.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. Or the fact that there wasn't any internal</p> <p>14 control tissue there?</p> <p>15 DR. ELMS:</p> <p>16 A. Again, no, I wouldn't be surprised.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. You wouldn't be surprised by that. Doctor,</p> <p>19 the idea of, the issue of fixation itself and</p> <p>20 the various problems that can have for ER and</p> <p>21 PR staining, you know, knowing what you do</p> <p>22 now, what if any steps, you know, in your</p> <p>23 position have you taken to address that?</p> <p>24 DR. ELMS:</p> <p>25 A. Well, personally I haven't taken steps, but</p>

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<p>1 our -</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Or what are you aware of?</p> <p>4 DR. ELMS:</p> <p>5 A. - department has. So that we now have a</p> <p>6 fixation policy, we document the time that the</p> <p>7 tissue goes in formalin, we document the time</p> <p>8 that it--or we document, rather, when it</p> <p>9 arrives in the lab. In the case of specimens</p> <p>10 like breast, for instance, they're brought to</p> <p>11 us fresh, the times are documented, the tissue</p> <p>12 is incised and fixed properly. So, I mean,</p> <p>13 the issue of fixation, to my way of thinking</p> <p>14 now, is--has been dealt with.</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Have there been any concerns expressed to you</p> <p>17 about fixation or tissue processing since you</p> <p>18 took over as director?</p> <p>19 DR. ELMS:</p> <p>20 A. No.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. In terms of current cases?</p> <p>23 DR. ELMS:</p> <p>24 A. In terms of current cases, no.</p> <p>25 COFFEY, Q.C.:</p>	<p>1 but I have no recollection of having done so.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Doctor, in that regard, you know, here in</p> <p>4 2005, just thinking about it now in terms of</p> <p>5 Peggy Deane, you reported it to, well, Dr.</p> <p>6 Rorke?</p> <p>7 DR. ELMS:</p> <p>8 A. Um-hm.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. And Dr. Cook?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And from your perspective now, as a staff</p> <p>15 pathologist at the time, throughout '05, was</p> <p>16 there any immediate steps taken to do any</p> <p>17 retesting of anyone else in April of 2005?</p> <p>18 DR. ELMS:</p> <p>19 A. When -</p> <p>20 COFFEY, Q.C.:</p> <p>21 Q. I mean by yourself?</p> <p>22 DR. ELMS:</p> <p>23 A. When I--I didn't take any steps to retest my</p> <p>24 cases, no.</p> <p>25 COFFEY, Q.C.:</p>
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<p>1 Q. Nothing brought to your attention?</p> <p>2 DR. ELMS:</p> <p>3 A. No.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Doctor, one final point, if we could. Again,</p> <p>6 please, at Exhibit C-0174? Doctor, this is</p> <p>7 the case involving a request by Dr. Zaidi I</p> <p>8 showed you earlier.</p> <p>9 DR. ELMS:</p> <p>10 A. Um-hm.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. And, you know, this change in result which is</p> <p>13 reflected here between addendum 2 and addendum</p> <p>14 3 that occurred in 2002, 2003, as you can see</p> <p>15 there, are you able to tell the Commissioner</p> <p>16 why it was that in 2005 you brought the matter</p> <p>17 to the attention of Dr. Cook, the conversion</p> <p>18 for Peggy Deane, and as best you can recall,</p> <p>19 and if you don't recall bringing it to his</p> <p>20 attention in '03, why that was?</p> <p>21 DR. ELMS:</p> <p>22 A. I may have, I may not have, I'm not have; I'm</p> <p>23 not sure. I reported it to the clinician</p> <p>24 involved. As I say, I'm not sure that I</p> <p>25 didn't do that, didn't report it to Dr. Cook,</p>	<p>1 Q. And to your knowledge did anyone?</p> <p>2 DR. ELMS:</p> <p>3 A. No.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. In your department?</p> <p>6 DR. ELMS:</p> <p>7 A. No.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. So as you described to the Commissioner</p> <p>10 earlier today, it was when the oncologists</p> <p>11 began to come forward with a case or two</p> <p>12 afterward?</p> <p>13 DR. ELMS:</p> <p>14 A. Yes, there was -</p> <p>15 COFFEY, Q.C.:</p> <p>16 Q. Expressions of concern?</p> <p>17 DR. ELMS:</p> <p>18 A. Yes.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. That that resulted in them individual cases</p> <p>21 being retested and then more and more?</p> <p>22 DR. ELMS:</p> <p>23 A. Yes.</p> <p>24 COFFEY, Q.C.:</p> <p>25 Q. Okay. Thank you, Commissioner. Thank you,</p>

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1 Doctor.
 2 THE COMMISSIONER:
 3 Q. Mr. Pritchard, do you have any questions of
 4 this witness?
 5 MR. PRITCHARD:
 6 Q. No, Commissioner, I don't have any questions
 7 of this witness. Thank you, Doctor.
 8 THE COMMISSIONER:
 9 Q. Mr. Simmons?
 10 MR. SIMMONS:
 11 Q. I have a few questions, Madam Commissioner. I
 12 wonder at this point if either counsel know
 13 and they may or may not, if Dr. Elms is coming
 14 back tomorrow anyway?
 15 THE COMMISSIONER:
 16 Q. Well, we'll find out how many others would
 17 wish to question him. Do you have any idea
 18 how long you might need?
 19 MR. SIMMONS:
 20 Q. Maybe 15 or 20 minutes.
 21 THE COMMISSIONER:
 22 Q. All right.
 23 MR. SIMMONS:
 24 Q. We need to reflect on it (inaudible).
 25 THE COMMISSIONER:

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1 Q. Oh, you're always holding out these carrots to
 2 me. Now, oh, Mr. Pritchett?
 3 MR. PRITCHETT:
 4 Q. We have no questions of this witness, thank
 5 you.
 6 THE COMMISSIONER:
 7 Q. Are you going to have any questions, Ms.
 8 Newbury?
 9 MS. NEWBURY:
 10 Q. I don't think so.
 11 MR. PIKE:
 12 Q. No questions.
 13 THE COMMISSIONER:
 14 Q. No questions. Do you have any questions, Mr.
 15 Brocklehurst?
 16 MS. BROCKLEHURST:
 17 Q. Just a couple.
 18 THE COMMISSIONER:
 19 Q. Just a couple?
 20 MS. BROCKLEHURST:
 21 Q. Yes.
 22 THE COMMISSIONER:
 23 Q. Mr. Browne, do you want to weigh in on a
 24 length of time?
 25 MR. BROWNE:

