Denise Dunn

From: Heather Predham
Sent: Monday, October 24, 2005 9:27 AM
To: Patricia Pilgrim; Dr. Robert Williams
Subject: [redacted]

Hi,

[redacted]

Heather

-----Original Message-----
From: Heather Predham
Sent: Monday, October 24, 2005 9:26 AM
To: [redacted]
Subject: [redacted]

[redacted]

ER/PR is the abbreviation for estrogen and progesterone receptors. If a person has been diagnosed with breast cancer, there is a Immunohistochemistry test that can be performed on the biopsy sample which determines the presence or absence of these receptors. If the receptors are present, then that person may respond well to adjuvant hormone therapy, such as Tamoxifen. The patient may end up on chemotherapy as well, but it is felt that Tamoxifen may decrease the metastatic aspects of the breast cancer.

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. 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.

We expanded our retesting 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 was unexpected and then placed the sensitivity of the Ventana System in question. At that point in time we halted testing at our site and asked Mount Sinai in Toronto to conduct our ongoing testing, as well as the retesting back to 1997.

We have conducted external reviews on our Ventana set-up and procedures, and on the pathology side of the Immunohistochemistry service and the technical side. All those reports are pending, but we do have some recommendations that can be implemented immediately. We have done the processing and staining for the other three boards in the province and we are coordinating their retesting as well.

Throughout all this time HIROC has been fully briefed and aware of our activity. Through Dan Boone they have provided feedback on correspondence to surgeons and family physicians and our media briefings. The only thing they have felt strongly about was sending a letter in July/August to all people whose samples would be retested. As there was no information about their individual results, we still investigating to determine if there was a problem, and we were unsure of when the new results would be available HIROC felt it would expose us unnecessarily to additional liability. This, of course, is from their experience in Labrador, where the crux of the class action lawsuit was the notification and the unnecessary stress related to it.

[redacted]

[redacted]

Thanks

Heather