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**To:** Abbott, John  
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**Subject:** Briefing Note- ER/PR

**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 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.

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**Approved by: Moira Hennessey**

**Date: May 2, 2006**