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1 Q. At this point I just have a couple of
 2 questions, I would say about five to ten
 3 minutes, but it may expand or shorten,
 4 depending on the questions they'll be asking.
 5 So I don't anticipate -
 6 THE COMMISSIONER:
 7 Q. We're looking at being able to finish by about
 8 5:00 and I don't know, but I don't imagine our
 9 witness would relish coming back tomorrow if
 10 he doesn't have to.
 11 MR. SIMMONS:
 12 Q. I have my doubts.
 13 THE COMMISSIONER:
 14 Q. Have I read that correctly?
 15 DR. ELMS:
 16 A. You've read that very correctly.
 17 THE COMMISSIONER:
 18 Q. Okay. Mr. Simmons.
 19 MR. SIMMONS:
 20 Q. This may, in fact, mean I'll be shorter rather
 21 than longer, Dr. Elms. Dr. Elms, as you know,
 22 I'm Dan Simmons, I'm the lawyer here for
 23 Eastern Health. I wonder if maybe you could
 24 describe for me a little bit more about what
 25 it is you do as the director of

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1 immunohistochemistry, a bit of a description
 2 of what it means hands on to be in that
 3 position, the type of function you carry out,
 4 the type of tasks that you do in that
 5 position?
 6 DR. ELMS:
 7 A. Well, what I have been doing largely has been
 8 I've had a much more hands-on role with the
 9 validation process than I had originally
 10 anticipated and I also read the controls and
 11 assess the tissue. Also, I look at difficult
 12 cases as a sort of a consultant role for other
 13 pathologists; I've received requests from
 14 other pathologists to assess their cases. And
 15 keep abreast of the literature, assess the
 16 need for new antibodies, the introduction of
 17 new antibodies, getting them validated.
 18 MR. SIMMONS:
 19 Q. Okay. How closely do you work with the
 20 technologists, the technical staff in the
 21 immunohistochemistry lab?
 22 DR. ELMS:
 23 A. Quite closely. We, as I say, we spend upwards
 24 of two hours a day every day. We read the
 25 controls, we discuss the cases. If there's

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1 proficiency testing material to be read, we go
2 through that.

3 MR. SIMMONS:

4 Q. Okay. We know that the historical structure
5 in the lab has had the technologists reporting
6 in a formal way to the pathology manager who
7 reports to the program director. How--does
8 that still work the same way now or have you
9 taken on some role where you have a role in
10 actually instructing or directing the
11 activities of the technologists in the IHC
12 lab?

13 DR. ELMS:

14 A. In terms of, for instance, doing the
15 validations, I have some role, yes. We still
16 have a parallel structure and we're working
17 still at deciding where it is I fit into that
18 structure. Ideally I'd be, I would assume, at
19 much the level of Mr. Dyer in the clinical
20 wing, so to speak, of the management of the
21 IHC lab.

22 MR. SIMMONS:

23 Q. Okay. I take it that when you assumed the
24 position as director of immunohistochemistry,
25 the precise details of what that position was

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1 going to involve may not have been well
2 defined at that point?

3 DR. ELMS:

4 A. That's correct.

5 MR. SIMMONS:

6 Q. And has it been a process as time has gone on
7 of working out how this position fits within
8 the structure and what's the best way to make
9 it work?

10 DR. ELMS:

11 A. That is correct.

12 MR. SIMMONS:

13 Q. Okay. And what has your experience been in
14 the position in regards to dealing with the
15 technologists and the other managers in the
16 system?

17 DR. ELMS:

18 A. It's been very good, actually, the
19 technologists and I work very closely
20 together.

21 MR. SIMMONS:

22 Q. Um-hm.

23 DR. ELMS:

24 A. And as things have improved, they have taken
25 on a more active role in the performance of

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1 tests, in the identification of cases, these
2 types of things. So that, for instance, the
3 reading of the controls, as I say, I've been
4 going over the workhorse controls with them.
5 We read our controls on a daily basis. And as
6 they have become familiar, we're still not at
7 a stage where it's routine that I have
8 designated a technologist to read the controls
9 and send them out, but I'm becoming more and
10 more confident that they're able to do that
11 because they can--they are able to identify
12 things much better now, they take a more, more
13 hands-on control.

14 MR. SIMMONS:

15 Q. Right. There's been recommendations that come
16 out of the external review reports from, among
17 other things, saying that the technologists
18 have a role in reading controls, and we know
19 that historically it has been the pathologists
20 here who have reviewed the external controls
21 and have looked at the internal controls on
22 slides here. Can you tell me are there any
23 particular advantages or disadvantages to
24 having the technologists involved in the
25 review and the reading of the controls, where

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1 do you see that?

2 DR. ELMS:

3 A. In terms of the running of the lab, it's very
4 advantageous because the accepted wisdom sort
5 of within immunohistochemistry now is that the
6 controls should be read by the medical
7 director or the medical director's designate.

8 MR. SIMMONS:

9 Q. Um-hm.

10 DR. ELMS:

11 A. And so the idea behind that is that there
12 should be two people. If the medical director
13 is away, if, God forbid, the medical director
14 is ill, there is someone else who can do it,
15 and so it's always good to have these skills
16 among more than one person in your lab. So
17 there is that benefit to doing that. And that
18 would be the main thing is the sort of a
19 diversification of ability.

20 MR. SIMMONS:

21 Q. Where do you see the technologists role in
22 reading the controls going, how do you see it
23 developing here, will it displace the
24 pathologist's role in reviewing controls or
25 will that continue?

