Genomic Health, Inc.
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Redwood City, CA 94063 USA
Toll Free Tel   866-ONCOTYPE (866-662-6897)
Worldwide Tel +1 650-569-2080
www.oncotypeDX.com

Genomic Health™ | oncotype DX®
Breast Cancer Assay

PATIENT REPORT

Patient/ID: Doe, Jane
Sex: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 556677771
Date of Surgery: 25-Sep-2008
Specimen Type/ID: Breast/SURG-0001

Requisition: R00003G
Specimen Received: 05-May-2009
Date Reported: 15-May-2009
Client: Community Medical Center
Ordering Physician: Dr. Harry D Smith
Submitting Pathologist: Dr. John P Williams
Additional Recipient: Dr. Sally M Jones

BREAST CANCER 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

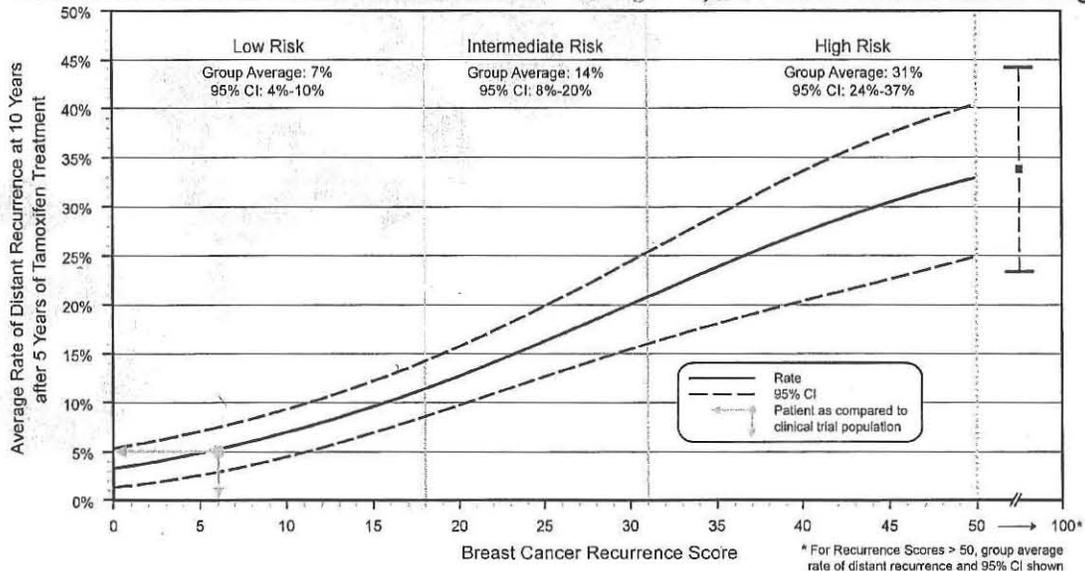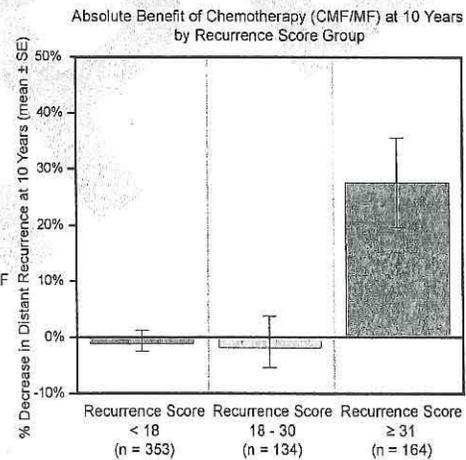**Breast Cancer Recurrence Score = 6**

The findings summarized in the Clinical Experience sections of this report are applicable to the patient populations defined in each section. It is unknown whether the findings apply to patients outside these criteria.

CLINICAL EXPERIENCE: PROGNOSIS FOR NODE NEGATIVE, ER-POSITIVE PATIENTS

The Clinical Validation study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer treated with 5 years of tamoxifen. Those patients who had a Recurrence Score of 6 had an Average Rate of Distant Recurrence of **5%** (95% CI: 3%-7%)

The following results are from a clinical validation study of 668 patients from the NSABP B-14 study. *N Engl J Med* 2004; 351: 2817-26.

Recurrence Score vs Distant Recurrence in Node Negative, ER-Positive Breast Cancer Prognosis

Node Negative

Y-axis: Average Rate of Distant Recurrence at 10 Years after 5 Years of Tamoxifen Treatment

	Low Risk	Intermediate Risk	High Risk
	Group Average: 7% 95% CI: 4%-10%	Group Average: 14% 95% CI: 8%-20%	Group Average: 31% 95% CI: 24%-37%

Legend:
— Rate
-- 95% CI
Patient as compared to clinical trial population

X-axis: Breast Cancer Recurrence Score

* For Recurrence Scores > 50, group average rate of distant recurrence and 95% CI shown

Laboratory Director: Patrick Joseph, MD

CLIA Number 05D1018272

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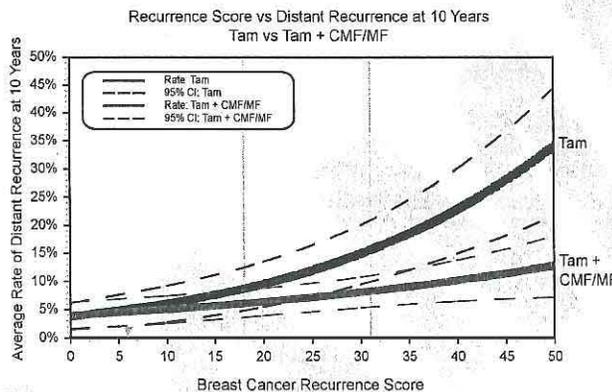**Date Reported:** 15-May-2009

RESULTS

Breast Cancer Recurrence Score = 6

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CLINICAL EXPERIENCE: CHEMOTHERAPY BENEFIT
FOR NODE NEGATIVE, ER-POSITIVE PATIENTS

The following results are from a clinical study involving 651 patients from the NSABP B-20 Study. The study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer. Patients were randomized to either tamoxifen alone or tamoxifen plus CMF or MF chemotherapy. For patients in the pre-specified group with Recurrence Scores ≥ 31, the group average 10-year rates (95% CI) of distant recurrence were 40% (25%, 54%) for Tam alone and 12% (6%, 18%) for Tam + CMF/MF. *J Clin Oncol.* 2006; 24(23): 3726-34.

Node Negative, ER-Positive Breast Cancer Chemotherapy Benefit

Recurrence Score vs Distant Recurrence at 10 Years
Tam vs Tam + CMF/MF

Absolute Benefit of Chemotherapy (CMF/MF) at 10 Years by Recurrence Score Group

Node Negative

Laboratory Director: Patrick Joseph, MD

CLIA Number 05D1018272

GHI004 Rev021