

CIHRT Exhibit P-0125 Page 1
DEPARTMENT OF HEALTH AND COMMUNITY SERVICES
BRIEFING NOTES – 2006

1. Question and Answers Briefing Note entitled Retesting of Breast Cancer Patients prepared by Debbie Morris and approved by Moira Hennessey dated February 23, 2006
2. Question and Answers Briefing Note entitled ER/PR Testing, Eastern Health prepared by Beverley Griffiths and approved by Moira Hennessey dated March 9, 2006
3. Question and Answers Briefing Note Spring 2006 entitled Retesting of Breast cancer patients (ER/PR) prepared by D. Morris and approved by M. Hennessey dated March 15, 2006
4. Question and Answers Briefing Note Spring 2006 entitled Retesting of Breast cancer patients (ER/PR) prepared by Debbie Morris and approved by Moira Hennessey dated April 27, 2006
5. Question and Answers Briefing Note Spring 2006 entitled Retesting of Breast cancer patients (ER/PR) prepared by D. Morris and approved by M. Hennessey dated May 2, 2006
6. Question and Answers Briefing Note Spring 2006 entitled Retesting of Breast cancer patients (ER/PR) prepared by D. Morris and approved by M. Hennessey dated May 18, 2006
7. Email from Moira Hennessey to Marilyn McCormack dated August 16, 2006 Subject, BN ER/PR Receptor Tests with attachments
8. Email from Moira Hennessey to John Abbott dated Thursday August 17, 2006 Subject, BN ER/PR Testing
9. Email from Marilyn McCormack to Moira Hennessey dated August 18, 2006 Subject, BN for the Premier on ER/PR Receptor Tests
10. Briefing Note entitled Update on Pathology Reports and Legal Action for Women Diagnosed with Breast Cancer prepared by Heather Predham, Eastern Health; Moira Hennessey, HCS and reviewed by M. McCormack; Gary Cake dated August 18, 2006
11. Briefing Note entitled Retesting of Breast Cancer Patients (ER/PR) prepared by Beverly Griffiths and approved by Moira Hennessey dated October 24, 2006

12. Question and Answers Briefing Note entitled ER/PR Testing, St. John's prepared by Beverley Griffiths and approved by Moira Hennessey dated November 6, 2006
13. Question and Answers Briefing Note entitled ER/PR Testing, St. John's prepared by B. Griffiths and approved by M. Hennessey dated November 27, 2006
14. Question and Answers Briefing Note entitled ER/PR Testing, St. John's drafted by B. Griffiths and approved by M. Hennessey dated November 27, 2006
15. Question and Answers Briefing Note entitled ER/PR Testing, St. John's drafted by B. Griffiths and approved by M. Hennessey dated December 12, 2006

**Questions and Answers Briefing Note
Department of Health and Community Services**

Title: Retesting of Breast Cancer Patients

Issue: Breast cancer patients are still looking for answers. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not. The public is concerned that not all samples have been retested by Mount Sinai to date.

Anticipated Questions:

- Has the testing been completed on the samples sent to Mount Sinai?
- Has everyone been notified of the results?
- What has been done to correct this problem?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. The Department has been working closely with Eastern Health since May when it was discovered that there was a problem with the testing of tissue samples for breast cancer patients with ER/PR receptors.
- Testing of the tissue samples sent to Mount Sinai, for the most part, has been completed and the vast majority of results are back and in various stages of review by a panel of physicians who will interpret the results. We know this process is taking time but our primary concern is that the patient's needs are being addressed.
- A quality review began immediately when the problem was discovered. Eastern Health has had the method of testing for ER/PR receptors reviewed by external consultants. Their recommendations have been implemented and the consultants are expected to return to Eastern Health in early April to review what has been done. It is expected that Eastern Health will begin testing of new patients at that time.

Other Suggested Response(s):

- Until the external consultants review the testing process and assure Eastern Health it is safe to proceed, the testing of new breast cancer patients with ER/PR receptors will be done at Mount Sinai.
- Patient safety is a primary focus for our health system. Regional health authorities have embarked on a national Safer Health Care Now campaign to implement six targeted interventions in patient care, e.g. rapid response teams, prevention of adverse drug events, and improved care for heart attack patient safety.

Background:

- In May, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive.
- Eastern Health has sent a total of 939 collected tissue samples from patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- The laboratory problem at the Health Sciences Centre could be repeated across Canada. An expert in medical technology has publicly stated that Canada lacks a national standards body and labs across the country should take a look at what they are doing to make sure they get it right.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.

Prepared by: Debbie Morris
Date: February 23, 2006

Approved by: Moira Hennessey

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, Eastern Health

Issue: Eastern Health released the outcome of its review of ER/PR testing in December. A mistake in testing may have led to incorrect treatment for 117 women in this province suffering from breast cancer. Legal proceedings have begun.

Anticipated Questions:

- Why has it taken more than one year for Eastern Health to go public and release the results of the ER/PR testing review?
- When will breast cancer screening test resume at the laboratory in St. John's?
- What has Government done to ensure the reliability and accuracy of the ER/PR testing at the St. John's hospitals?
- Are pathologists or laboratory staff to blame for the incorrect ER/PR test results?

Key Messages:

- Providing quality health services to the people of this province is a priority for our Government. We regret that the past two years (since May 2005) has been a stressful period for some patients and their families.
- When the ER/PR testing problem was discovered in May 2005, arrangements were put in place quickly for an independent laboratory to review the test results and complete ongoing work. Eastern Health took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the outcomes to the public in December 2006.
- Eastern Health's first priority was its patients. Clinical team members communicated individually with all patients impacted by this review. The organization has acted in what it determined to be in the best interest of its patients.
- Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- There were multiple factors involved in the ER/PR testing. There has been no blame assigned within Eastern Health. Since legal proceedings have been initiated, Government will have to allow the legal process to determine if in fact error has occurred.

Other Suggested Response(s):

- Eastern Health has put a number of measures in place to provide a high standard of ER/PR testing. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training.
- Eastern Health has implemented the recommendations from two external reviews and a dedicated laboratory has been established to perform the ER/PR testing with 3 designated technologists, a lab medical director, and a dedicated cutter. A centre of excellence for breast cancer cases has been established at Eastern Health so

that examination and reporting will be directed to a dedicated group of pathologists.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. The tests examine hormone receptors Estrogen (ER) or Progesterone (PR) in breast cancer cells to help physicians determine what course of treatment to follow for each patient (eg. chemotherapy, radiation).
- In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratory. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All retesting has been completed. The chronology of the ER/PR retesting is attached as Annex I.
- Eastern Health did not initially advise patients of the retesting (despite the Department's suggestion that it should consider doing so) and many learned of it from the media before they were contacted by Eastern officials last Fall. Eastern waited for the actual results before disclosing information to the patients instead of telling them that they may or may not be impacted by the review; Eastern didn't know what this would mean for them without the results. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.
- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Patients Requiring Treatment Changes	117
- The 939 patients included 176 individuals who are deceased. One hundred and one (101) patients were retested and results received. There were two (2) patients who were retested upon request. The remaining 73 will not be retested unless the families request it.
- Last Spring (2006), the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the approximately 40 plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has filed an affidavit in court on December 15, 2006. The lawyers for the plaintiff and the defendant have filed documents for certification and case law with the court on February 9, 2007. A hearing of the certification application is scheduled for May 23-25, 2007.
- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in

technology, recruitment of four pathology assistants, accreditation with the CCHSA and consolidation of pathologist review of breast tissue samples.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: March 9, 2006

**Question and Answer Briefing Note – Spring 2006
Department of Health and Community Services**

Title: Retesting of Breast Cancer Patients (ER/PR)

Issue: Breast cancer patients are still looking for answers. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not. The public is concerned that not all samples have been retested by Mount Sinai to date.