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<p>1 DR. ELMS: 2 A. I would--not so much displace. I know, for 3 instance, in PhenoPath it pretty much had 4 displaces and it was the senior techs who read 5 them. In the lab now I would see it being a 6 joint effort. 7 MR. SIMMONS: 8 Q. Um-hm. 9 DR. ELMS: 10 A. I certainly would not want to have a situation 11 where the technologists were letting go all 12 the controls, and I didn't see them, just 13 because as I said, in immunohistochemistry the 14 general wisdom is that that shouldn't happen. 15 But, I would be very comfortable with, for 16 instance, once I have gone through the 17 histologic processes of them and the techs 18 feel comfortable and we have certified in some 19 fashion their ability to do it, with letting 20 them on a, you know, with them on a day-to-day 21 basis signing out individual cases if need be. 22 But I certainly wouldn't see it as them 23 totally usurping my role as the person who 24 reads the controls. 25 MR. SIMMONS:</p>	<p>1 MR. SIMMONS: 2 Q. Right. What role is she playing now in the 3 IHC lab? 4 DR. ELMS: 5 A. She has been working at developing our control 6 bank. She has taken over from Mr. Green the 7 performance of the validations, the 8 identification of the validation tissue. 9 Prior to her coming on stream myself and Mr. 10 Green would have to search for the cases and 11 that necessarily takes time from both of us; 12 she now does that, prepares the slides, and 13 when we--as we're doing our validation runs, 14 it's she that works through them and then 15 brings them to me and we go over them 16 together. 17 MR. SIMMONS: 18 Q. Her position is an additional position in the 19 IHC lab? 20 DR. ELMS: 21 A. Yes. 22 MR. SIMMONS: 23 Q. In addition to the technologists who were 24 there when you took up your director position, 25 correct?</p>
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<p>1 Q. Right, okay. You mentioned Ms. Gamberg as 2 being someone that knew in the 3 immunohistochemistry service since you have-- 4 and she's joined it since you've become the 5 director, I believe? 6 DR. ELMS: 7 A. Yes. 8 MR. SIMMONS: 9 Q. Yes. Is there a title for her position now, 10 because I--there may not be. 11 DR. ELMS: 12 A. We've mooted the title of technical director, 13 but we don't really have a title for her, as 14 yet. 15 MR. SIMMONS: 16 Q. Right. And what's her background and 17 qualifications? 18 DR. ELMS: 19 A. Her background is in immunology and she has a 20 great deal of experience in quality assurance. 21 MR. SIMMONS: 22 Q. Um-hm. 23 DR. ELMS: 24 A. And so it was for those two areas of expertise 25 that I was most interested in having her.</p>	<p>1 DR. ELMS: 2 A. Yes. 3 MR. SIMMONS: 4 Q. And does she have to perform any duties 5 outside the IHC service? 6 DR. ELMS: 7 A. No. 8 MR. SIMMONS: 9 Q. No. So she is dedicated to the IHC service. 10 And is she a laboratory technologist herself? 11 DR. ELMS: 12 A. Yes. 13 MR. SIMMONS: 14 Q. Yes. In addition to having a background in 15 immunology and I believe she has a PhD in - 16 DR. ELMS: 17 A. Immunology. 18 MR. SIMMONS: 19 Q. In that area, okay. And who is it that 20 primarily directs her work? 21 DR. ELMS: 22 A. That would be me. 23 MR. SIMMONS: 24 Q. And how has that been working out? 25 DR. ELMS:</p>

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<p>1 A. Very well.</p> <p>2 MR. SIMMONS:</p> <p>3 Q. Now you've described the current process for</p> <p>4 antibody validation and if I understand what</p> <p>5 you said, Ms. Gamberg is now going to play a</p> <p>6 role in that, and you've also mentioned</p> <p>7 current--the proficiency testing programs and</p> <p>8 I believe you mentioned four.</p> <p>9 DR. ELMS:</p> <p>10 A. Yes.</p> <p>11 MR. SIMMONS:</p> <p>12 Q. One is the CAP program that has been in place</p> <p>13 for some time?</p> <p>14 DR. ELMS:</p> <p>15 A. Yes.</p> <p>16 MR. SIMMONS:</p> <p>17 Q. If I understand correctly, that's a program</p> <p>18 where the--is it the College of American</p> <p>19 Pathologists operates it?</p> <p>20 DR. ELMS:</p> <p>21 A. Yes.</p> <p>22 MR. SIMMONS:</p> <p>23 Q. And they will send a case consisting of a</p> <p>24 number of slides which are to be reviewed and</p> <p>25 interpreted and reported on by the</p>	<p>1 DR. ELMS:</p> <p>2 A. Yes.</p> <p>3 MR. SIMMONS:</p> <p>4 Q. And the ER/PR, two of the antibodies for which</p> <p>5 Eastern Health participates in the UK NEQAS</p> <p>6 program, I believe?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 MR. SIMMONS:</p> <p>10 Q. And other antibodies as well?</p> <p>11 DR. ELMS:</p> <p>12 A. Yes.</p> <p>13 MR. SIMMONS:</p> <p>14 Q. Okay, and how often are their submissions to</p> <p>15 the UK NEQAS program?</p> <p>16 DR. ELMS:</p> <p>17 A. Quarterly.</p> <p>18 MR. SIMMONS:</p> <p>19 Q. And do you play any role in monitoring the</p> <p>20 results of that, that program?</p> <p>21 DR. ELMS:</p> <p>22 A. Yes.</p> <p>23 MR. SIMMONS:</p> <p>24 Q. And what has your experience been with the</p> <p>25 results for ER/PR testing from the UK NEQAS</p>
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<p>1 pathologists?</p> <p>2 DR. ELMS:</p> <p>3 A. Yes, a number of cases.</p> <p>4 MR. SIMMONS:</p> <p>5 Q. Okay, and the UK NEQAS program we have heard</p> <p>6 about here before.</p> <p>7 DR. ELMS:</p> <p>8 A. Um-hm.</p> <p>9 MR. SIMMONS:</p> <p>10 Q. And if I understand correctly, in that</p> <p>11 program, they will send the laboratory a</p> <p>12 slide, slides that have been prepared by them</p> <p>13 for staining and they will also send, I</p> <p>14 believe, tissue samples for slides to be</p> <p>15 prepared?</p> <p>16 DR. ELMS:</p> <p>17 A. No, they send slides prepared by them.</p> <p>18 MR. SIMMONS:</p> <p>19 Q. Yes.</p> <p>20 DR. ELMS:</p> <p>21 A. And then we prepare equivalent slides from our</p> <p>22 own in-house tissue.</p> <p>23 MR. SIMMONS:</p> <p>24 Q. Okay. So there is a NEQAS prepared slide and</p> <p>25 an in-house slide as part of that program.</p>	<p>1 program?</p> <p>2 DR. ELMS:</p> <p>3 A. They've been quite--we have, at times,</p> <p>4 received full scores.</p> <p>5 MR. SIMMONS:</p> <p>6 Q. Okay. You mentioned also CIQC.</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 MR. SIMMONS:</p> <p>10 Q. And I believe that is a relatively new</p> <p>11 program?</p> <p>12 DR. ELMS:</p> <p>13 A. Yes.</p> <p>14 MR. SIMMONS:</p> <p>15 Q. Is that fully implemented yet or is that still</p> <p>16 in the development stages?</p> <p>17 DR. ELMS:</p> <p>18 A. It's at the transition stage between that.</p> <p>19 They've had three runs now. We have taken</p> <p>20 part in the last two.</p> <p>21 MR. SIMMONS:</p> <p>22 Q. And who is running that program or sponsoring</p> <p>23 it?</p> <p>24 DR. ELMS:</p> <p>25 A. That's run in B.C. at the B.C. Cancer Agency.</p>

