

From: [Heather Predham](#)
To: [Susan Bonnell;](#)
Subject: briefing note
Date: September-30-05 1:47:40 PM
Attachments: [Briefing Note, Sept 30, 2005.doc](#)

Hi,

How's this? The bold and underline sections need to be confirmed.....

Heather

Briefing Note
ER/PR Testing Results
September 14, 2005

In 1997, a Dako semi-automated/manual system was installed for the Immunohistochemistry Service and replaced the bioassay method of testing for ER/PR receptors. This Dako system was replaced in 2004 by an automated Ventana system with onboard antigen retrieval.

In 2005, a patient, initially tested in 2002 with the Dako system and reported as ER/PR negative, was retested with the Ventana system and now 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.

Retesting was expanded to include all samples initially tested as negative in 2002 on the Dako system. Of the **57 retested on the Ventana system, 38 now showed positive results**. This high conversion rate then placed the sensitivity of the Ventana System in question.

A representative from Ventana has visited the Immunohistochemistry Service to review use and practices of the Ventana system. In their written report, they stated that they found the system to be operating as expected and that the procedures used by our technicians were appropriate and as trained.

An external peer review was conducted **September 15-16, 2005** to review current practices and procedures within the Immunohistochemistry Service.

Current Activities:

- ER/PR results obtained from the Ventana system from April 2004 to August 9, 2005 will be correlated with ER/PR results of the same samples conducted by Mount Sinai and Montreal General.
- All negative samples from 1999 to 2003 (with the exception of samples from other regional boards) have been collected and sent to Mount Sinai Hospital, Montreal, for retesting. Mount Sinai uses a semi-automated system of testing for ER/PR. 323 samples reported as weakly positive to negative have been sent to Mt. Sinai for retesting. Seventy-five of the samples have now been retested and reported by Mt. Sinai using its Dako system. Of the 75 samples retested thus far, Mt. Sinai has confirmed the results reported by the subscriber in 41 cases. 12 of the 75 had been reported previously as negative for ER but positive for PR

or vice versa, and found by Mt. Sinai to be positive for both. 20 of the 75 samples had previously been reported as both ER and PR negative and now are determined by Mt. Sinai as positive. The remaining 248 samples retested by Mt. Sinai will be reported shortly. Samples for 1997-1998 and for two regional boards from outside Eastern Health area will soon be sent for retesting.

- All laboratory directors in the province have been contacted to submit all negative ER and PR reports and samples for this same time period for retesting. This process is underway.
- Reporting of ER/PR by the Laboratory Medicine Program is currently on hold. All current requests for ER/PR are being forwarded to Mount Sinai for processing, interpretation and reporting.