oncotype DX®

Breast Recurrence Score

NODE-POSITIVE REPORT

TREAT WITH EVEN MORE CONFIDENCE

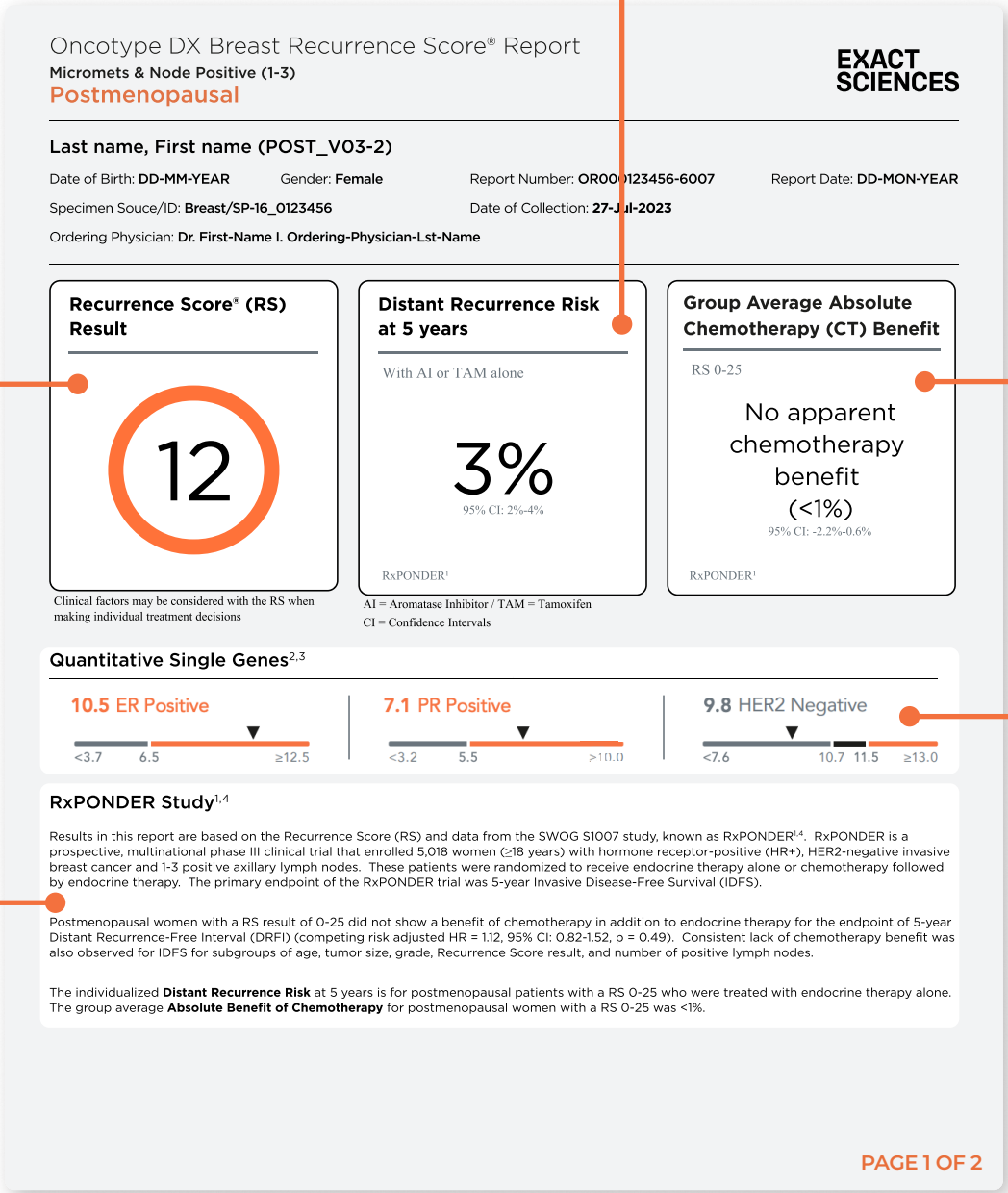
Shows either the individualized risk of distant recurrence or the individualized risk of recurrence or mortality when treated with endocrine therapy alone.

Based on a continuous scale of 0-100 and reflects individual tumor biology. The higher the patient's score, the higher the risk of distant recurrence and likelihood of chemotherapy benefit.

Represents the likelihood that adding chemotherapy will reduce distant recurrence risk (for applicable patients).

Helps to confirm HR+, HER2- status.

Contains relevant study details from either RxPONDER or SWOG 8814.



