

New Test For Breast Cancer Making Individualized Treatment Decisions A Reality

(NAPSA)—Widely hailed as the next frontier in medical advances, the promise of individualized medicine is becoming a reality thanks to progress in understanding the molecular basis of diseases such as breast cancer. Scientists can now develop treatments that are tailored to individual genetic profiles, as well as tests to predict how a patient will respond to existing therapies.

Today, some women with early-stage breast cancer and their physicians can make more informed treatment decisions with the Oncotype DX Breast Cancer Assay. This service provides quantitative information about genes from a woman's individual tumor to generate a Recurrence Score between zero and 100, indicating whether she is at high, intermediate or low risk for her cancer returning after treatment.

Oncotype DX is intended for patients with node-negative, estrogen receptor-positive breast cancer who are likely to be treated with hormonal therapy. Approximately half of the 230,000 patients diagnosed with breast cancer in the United States each year fall into this category, and are frequently offered treatment with chemotherapy, a widely used treatment with considerable side effects. Clinical studies show that chemotherapy improved patient survival rates in only 4 out of 100 patients, yet thousands of women continue to elect this costly and toxic treatment with only limited information about whether they might respond to it.

A recent study demonstrated that women with high Recurrence Scores are more likely to benefit from chemotherapy, whereas women with lower scores derive only minimal benefit. Further,

PATIENT REPORT

Patient: Doe, Jane
Site: Farnam
DOB: 01/01/1950
Medical Record/Physician #: 123456789
Date of Surgery: 11/23/2004
Specimen ID: SURF-0001

Registration: R100000
Date Received: 11/23/2004
Date Reported: 12/15/2004
Clinic: Community Medical Center
Treating Physician: Dr. Henry D. Smith
Submitting Pathologist: Dr. John W. Williams
Additional Physician: Dr. Sally M. Jones

ASSAY DESCRIPTION

Oncotype DX Breast Cancer Assay uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The "Recurrence Score" is calculated from the gene expression results. The Recurrence Score ranges from 0-100.

RESULTS

Recurrence Score = 10. Test results should be interpreted using the information in the Clinical Experience section below, which applies only to patients consistent with this clinical experience.

CLINICAL EXPERIENCE

Patients with a Recurrence Score of 10 in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of 7% (95% CI: 5%-9%).

The following results are from a clinical validation study with prospectively defined endpoints involving 10,000 patients. The patients enrolled in the study were divided, either for or node-negative, ER-positive, and treated with tamoxifen. All p-values <0.0005. DOI: 10.1215/0022-0028

Laboratory Director: Patrick Joseph, MD
CLIA Number: 04D0701722
This test was developed and its performance characteristics determined by Genentech Health, Inc. The laboratory is registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are subjective to the verifying physician's review.

The Oncotype DX service analyzes a specific set of genes within a woman's individual tumor to measure whether her cancer will return following treatment as well as her response to chemotherapy.

only 25% of women fell into the high-risk group, compared to 50% in the low-risk group, indicating that this common treatment is not appropriate for every patient.

Elizabeth Sloan of New York City is one of the many breast cancer patients not likely to respond to chemotherapy. An active mother with two young boys, Elizabeth was considering having another child when she was diagnosed at just 40 years old. She wanted to avoid chemotherapy, with its disruptive, short-term side effects and potentially serious long-term implications, but also wanted to be absolutely certain that it wouldn't help her.

Working with her doctor, Ruth Oratz, M.D., at NYU Medical Center, Elizabeth decided to have the Oncotype DX assay, and was delighted when her Recurrence

Score turned out to be low—indicating that she may not benefit significantly from chemotherapy.

“No two women with breast cancer are exactly alike. Oncotype DX provides information that goes beyond standard measures, like age, tumor size and tumor grade, in determining the likelihood of disease recurrence,” says Dr. Oratz. “Oncotype DX gave Elizabeth and me added confidence and peace of mind in selecting the most fitting treatment for her.”

For Susan Bakken of Denver, Colorado, Oncotype DX provided a different kind of peace of mind. Susan's Recurrence Score indicated that she was at high risk of cancer recurrence, and would likely benefit significantly from chemotherapy—to both her surprise and her doctor's.

“Based on the other tests I had, my doctor said he wouldn't have otherwise recommended chemotherapy. I was shocked to find out my result, but I was so glad I did because I believe this test basically saved my life,” explained Susan.

Elizabeth Sloan is also grateful for the information she gained from Oncotype DX. “Not all cancers are the same, so why treat everyone the same way with something so toxic?” she said. “It's so remarkable that finally, doctors can distinguish one person's cancer from another—I'm just so thankful.”

Oncotype DX is a simple test that can only be ordered by a physician. It is performed on a small amount of breast tumor tissue removed during a standard lumpectomy, mastectomy or biopsy, meaning no additional procedure is required. For more information about the service, talk to your physician or visit www.oncotypedx.com.