Anticipated Questions:

- Has the testing been completed on the samples sent to Mount Sinai?
- Has everyone been notified of the results?
- What has been done to correct this problem?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. The Department has been working closely with Eastern Health since last May when it was discovered that there was a problem with the testing of tissue samples for breast cancer patients with estrogen and progesterone (ER/PR).
- Testing of the tissue samples sent to Mount Sinai, for the most part, has been completed and the vast majority of results are back and in various stages of review by a panel of physicians who will interpret the results. We know this process is taking time but our primary concern is that the patients' needs are being addressed.
- A quality review began immediately when the problem was discovered. Eastern Health has had the method of testing for ER/PR receptors reviewed by external consultants. Their recommendations have been implemented and the consultants returned to Eastern Health in early April for an assessment of progress. It is expected that Eastern Health will begin testing of new patients in St. John's once the final consultants report has been received and reviewed, likely in late May.

Other Suggested Response(s):

- Until the external consultants review the testing process and assure Eastern Health it is safe to proceed, the testing of new breast cancer patients with ER/PR receptors will be done at Mount Sinai.
- Patient safety is a primary focus for our health system. Regional health authorities have embarked on a national Safer Health Care Now campaign to implement six targeted interventions in patient care, e.g. rapid response teams, prevention of adverse drug events, and improved care for heart attack patients.

Background:

- In May, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive.
- Eastern Health has sent a total of 939 collected tissue samples from patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.
- The laboratory problem at the Health Sciences Centre could be repeated across Canada. An expert in medical technology has publicly stated that Canada lacks a national standards body and labs across the country should take a look at what they are doing to make sure they get it right.

Prepared by: Debbie Morris

Approved by: Moira Hennessey

Date: March 15, 2006

**Question and Answer Briefing Note – Spring 2006
Department of Health and Community Services**

Title: Retesting of Breast Cancer Patients (ER/PR)

Issue: Breast cancer patients are still looking for answers. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not. The public has been concerned in the past that not all samples have been retested by Mount Sinai to date.

Anticipated Questions:

- Has the testing been completed on the samples sent to Mount Sinai?
- Has everyone been notified of the results?
- What has been done to correct this problem?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. The Department has been working closely with Eastern Health since last May when it was discovered that there was a problem with the testing of tissue samples for breast cancer patients with estrogen and progesterone (ER/PR).
- Most of the test results are back from Mount Sinai. These results are in various stages of review by a panel of physicians who will interpret the results. The Authority is in discussions with Mount Sinai regarding receiving the remaining 16 test results. We know this process is taking time but our primary concern is that the patients' needs are being addressed.
- A quality review began immediately when the problem was discovered. Eastern Health has had the method of testing for ER/PR receptors reviewed by external consultants. Their recommendations have been implemented and the consultants returned to Eastern Health in early April to assess progress. Eastern Health expects to begin testing of new patients in St. John's once the consultants' final report has been received and reviewed, likely in late May.

Other Suggested Response(s):

- Until the external consultants complete their review and assure Eastern Health it is safe to proceed, the testing of new breast cancer patients with ER/PR receptors will be done at Mount Sinai.
- Patient safety is a primary focus for our health system. Regional health authorities are participating in a national safety initiative to reduce adverse events and improved patient care.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO

Background:

- In May, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive.
- Eastern Health has sent a total of 939 collected tissue samples from patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.
- The laboratory problem at the Health Sciences Centre could be repeated across Canada. An expert in medical technology has publicly stated that Canada lacks a national standards body and labs across the country should take a look at what they are doing to make sure they get it right.

Prepared by: Debbie Morris

Approved by: Moira Hennessey

Date: April 27, 2006

Question and Answer Briefing Note – Spring 2006
Department of Health and Community Services

Title: Retesting of Breast Cancer Patients (ER/PR)

Issue: Breast cancer patients are still looking for answers. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not. The public has been concerned in the past that not all samples have been retested by Mount Sinai to date.

Anticipated Questions:

- Has the testing been completed on the samples sent to Mount Sinai?
- Has everyone been notified of the results?
- What has been done to correct this problem?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. The Department has been working closely with Eastern Health since last May when it was discovered that there was a problem with the testing of tissue samples for breast cancer patients with estrogen and progesterone (ER/PR).
- Most of the test results are back from Mount Sinai. These results are in various stages of review by a panel of physicians who will interpret the results. The Authority is in discussions with Mont Sinai regarding receiving the remaining 16 test results. We know this process is taking time but our primary concern is that the patients' needs are being addressed.
- A quality review began immediately when the problem was discovered. Eastern Health has had the method of testing for ER/PR receptors reviewed by external consultants. Their recommendations have been implemented and the consultants returned to Eastern Health in early April to assess of progress. Eastern Health expects to begin testing of new patients in St. John's once the consultants' final report has been received and reviewed, likely in late May.

Other Suggested Response(s):

- Until the external consultants complete their review and assure Eastern Health it is safe to proceed, the testing of new breast cancer patients with ER/PR receptors will be done at Mount Sinai.
- Patient safety is a primary focus for our health system. Regional health authorities are participating in a national safety initiative to reduce adverse events and improved patient care.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive.
- Eastern Health has sent a total of 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. Test results have been received on 923 patients.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.
- The laboratory problem at the Health Sciences Centre could be repeated across Canada. An expert in medical technology has publicly stated that Canada lacks a national standards body and labs across the country should take a look at what they are doing to make sure they get it right.

Prepared by: Debbie Morris

Approved by: Moira Hennessey

Date: May 2, 2006

**Question and Answer Briefing Note – Spring 2006
Department of Health and Community Services**

Title: Retesting of Breast Cancer Patients (ER/PR)

Issue: Breast cancer patients are still looking for answers. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not. The family of one patient has filed a statement of claim against Eastern Health.

Anticipated Questions:

- Has the testing been completed on the samples sent to Mount Sinai and has everyone been notified of the results?
- What has been done to correct this problem?
- What is Government doing to restore public confidence in the testing procedures at Eastern Health?
- What is Government's response to the statement of claim brought against Eastern Health by the family of the late Michelle Hanlon?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. A quality review began immediately when the problem was discovered last May. Eastern Health had external consultants review the method of testing for ER/PR receptors being used. The consultants' recommendations have been implemented. They returned to Eastern Health in early April this year to assess the progress. Eastern Health expects to begin testing of new patients in St. John's once the consultants' final report has been received and reviewed, likely in late May.
- All the test results are back from Mount Sinai Hospital in Toronto. These results are in various stages of review by a panel of physicians who will interpret the results. We know this process is taking time but our primary concern is that the patients' needs are being addressed.
- Government is unable to comment at this time on the statement of claim due to the legal proceedings.

Other Suggested Response(s):

- Until the external consultants provide their final report and assure Eastern Health it is safe to proceed, the testing of new breast cancer patients with ER/PR receptors will continue at Mount Sinai.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered some inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive.
- Eastern Health has sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. All test results are now back.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.
- Eastern Health has filed a statement of defence to a claim brought against them by the family of the late Michelle Hanlon. Ms Hanlon had initially tested negative for ER/PR on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result had been known earlier appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern's statement of defence is asking that the case be dismissed.
- CBC Radio aired a story today about the statement of claim filed by Michelle Hanlon's family, noting that Eastern had filed a statement of defence. Peter Dawe, Canadian Cancer Society, was quoted and stated that he hopes for good information from Eastern Health shortly. He questioned the accuracy of the test results in laboratories across the country and he will raise the issue with his national and provincial counterparts. He also stressed the importance of Eastern Health restoring public confidence in their testing procedures.
- An expert in medical technology publicly stated last fall that Canada lacks a national standards body and laboratories across the country should take a look at what they are doing to make sure they get it right.