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<p>1 MR. SIMMONS: 2 Q. Can you tell me how that proficiency testing 3 program is working so far? What comprises it? 4 DR. ELMS: 5 A. We receive a tissue micro ray slide from CIQC. 6 That is a specific technology in which small 7 portions of tissue are cut from a block and 8 these are all then embedded in a single block 9 and they're embedded in an array in order. 10 That slide is sent to us and then we stain it. 11 We're then given a little template, a map, so 12 that the way that the--it's done in a 13 rectangle, but there's a gap in the top left 14 corner, so you know that the piece of tissue 15 immediately to the left of it is zero. That's 16 the benchmark. 17 MR. SIMMONS: 18 Q. So you know which way is up. 19 DR. ELMS: 20 A. And you know which way is up, and then the 21 next one over from that is number one, two, 22 three, four and along and we're given a map, 23 so to speak, with that and we grade each of 24 these portions of tissue and then we send it 25 to CIQC and they review it, and they have an</p>	<p>1 on. If however you have concordance with 2 other labs, then you're standardized with 3 regard to the other labs. 4 MR. SIMMONS: 5 Q. Okay, and has there been a run for ER and PR 6 in the CIQC program? 7 DR. ELMS: 8 A. Yes. 9 MR. SIMMONS: 10 Q. And how has--do you know how well your lab has 11 done? 12 DR. ELMS: 13 A. We've done well. 14 MR. SIMMONS: 15 Q. So that's the CAP proficiency testing, UK 16 NEQAS, CIQC and there's also, I believe, 17 proficiency testing offered by the QMPLS 18 program from Ontario, isn't it? 19 DR. ELMS: 20 A. Yes. 21 MR. SIMMONS: 22 Q. And how does that work? 23 DR. ELMS: 24 A. That is they send us slides and we--in much 25 the same way as UK NEQAS. They send us a</p>
<p>Page 374</p> <p>1 online resource where we can see our slides, a 2 micro photograph of our slides, and compare 3 them with the micro photographs of other 4 slides from other labs taking part in the 5 program, and we also get what's called a 6 garrattogram and that is a two by two lay out, 7 a table, in which each lab has a column and 8 then each row coming down is a specific case 9 that was on the slide. And so we have a list 10 of all the labs across the country with all 11 the case--that take part in the program, with 12 all the cases that are being tested at that 13 time, and then in the case of ER, it's colour 14 coded so that a red means positive. So if we 15 called it positive, we'd have a red for that 16 particular case. And the advantage of doing 17 it that way is that you can by eye then 18 compare yourself to other labs across the 19 country. So that if you--you can see how high 20 the concordance is all across the country and 21 where our lab sits in relation to others. So 22 if in each one you see that you're getting a-- 23 you're saying negative when someone else is 24 getting positive, then you know that you're 25 doing something--that there's something going</p>	<p>Page 376</p> <p>1 slide and we provide a slide of our own in- 2 house material. We stain it and submit it 3 back to them and then they assess our staining 4 and we're presented back with a report that 5 gives a very detailed list of the various 6 aspects of the slide that they look at and 7 what our score is. We're given what the 8 maximum score is and what the average score is 9 on those that took part, and then in each 10 area, the score is summarized into a final 11 score and then there's an overall final score 12 and we can also again visually access that 13 online. 14 MR. SIMMONS: 15 Q. Okay, and in addition to all that, you've also 16 told us that approximately 20 percent of the 17 ER/PR slides that have been produced here, 18 those specimens have also been sent to Mount 19 Sinai for them to retest for comparison 20 purposes? 21 DR. ELMS: 22 A. Yes. 23 MR. SIMMONS: 24 Q. You were asked some questions about 25 technologists training in IHC and you told us,</p>

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<p>1 as we've heard elsewhere, that Mr. Green, for 2 example, went to Montreal General or Jewish 3 General, I believe.</p> <p>4 DR. ELMS:</p> <p>5 A. Jewish General.</p> <p>6 MR. SIMMONS:</p> <p>7 Q. For a couple weeks, and that some of the 8 technologists have been to the Ventana 9 facility, I believe in Arizona.</p> <p>10 DR. ELMS:</p> <p>11 A. Yes.</p> <p>12 MR. SIMMONS:</p> <p>13 Q. Where they've done some training as well. Do 14 you know if there is anything like a school 15 anywhere that a technologist can go to to 16 learn IHC training?</p> <p>17 DR. ELMS:</p> <p>18 A. Not that I know of.</p> <p>19 MR. SIMMONS:</p> <p>20 Q. Have you ever heard of any such thing being 21 available, being possible to do that?</p> <p>22 DR. ELMS:</p> <p>23 A. No.</p> <p>24 MR. SIMMONS:</p> <p>25 Q. Are you aware of any types of training</p>	<p>1 A. At St. Clare's.</p> <p>2 MR. SIMMONS:</p> <p>3 Q. Is there a plan for that to change?</p> <p>4 DR. ELMS:</p> <p>5 A. Yes.</p> <p>6 MR. SIMMONS:</p> <p>7 Q. And you are moving to Health Science Centre?</p> <p>8 DR. ELMS:</p> <p>9 A. Yes.</p> <p>10 MR. SIMMONS:</p> <p>11 Q. And do you know when that's planned to take 12 place?</p> <p>13 DR. ELMS:</p> <p>14 A. I hope to move later on this month.</p> <p>15 MR. SIMMONS:</p> <p>16 Q. Okay. Will that in any way help facilitate 17 your role as director of immunohistochemistry?</p> <p>18 DR. ELMS:</p> <p>19 A. Greatly.</p> <p>20 MR. SIMMONS:</p> <p>21 Q. Has there been any kind of impediment 22 preventing you from moving before this?</p> <p>23 DR. ELMS:</p> <p>24 A. Lack of space. There haven't been offices 25 that I would be able to avail of.</p>
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<p>1 specific to performing IHC that would be 2 available for technologists, other than the 3 types of opportunities that have been taken 4 advantage of here?</p> <p>5 DR. ELMS:</p> <p>6 A. Well, as I said, we also subscribe to online 7 seminars and there are also conferences going 8 on yearly. Our technologists are going off to 9 a conference later this month actually and we 10 have obtained funding for that.</p> <p>11 MR. SIMMONS:</p> <p>12 Q. Is there anything else though that you're 13 aware of that would be a good opportunity for 14 them, another -</p> <p>15 DR. ELMS:</p> <p>16 A. Not that I'm aware of.</p> <p>17 MR. SIMMONS:</p> <p>18 Q. Okay. Do you know if there's any formal 19 certifications of any sort available for 20 technologists for IHC?</p> <p>21 DR. ELMS:</p> <p>22 A. Again, not that I'm aware of.</p> <p>23 MR. SIMMONS:</p> <p>24 Q. Your office is currently located where?</p> <p>25 DR. ELMS:</p>	<p>1 MR. SIMMONS:</p> <p>2 Q. Now you have reviewed the external review 3 reports that were prepared by Dr. Banerjee and 4 Ms. Wegrynowski, and the QMP-LS report from 5 December of 2007 and all the recommendations 6 contained in those reports, I believe?</p> <p>7 DR. ELMS:</p> <p>8 A. Yes.</p> <p>9 MR. SIMMONS:</p> <p>10 Q. Okay. As director of immunohistochemistry, 11 have you been specifically charged in any 12 general way with the implementation of all 13 those recommendations or has your role been 14 narrower?</p> <p>15 DR. ELMS:</p> <p>16 A. My role has been narrower. As I said, some of 17 the recommendations to do with documentation 18 of the running of the machines were in place 19 when I started.</p> <p>20 MR. SIMMONS:</p> <p>21 Q. Yes. Are you aware of any significant 22 initiatives yet to be taken or yet to be 23 tackled coming out of any of those reports?</p> <p>24 DR. ELMS:</p> <p>25 A. Significant initiatives, no.</p>

