

**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.

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ANNEX I – CHRONOLOGY OF ER/PR RETESTING

- 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 and in September the accreditation process for the lab was initiated.
- 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 and since that time, one client issue was identified. The individual had not been seen by a doctor to obtain her test results despite a number of attempts by Eastern Health to establish contact. She has since received follow up by the physician.