Prepared by: Debbie Morris

Approved by: Moira Hennessey

Date: May 18, 2006

From: Moira Hennessey
To: McCormack, Marilyn
Date: Wed, Aug 16, 2006 7:44 AM
Subject: Re: BN - ER/PR Receptor tests

Hi Marilyn,
I will answer your questions as best as I can from a distance..

1. The NL panel reviewed 422 test results after they came back from Mount Sinai. These results are included in the 939 tissue samples . The NL panel consists of reps from medical oncology, pathology, surgery and quality.
2. The 28 test results confirmed as negative by the NL panel were sent to Mount Sinai. The panel chose to review these results because there was a slight change on the patient's ER/PR status from time of original diagnosis to retesting.
3. There are only 13 of the 208 who are being treated with Tamoxifen for metastatic disease. Because this treatment was started since their original diagnosis and before the test results were reviewed by Mount Sinai and the NL panel, there are no treatment recommendations since the retesting.
4. The 3 patients include one patient who was diagnosed with invasive carcinoma when the review by the NL panel indicate it was DCIS and two patients were diagnosed with DCIS with a large amount of invasive component but upon review, the invasive component is much less.

There are 39 patients confirmed with DCIS and 14 still under review. I don't know when the reviews will be completed or if these patients have been notified. If you need this info today, you can check with Heather Predham directly.

Moira

Sent via Blackberry
Government of Newfoundland and Labrador

>>> Marilyn McCormack 8/15 11:22 am >>>
Hi Moira

Hope your trip to Labrador is going well and the weather is as nice there as it is here on the Island. Sorry to bother you again on this note but I am trying to ensure I am reading the information correctly. .

I received the BN from Yvonne as you directed. I still have a few questions

1. Can you tell me about the NL panel. Did they review the results here PRIOR to the tests going to Mount Sinai or did they decide which tests were to be retested at Mount Sinai? I'm not clear what their role was/is?
2. The note indicates 28 patients test results confirmed negative by NL panel. Were these tests also sent to Mount Sinai (or not) and if so I assume the results were the same from Mount Sinai as found by the NL panel?
3. The patients whose ER/PR status changed from negative to positive - 208- but with no treatment recommendations. The comments section advises some of these patients were considered low risk, previously could not tolerate or did not want Tamoxifen or have since been placed on Tamoxifen for metastatic disease. Does this mean that these patients all have metastatic disease or do we know how many of the 208 do? And would this be the result of them not having been given Tamoxifen (because their original test results were negative) when they should have been given Tamoxifen?The note says no

recommendations for treatment yet the comments indicate there has been changes in the treatment being provided. Can you clarify. I find the information confusing.

4. Of the 56 patients with DCIS do I assume only 3 women were incorrectly diagnosed with DCIS? Then there were 39 who were confirmed DCIS? And do we have any idea when the other 14 will be reviewed and by who? It says the patients have been notified. I assume this includes the 14 women whose test results are still pending the review? Is that right?

Thanks Maira for any clarification you can provide. I feel I should ask the questions as if it's not clear to me it will likely be unclear for others as well.

I made the other changes you recommended. Hopefully we can conclude soon

Marilyn

Eastern Health
 Summary of ER/PR Retesting
 August 11, 2006

The total number of patient tissues sent for retesting at Mount Sinai was 939 and the majority of the test results (923) have been returned.

The test results include:

Category	Number	Comments
Patient test results confirmed negative by Mount Sinai	341	No change in patient's treatment plan.
Patient test results confirmed negative by NL panel	28	Patients whose original test results were considered negative by heating physician and treated appropriately. There was a slight change in ER/PR status but review by panel confirmed negative ER/PR status.
Patient test results confirmed positive by NL panel	12	Patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by panel confirmed positive ER/PR status.
Patient ER/PR status changed from negative to positive but no treatment recommendations	208	Includes patients deemed at low risk of recurrence, previously could not tolerate or did not want Tamoxifen, or have since been placed on Tamoxifen for metastatic disease.
Patient ER/PR status changed from negative to positive and there are treatment recommendations	109	Includes patients who have been impacted by the delay in receiving Tamoxifen and patients whose results have not changed significantly but the clinical definition of positive and negative has changed since time of diagnosis.
Ductal Carcinoma in Situ (DCIS)	56	Tamoxifen is not recommended for DCIS. There are 39 confirmed and 14 under review. The panel has identified 3 patients who were incorrectly diagnosed in their original pathology report which may have led them to being treated excessively. Patients have been notified.
Required assessment prior to recommendation	5	Panel could not make a recommendation without seeing the patient. Information has been communicated to patient and follow-up care offered.
Retro converters	4	Patients considered positive at time of initial ER/PR testing. These individuals received hormonal treatment. Retesting at Mount Sinai confirmed these were false positives.
Patients identified as deceased by chart review or contact with family member	176	Based on June 2006 ethics review, a public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health.
TOTAL	939	

Prepared by: Heather Predham,
Assistant Director, Quality and Risk Management

Date: July 31, 2006

Re: Estrogen and Progesterone Receptor Testing: Update

The total number of patients sent for retesting was 939. The majority of results have been returned, reviewed and the individual patients informed. **Exceptions** to this are listed below:

Ductal Carcinoma In Situ (DCIS):

DCIS is a diagnosis made by the pathologist when the cancer cells grow inside the ducts of the breast. DCIS means that there is no, or only a very limited amount of, invasive component of the disease and this diagnosis would form the basis of the plan of treatment. As I understand it, from our specialists, Tamoxifen is not recommended for DCIS. There is, therefore, no reason to test the ER/PR status.

Of the results returned from Mount Sinai, there were ones that Mount Sinai did not retest as they diagnosed them as being DCIS. Initially, the panel reviewed the original pathology report and if that report diagnosed the person as having DCIS, then there was no further action required: the patient is confirmed DCIS and does not have to be retested for ER/PR.

If the panel could not do this initial step, then two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS".

However, our review has also revealed patients who were incorrectly diagnosed in their original pathology report with an invasive disease. This may have led them to being treated with Tamoxifen or chemotherapy. At this time, there are three women who fall in this category. Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care have disclosed this information to those affected.

There are **14** more DCIS patients throughout Newfoundland and Labrador that require further review by pathology.

"Retro" Convertors

All patients who were negative for ER were included in the retesting process. As the clinical definition of negative changed over the years, all patients with an ER of 30% or less were retested.

That means that in the group retested there are women who, although their ER level met this definition of negative, were considered positive at the time and received hormonal treatment. However, in **4** cases, retesting by Mount Sinai identified that women in this category now have an ER/PR status of 0% which has been confirmed by subsequent retesting at Mount Sinai.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care will meet with them in the near future to disclose this information.

Deceased

174 patients are identified as being deceased. In June, an ethics review was conducted regarding notification of these families. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.

Legal activity

Hanlon claim

This claim was served on Eastern Health in December 2005. Ms. Hanlon has subsequently passed away. Eastern Health's defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

Doucette Claim

This statement of claim was recently filed with the intention to proceed under the class action legislation. The next step in this process is for the Plaintiff's lawyer to file, with the court, the parameters in which he intends to proceed. This is part of the process in his application to the court to seek a class of patients to be certified.