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1 MR. SIMMONS:
 2 Q. Okay. Now there's probably always room for
 3 growth and improvement in a service like this,
 4 in a technological scientific based service.
 5 Are there any areas, are there any things that
 6 you would still like to see done that would
 7 improve your ability to do your job or the
 8 lab's ability to deliver quality, reliable IHC
 9 testing?
 10 DR. ELMS:
 11 A. I would like to see a greater emphasis put on
 12 administrative support. As it stands now, I
 13 do not have a secretary. I do not have a
 14 filing cabinet and no place to file anything.
 15 When there are memos to be done, I either type
 16 them myself or someone is found to do it. In
 17 the purpose of typing memos, that's not such a
 18 bad things, but when you're talking about the
 19 collating of this kind of quality assurance
 20 data and the documentation and validations,
 21 that becomes--it's not satisfactory to have
 22 one person today and another person tomorrow.
 23 You need someone who knows what--who
 24 understands what the material is.
 25 MR. SIMMONS:

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1 Q. Yes. You've been in, I'll say, the system
 2 here now for ten years or more. Is the lack
 3 of that sort of administrative support
 4 something unique to pathology or the
 5 laboratory or is that more common in your
 6 experience through the health care system?
 7 DR. ELMS:
 8 A. My only experience outside of this was in
 9 working as an emergency physician and the
 10 general attitude as an emergency physician is
 11 that you're an independent contractor. So it
 12 wasn't expected that there would be any of
 13 that kind of administrative support. You
 14 would provide that on your own. So I can't
 15 say what goes on in other departments other
 16 than pathology.
 17 MR. SIMMONS:
 18 Q. Okay. It's 5:00. Thank you very much, Dr.
 19 Elms.
 20 DR. ELMS:
 21 A. Thank you.
 22 THE COMMISSIONER:
 23 Q. Mr. Pritchett, are you of the same position,
 24 no questions?
 25 MR. PRITCHETT:

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1 Q. I am, Commissioner, thank you.
 2 THE COMMISSIONER:
 3 Q. Ms. Newbury?
 4 MS. NEWBURY:
 5 Q. I just have a couple questions.
 6 DR. FORD ELMS, EXAMINATION BY MS. JENNIFER NEWBURY
 7 MS. NEWBURY:
 8 Q. Good afternoon, Dr. Elms. Jennifer Newbury
 9 for the Canadian Cancer Society, Newfoundland
 10 and Labrador Division. I just wanted to ask
 11 you a couple of questions about a couple of
 12 the pathology reports that you've been shown
 13 earlier today, starting with C-0174, please.
 14 This is the repeat test requested by Dr.
 15 Zaidi, and as we've gone through that earlier
 16 today, there have been a change in results
 17 from 2002 to 2003, and you've indicated that
 18 you can't recall whether or not this had been
 19 reported to anyone at the time, as you did
 20 with Ms. Deane's case when you reported it to
 21 Dr. Cook, and I'm just wondering if you would
 22 have expected that some record would have been
 23 kept if you had made such a formal report or
 24 an informal report to anyone, such as Dr.
 25 Cook?

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1 DR. ELMS:
 2 A. No, not as a matter of routine.
 3 MS. NEWBURY:
 4 Q. Okay, and why not?
 5 DR. ELMS:
 6 A. I would have reported this--had I reported it,
 7 and as I say, I don't recall doing so, but I
 8 would have reported it to Dr. Cook. I'm not
 9 sure what he would have done as a report. I
 10 certainly wouldn't have at the time expected
 11 to have done so.
 12 MS. NEWBURY:
 13 Q. And you're not aware then of any protocols or
 14 any requirements that are placed upon a person
 15 to whom you're reporting to make a note of it?
 16 DR. ELMS:
 17 A. Not at the time, no.
 18 MS. NEWBURY:
 19 Q. Okay, and if you encountered such a situation
 20 today, how would you address that, in terms of
 21 any reporting protocols?
 22 DR. ELMS:
 23 A. Knowing what I know now?
 24 MS. NEWBURY:
 25 Q. Yes.

