



**Eastern
Health**

NEWS RELEASE

Eastern Health releases outcomes of laboratory review

EMBARGO – 9 a.m., December 12, 2006 – St. John's, Newfoundland and Labrador – Eastern Health today released the outcomes of its review of estrogen and progesterone receptor (ER/PR) testing conducted by the laboratory at the Health Sciences Centre since 1997. Eastern Health has been focused on collecting, sending, retesting and reviewing all test samples and conducting an extensive quality review within the laboratory since October 2005.

"From the beginning, our health care providers have been motivated by a desire to ensure that our patients have every treatment opportunity that may be available to them and to make sure we provide quality services to the public," said Dr. Oscar Howell, Vice-President of Medical Services for Eastern Health. "In the review period, from 1997 to 2005, 2,760 ER/PR tests were conducted by our laboratory. 939 of these test results were originally negative. These test samples were sent to Mount Sinai Laboratory in Toronto for review. In the majority of cases, the patient's treatment was confirmed appropriate. However, 117 patients had been identified as requiring treatment changes by a panel of oncologists, pathologists and surgeons."

Breast tumor samples are tested for estrogen and progesterone receptors to determine if hormonal therapy such as the drug Tamoxifen may be one treatment option for patients.

Patients who have been notified of a change in result have since met with their treating physicians to determine their current treatment options.

Eastern Health's first priority is its patients and the organization is committed to notifying them about issues that may impact upon their diagnosis or treatment. "Our clinical team members have communicated individually with all patients impacted by this review," says Dr. Howell. "We have had many conversations with the patients involved and we are always willing to discuss the details of a patient's care with them. However, patient confidentiality is an important principle in health care so we do not discuss the details of individual cases publicly."

"We have been assured through our review process, which included consultation with national experts in laboratory medicine, that when we reinstate testing we will provide the people of this province with a high standard of estrogen and progesterone receptor testing," added Dr. Howell.

Eastern Health is dedicated to improving the system. As a result of this review the organization has implemented new means of ensuring high standard patient care such as: improving a Quality Management Program; seeking accreditation for the entire laboratory; and ensuring all technologists and pathologists have received specialized training in immunohistochemistry. The organization is expected to reinstate ER/PR testing at the Health Sciences Centre in the coming year.

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ER/PR RETESTING **CHRONOLOGY** **DECEMBER 11, 2006**



Eastern Health

April 2004: Eastern Health (then the Health Care Corporation of St. John's) installed a new Ventana system for use in our immunohistochemistry laboratory. This more extensively automated system replaced the Dako System, a complicated, manual and multi-phase procedure with more than 40 steps. The Dako system was an advance from biochemical assay, used prior to 1997.

May 2005: One of our oncologists was treating an individual whose ER/PR was originally tested in 2002 (using the Dako system) and shown to be negative. Given the nature of this woman's cancer, her age and other factors, the oncologist requested that the test be repeated. The second test was conducted on the new Ventana system, and converted to a positive result.

Representatives from the Laboratory Program met with oncologists to discuss this new result and a decision was made to retest five more negative patients, who all converted to positive.

June 2005: It was decided to retest all negative results from 2002 to determine if these were isolated cases or symptomatic of a bigger issue. The chief of pathology wrote to all Laboratory directors in the province to return all negative ER/PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system.

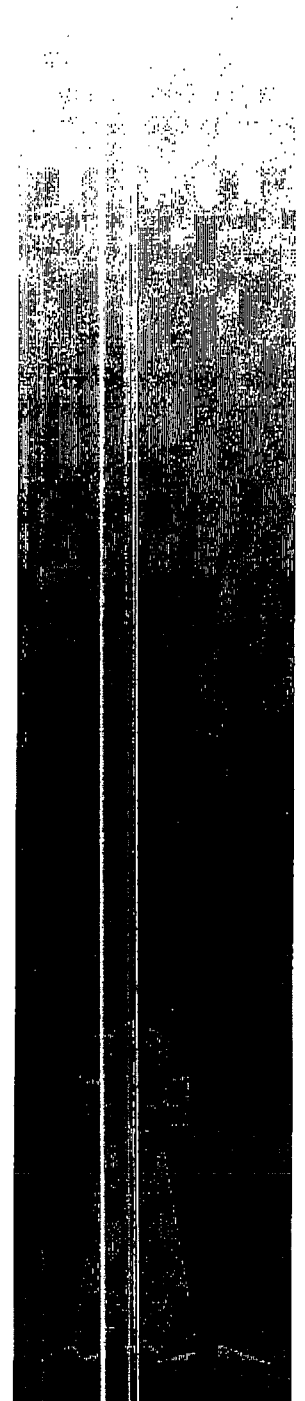
Early July 2005: A meeting was scheduled and the decision was made that all patients who were ER/PR negative from 1997-2004 would be retested internally on the Ventana System with testing to take place over the next number of weeks.

Late July 2005: The decision was made to stop reporting ER/PR in our laboratory and to arrange for an independent and external laboratory to complete our retesting as well as ongoing work.

August 2005: Mt. Sinai Hospital, considered to be a "gold standard" laboratory internationally, agreed to take on the project. Our laboratory began the process of collecting, packaging and shipping all negative* test results from 1997-2005 to Toronto.

** The definition of "negative" has changed within the seven year period in question. Originally, oncologists believed that tumors with less than 30% positivity for ER/PR should be considered negative. With advancing understanding of cancer and treatment, the negative rate has dropped, first to 10% and now to 1%. Today, oncologists believe that any positivity may be worth treating with hormonal therapy.*

Early October 2005: The first set of results arrived from Mt. Sinai.



Mid October 2005: The organization established a Tumor Board comprised of two (2) oncologists, two (2) surgeons, two (2) pathologists, one (1) representative from the Quality Department and one (1) support person. The Tumor Board was tasked with reviewing the results as they arrived, reviewing charts, and making treatment recommendations for each patient.

The Tumor Board met once a week from October 2005 to May 2006 reviewing individual cases and making recommendations.

Mid October 2005: The organization conducted the first of numerous media interviews, and provided what background information was available at that time. Advertising was also purchased informing the general public of the retesting in general.

October 2005: Patient Relations representatives from Eastern Health telephoned all individuals whose specimens were being sent away for retesting.

The laboratory conducted the first of a number of external review processes. During this period, the laboratory also attempted to gain insight from other laboratories across Canada regarding their experiences with ER/PR testing.

November/ December 2005: The organization expressed concerns to Mt. Sinai about the slow pace of reports. However, they were experiencing unexpected manpower issues and were unable to move the tests through the system any faster.

Late January 2006: The last batch of samples arrived at Eastern Health from the other provincial health authorities. They were forwarded to Mt. Sinai for review.

February 2006: The last test results were received from Mt. Sinai.

February - May 2006: Concentrated effort of the Tumor Board to review test results, write recommendations and conduct disclosures. A six month period (*May to October*) follows to ensure that the organization has completed all the disclosures possible and that every patient has had every opportunity to contact their physicians.

June - November 2006: The new Chief Pathologist and the new Vice-President, Medical Services worked on the results of the quality review process; established a centre of excellence for breast cancer pathology; assigned a head pathologist for immunohistochemistry; and generally prepared for the continuation of ER/PR testing in our laboratory.

September 2006: A statistical review is initiated to examine the numbers and arrive at conclusions. This information will form the basis of the quality review. Analysis is currently continuing.

Late November 2006: The organization completes its quality review.