From: Moira Hennessey
To: Abbott, John
Date: Thu, Aug 17, 2006 12:41 PM
Subject: Fwd: BN - ER/PR Testing

John,

FYI and review. This note will likely go to the PO later today or tomorrow.

Moira

Moira Hennessey

Assistant Deputy Minister - Regional Health Operations
Department of Health and Community Services
Government of Newfoundland and Labrador
Phone: 709.729.3127
Fax: 709.729.4009
E-mail: MHennessey@gov.nl.ca

>>> Marilyn McCormack 8/17/2006 11:26 AM >>>
HI Moira

I was able to clarify the information on the NL Panel and their role with Heather Predham. I included an extra bullet under Background (last bullet) to describe the NL panel and their role . In the introduction to the chart I made reference again to the panel. In my opinion the note is clear now and with your approval I will forward to Gary. Please advise

Marilyn

CC: Griffiths, Beverley; Mundon, Tansy ; Rumboldt, John

Briefing Note

Title: Update on Pathology Reports and Legal Action for Women Diagnosed with Breast Cancer

Issue: Current status of pathology testing and legal claims related to women diagnosed with breast cancer.

Background:

- In May, 2005 the laboratory at the Health Sciences Center discovered some inconsistent results in breast tumor samples. Specifically ER (estrogen) and PR (progesterone) receptor tests which were completed to determine whether a particular tumor needed hormones, such as estrogen or progesterone to grow, varied in a number of samples.
- The result of receptor tests direct the treatment to be provided. For example, women who had a positive test result from the receptor test may respond to hormone therapy such as the drug Tamoxifen. Tamoxifen is taken by mouth and generally carries fewer side effects than other forms of treatment for cancer such as chemotherapy. If ER and PR tests are negative the patient is given chemotherapy.
- Since the discovery of these inconsistent results Eastern Health has sent 939 collected tissue samples for patients who had tested negative ER and PR results from 1997-2005 to Mount Sinai for retesting. Test results have been received on 923 patients.
- Eastern Health also established a panel of professionals representing medical oncology, pathology, surgery, and quality services (NL Panel) who reviewed the test results coming back from Mount Sinai whenever there was a change in the patients initial test results.

Current Status: (Pathology Reports)

The total number of patient tissues sent for retesting at Mount Sinai was 939 and the majority of the test results (923) have been returned. The following table details the results from Mount Sinai and also provides information on the 422 test results with changes that were reviewed by the NL panel upon receipt from Mount Sinai.

The test results include:

Category	Number	Comments
Patient test results confirmed negative by Mount Sinai	341	No change in patient's treatment plan.
Patient test results confirmed negative by NL panel	28	Patients whose original test results were considered negative by treating physician and treated appropriately. There was a slight change in ER/PR status as a result of the testing at Mount Sinai but following a second review by the NL panel the negative

		ER/PR status was confirmed.
Patient test results confirmed positive by NL panel	12	Patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by NL panel confirmed positive ER/PR status.
Patient ER/PR status changed from negative to positive but no treatment recommendations	208	There are 13 patients of the 208 who are being treated for metastatic disease. However these patients began treatment since their original diagnosis but before the test results were reviewed by Mount Sinai and the NL panel therefore there are no treatment recommendations for them. The remainder includes patients deemed at low risk of recurrence, previously could not tolerate or did not want Tamoxifen, or have since been placed on Tamoxifen for metastatic disease.
Patient ER/PR status changed from negative to positive and there are treatment recommendations	109	Includes patients who have been impacted by the delay in receiving Tamoxifen and patients whose results have not changed significantly but the clinical definition of positive and negative has changed since time of diagnosis.
Ductal Carcinoma in Situ (DCIS)	56	Tamoxifen is not recommended for DCIS. There are 39 confirmed and 14 under review. The panel has identified 3 patients who were incorrectly diagnosed in their original pathology report which may have led them to being treated excessively. One of these three women was diagnosed with invasive carcinoma when the review by the NL panel indicated it was DCIS. The other two women were diagnosed with DCIS with a large amount of invasive component but upon review, the invasive component is much less. Patients have been notified.
Required assessment prior to recommendation	5	Panel could not make a recommendation without seeing the patient. Information has been communicated to patient and follow-up care offered.
Retro converters	4	Patients considered positive at time of initial ER/PR testing. These individuals received hormonal treatment. Retesting at Mount Sinai confirmed

		these were false positives.
Patients identified as deceased by chart review or contact with family member	176	Based on June 2006 ethics review, a public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health.
TOTAL	939	

Current Status: (Legal Activity):

- Currently only two legal claims have been filed as follows:

Michelle Hanlon. A claim was served on Eastern Health on behalf of Ms Hanlon in December, 2005. Ms Hanlon has subsequently passed away but her claim is being followed by her family. Ms Hanlon had originally tested ER/PR negative and therefore was not treated with Tamoxifen. Later she tested ER/PR positive. Eastern Health's defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

Verna Doucette: This statement of claim was recently filed with the intention to proceed under the class action legislation. (This will be the model case). Ms Doucette also tested ER/PR negative and was not treated with Tamoxifen. Later she tested ER/PR positive. The next step in the process is for the Plaintiff's lawyer to file, with the court, the parameters in which he intends to proceed. This is part of the process in his application to the court to seek a class of patients to be certified.

****Recent media reports identified Myrtle Lewis has joined other women who have signed on to take part in a class action lawsuit. Myrtle Lewis was completely misdiagnosed and as a result of an individual pathologist who read her test results wrong she has undergone radical surgery and extensive chemotherapy. Mrs. Lewis had pre-cancerous cells which did not require the extensive treatment she went through. The statement of claim filed by Mr. Ches Crosbie was served to the defendant, Eastern Health on July 7, 2006.**

Summary:

The legal action initiated by Mrs. Myrtle Lewis is a result of a misdiagnosis and is not linked to the problems described in this note with the ER/PR receptor tests which had to be repeated.

Eastern Health advises 22 women were impacted by the change in status of the ER/PR Receptor tests. These women had changes in the progress of their disease from the initial confirmation of the disease and the beginning of their treatment to the retesting done at Mount Sinai

However, all of the 939 patients (or families of those who have died) whose test results were reviewed **could potentially** become applicants in a class action lawsuit. The basis of their claims may differ depending on the criteria established. The lawyer initiating the suit has included in his claim for damages not only the problem with the lab where test results were inaccurate but also the stress suffered by those who were told in advance the testing was being repeated and the time they were required to wait before information was available to them on their individual cases. Currently legal counsel for Eastern Health is reviewing the legal position for Eastern Health.

Impacts of Treatment with Tamoxifen:

The drug Tamoxifen is believed to prevent the growth of cancer in ER/PR positive patients. It does have possible side effects which includes; endometrial cancer, blood clots in the legs, stroke, abnormal growth of uterine tissue, hair and nail thinning, and fertility problems. Patients however who do not receive Tamoxifen but are ER/PR positive may experience further problems with cancer.

Reasons for the Erroneous Results and Steps taken to Prevent Reoccurrence:

Eastern Health has engaged external consultants to review the procedures at the laboratory. When all reports are received they will be reviewed and the recommendations will be implemented. The goal is to have the laboratory accredited.

Until these processes are completed all samples will continue to be retested at Mount Sinai.

.Action Required:

- This note is provided for information purposes only. Should the Premier require further detail officials from Eastern Health as well as their legal counsel will be available for an in person briefing.

