

From: Tansy Mundon
To: Hynes, Darrell
Date: 10/3/2005 8:12:56 AM
Subject: Briefing Note - ER/PR testing

Darrell,
Here is briefing note provided on issue in the Independent. Moira is back in the office today and I'll discuss with her. I'll also check on the ambulance issue.

Tansy

Briefing Note
ER/PR Testing Results
September 30, 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 was positive 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 these samples, a majority 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, by the Chief Pathologist of the British Columbia Cancer Institute and the Chief Technologist from Mount Sinai Hospital, was conducted September 15 - 22, 2005, to review current practices and procedures within the Immunohistochemistry Service. Debriefing was held after each review and a full report from each is expected within the next few weeks.

Current Activities:

§ All negative samples from 1999 to 2004 (with the exception of samples from other regional health authorities) have been collected and sent to Mount Sinai Hospital, Montreal, for retesting. Mount Sinai uses a semi-automated system of testing for ER/PR. Three hundred twenty-three samples reported as weakly positive to negative have been sent to Mt. Sinai for retesting. To date, 153 samples have been reported by Mount Sinai; 73 have been reviewed, and it appears that of those there are 16 * 20 individuals whose treatment could be impacted. Samples for 1997-1998 and for two regional health authorities from outside Eastern Health area will soon be sent for retesting.

§ All laboratory directors in the province were contacted over the past few months to submit all negative ER and PR reports and samples for this same time period for retesting. This process is underway. Seventy-eight samples from 1997 * 2004 from Gander and Carbonear are in the process of being submitted. Specimens from Grand Falls have just been received.

§ 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.