**Susan Bonnell**

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**Sent:** Tuesday, July 19, 2005 2:06 PM
**To:** George Tilley
**Subject:** DRAFT

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Briefing Note – ER/PR Receptors

Background:

On May 11th, Dr. Joy McCarthy contacted Dr. Don Cook to retest a patient who previously tested negative for Estrogen and Progesterone Receptors in 2002. Using new technology for immunoperoxidase staining installed at the General Hospital Histology Lab in April of 2004, this woman sample was retested and discovered to be positive for ER and PR.

On May 17th, representatives from the Laboratory Program met with Drs. McCarthy and Kara Laing to discuss this new result and a decision was made to retest five more negative patients, who all retested positive.

It was decided to retest all negative results from 2002 to determine is this was a few isolated cases or a bigger issue. Samples collected from 25 women, initially tested as negative in 2002, were retested. 16 of these came back positive. Testing is currently being done on 33 more patients. Approximately 12 of these patients have been informed by their oncologists.

On June 13, 2005, Dr. Cook wrote to all Laboratory directors in the province to submit all negative ER and PR cases for the year 2002 for retesting with the new, more sensitive Ventana system.

Actions:

- On Thursday, July 14th, the decision was that all patients who were ER and PR negative from 1997-2004 will be retested, beginning with the 2002 patients. This testing will take place over the next number of weeks.

- To date, no samples have been received from the Provincial Laboratory Directors. Dr. Cook will contact all Laboratory Directors again requesting samples from 1997 to 2004.

- As a precautionary measure and to back-up the validity of the new technology, the current testing standards (Ventana system) are being assessed by cross-referencing our results with another laboratory. (Mount Sinai)

- Extra resources have been identified within the HCCSJ lab to undertake identification and retesting. The list of patients will be double-checked with the names on the Cancer Registry to ensure none have been missed.

- HIROC have been contacted to determine if they are aware of any other issues with the Dako testing system

- Women who have to have their treatment altered because of this result will be contacted by her family doctor or oncologist.

- The public will have to be informed. Corporate Communications have been involved and, as at least five patients are aware of this information already, disclosure has to be made quickly. After meeting with the surgeons and oncologists, it was decided to wait until we were able to get more information regarding retesting, the anticipated timelines and a support line established. This support line for patients will be coordinated through QSI. Legal counsel will review the proposed media release before it is distributed.

- Once the magnitude of the problem and the relevant time frames has been determined, an external technical consultation will need to be undertaken to assess standards and quality of service.

Notes:

- We do expect a higher number of positives due to the sensitivity of the newer equipment

- Timelines required to do the retesting internally will be determined as soon as possible. If it is determined to be too time-consuming, options to utilize external laboratories will be explored.

- It has been determined that positive controls were conducted everyday, as part of the quality assurance process within the lab. The results were read and documented daily by a pathologist. Also the processes used by HCCSJ technicians were those outlined in the Dako procedure manual.

- Estimates are that 50 – 85 per cent of all breast cancers exhibit estrogen receptors and that such tumours are commonly found in post-menopausal women.

- A high percentage of tumours with estrogen receptors may regress after hormonal manipulation whereas only a small number (about 5 per cent) of those that are negative respond. The highest response rates are in patients with tumours exhibiting both ER and PR receptors. Breast cancer patients with high level hormone receptors have a slightly better prognosis than those without receptors.

- The Dako test was implemented in 1997 to replace an a bioassey method for ER/PR receptors. All samples which initially tested as negative from 1997 until the implementation of the Ventana system in April 2004 will be retested. As the test results can affect future treatment, patients that are still living will have the testing done first, before it is done on those that are deceased.