Prepared by/Approved by: Heather Predham, Eastern Health; Moira Hennessey, HCS

Reviewed by: Marilyn McCormack; Gary Cake, Cabinet Secretariat

Date: August 18, 2006

From: Marilyn McCormack
To: Moira Hennessey
Date: 8/18/2006 10:59:24 AM
Subject: BN for Premier on ER/PR Receptor Tests

Hi Moira

Attached is the **FINAL** copy of the above noted Briefing Note if you approve of same. I had to go back to Heather to ask how many women were most impacted by the change in status of the ER/PR receptor testing. She gave me the number 22 as indicated on the third page of the BN. Gary also wanted to know how many were likely to initiate legal action and according to Heather any or all of the 939 women(or their families) could do so. Eaxact numbers would not be known at this time. She explained that even if the results were correct from the initial testing to the retesting at Mount Sinai the stress caused to some women/families by knowing they were being retested , how long they had to wait for information, etc. could be a basis to intitiate an action or to participate in the class action if thats the way this proceeds..

If yqu are okay with this note Gary has approved it and it will go as is. Please advise as soon as possible

Marilyn

Briefing Note

Title: Update on Pathology Reports and Legal Action for Women Diagnosed with Breast Cancer

Issue: Current status of pathology testing and legal claims related to women diagnosed with breast cancer.

Background:

- In May, 2005 the laboratory at the Health Sciences Center discovered some inconsistent results in breast tumor samples. Specifically ER (estrogen) and PR (progesterone) receptor tests which were completed to determine whether a particular tumor needed hormones, such as estrogen or progesterone to grow, varied in a number of samples.
- The result of receptor tests direct the treatment to be provided. For example, women who had a positive test result from the receptor test may respond to hormone therapy such as the drug Tamoxifen. Tamoxifen is taken by mouth and generally carries fewer side effects than other forms of treatment for cancer such as chemotherapy. If ER and PR tests are negative the patient is given chemotherapy.
- Since the discovery of these inconsistent results Eastern Health has sent 939 collected tissue samples for patients who had tested negative ER and PR results from 1997-2005 to Mount Sinai for retesting. Test results have been received on 923 patients.
- Eastern Health also established a panel of professionals representing medical oncology, pathology, surgery, and quality services (NL Panel) who reviewed the test results coming back from Mount Sinai whenever there was a change in the patients initial test results.

Current Status: (Pathology Reports)

The total number of patient tissues sent for retesting at Mount Sinai was 939 and the majority of the test results (923) have been returned. The following table details the results from Mount Sinai and also provides information on the 422 test results with changes that were reviewed by the NL panel upon receipt from Mount Sinai.

The test results include:

Category	Number	Comments
Patient test results confirmed negative by Mount Sinai	341	No change in patient's treatment plan.
Patient test results confirmed negative by NL panel	28	Patients whose original test results were considered negative by treating physician and treated appropriately. There was a slight change in ER/PR status as a result of the testing at Mount Sinai but following a second review by the NL panel the negative

		ER/PR status was confirmed.
Patient test results confirmed positive by NL panel	12	Patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by NL panel confirmed positive ER/PR status.
Patient ER/PR status changed from negative to positive but no treatment recommendations	208	There are 13 patients of the 208 who are being treated for metastatic disease. However these patients began treatment since their original diagnosis but before the test results were reviewed by Mount Sinai and the NL panel therefore there are no treatment recommendations for them. The remainder includes patients deemed at low risk of recurrence, previously could not tolerate or did not want Tamoxifen, or have since been placed on Tamoxifen for metastatic disease.
Patient ER/PR status changed from negative to positive and there are treatment recommendations	109	Includes patients who have been impacted by the delay in receiving Tamoxifen and patients whose results have not changed significantly but the clinical definition of positive and negative has changed since time of diagnosis.
Ductal Carcinoma in Situ (DCIS)	56	Tamoxifen is not recommended for DCIS. There are 39 confirmed and 14 under review. The panel has identified 3 patients who were incorrectly diagnosed in their original pathology report which may have led them to being treated excessively. One of these three women was diagnosed with invasive carcinoma when the review by the NL panel indicated it was DCIS. The other two women were diagnosed with DCIS with a large amount of invasive component but upon review, the invasive component is much less. Patients have been notified.
Required assessment prior to recommendation	5	Panel could not make a recommendation without seeing the patient. Information has been communicated to patient and follow-up care offered.
Retro converters	4	Patients considered positive at time of initial ER/PR testing. These individuals received hormonal treatment. Retesting at Mount Sinai confirmed

		these were false positives.
Patients identified as deceased by chart review or contact with family member	176	Based on June 2006 ethics review, a public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health.
TOTAL	939	

Current Status: (Legal Activity):

- Currently only two legal claims have been filed as follows:

Michelle Hanlon. A claim was served on Eastern Health on behalf of Ms Hanlon in December, 2005. Ms Hanlon has subsequently passed away but her claim is being followed by her family. Ms Hanlon had originally tested ER/PR negative and therefore was not treated with Tamoxifen. Later she tested ER/PR positive. Eastern Health's defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

Verna Doucette: This statement of claim was recently filed with the intention to proceed under the class action legislation. (This will be the model case). Ms Doucette also tested ER/PR negative and was not treated with Tamoxifen. Later she tested ER/PR positive. The next step in the process is for the Plaintiff's lawyer to file, with the court, the parameters in which he intends to proceed. This is part of the process in his application to the court to seek a class of patients to be certified.

****Recent media reports identified Myrtle Lewis has joined other women who have signed on to take part in a class action lawsuit. Myrtle Lewis was completely misdiagnosed and as a result of an individual pathologist who read her test results wrong she has undergone radical surgery and extensive chemotherapy. Mrs. Lewis had pre-cancerous cells which did not require the extensive treatment she went through. The statement of claim filed by Mr. Ches Crosbie was served to the defendant, Eastern Health on July 7, 2006.**

Summary:

The legal action initiated by Mrs. Myrtle Lewis is a result of a misdiagnosis and is not linked to the problems described in this note with the ER/PR receptor tests which had to be repeated.

Eastern Health advises 22 women were greatly impacted by the change in status of the ER/PR Receptor tests. These women had changes in the progress of their disease from the initial confirmation of the disease and the beginning of their treatment to the retesting done at Mount Sinai

However, all of the 939 patients (or families of those who have died) whose test results were reviewed **could potentially** become applicants in a class action lawsuit. The basis of their claims may differ depending on the criteria established. The lawyer initiating the suite has included in his claim for damages not only the problem with the lab where test results were inaccurate but also the stress suffered by those who were told in advance the testing was being repeated and the time they were required to wait before information was available to them on their individual cases. Currently legal counsel for Eastern Health is reviewing the legal position for Eastern Health.

Impacts of Treatment with Tamoxifen:

The drug Tamoxifen is believed to prevent the growth of cancer in ER/PR positive patients. It does have possible side effects which includes; endometrial cancer, blood clots in the legs, stroke, abnormal growth of uterine tissue, hair and nail thinning, and fertility problems. Patients however who do not receive Tamoxifen but are ER/PR positive may experience further problems with cancer.

Reasons for the Erroneous Results and Steps taken to Prevent Reoccurrence:

Eastern Health has engaged external consultants to review the procedures at the laboratory. When all reports are received they will be reviewed and the recommendations will be implemented. The goal is to have the laboratory accredited.

Until these processes are completed all samples will continue to be retested at Mount Sinai.

Action Required:

- This note is provided for information purposes only. Should the Premier require further detail officials from Eastern Health as well as their legal counsel will be available for an in person briefing.

