FDA approves new breast cancer lab test

July 17 2007

The U.S. Food and Drug Administration has approved the first molecular-based laboratory test for detecting whether breast cancer has metastasized.

The GeneSearch BLN Assay test approved Monday detects molecules that are abundant in breast tissue but are scarce in a normal lymph node.

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

"The GeneSearch BLN Assay offers a new approach to sentinel node testing," said Dr. Daniel Schultz, 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."

The GeneSearch BLN Assay is manufactured by Veridex, a Johnson & Johnson subsidiary located in Warren, N.J.