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 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 in St. John's at that time.

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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.

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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

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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.

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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.

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- 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

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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.

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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 May 18, 2006 Date:

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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. Pastern 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. Lastern 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.

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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.

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- 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

ER/PR CASE ANALYSIS



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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 aromitase inhibitor: 148 (This group includes a group identified as being potentially impacted: those not placed on Lamoxiten 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 aromitase inhibitor: 96
 - Originally diagnosis revised: 4
- Originally had a degree of ER positivity but on retesting was important that those paties negative: 4

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Patients who are deceased (176):

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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

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- 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.

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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

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Department of Health and Community Services

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

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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 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.

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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.

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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

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