Prepared by/Approved by: Heather Predham, Eastern Health; Moira Hennessey, HCS

Reviewed by: Marilyn McCormack; Gary Cake, Cabinet Secretariat

Date: August 18, 2006

2006/08/18

Briefing Note

Department of Health and Community Services

Title: Update on Pathology Reports and Legal Action for Women Diagnosed with Breast Cancer

Issue: Current status of pathology testing and legal claims related to women diagnosed with breast cancer.

Background:

- In May, 2005 the laboratory at the Health Sciences Center discovered some inconsistent results in breast tumor samples. Specifically ER (estrogen) and PR (progesterone) receptor tests which were completed to determine whether a particular tumor needed hormones, such as estrogen or progesterone to grow, varied in a number of samples.
- The result of receptor tests direct the treatment to be provided. For example, women who had a positive test result from the receptor test may respond to hormone therapy such as the drug Tamoxifen. Tamoxifen is taken by mouth and generally carries fewer side effects than other forms of treatment for cancer such as chemotherapy. If ER and PR tests are negative the patient is given chemotherapy.
- Since the discovery of these inconsistent results Eastern Health has sent 939 collected tissue samples for patients who had tested negative ER and PR results from 1997-2005 to Mount Sinai for retesting. Test results have been received on 923 patients.
- Eastern Health also established a panel of professionals representing medical oncology, pathology, surgery, and quality services (NL Panel) who reviewed the test results coming back from Mount Sinai whenever there was a change in the patients initial test results.

Current Status: (Pathology Reports)

The total number of patient tissues sent for retesting at Mount Sinai was 939 and the majority of the test results (923) have been returned. The following table details the results from Mount Sinai and also provides information on the 422 test results with changes that were reviewed by the NL panel upon receipt from Mount Sinai.

The test results include:

Category	Number	Comments
Patient test results confirmed negative by Mount Sinai	341	No change in patient's treatment plan.
Patient test results confirmed negative by NL panel	28	Patients whose original test results were considered negative by treating physician and treated appropriately. There was a slight change in ER/PR status as a result of the testing at

		Mount Sinai but following a second review by the NL panel the negative ER/PR status was confirmed.
Patient test results confirmed positive by NL panel	12	Patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by NL panel confirmed positive ER/PR status.
Patient ER/PR status changed from negative to positive but no treatment recommendations	208	There are 13 patients of the 208 who are being treated for metastatic disease. However these patients began treatment since their original diagnosis but before the test results were reviewed by Mount Sinai and the NL panel therefore there are no treatment recommendations for them. The remainder includes patients deemed at low risk of recurrence, previously could not tolerate or did not want Tamoxifen, or have since been placed on Tamoxifen for metastatic disease.
Patient ER/PR status changed from negative to positive and there are treatment recommendations	109	Includes patients who have been impacted by the delay in receiving Tamoxifen and patients whose results have not changed significantly but the clinical definition of positive and negative has changed since time of diagnosis.
Ductal Carcinoma in Situ (DCIS)	56	Tamoxifen is not recommended for DCIS. There are 39 confirmed and 14 under review. The panel has identified 3 patients who were incorrectly diagnosed in their original pathology report which may have led them to being treated excessively. One of these three women was diagnosed with invasive carcinoma when the review by the NL panel indicated it was DCIS. The other two women were diagnosed with DCIS with a large amount of invasive component but upon review, the invasive component is much less. Patients have been notified.
Required assessment prior to recommendation	5	Panel could not make a recommendation without seeing the patient. Information has been communicated to patient and follow-up care offered.
Retro converters	4	Patients considered positive at time of initial ER/PR testing. These individuals

		received hormonal treatment. Retesting at Mount Sinai confirmed these were false positives.
Patients identified as deceased by chart review or contact with family member	176	Based on June 2006 ethics review, a public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health.
TOTAL	939	

Current Status: (Legal Activity):

- Currently only **two** legal claims have been filed as follows:

Michelle Hanlon. A claim was served on Eastern Health on behalf of Ms Hanlon in December, 2005. Ms Hanlon has subsequently passed away but her claim is being followed by her family. Ms Hanlon had originally tested ER/PR negative and therefore was not treated with Tamoxifen. Later she tested ER/PR positive. Eastern Health’s defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

Verna Doucette: This statement of claim was recently filed with the intention to proceed under the class action legislation. (This will be the model case). Ms Doucette also tested ER/PR negative and was not treated with Tamoxifen. Later she tested ER/PR positive. The next step in the process is for the Plaintiff’s lawyer to file, with the court, the parameters in which he intends to proceed. This is part of the process in his application to the court to seek a class of patients to be certified.

****Recent media reports identified Myrtle Lewis has joined other women who have signed on to take part in a class action lawsuit. Myrtle Lewis was completely misdiagnosed and as a result of an individual pathologist who read her test results wrong she has undergone radical surgery and extensive chemotherapy. Mrs. Lewis had pre-cancerous cells which did not require the extensive treatment she went through. The statement of claim filed by Mr. Ches Crosbie was served to the defendant, Eastern Health on July 7, 2006.**

Summary:

The legal action initiated by Mrs. Myrtle Lewis is a result of a misdiagnosis and is not linked to the problems described in this note with the ER/PR receptor tests which had to be repeated.

Eastern Health advises 22 women were impacted by the change in status of the ER/PR Receptor tests. These women had changes in the progress of their disease from

the initial confirmation of the disease and the beginning of their treatment to the retesting done at Mount Sinai

However, all of the 939 patients (or families of those who have died) whose test results were reviewed **could potentially** become applicants in a class action lawsuit. The basis of their claims may differ depending on the criteria established. The lawyer initiating the suit has included in his claim for damages not only the problem with the lab where test results were inaccurate but also the stress suffered by those who were told in advance the testing was being repeated and the time they were required to wait before information was available to them on their individual cases. Currently legal counsel for Eastern Health is reviewing the legal position for Eastern Health.

Impacts of Treatment with Tamoxifen:

The drug Tamoxifen is believed to prevent the growth of cancer in ER/PR positive patients. It does have possible side effects which includes; endometrial cancer, blood clots in the legs, stroke, abnormal growth of uterine tissue, hair and nail thinning, and fertility problems. Patients however who do not receive Tamoxifen but are ER/PR positive may experience further problems with cancer.

Reasons for the Erroneous Results and Steps taken to Prevent Reoccurrence:

Eastern Health has engaged external consultants to review the procedures at the laboratory. When all reports are received they will be reviewed and the recommendations will be implemented. The goal is to have the laboratory accredited.

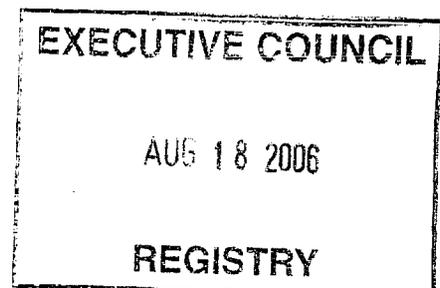
Until these processes are completed all samples will continue to be retested at Mount Sinai.

Action Required:

- This note is provided for information purposes only. Should the Premier require further detail officials from Eastern Health as well as their legal counsel will be available for an in person briefing.

Prepared by/Approved by: Heather Predham, Eastern Health; Moira Hennessey, HCS
Reviewed by: Marilyn McCormack; Gary Cake, Cabinet Secretariat

August 18, 2006



**Briefing Note
October 24, 2006**

Title: Retesting of Breast Cancer Patients (ER/PR)

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive. The tests examine hormone receptors in breast cancer cells for ER and PR and help physicians determine what course of treatment to follow for each patient.
- Eastern Health sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. This number represents about 27% of the patients tested for breast cancer. All retesting has been completed. Eastern Health did not advise patients of the retesting and many learned of it from the media.
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.