Oncotype DX Breast Recurrence Score® Report

Micromets & Node Positive (1-3)

Postmenopausal

EXACT SCIENCES

Last name, First name (POST_V03-2)

Date of Birth: **DD-MM-YEAR** Gender: **Female** Report Number: **OR00[illegible]123456-6007** Report Date: **DD-MON-YEAR**

Specimen Souce/ID: **Breast/SP-16_0123456** Date of Collection: **27-Jul-2023**

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

Recurrence Score® (RS) Result

12

Clinical factors may be considered with the RS when making individual treatment decisions

Distant Recurrence Risk at 5 years

With AI or TAM alone

3%

95% CI: 2%-4%

RxPONDER[1]

AI = Aromatase Inhibitor / TAM = Tamoxifen

CI = Confidence Intervals

Group Average Absolute Chemotherapy (CT) Benefit

RS 0-25

No apparent chemotherapy benefit (<1%)

95% CI: -2.2%-0.6%

RxPONDER[1]

Quantitative Single Genes[2,3]

10.5 ER Positive — <3.7 6.5 ≥12.5

7.1 PR Positive — <3.2 5.5 >10.0

9.8 HER2 Negative — <7.6 10.7 11.5 ≥13.0

RxPONDER Study[1,4]

Results in this report are based on the Recurrence Score (RS) and data from the SWOG S1007 study, known as RxPONDER[1,4]. RxPONDER is a prospective, multinational phase III clinical trial that enrolled 5,018 women (≥18 years) with hormone receptor-positive (HR+), HER2-negative invasive breast cancer and 1-3 positive axillary lymph nodes. These patients were randomized to receive endocrine therapy alone or chemotherapy followed by endocrine therapy. The primary endpoint of the RxPONDER trial was 5-year Invasive Disease-Free Survival (IDFS).

Postmenopausal women with a RS result of 0-25 did not show a benefit of chemotherapy in addition to endocrine therapy for the endpoint of 5-year Distant Recurrence-Free Interval (DRFI) (competing risk adjusted HR = 1.12, 95% CI: 0.82-1.52, p = 0.49). Consistent lack of chemotherapy benefit was also observed for IDFS for subgroups of age, tumor size, grade, Recurrence Score result, and number of positive lymph nodes.

The individualized **Distant Recurrence Risk** at 5 years is for postmenopausal patients with a RS 0-25 who were treated with endocrine therapy alone. The group average **Absolute Benefit of Chemotherapy** for postmenopausal women with a RS 0-25 was <1%.

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oncotype DX®

Breast Recurrence Score

NODE-POSITIVE REPORT

Displays the patient's individualized Recurrence Score® result in the context of the relevant study data from either RxPONDER or SWOG 8814, if available.

Oncotype DX Breast Recurrence Score® Report

Micromets & Node Positive (1-3)

Postmenopausal

EXACT SCIENCES

Last name, First name (POST_V03-2)

Date of Birth: **DD-MM-YEAR** Gender: **Female** Report Number: **OR000123456-6007** Report Date: **DD-MON-YEAR**

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

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

Medical Record/Patient #: **DD-MM-YEAR**

Client: **Community Medical Center**

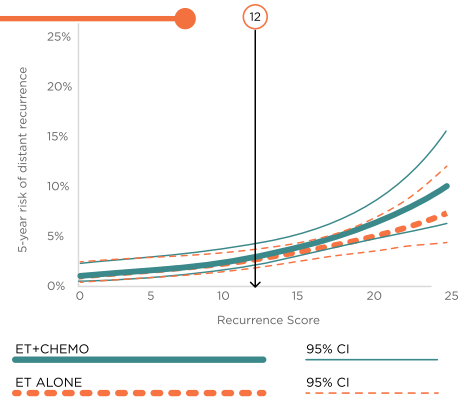
Date of Collection: **27-Jul-2023**

Specimen Received: **29-Jul-2023**

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

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

RxPONDER[5]



Methods and Limitations

The Oncotype DX Breast Recurrence Score test uses RT-PCR to provide information on prognosis and the magnitude of chemotherapy benefit to guide chemotherapy treatment decisions in patients with early-stage, HR+, HER2-negative and lymph node-negative or lymph node-positive (N1) 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, in accordance with your community's standard of care.

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

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[2,3]. 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.

The definitions of **menopausal status** based upon the RxPONDER[4] trial are as follows:

- **Premenopausal:** Less than 6 months since last menstrual period and no prior bilateral oophorectomy and not on estrogen replacement.
- **Postmenopausal:** Prior bilateral oophorectomy or more than 12 months since last menstrual period with no prior hysterectomy.
- If these definitions did not apply, patients were categorized as premenopausal if <50 years and postmenopausal if ≥50 years.

Distant Recurrence-Free Interval (DRFI): Time from randomization to distant recurrence or death from breast cancer.

Invasive Disease-Free Survival (IDFS): Time from randomization to invasive breast cancer recurrence (local, regional, or distant), second invasive primary cancer (breast cancer or not), or death from any cause.

References:

1. Kalinsky et al. San Antonio Breast Cancer Symposium. 2021. 2. Badve et al. J Clin Oncol. 2008. 3. Baehner et al. J Clin Oncol. 2010. 4. Kalinsky et al. NEJM. 2021. 5. Data on File

Laboratory Director(s): F. Baehner,MD; H. Bailey, 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 and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

The Oncotype DX Breast Recurrence Score Test is an in vitro diagnostic device. CE marked under Regulation (EU) 2017/46 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. In Japan, the test has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare as the Oncotype DX Breast Recurrence Score Program and is covered by National Health Insurance.

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