

**Keats, Kelly**

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**From:** Stephanie Power  
**Sent:** Wednesday, October 05, 2005 1:51 PM  
**To:** Keats, Kelly  
**Cc:** Alteen, Larry  
**Subject:** Briefing Note

Hi Kelly,

Attached is a briefing note that I prepared for Dave and Larry. They may need to distribute this to some stakeholders in the near future; however, I know that Larry will want to make several changes to it before that occurs. As I will be away for the next week, I am forwarding this to you so that you will be able to do so in my absence.

Thank you.

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Stephanie L. Power, BPR  
Director of Communications and Planning  
Central Health  
709.292.2629 (phone)  
709.292.2249 (fax)

### **Briefing Note**

**Issue:** ER/PR receptor tests resulting in false negatives.

**Background:**

ER/PR refers to estrogen and progesterone receptors in breast tissue. If a patient has breast cancer and tests positive for ER/PR receptors, the patient would typically receive Tamoxifen as an initial course of treatment. When test results indicate a negativity for ER/PR receptors, the patient would normally chemotherapy treatments.

In 1997, a Dako semi-automated/manual system was installed for immunohistochemistry service and was replaced by a Ventana system in April, 2004. On May 11, 2005, a patient initially tested in 2002 with the Dako system and reported as ER/PR negative, was retested with the Ventana system and indicated a strong positivity for estrogen and progesterone receptors. Four other patients initially tested as negative in 2002 were also retested and all tested positive with the Ventana system.

On June 13, 2005, Dr. Cook wrote to all Laboratory Directors in the province and requested that they return all negative ER and PR specimens for the year 2002 for retesting on the new, more sensitive Ventana system. In mid-June a list of all patients that tested negative for ER/PR receptors during that period was compiled and sent with the corresponding specimens to Eastern Health on June 29, 2005. Retesting was then expanded to include all samples that initially tested negative in 2002 on the Dako system. Of 57 retests using the Ventana system, 38 showed positive results. This high conversion rate was unexpected and placed the sensitivity of the Ventana system in question.

Additionally, on September 6, 2005 a list of all patients that tested negative for ER/PR receptors for the period of May 1997 to March 2004 was compiled and sent with the corresponding specimens to Eastern Health. Combined, these lists include 88 patients from CNRHC and 62 patients from JPMH.

**Current Status:**

External pathology and technical reviews have been completed on the Ventana machine, these reports are pending. However, some recommendations have already been implement. Retesting of all specimens for these years is currently underway at Mt. Sinai Hospital in Toronto, the leading breast cancer research and treatment facility in the country. Additionally, all new requests for testing are being sent to Mt. Sinai.

Results are arriving at the Health Sciences Centre in batches. Although none of the retests to date have been for patients of Central Health, it is predicted that their may be a 25 per cent conversion rate. This means that approximately 38 patients of Central Health will need to be contacted to and told that the result of their initial test was incorrect (they tested negative, but were in fact positive). For many patients, this will mean that they underwent a harsher more invasive course of treatment (chemotherapy) unnecessarily.

**Key Messages:**

- Medical professionals from Central Health have compiled a list of all clients tested for ER/PR receptors between the years of 1997 to 2004.
- From that list, all specimens belonging to clients who tested negative (based on the criteria as determined by oncologists at Eastern Health) have been sent to Mt. Sinai for retesting.
- Officials at Central are currently in the process of compiling a list of all clients who's specimens have been sent for retesting.
- Once all clients have been identified, general practitioners and senior medical officers will contact those clients.
- It is anticipated that retesting results from Mt. Sinai may not be available for four to six months.
- All patients who's test result show a variance will be contacted at the earliest possible opportunity.

**Other:**

- Eastern Health has been in contact with several hospitals across the country that previously used the Dako system. None had identified this issue; however, upon retesting of their own specimens, many have also encountered a similar conversion rate. As a result, they are also in the process of beginning retesting at other laboratories.
- As there are very few specialized laboratories in the country, the increased demand for retesting will likely make for a lengthy waiting period.

**Drafted by:** S. Power, 292-2629

**Approved by:**

October 4, 2005