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1 DR. ELMS:
 2 A. I would very much document it, yes, and look
 3 into the situation.
 4 MS. NEWBURY:
 5 Q. Okay, and are there any formal procedures in
 6 place that you know that you would go to this
 7 procedure or that procedure to follow or would
 8 you just -
 9 DR. ELMS:
 10 A. Not that I know of right now.
 11 MS. NEWBURY:
 12 Q. Okay. But you would make sure that you had it
 13 documented?
 14 DR. ELMS:
 15 A. Yes.
 16 MS. NEWBURY:
 17 Q. And you had reported it to someone?
 18 DR. ELMS:
 19 A. Yes.
 20 MS. NEWBURY:
 21 Q. And if I could have Exhibit C-0156, please?
 22 And this is the pathology reports related to
 23 Peggy Deane, and you may want to refer to
 24 that. You'd indicated earlier this morning
 25 that you had, subsequent to the retesting with

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1 the different results for ER/PR, you went back
 2 to verify the diagnosis that you had given,
 3 the lobular carcinoma, and that was a couple
 4 of days after.
 5 DR. ELMS:
 6 A. Yes.
 7 MS. NEWBURY:
 8 Q. Is that recorded anywhere here in this
 9 document?
 10 DR. ELMS:
 11 A. No.
 12 MS. NEWBURY:
 13 Q. Okay, and why not?
 14 DR. ELMS:
 15 A. I went back as an educational measure, more
 16 than anything. I wanted to see what I had
 17 done and what I had said and compare it to
 18 what I had been told, Sloan Kettering had
 19 said.
 20 MS. NEWBURY:
 21 Q. Okay, and if you were to do that again today,
 22 for example, even if it is just for your own
 23 educational purposes, would you make a record
 24 of that anywhere?
 25 DR. ELMS:

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1 A. I might make a record for my own sake. I
 2 don't think I'd make a record for the
 3 patient's chart.
 4 MS. NEWBURY:
 5 Q. Okay. There's no requirement that you're
 6 aware of?
 7 DR. ELMS:
 8 A. No.
 9 MS. NEWBURY:
 10 Q. And would it be beneficial, do you think, to
 11 report it on a report, to say that it's been
 12 double checked?
 13 DR. ELMS:
 14 A. In this kind of instance, I would think the
 15 patient would know that it had been checked
 16 elsewhere and would know that result. If I
 17 was to review that case, I would think one of
 18 two things, either I would agree with my
 19 original assessment or that I would agree with
 20 the other one. I'm not sure that that would
 21 be of benefit, but it's not for me to second
 22 guess what's beneficial to the patient, in
 23 terms of what the patient would understand.
 24 But I'm not sure that would not simply add to
 25 the confusion, especially if I disagreed. I

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1 mean, if you have Sloan Kettering saying we
 2 think one thing and I say something else and
 3 then put my foot down and say "no, I'm right,"
 4 I can't see that being beneficial for a
 5 patient.
 6 MS. NEWBURY:
 7 Q. What about to just provide the information and
 8 even if you personally can't resolve that
 9 issue, at least then the patient or her
 10 treating clinicians would know that?
 11 DR. ELMS:
 12 A. Well again, if I have already made an opinion
 13 on the case and now an expert has disagreed
 14 with my opinion, I'm not sure that it would
 15 benefit for -
 16 MS. NEWBURY:
 17 Q. If you had disagreed with your original
 18 opinion, do you think that would be of any
 19 value?
 20 DR. ELMS:
 21 A. Yes, I mean, it would be worthwhile, I guess,
 22 for the patient to know that. As it stands,
 23 there's really no protocol whereby we do that.
 24 MS. NEWBURY:
 25 Q. Now in this case here, I think with Ms.

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1 Deane's reports, it turns out that the
 2 diagnosis from the retest was the same as your
 3 original one. It was still lobular carcinoma.
 4 I just want to make sure.
 5 DR. ELMS:
 6 A. That was my understanding.
 7 MS. NEWBURY:
 8 Q. Okay, and you had put in some comments about
 9 some features of ductal carcinoma as well, but
 10 essentially it was still considered lobular
 11 carcinoma, as far as you know?
 12 DR. ELMS:
 13 A. That was my understanding.
 14 MS. NEWBURY:
 15 Q. Okay. It's also noted there that there was a
 16 reference that you had a discussion with Dr.
 17 David Pace. This was early, back in June of
 18 2002.
 19 DR. ELMS:
 20 A. Yes.
 21 MS. NEWBURY:
 22 Q. So before any of the retesting was done, and
 23 this morning you'd indicated that you had
 24 actually called Dr. Rorke immediately when you
 25 still had the specimen on the slide, to let

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1 him know of the new ER/PR results.
 2 DR. ELMS:
 3 A. Yes.
 4 MS. NEWBURY:
 5 Q. Is that recorded anywhere here in this report?
 6 DR. ELMS:
 7 A. No.
 8 MS. NEWBURY:
 9 Q. Okay, and in this case, the actual written
 10 diagnosis wasn't made until May 31st, as
 11 indicated -
 12 DR. ELMS:
 13 A. The actual written documentation of what I had
 14 found on the ER/PR retest, no, it wasn't.
 15 MS. NEWBURY:
 16 Q. Okay, and why not have recorded your call to
 17 Dr. Rorke, even if you didn't go into the
 18 detail there?
 19 DR. ELMS:
 20 A. The original phone call with Dr. Pace was
 21 probably on the basis of the patient in the
 22 clinic awaiting the result and we would
 23 document that. If there was going to be a
 24 delay in us signing out the case, we would
 25 document that we had called them. But in this

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1 instance, as I said, the case had been dealt
 2 with and I was content that the oncologist
 3 dealing with Ms. Deane knew the result and
 4 would act on it. So it was--that was what was
 5 most important for me, was that they knew it
 6 and could act on it, because I knew they were
 7 waiting for the material.
 8 MS. NEWBURY:
 9 Q. Okay. So if you had a situation today where
 10 you had done a retest for whatever reason, and
 11 didn't get around to providing a written
 12 report until some weeks after, would you -
 13 DR. ELMS:
 14 A. Yes.
 15 MS. NEWBURY:
 16 Q. - proceed in the same manner or would you
 17 write a note?
 18 DR. ELMS:
 19 A. I would document that, at this point.
 20 MS. NEWBURY:
 21 Q. Thank you, Dr. Elms. Those are all the
 22 questions I have.
 23 THE COMMISSIONER:
 24 Q. Mr. Pike, you're still of the same view?
 25 MR. PIKE:

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1 Q. No questions. Thank you.
 2 THE COMMISSIONER:
 3 Q. All right. Ms. Brocklehurst?
 4 DR. FORD ELMS, EXAMINATION BY MS. LAURA BROCKLEHURST
 5 MS. BROCKLEHURST:
 6 Q. Thank you. Good afternoon, Dr. Elms. I'm
 7 Laura Brocklehurst with Ches Crosbie, here on
 8 behalf of the class members. Can I get
 9 document C-0174, please? Perfect. I know you
 10 had said earlier that you can't recall if
 11 you'd actually reported this conversion or
 12 not. Is there any reason that you can
 13 remember that you would have reported it or
 14 conversely, any reason that you would not have
 15 reported it?
 16 DR. ELMS:
 17 A. I would have wanted to make my supervisor
 18 aware that this had happened in the lab, in
 19 the same spirit that I had reported Ms.
 20 Deane's changed tests.
 21 MS. BROCKLEHURST:
 22 Q. Okay. So you did think it was important to
 23 let somebody know?
 24 DR. ELMS:
 25 A. Yes.

