



Corporation of St. John's

Department of Laboratory Medicine

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FAX TRANSMISSION

To: Irish Wegrynowski

Date: Sept. 14-05

From: Dr. Don Cook

Pages (including Cover): 3

Subject:

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Comments:

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Terms of Reference

External Quality Review of the Immunohistochemistry Service

Purpose:

To review the operation, and make recommendations, as to the processes involved in a service of the Laboratory Medicine Program.

Accountability:

The External Quality Review Consultant will take direction from and make recommendations to the Leadership Team of the Laboratory Medicine Program

Timeframe:

Review and report to be complete within 3 months.

Responsibilities:

1. To review current practices and procedures within the Immunohistochemistry Service of the Laboratory Medicine Program.
2. To interview individuals who may have relevant facts or pertinent background information of the Immunohistochemistry service, with particular emphasis in ER/PR.
3. To identify other issues of concern, using a systems approach, which may have contributed to the situation being reviewed.
4. To provide recommendations as appropriate to deal with any issues identified during the review.
5. To summarize the findings of the Quality Review in a confidential report.

Case Summary

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. As a result, all negative samples since 1997 have been sent to an external laboratory for retesting.

Report:

The External Quality Review shall be in writing and include the team's recommendations. The recommendations will be shared with involved staff members.

The Peer Review, its conclusions and the final report are protected under the Evidence Act and, as such, the final report will not be available to any third party and as well the final report is protected from any subsequent legal proceedings.