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CLIA Number 05D1018272

Breast Cancer Report - Node Positive Prognosis and Chemotherapy Benefit (1-3 N+)

Patient/ID: PATIENT, SAMPLE
Gender: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 1234567-01
Date of Collection: 27-Oct-2016
Specimen Type/ID: Breast/SP-16_0123456

Report Number: OR000123456-01
Specimen Received: 29-Oct-2016
Date Reported: 11-Nov-2016
Client: Community Medical Center
Ordering Physician: Dr. Ordering
Additional Recipient: Dr. Additional
Pathologist: Dr. Pathologist

Recurrence Score[®] Result

6

Oncotype DX[®] Breast Recurrence Score test uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score result is calculated from the gene expression results and ranges from 0-100.

The findings are applicable to women who have estrogen receptor positive (ER+) breast cancer with 1-3 positive nodes, and who will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience: The following results are from a clinical validation study that included 367 patients from the SWOG 8814 study. The study included post-menopausal patients with N+, ER+ breast cancer who were randomized to either tam alone or CAF chemotherapy followed by tam (CAF-T). The endpoint for this study was disease-free survival (time to local or distant recurrence, new primary breast cancer, or death from any cause) and 5-year risks are presented.¹

Prognosis and Chemotherapy Benefit: 5-Year Risk of Recurrence or Mortality after 5 Years of Tam, Based on the Recurrence Score Result

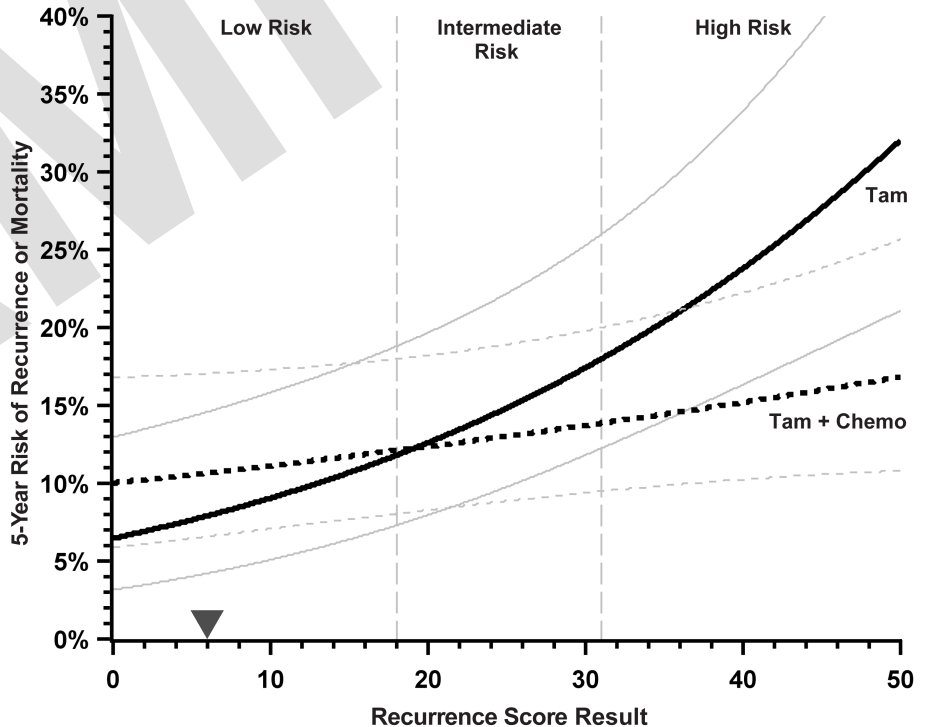
1-3 Positive Nodes 5-Year Risk of Recurrence or Mortality

Tam Alone

8% ———
(95% CI: 4%-15%)

Tam + Chemo

11% - - - - -
(95% CI: 7%-17%)



¹ Albain et al. Lancet Oncol. 2010.

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

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.

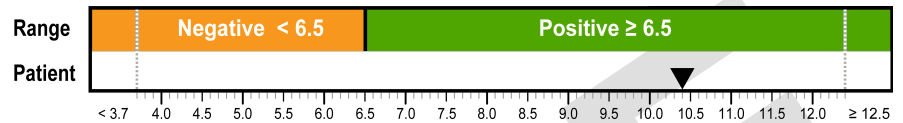
Quantitative Single Gene Report

Patient/ID: PATIENT, SAMPLE
Gender: Female
Date of Birth: 01-Jan-1950

Report Number: OR000123456-01
Specimen Received: 29-Oct-2016
Date Reported: 11-Nov-2016

The Oncotype DX[®] test uses RT-PCR to determine the RNA expression of the genes below. These results may differ from estrogen receptor (ER), progesterone receptor (PR), or human epidermal growth factor receptor 2 (HER2) results reported using other methods or reported by other laboratories.¹ The ER, PR, and HER2 Scores are also included in the calculation of the Recurrence Score result.

ER Score = **10.4** **Positive**



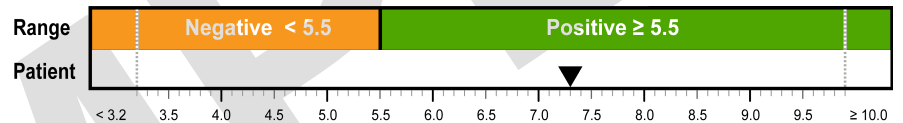
The ER Score positive/negative cut-off of 6.5 units was validated from a study of 761 samples using the 1D5 antibody (immunohistochemistry) and 607 samples using the SP1 antibody (immunohistochemistry). The standard deviation for the ER Score is less than 0.5 units.²

Clinical Experience:

For ER+ breast cancer, the magnitude of tamoxifen benefit increases as the ER Score increases from 6.5 to ≥12.5.³

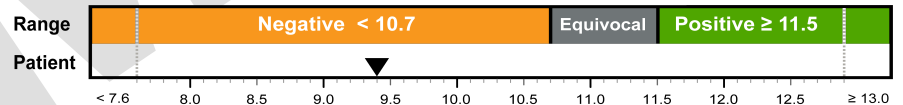
Please note: The Average Risk of Distant Recurrence reported on Page 1 based on the Recurrence Score result was determined in patients who received 5 years of tamoxifen treatment and takes into account the magnitude of tamoxifen benefit indicated by the ER Score.

PR Score = **7.3** **Positive**



The PR Score positive/negative cut-off of 5.5 units was validated from a study of 761 samples using the PR636 antibody (immunohistochemistry) and another study of 607 samples using the PR636 antibody (immunohistochemistry). The standard deviation for the PR Score is less than 0.5 units.²

HER2 Score = **9.4** **Negative**



The HER2 positive cut-off of ≥ 11.5 units, equivocal range from 10.7 to 11.4 units, and negative cut-off of <10.7 units were validated from concordance studies of 755 samples using the HercepTest[™] assay (immunohistochemistry) and another study of 568 samples using the PathVysion[®] assay (FISH). The standard deviation for the HER2 score is less than 0.5 units.⁴

References:

- ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor); HER2 Score based on quantitative ERBB2 expression.
- Badve et al. *J Clin Oncol*. 2008. and Baehner et al. ASCO Breast 2007. Abstract 88.
- Kim et al. *J Clin Oncol*. 2011.
- Baehner et al. *J Clin Oncol*. 2010. and Baehner et al. ASCO Breast 2007. Abstract 41.

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