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<p>1 MS. BROCKLEHURST: 2 Q. Okay. Did you have an obligation to report it 3 or is it just something you thought was 4 important to do? 5 DR. ELMS: 6 A. I'm not sure that I would have had an 7 obligation, but I would have felt it important 8 to do it. 9 MS. BROCKLEHURST: 10 Q. Was there a database being kept of the 11 conversions, do you know? 12 DR. ELMS: 13 A. No. 14 MS. BROCKLEHURST: 15 Q. There wasn't? 16 DR. ELMS: 17 A. No, not that I know of. 18 MS. BROCKLEHURST: 19 Q. Okay. So how would a conversion rate have 20 been known or would there have been any way to 21 know? 22 DR. ELMS: 23 A. At that point? 24 MS. BROCKLEHURST: 25 Q. Yes.</p>	<p>1 DR. ELMS: 2 A. Are you asking me is it usual to expect - 3 MS. BROCKLEHURST: 4 Q. Yes. 5 DR. ELMS: 6 A. No, I'm not aware of any pattern that would 7 exist with that. 8 MS. BROCKLEHURST: 9 Q. Okay. So there's no actual pattern of 10 separate cases around this time that would 11 have had similar numbers? 12 DR. ELMS: 13 A. Not that I'm aware of. 14 MS. BROCKLEHURST: 15 Q. Okay. Is there anyone who would have been in 16 a position to notice such a pattern? Like is 17 there any one person who would have been 18 seeing several conversions who would have been 19 able to notice pattern? 20 DR. ELMS: 21 A. No, not that I'm aware of. 22 MS. BROCKLEHURST: 23 Q. Okay, and can I get document C-0228, please? 24 Dr. Vaze, is that how you pronounce that? 25 DR. ELMS:</p>
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<p>1 DR. ELMS: 2 A. I'm not sure that there would have been. 3 MS. BROCKLEHURST: 4 Q. There wouldn't have been, okay. This case, I 5 believe--am I able to scroll down here? 6 THE COMMISSIONER: 7 Q. Yes, you should be able to. 8 MS. BROCKLEHURST: 9 Q. This case, I believe, went to about a 10 to 15 10 percent ER and 75 percent PR. I think we saw 11 that somewhere. 12 DR. ELMS: 13 A. Something of that nature. 14 MS. BROCKLEHURST: 15 Q. I thought I saw that here somewhere earlier. 16 What page, I'm not sure. 17 THE COMMISSIONER: 18 Q. There you go. 19 DR. ELMS: 20 A. Here we are. 21 MS. BROCKLEHURST: 22 Q. Perfect. Was there a pattern of high PRs and 23 low ERs correlating with each other, and is 24 that normal to have such high numbers for the 25 PR and such low numbers for the ER?</p>	<p>1 A. Vaze. 2 MS. BROCKLEHURST: 3 Q. Vaze, okay. You said earlier that you were 4 unaware of his conversion at the time? 5 DR. ELMS: 6 A. As far as I'm aware of. 7 MS. BROCKLEHURST: 8 Q. Okay. So it seems like, you know, independent 9 or individual doctors weren't communicating 10 with each other about mistakes, or I think 11 adverse events they were called, when they 12 occurred. So again, I guess there was no way 13 then for any one person to know what a 14 conversion rate would have been? 15 DR. ELMS: 16 A. That's correct. 17 MS. BROCKLEHURST: 18 Q. Okay. Okay, I just wanted to clarify that. 19 And back to Exhibit C-0156, please? Peggy 20 Deane, perfect. Was there anything specific 21 or unique to Peggy Deane's case that would 22 have caused you to look back again at her 23 diagnosis once there was a conversion? 24 DR. ELMS: 25 A. Nothing specific.</p>

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1 MS. BROCKLEHURST:
 2 Q. Okay. So there was nothing special about her
 3 case as opposed to -
 4 DR. ELMS:
 5 A. No.
 6 MS. BROCKLEHURST:
 7 Q. - I think there was one other unnamed
 8 conversion we saw earlier. There's nothing
 9 special about hers that would have triggered
 10 it?
 11 DR. ELMS:
 12 A. No.
 13 MS. BROCKLEHURST:
 14 Q. So do you know why it was that you would have
 15 looked into hers?
 16 DR. ELMS:
 17 A. Well, I mean, I reviewed her case when I was
 18 asked to repeat the stain and then compared
 19 the stains when I got the positive back, but
 20 that's--I mean, you'd do that with any case
 21 that that kind of a situation exists in, and
 22 it certainly wasn't the case that that case,
 23 that one case spurred me to go back and look
 24 at others. I reported that to my supervisor
 25 who then discussed it with the oncologists and

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1 then over the course of those discussions, the
 2 situation developed.
 3 MS. BROCKLEHURST:
 4 Q. Okay. So there was nothing special about this
 5 one case.
 6 DR. ELMS:
 7 A. No.
 8 MS. BROCKLEHURST:
 9 Q. It was just the beginning. Okay, that's all I
 10 have. Thank you.
 11 THE COMMISSIONER:
 12 Q. Thank you. Mr. Browne?
 13 DR. FORD ELMS, EXAMINATION BY MR. PETER BROWNE
 14 MR. BROWNE:
 15 Q. Thank you, Commissioner. We're drawing to a
 16 close, Dr. Elms. Just a couple of questions I
 17 want to cover off with you. First of all, I
 18 want to go back to some questions Mr. Coffey
 19 asked you fairly early on in this morning's
 20 session and it had to do with, I guess some
 21 technically unsatisfactory slides that you
 22 recognized back in either 2001, 2002, in that
 23 time frame.
 24 DR. ELMS:
 25 A. Yes.

