

## Reporter Backgrounder: Oncotype DX Breast Recurrence Score® Test

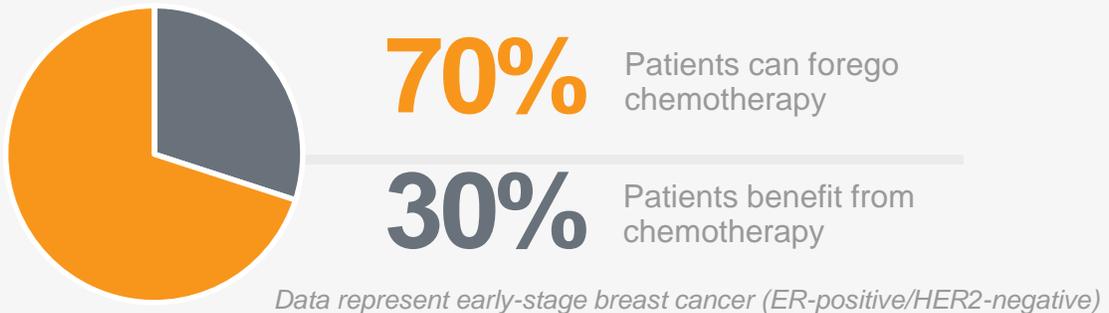
### Oncotype DX® Test Ushers in a New Era in the Treatment of Early-stage Breast Cancer by Definitely Determining Chemotherapy Benefit

Not every breast cancer patient needs the same treatment. While chemotherapy can be effective for some patients, not all benefit in the same way. The biology of cancer is complex, and patients with breast cancer need more definitive information about chemotherapy treatment benefit.

Nearly 1 million early-stage (ER-positive/HER2-negative) breast cancer patients in more than 90 counties have used the Oncotype DX Breast Recurrence Score test to predict their individual likelihood of chemotherapy benefit to enable them and their physicians to personalize their course of care.



Laurie L., Oncotype DX-tested patient

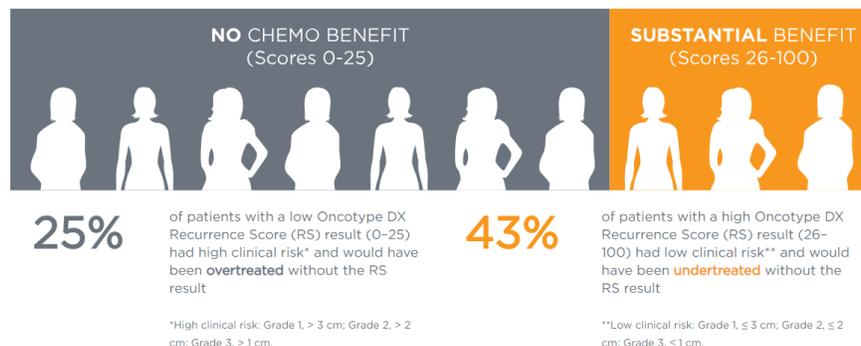


### What is the Oncotype DX Breast Recurrence Score Test?

Designed specifically for newly-diagnosed early-stage (ER-positive/HER2-negative) breast cancer, the Oncotype DX Breast Recurrence Score test is distinguished by international clinical guidelines as the only genomic test predictive of chemotherapy benefit. After the test has been performed on the tumor tissue sample previously obtained during the original surgery, and the level of activity of cancer-related genes has been assessed, patients receive a Recurrence Score® result – a number between 0 and 100.

A Recurrence Score result in the range 0-25 means that cancer is less likely to come back if treated with hormonal therapy alone and that chemotherapy will not add additional benefit over hormone therapy alone or change the clinical outcomes in most patients.

A Recurrence Score result in the range 26-100 suggests a greater risk that cancer will come back, and that chemotherapy, used in addition to hormone therapy, is very likely to provide substantial benefit in reducing this risk.



## Data and Guidelines Support Using the Test as Standard of Care

- Oncotype DX Breast Recurrence Score® is the only test that predicts chemotherapy benefit, as demonstrated in multiple studies with consistent results providing the highest level of clinical evidence (Level 1).
- Trusted by physicians and patients for over a decade, the test is recognized as the gold standard to determine early-stage breast cancer treatment, which is why multiple research groups rely on the test for their research.
- Results from the largest-ever adjuvant breast cancer trial – TAILORx – demonstrate that the Oncotype DX® test identifies a vast majority of women with early-stage breast cancer who receive no benefit from chemotherapy and the important minority of women for whom chemotherapy can be life-saving. The findings from this trial, sponsored by the NCI and conducted by the ECOG-ACRIN Cancer Research Group, were published in *The New England Journal of Medicine*.<sup>1</sup>
- Supported by multiple rigorous clinical validation studies and prospective outcome data in more than 70,000 patients.
- Included in all major international clinical guidelines including: ASCO®, NCCN® in the U.S., and St. Gallen, ESMO and NICE in Europe.

**“The TAILORx results provide an unprecedented level of precision and the highest level of evidence supporting the use of Oncotype DX to guide adjuvant chemotherapy use.”**

- Joseph A. Sparano, M.D., associate director for clinical research at the Albert Einstein Cancer Center and Montefiore Health System in New York City and vice chair of the ECOG-ACRIN Cancer Research Group

## The Test is Widely Covered by Insurance

All major U.S. insurance carriers, including Medicare, cover the Oncotype DX Breast Recurrence Score test for eligible patients with early-stage invasive breast cancer.

## What is Genomic Testing and Why is It Important for Cancer Patients?

While genomics and genetics may sound similar, they focus on different information. Genetics is the study of how traits are passed from one generation to the next through specific genes and alterations that may give rise to particular health conditions. Genomics, on the other hand, looks at groups of genes expressed within specific tissue or location in the body, their functions and how they interact with one another. Genomics applied to tumor tissues from cancer patients is a powerful tool to better characterize the cancer and predict how a tumor is likely to grow and respond to treatment. Genomic testing is increasingly being used by physicians to help better understand patients' individual tumor biology and determine the most appropriate treatment approach.

<sup>1</sup>Sparano JA, Gray RJ, Makower DF, Pritchard KI, Albain KS, et al. Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer. *N Engl J Med*. 2018;10;379:111-121.