

# Veridex GeneSearch Breast Lymph Node Assay

FDA Panel Presentation  
Introduction

Division Of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and  
Safety  
Center for Devices and Radiological Health  
November 16, 2006

Scientific Review Team:

James P. Reeves, Ph. D. - Lead Reviewer

Gene Pennello, Ph. D. - Statistician

Max Robinowitz, M. D. Medical Officer - Pathologist

Roxolana Horbowyj, M. D. Medical Officer - Surgeon

# FDA review

- Assay design
- intended use population and setting
- analytical issues
- clinical validity
- clinical utility

## Proposed Intended Use

A qualitative *in vitro* test for the rapid detection of clinically relevant (> 0.2 mm) metastases in lymph node tissue removed from breast cancer patients. Results from the assay can be used to guide the decision to excise additional lymph nodes and to aid in patient staging.

# Topics of Interest

- As a qualitative test, with a cut-off aimed at detecting micrometastatic disease, use of the GeneSearch BLN assay will change current medical practice. The clinical value of detecting micrometastases is a topic of active investigation and debate.
- As a standalone test, the GeneSearch BLN assay does provide information about the presence of micro- and/or macrometastatic tumor in sentinel nodes.

# Topics of Interest

- The sensitivity of the GeneSearch BLN assay for intra-operative use certainly exceeds that of not testing and exceeds the sensitivity of frozen section consultation aimed at micro- and/or macrometastatic disease.
- After extensive histologic examination, the confirmation rate for positive GeneSearch BLN results (i.e. specificity) is less than the rate commonly reported in the literature for positive frozen section sentinel node diagnoses, and may be less than the confirmation rate found in sponsor's study for positive frozen section diagnoses.

# GeneSearch Test Results: Safety and Effectiveness Issues Associated with True and False Results

<b>True Positive</b> PPV = x% (x%, x%)	<b>False Positive</b> 1-PPV = x%
<ul style="list-style-type: none"> <li>• ALND performed w/o need for second operation</li> <li>• Verified as positive by permanent section, but not involved in intra-operative decision</li> </ul>	<ul style="list-style-type: none"> <li>• Potentially preventable ALND (possibly unable to make histological determination since action already taken)</li> <li>• Permanent section not involved in intra-operative decision</li> </ul>
<b>True Negative</b> NPV = x% (x%, x%)	<b>False Negative</b> 1- NPV = x%
<ul style="list-style-type: none"> <li>• No ALND performed</li> <li>• Verified as negative by permanent section</li> <li>• No second operation required</li> </ul>	<ul style="list-style-type: none"> <li>• No ALND performed</li> <li>• Permanent section detects tumor 1-2 days after breast lumpectomy</li> <li>• Patient must be called back for second operation</li> </ul>

# Speakers

- Dr. Roxolana Horbowyj – a general and critical care surgeon specializing in the breast
- Dr. Max Robinowitz- Pathologist
- Dr. James P. Reeves - Scientist
- Dr. Gene Pennello – Statistician
- Dr. James P. Reeves



# U.S. Food and Drug Administration