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1 MR. BROWNE:
 2 Q. And I think you answered that on occasion you
 3 noticed a couple of difficulties or problems
 4 with slides and those included wrinkles,
 5 knife, was it chatter?
 6 DR. ELMS:
 7 A. Knife chatter, yes.
 8 MR. BROWNE:
 9 Q. Okay, and then the last item was tissue
 10 boiling off the slides.
 11 DR. ELMS:
 12 A. Yes.
 13 MR. BROWNE:
 14 Q. Do you ever recall with regard to the last
 15 issue, tissue boiling off the slides, did you
 16 ever recall speaking with any of the lead
 17 techs, I think at that time it would have been
 18 either Ms. Butler or Ms. Walsh, about that
 19 issue and do you recall any response from them
 20 as to what steps they may have been taking?
 21 DR. ELMS:
 22 A. Yes, in those instances, I would have called.
 23 I called Ms. Butler and spoke with her on a
 24 couple of occasions about this issue and she
 25 informed me that it was an issue that was

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1 recognized, and I was certainly given the
 2 impression that others had said similar, and
 3 they were trying to solve the issue and were
 4 taking various steps to correct it, using
 5 positive slides, various other steps, and that
 6 they were looking into it.
 7 MR. BROWNE:
 8 Q. So one of the steps they were looking into, is
 9 it what we've heard about this previously,
 10 positively charged slides?
 11 DR. ELMS:
 12 A. Yes.
 13 MR. BROWNE:
 14 Q. As a matter of fact, and I know this is a
 15 difficult exhibit to call up, Registrar, but
 16 I'll ask Dr. Elms if he recalls seeing this.
 17 It's P-2151 and that's the 300 page policy
 18 manual that you were shown here this
 19 afternoon.
 20 DR. ELMS:
 21 A. Uh-hm.
 22 MR. BROWNE:
 23 Q. I think among that, there was a policy, I
 24 think at pages somewhere between pages 201 and
 25 203, addressing positively charged slides.

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1 Can you indicate the significance of
 2 positively charged slides in IHC generally to
 3 the Commissioner, please?
 4 DR. ELMS:
 5 A. They increase adherence of tissue, so the
 6 tissue will stay on better, will adhere better
 7 to the glass slide.
 8 MR. BROWNE:
 9 Q. Okay, it's not that necessary, I think we saw
 10 it there, is it 205? Maybe we could just go
 11 to 205? Yes, right here. Doctor, in fact,
 12 page 205, there's a reference there to 25 by
 13 77 superfrost slides positively charged.
 14 DR. ELMS:
 15 A. Yes.
 16 MR. BROWNE:
 17 Q. So there is in fact a policy for that purpose
 18 because of its relevance to IHC.
 19 DR. ELMS:
 20 A. Yes.
 21 MR. BROWNE:
 22 Q. Okay. Now as well, Mr. Coffey and the
 23 Commissioner asked you, I think on a couple of
 24 occasions about--if we could, Registrar, go to
 25 P-2407, page 72 and I think you recall this

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1 comment, Dr. Elms, that you made a reference
 2 to totally negative staining in the neoplastic
 3 tissue. And I think you answered the
 4 Commissioner this afternoon that you felt the
 5 request for the repeat was for something other
 6 than the absence of staining of an internal
 7 control.
 8 DR. ELMS:
 9 A. Yes.
 10 MR. BROWNE:
 11 Q. Could this be related to the boiling off of
 12 tissue?
 13 DR. ELMS:
 14 A. Yes.
 15 MR. BROWNE:
 16 Q. And what--could you explain that further how
 17 that would be relevant to your comment?
 18 DR. ELMS:
 19 A. It could very well be that, I mean there were
 20 cases where tissue would boil off the slides,
 21 it could very well be that all that remained
 22 adherent was normal tissue and that the
 23 statement was more one of all I've got is
 24 normal tissue and that even hasn't stained.
 25 MR. BROWNE:

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1 Q. And then lastly, Dr. Elms, you were shown two
 2 reports, C-174 and I think we've gone over
 3 that just recently with Ms. Newbury and with
 4 Ms. Brocklehurst and in comparison to Ms.
 5 Deane, which was C-156. Now, both were
 6 repeats. In once case it was Dr. Zaidi and in
 7 the second, I guess, it was either Dr.
 8 McCarthy, Dr. Laing who communicated that to
 9 you. Was there--do you recall, was there any
 10 clinical significance discussed with you or
 11 when you related the results, I'm talking
 12 about Ms. Deane now, to Dr. Rorke -
 13 DR. ELMS:
 14 A. Uh-hm.
 15 MR. BROWNE:
 16 Q. Do you recall whether there was any discussion
 17 around any clinical significance to the new
 18 result, the repeat result, did Dr. Rorke
 19 mention that there was significance to the
 20 patient because of this change?
 21 DR. ELMS:
 22 A. That she would now be able to be treated with
 23 Tamoxifen.
 24 MR. BROWNE:
 25 Q. Right. In terms of the repeat with Dr. Zaidi,

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1 do you recall if there was any such discussion
 2 in that respect?
 3 DR. ELMS:
 4 A. No.
 5 MR. BROWNE:
 6 Q. So there was a difference in terms of what
 7 information you received back from the
 8 oncologist from Ms. Deane, verses what you
 9 received back from Dr. Zaidi?
 10 DR. ELMS:
 11 A. Yes.
 12 MR. BROWNE:
 13 Q. And there was, from the information you
 14 received from Dr. Rorke, some clinical
 15 significance to the repeat result?
 16 DR. ELMS:
 17 A. Yes.
 18 MR. BROWNE:
 19 Q. That's all the questions I have, Commissioner.
 20 The only other area, Dr. Elms, is that the
 21 Commissioner--we invite witnesses at this time
 22 if they want to make any comments or
 23 recommendations or any observations to the
 24 Commissioner, then this is your opportunity.
 25 DR. ELMS:

1 A. None at this time, just thank you very much
 2 for enabling me to make my testimony. I look
 3 forward to your report, Madam Commissioner.
 4 THE COMMISSIONER:
 5 Q. Thank you.
 6 MR. BROWNE:
 7 Q. Mr. Coffey may have some -
 8 THE COMMISSIONER:
 9 Q. Do you have anything arising, Mr. Coffey?
 10 COFFEY, Q.C.:
 11 Q. No, Commissioner, thank you.
 12 MR. BROWNE:
 13 Q. Commissioner, do you have any questions for -
 14 THE COMMISSIONER:
 15 Q. I don't.
 16 MR. BROWNE:
 17 Q. Oh good.
 18 THE COMMISSIONER:
 19 Q. Yes, you'll be terribly glad to learn. I do
 20 thank you, Dr. Elms for assisting us. It's
 21 not easy to be the first up on the first
 22 school day, so I do appreciate your coming
 23 along and taking that role for us. For
 24 counsel, I wish to advise that administration
 25 says that there's a CD for you before you

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

1 leave today, just so that you can feel like
 2 you're really back -
 3 MR. BROWNE:
 4 Q. Homework on the first day of school.
 5 THE COMMISSIONER:
 6 Q. Homework on the first day, exactly. Thank you
 7 all, we'll meet again at 9:30 in the morning.

Inquiry on Hormone Receptor Testing

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