Current Status:

- Eastern has not publicly released the results of the retesting at this time except confidentially to individual patients. The Authority is currently reviewing all charts to ensure that all individuals have been contacted. The full review should be completed by the end of November.
- CBC News reported on October 19 that forty-one women join class action bid on faulty breast cancer tests. The Independent, in an article on October 20, reported that at least 39 cancer patients have filed papers with Ches Crosbie, a St. John's lawyer, to bring forward a class action suit against Eastern Health.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.

- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.

Prepared by: Beverly Griffiths
Approved by: Moira Hennessey

Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, St. John's

Issue: The retesting of patients and informing them of the ER/PR test results has taken about 18 months. This is too long for cancer patients to wait for answers.

Anticipated Questions:

- Have all those affected been notified of their test results?
- Are all test results back from Mount Sinai?
- What assurances can you give the public that this won't happen again?

Key Messages:

- Our first priority was and continues to be the patients who had negative ER/PR results. I would like to assure the public that we take these matters seriously and there is a team of clinical and administrative people working on this issue. We are dedicated to improving the system, learning from our experiences and ensuring quality care.
- More than 900 test samples were sent to Mount Sinai Laboratory and all the test results are back. Eastern Health is rechecking charts to ensure all individuals or their families have been contacted. This review is now ongoing and should be concluded by the end of November. Eastern Health expects to begin testing of new patients in St. John's shortly after review is completed.
- While this has been an unfortunate event for all of us, we are focused on ensuring patients have every treatment option that may be available to them and on addressing system issues that arise.

Other Suggested Response(s):

- A quality review began immediately when the problem was discovered in May 2005. Eastern Health had external consultants review the method of testing for ER/PR receptors being used. The consultants' recommendations have been implemented. They returned to Eastern Health in early April this year to assess the progress and were pleased that measures were put in place to address the concerns.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive. The tests examine hormone receptors in breast cancer cells for ER and PR and help physicians determine what course of treatment to follow for each patient.
- Eastern Health sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. This number

represents about 27% of the patients tested for breast cancer. All retesting has been completed. Eastern Health did not advise patients of the retesting and many learned of it from the media.

- Eastern has not publicly released the results of the retesting at this time except confidentially to individual patients. The Authority is currently reviewing all charts to ensure that all individuals have been contacted. The full review should be completed by the end of November.
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- CBC News reported on October 19 that forty-one women join class action bid on faulty breast cancer tests. The Independent, in an article on October 20, reported that at least 39 cancer patients have filed papers with Ches Crosbie, a St. John's lawyer, to bring forward a class action suit against Eastern Health.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: November 6, 2006

**Question and Answer Briefing Note
Department of Health and Community Services**

Title: ER/PR Testing, St. John's

Issue: Breast cancer survivors want answers about mistakes in a breast cancer screening test. Eastern Health discovered the problem a year and a half ago and on December 12 they released outcomes of the laboratory review.

Anticipated Questions:

- Why did it take 18 months for the review to be completed?
- Have all 117 patients affected been notified?
- Were patients put in danger because of the length of time for completion of the review?
- There were 117 patients who did not receive timely cancer therapies. Are the pathologists and/or technicians at fault here?
- What has been done to ensure this will not happen again and can you give assurances to the public and particularly breast cancer patients?

Key Messages:

- We take this matter seriously and regret that this has been a stressful time for some cancer patients. This is the first opportunity to release all of the numbers as the process to collect, send, retest, review and analyze 939 tests by an expert panel. As the results were received from Mt. Sinai, individual patients were immediately contacted.
- Our first priority was to the 117 patients who had negative ER/PR results and as the results were sent back from Mt. Sinai we took all measures possible to ensure the patients were contacted. We were very up front and open with patients in one-on-one sessions. A panel of experts reviewed each of the 117 patients and recommended any changes in their treatment plans. Some of the changes are because of the conversion in their ER/PR test result from negative to positive; some because the definition of "negative" has changed and some because of where patients are today with their disease. There were multiple factors to consider.
- It is impossible to predict how the impact of this review will impact specific patients into the future. The delay in testing was only a matter of weeks or months and is unlikely to be significant. I must emphasize that in the vast majority of the cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.
- All health authorities in the province employ competent and nationally recognized specialists and technicians who are dedicated to providing the highest quality care possible to our patients. Employees and physicians brought this issue forward and have been working diligently to ensure that the retesting and the quality review process have been conducted as efficiently and as effectively as possible.

- Eastern Health has implemented or in the process of implementing all recommendations from the external reviews. A designated laboratory has been identified to perform the ER/PR testing in a separate department with 3 designated technologists, a lab medical director, and a dedicated cutter and all staff received specialized training. A centre of excellence for all breast cancer cases has been established so that all examination and reporting will be directed to a dedicated group of pathologists. The dedicated lab has established a Quality Management Program and the accreditation process has been initiated for the entire laboratory department.

Other Suggested Response(s):

- A quality review began immediately when the problem was discovered in May 2005. Eastern Health had external consultants review the method of testing for ER/PR receptors being used. The consultants' recommendations have been implemented. They returned to Eastern Health in early April this year to assess the progress and were pleased that measures were put in place to address the concerns.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive. The tests examine hormone receptors in breast cancer cells for ER and PR and help physicians determine what course of treatment to follow for each patient.
- Eastern Health sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. This number represents about 27% of the patients tested for breast cancer. All retesting has been completed. **Eastern Health did not advise patients of the retesting and many learned of it from the media.**
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- CBC News reported on October 19 that forty-one women join class action bid on faulty breast cancer tests. The Independent, in an article on October 20, reported that at least 39 cancer patients have filed papers with Ches Crosbie, a St. John's lawyer, to bring forward a class action suit against Eastern Health.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.

- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.
- Eastern Health provided a briefing to the HCS Minister on November 23. The details are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Results Obtained and Reviewed	939
-	Patients Who Are Deceased	176
-	Patients	117

Further details on the retesting results are attached.
- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in technology, recruitment of four pathology assistants, and consolidation of pathologist review of breast tissue samples. Eastern is also pursuing accreditation of the laboratory sciences.
- CBC News reported on November 23 on the problems with ER/PR testing, the length of time (18 Months) the review is taking and lack of public communication on the matter.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: November 27, 2006

ER/PR CASE ANALYSIS



BRIEFING FOR THE DEPARTMENT OF
HEALTH AND COMMUNITY SERVICES: NOVEMBER 23, 2006

Total cases reviewed 1997-August 2005: 2760 cases

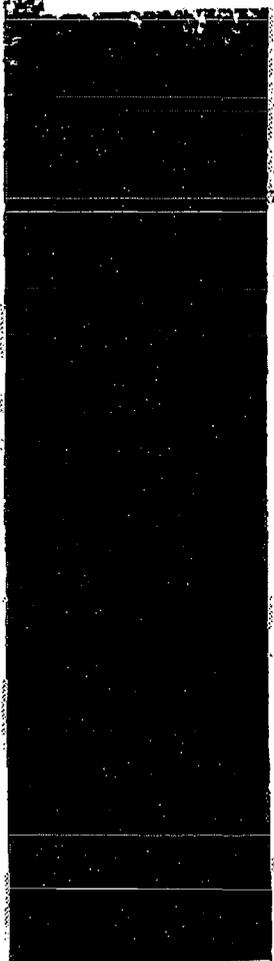
Total retested: 939.

