



New Device Approvals

PATHWAY™ Her 2 (Clone CB11)- P990081

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: PATHWAY™ Her 2 (Clone CB11)
Manufacturer: Ventana Medical Systems, Inc.
Address: 3865 North Business Center Drive, Tucson, AZ 85705
Approval Date: November 28, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990081a.pdf>

What is it? An automated test to detect abnormal amounts of a protein called Her2 in breast cancer tissue. Using a product called Herceptin to reduce the amount of Her2 in these cancers can be an effective treatment. But before deciding to use Herceptin, it is important to be sure the cancer has elevated Her2 levels, because Herceptin itself can have serious risks.

How does it work? A sample of a breast cancer tissue is treated with a material that binds to Her2. Then dye is added to the tissue. Where the color is strong, the breast cancer tissue has large amounts of Her2.

<http://www.medscape.com/Medscape/Nurses/TreatmentUpdate/2000/tu02/public/toc-tu02.html>

When is it used? To choose breast cancer patients for Herceptin® treatment.

http://www.fda.gov/fdac/departs/1999/199_upd.html

What will it accomplish? Breast cancer is the most common newly diagnosed malignancy in American women and is the second leading cause of cancer-related death. The FDA approved therapeutic Herceptin® has been shown to benefit some breast cancer patients by arresting, and in some cases reversing, the growth of their cancer. This test determines which breast cancer patients are more likely to benefit from Herceptin® therapy.

When should it not be used? There are no known contraindications to date for this test.

Additional information: Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/p990081.html>

Other:

- MQSA Consumers: <http://www.fda.gov/cdrh/mammography/consumers-rev.html>
- Mammograms and Breast Cancer Brochure: <http://www.fda.gov/cdrh/consumer/mammobrochure.html>

(Updated 3/22/01)