

Lab Test to Detect Metastatic Breast Cancer

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FDA News
FOR IMMEDIATE RELEASE
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FDA Approves First Molecular-Based Lab Test to Detect Metastatic Breast Cancer

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01667.html>

The U.S. Food and Drug Administration today approved the first molecular-based laboratory test for detecting whether breast cancer has spread (metastasized) to nearby lymph nodes. The GeneSearch BLN Assay detects molecules that are abundant in breast tissue but scarce in a normal lymph node.

The presence or absence of breast cancer cells in underarm lymph nodes is a powerful predictor of whether the cancer has spread and is used to help decide appropriate therapy for a woman with metastatic breast cancer.

Lymph nodes are part of the system that helps protect the body against infection. The first lymph node that filters fluid from the breast is called the "sentinel node," because that is where breast cancer cells are likely to spread first.

During a lumpectomy or mastectomy to remove a breast tumor, surgeons commonly remove the sentinel node for examination under a microscope. Sometimes the sentinel node is examined immediately and if tumor cells are found, additional lymph nodes are removed. A more extensive microscopic examination, requiring one to two days for results, is

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almost always performed. If tumor cells are only found with the later microscopic examination, the patient may require a second surgery to remove the remaining lymph nodes.

"The GeneSearch BLN Assay offers a new approach to sentinel node testing," said Daniel Schultz, M.D., director of the FDA's Center for Devices and Radiological Health. "Results of this rapid test are available while patients are on the operating table, providing a way for some women to avoid a second operation."

In a clinical trial, the GeneSearch BLN Assay showed strong agreement with results from extensive microscopic examination of the lymph nodes of 416 patients. The test accurately predicted that breast cancer had spread nearly 88 percent of the time in women with metastasis. Patients without metastasis were identified accurately 94 percent of the time.

Most of the women were also studied to compare the BLN Assay with immediate microscopic examination during surgery. The test gave fewer false negative results, but slightly more false positive results. A false negative test result, when the cancer has actually spread, may delay the needed removal of additional lymph nodes. A false positive test, indicating metastasis when there is none, may result in a more extensive surgery and puts the women at risk of unnecessary lymphedema (swelling due to fluid build-up following lymph node removal) and other side effects.

The GeneSearch BLN Assay is manufactured by Veridex, a Johnson & Johnson Company, of Warren, N.J.

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