Results obtained and reviewed: 763

- ✓ No change in results and subsequently no change in treatment: 433
 - Confirmed negative: 341
 - Confirmed negative from panel: 28
 - Confirmed positive: 12
 - DCIS: 52
- ✓ No change in results; requires change in treatment as definition of negative has changed: 13
- ✓ Change in results but does not require treatment change: 213
 - No recommendation because they are low risk: 60
 - No recommendation because they are previously treated with Tamoxifen or another aromatase inhibitor: 148
(This group includes a group identified as being potentially impacted: those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13))
 - No treatment because they required assessment prior to recommendation: 5
- ✓ Change in results and requires treatment change: 104
 - Recommended for treatment with Tamoxifen or aromatase inhibitor: 96
 - Originally diagnosis revised: 4
 - Originally had a degree of ER positivity but on retesting was negative: 4

Patients who are deceased (176):

- ✓ 101 were retested and results received
- ✓ There have been 2 retested upon request. The remaining 73 will not be retested unless the families approach us.



Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, St. John's

Issue: Breast cancer survivors want answers about mistakes in a breast cancer screening test. Eastern Health discovered the problem a year and a half ago but they are still not saying what went wrong or how many women got false results.

Anticipated Questions:

- Why is it taking so long for cancer survivors to get answers?
- Have all those affected been notified of their test results?
- Are all test results back from Mount Sinai?
- What assurances can you give the public that this won't happen again?

Key Messages:

- Our first priority was and continues to be the patients who had negative ER/PR results. I would like to assure the public that we take these matters seriously and there is a team of clinical and administrative people working on this issue. We are dedicated to improving the system, learning from our experiences and ensuring quality care.
- More than 900 test samples were sent to Mount Sinai Laboratory and all the test results are back. Eastern Health has made every effort to contact the patients or families involved. This review is in the final stages and should be concluded in the near future. Eastern will provide a briefing to the public within a week or two.
- Eastern Health has put a number of measures in place to reduce the risk of a recurrence of a similar issue. Eastern Health expects to begin testing of new patients in St. John's shortly after the review is completed.
- While this has been an unfortunate event for all of us, we are focused on ensuring patients have every treatment option that may be available to them and on addressing system issues that arise.

Other Suggested Response(s):

- A quality review began immediately when the problem was discovered in May 2005. Eastern Health had external consultants review the method of testing for ER/PR receptors being used. The consultants' recommendations have been implemented. They returned to Eastern Health in early April this year to assess the progress and were pleased that measures were put in place to address the concerns.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was

retested on a new VANTANA system in 2005 and the test results were positive. The tests examine hormone receptors in breast cancer cells for ER and PR and help physicians determine what course of treatment to follow for each patient.

- Eastern Health sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. This number represents about 27% of the patients tested for breast cancer. All retesting has been completed. Eastern Health did not advise patients of the retesting and many learned of it from the media.
- Eastern has not publicly released the results of the retesting at this time except confidentially to individual patients. The Authority is currently reviewing all charts to ensure that all individuals have been contacted. The full review should be completed by the end of November or early December.
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- CBC News reported on October 19 that forty-one women join class action bid on faulty breast cancer tests. The Independent, in an article on October 20, reported that at least 39 cancer patients have filed papers with Ches Crosbie, a St. John's lawyer, to bring forward a class action suit against Eastern Health.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.
- Eastern Health provided a briefing to the HCS Minister on November 23. The details are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Results Obtained and Reviewed	763
-	Patients Who Are Deceased	176

Further details on the retesting results are attached.

- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in technology, recruitment of four pathology assistants, and consolidation of pathologist review of breast tissue samples. Eastern is also pursuing accreditation of the laboratory sciences.

- CBC News reported on November 23 on the problems with ER/PR testing, the length of time (18 Months) the review is taking and lack of public communication on the matter.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: November 27, 2006

Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, St. John's

Issue: A mistake in testing may have led to incorrect treatment for 117 women in this province suffering from breast cancer. Not receiving proper treatment could mean a life and death issue for women going through cancer.

Anticipated Questions:

- As Minister of Health and Community Services, have you lost confidence in the physicians and managers at Eastern Health responsible for breast cancer screening?
- Why has it taken more than one year for Eastern Health to go public and release the results?
- What is the rate of error?
- When will breast cancer screening test resume at the laboratory in St. John's?

Key Messages:

- Providing quality health services to the people of this province is a priority for our Government. We regret that this may have been a stressful period for patients and their families. We are confident that Eastern Health is dedicated to improving the system and has implemented new means of ensuring a high standard of care for breast cancer patients.
- Eastern Health acted quickly and initiated retesting of ER/PR test results when the problem was discovered in May 2005. Arrangements were put in place for an independent laboratory to review the test results and complete ongoing work. The health authority took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the findings to the public.
- Eastern Health has been upfront and open with patients as soon as information about their personal situations was available. The organization has acted in what it determined to be in the best interest of its patients.
- Test samples for 939 breast cancer patients between 1997 and 2005 were retested. One hundred and seventeen (117) patients had recommended changes in their treatment plans as a result of review by a panel of experts. There were multiple factors involved. Since legal proceedings have been initiated, we will have to allow the legal process to determine if in fact error has occurred.
- Eastern Health expects to begin testing of new patients in St. John's in the new year.

Other Suggested Response(s):

- Eastern Health has put a number of measures in place to reduce the risk of a similar problem occurring in the future. While this has been an unfortunate event, we are focused on ensuring patients have every treatment option that may be available to them and on addressing system issues that arise.

- Eastern Health has implemented or in the process of implementing all recommendations from the external reviews. A dedicated laboratory has been identified to perform the ER/PR, testing with 3 designated technologists, a lab medical director, and a dedicated cutter and all staff received specialized training. A centre of excellence for breast cancer cases has been established so that examination and reporting will be directed to a dedicated group of pathologists. The dedicated lab has established a Quality Management Program and the accreditation process has been initiated for the entire laboratory department.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. The tests examine hormone receptors Estrogen (ER) or Progesterone (PR) in breast cancer cells to help physicians determine what course of treatment to follow for each patient (eg. chemotherapy, radiation).
- The chronology of the ER/PR retesting is as follows:
 - May 2005 – an oncologist discovered inconsistent test results on a patient who tested ER/PR negative in 2002 on a DAKO system and ER/PR positive in 2005 on the new VANTANA system.
 - July 2005 – decision made to retest internally all patients who were ER/PR negative from 1997 to 2004. Technology has changed over time and is more sensitive to picking up ER/PR negatives and positives.
 - Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and ongoing work.
 - August 2005 - process of collecting packaging and shipping negative test results to Mount Sinai began.
 - October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one rep from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting.
 - February 2006 – the last test results were received from Mount Sinai.
 - February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information to patients.
 - June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/PR testing in St. John's.
 - Late November 2006 – Eastern Health completes its quality review.
 - December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media.
- In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratory. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All retesting has been completed.
- Eastern Health did not initially advise patients of the retesting and many learned of it from the media before they were contacted by Eastern officials last Fall.

Eastern intended to wait for the results before disclosing actual information to the patients instead of having to tell them that they may or may not be impacted by the review and that Eastern didn't know what this would mean for them. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.

- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Patients Requiring Treatment Changes	117
- The 939 patients included 176 individuals who are deceased. One hundred and one patients were retested and results received. There were two patients who were retested upon request. The remaining 73 will not be retested unless the families request it.
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the approximately 40 plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.
- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in technology, recruitment of four pathology assistants, and consolidation of pathologist review of breast tissue samples. Eastern is also pursuing accreditation of the laboratory sciences.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

Date: December 12, 2006