



WOMEN'S HEALTH

New Breast Cancer Treatment Guidelines Recommend Test To Personalize Treatment

(NAPSA)—When faced with the diagnosis of breast cancer, many women will undergo chemotherapy following surgery to reduce the chance of cancer returning. For those women, the dilemma of facing chemotherapy or dealing with the possibility that their cancer could return is overwhelming, even with a doctor's help.

Many women believe that chemotherapy is a required element of treatment. But research shows that only four out of every 100 women with Stage 1 breast cancer actually benefit from chemotherapy.

Now, the American Society of Clinical Oncology (ASCO), the world's leading professional organization representing physicians who treat cancer patients, has issued new Clinical Practice Guidelines that for the first time include molecular diagnostics in treatment planning to help make these difficult decisions easier. ASCO's updated guidelines, which outline appropriate cancer treatment methods, recommend a breast cancer test called Oncotype DX™ to calculate the likelihood that cancer could return and the benefit of using chemotherapy for a large portion of early-stage breast cancer patients. By using this test, women and their doctors can make a more informed decision about whether the potential benefit of chemotherapy outweighs the side effects.

“ASCO's new guidelines include only markers based on proven clinical decision-making impact and high levels of clinical validation,” said Dr. Gabriel N. Hortobagyi, FACP, professor and chairman, Department of Breast Medical Oncology, The University of Texas M.D. Anderson Cancer Center. “While exciting research and multiple prognostic tools are available today, Oncotype DX is the only genomic test with sufficient clinical evidence to support its use in clinical practice.”

Oncotype DX looks at 21 genes

PATIENT REPORT

Patient: Doe, Jane
Sex: Female
DOB: 01/01/1960
Medical Record/Patient #: 556677771
Date of Surgery: 11/20/2004
Specimen ID: SURG-0001

Requisition: R0000004
Date Received: 12/01/2004
Date Reported: 12/13/2004
Client: Community Medical Center
Treating Physician: Dr. Henry D. Smith
Submitting Pathologist: Dr. John P. 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 range is from 0-100.

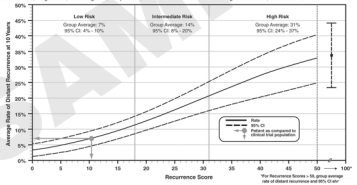
RESULTS

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-derived endpoints involving 808 patients. The patients enrolled in the study were female, stage I to II, node-negative, ER-positive, and treated with tamoxifen. (M. Eng J. Clin Oncol 2004; 22:1387-95)



Laboratory Director: Patrick Joseph, MD

CLIA Number 05D1018272

This test was developed and its performance characteristics determined by Genentech Health, Inc. The laboratory is regulated 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 additive to the treating physician's notes.



Oncotype DX 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.

in a woman's tumor tissue to calculate a Recurrence Score™, an individualized number between 0 and 100. The lower the score, the lower the chances are that a woman's breast cancer will come back, and the less likely that she will benefit from chemotherapy.

“I felt confident in Oncotype DX because the result was based on 21 genes from my tumor,” said Penny Smith, a breast cancer patient who decided against chemotherapy after receiving a low Recurrence Score. “I felt that I was getting good information and it was going to give me back control over fighting my cancer.”

Oncotype DX is used for patients with estrogen receptor-positive, node-negative, early-stage breast cancer—approximately half of newly diagnosed cases. It is the only test with extensive clinical evidence demonstrating the ability to identify patients who will benefit from chemotherapy.

For more information about treatment decisions for breast cancer, visit www.MyTreatmentDecision.com.