Genomic Health

oncotype DX® Breast Recurrence Score

Oncotype DX Breast Recurrence Score® Report

Node Negative

PATIENT, SAMPLE

Date of Birth: **01-Jan-1950** Gender: **Female** Report Number: **OR000123456-3130** Report Date: **04-Sep-2018**

Specimen Source/ID: **Breast/SP-16_0123456**

Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

Recurrence Score® Result (RS)

20

Distant Recurrence Risk at 9 Years

With AI or TAM Alone

6%

TAILORx

Absolute Chemotherapy Benefit*

RS 11-25 All Ages

<1%

TAILORx

AI = Aromatase Inhibitor / TAM = Tamoxifen

*Exploratory Subgroup Analysis for TAILORx and NSABP B-20: Absolute Chemotherapy (CT) Benefit by Age and RS

Age	RS 0-10	RS 11-15	RS 16-20	RS 21-25	RS 26-100
>50 years	No CT Benefit (<1%)				>15% CT Benefit
≤50 years	No CT Benefit (<1%)		~1.6% CT Benefit	~6.5% CT Benefit	>15% CT Benefit

Quantitative Single-Gene Scores

11.5 ER Positive

<3.7 6.5 ≥12.5

5.7 PR Positive

<3.2 5.5 ≥10.0

9.2 HER2 Negative

<7.6 10.7 11.5 ≥13.0

Laboratory Director(s): S. Shak, MD; F. Baehner, MD; H. Bailey, MD & P. Joseph, MD

Genomic Health, Inc., 301 Penobscot Drive, Redwood City, CA 94063, USA - CLIA Number 05D1018272

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

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Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

Medical Record/Patient #: **1234567-01** Client: **Community Medical Center**

Date of Collection: **20-Aug-2018**

Specimen Received: **22-Aug-2018**

Additional Recipient: **Dr. First-Name I. Recipient-Physician-Last-Name**

Pathologist: **Dr. First-Name I. Pathologist-Last-Name**

The Oncotype DX Breast Recurrence Score test uses RT-PCR to determine the expression of a panel of 21 genes (16 cancer-related, 5 reference) in tumor tissue.

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide prognostic and predictive information to guide the systemic treatment decisions with hormonal therapy and/or chemotherapy for patients diagnosed with ER+, HER2- invasive breast cancer. Decisions on treatment should also be based on independent medical judgment of the treating physician taking into consideration all available information concerning the patient's medical condition, including other pathological tests, in accordance with your communities' standard of care.

The **Recurrence Score Result (RS)**, which ranges from 0-100, is calculated from the quantitative RT-PCR analysis of the 21 genes.

The **Distant Recurrence Risk** at 9 Years (Prognosis), in patients with N–, ER+ breast cancer treated with endocrine therapy alone, is provided by the TAILORx[1] trial for RS 0-25 and by the NSABP B-14[2] trial for RS 26-100. Risk is for individual RS results. The 95% confidence intervals for distant recurrence at 9 years are ±2% or less for RS 0-22, and range from ±3% to ±11% as RS increases from 23-50. The TAILORx trial enrolled 10,273 patients and 5,018 patients with RS 0-25 were treated with endocrine therapy (tamoxifen or an aromatase inhibitor) alone. The NSABP B-14 trial enrolled 668 patients who were treated with tamoxifen alone.

The **Absolute Benefit of Chemotherapy** for all ages is provided by the TAILORx trial for RS 11-25 and by the NSABP B-20[3] trial for RS 0-10 and RS 26-100. Results for the reduction in distant recurrence at 9 years are for the TAILORx-defined RS groups 0-10, 11-25, and 26-100. TAILORx trial enrolled 10,273 patients and 6,711 were randomized to endocrine therapy (tamoxifen or an aromatase inhibitor) alone or endocrine therapy plus chemotherapy (including anthracyclines and/or taxanes). The NSABP B-20 clinical trial enrolled 651 patients who were randomized to treatment with tamoxifen alone or tamoxifen plus CMF/MF chemotherapy. The magnitude of the absolute benefit of chemotherapy was ~6% at RS 26, and increased as the RS results increased from 26-100, with an average absolute benefit of ~24% and a conservative group estimate of >15% based on the width of the confidence intervals.

Exploratory Subgroup Analysis for TAILORx and NSABP B-20 indicate that RS and age are the strongest predictors of chemotherapy benefit. The absolute reduction of distant recurrence from chemotherapy for patients >50 years and ≤50 years is shown here for RS groups: 11-15, 16-20, and 21-25 from TAILORx, and 0-10 and 26-100 from NSABP B-20.

Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR, and HER2, using the published validated cut-offs[4] . The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

References:

1. Sparano et al. *N Engl J Med.* 2018.; ECOG and Genomic Health (data on file). 2. Paik et al. *N Engl J Med.* 2004. 3. Paik et al. *J Clin Oncol.* 2006.; Sparano and Paik *J Clin Oncol.* 2008.
4. Badve et al. *J Clin Oncol.* 2008.; Baehner et al. *J Clin Oncol.* 2010.