Patient Report

PATIENT

Name: Jane Doe
Date of Birth: 01/01/1964
Medical Record #: 8675309

SPECIMEN INFORMATION

Order Date: 01/24/2026
Specimen ID: AB-12345-A
Specimen Collection Date: 01/23/2026
Specimen Received Date: 01/27/2026
Order Number: 98765

ORDERING CLINICIAN

Name: Dr. Jones
Practice: West Coast Oncology
Address: 123 Ocean Beach Way,
Coastaltown, CA 92123

CLINICAL AND PATHOLOGY INFORMATION

SPECIMEN
Surgical Resection

TUMOR SIZE
≤2 cm

LYMPH NODE STATUS
Node-negative

HORMONE RECEPTOR STATUS
ER+ / PR+

MENOPAUSAL STATUS
Post Menopausal

PROSIGNA TEST RESULT

Risk of Recurrence (ROR) Score[1,2]

78

(Score ranges 0-100)

10-Year Probability of Distant Recurrence (DR)[1,2]

27%

With standard locoregional therapy and 5 years of endocrine therapy

Predicted Chemotherapy Benefit[2,3]

Yes

Intrinsic Subtype

Luminal B

Prosigna Test Result Summary

A Risk of Recurrence (ROR) Score of 78 results in a 10-year Probability of Distant Recurrence of 27% and a Predicted Chemotherapy Benefit.

ADDITIONAL INFORMATION

Tumor Size and Lymph Node Status

Physical exam or imaging may be used to initially assess tumor size and lymph node status. Final tumor size and lymph node status should be assessed by pathology for accuracy.

Risk of Recurrence (ROR) Score

The ROR score is generated from gene expression profiling used to assess intrinsic subtypes and a proliferation score which are then weighted together with tumor size to provide the ROR score. The ROR score ranges from 0 through 100 and correlates with the probability of distant recurrence (DR) in the tested population. The percentage shown in the 10-year probability of distant recurrence box above is the modeled probability of distant recurrence at 10 years with 5 years of endocrine therapy for the individual ROR measured. Please see Table 1 on page 3 for details regarding the observed probabilities and the associated 95% confidence limits.

10-Year Probability of Distant Recurrence

The Prosigna algorithm was used in retrospective analysis of the ABCSG-8 clinical trial which included more than 1400 patients with varying risks of distant recurrence. The retrospectively fitted model related ROR score to 10-year distant recurrence for node-negative patients in the ABCSG-8 study.

Predicted Chemotherapy Benefit

Patients with an ROR ≤ 60 are predicted to have minimal to no benefit from chemotherapy, whereas those with an ROR > 60 are predicted to benefit from chemotherapy. Chemotherapy benefit prediction is based on the results of the OPTIMA clinical trial.

In the OPTIMA trial, participants were randomized to Prosigna-guided adjuvant therapy or standard chemotherapy followed by endocrine therapy. In the Prosigna-guided arm, chemotherapy was administered only to participants with an ROR score > 60; those with an ROR ≤ 60 were treated with endocrine therapy alone (including ovarian suppression in premenopausal women). Using a non-inferiority margin of no more than 3%, Prosigna-guided therapy was non-inferior for invasive breast cancer-free survival, supporting the use of Prosigna ROR to guide chemotherapy decisions.

Intrinsic Subtype

Intrinsic subtypes as classified by gene expression profiling. Concordance with histopathologic subtyping is not established. The intrinsic subtype is only reported as a constituent component of the Prosigna® test.

Approved By:
E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

CLIA ID Veracyte Labs SD# 05D2055897
Lab Director: [Lab Director Name, MD]

A copy of this form shall be as valid as the original. This test was developed and its performance characteristics determined by Veracyte Labs. The laboratory is regulated under CLIA '88 as qualified to perform high complexity clinical testing. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research.

veracyte | Prosigna

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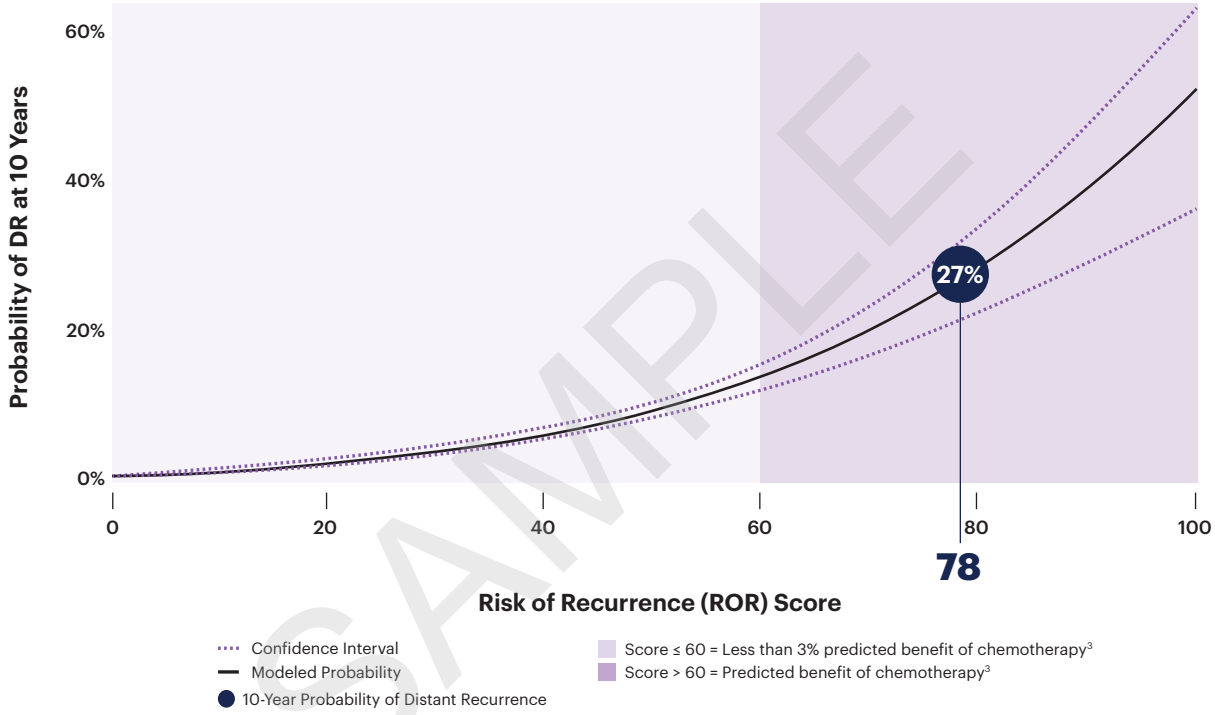
	Order Number: 98765	

ADDITIONAL CLINICAL EVIDENCE

Prognosis for node-negative breast cancer patients was determined based on the probability of distant recurrence (DR) for this patient population in the validation study ABCSG-8. This study analyzed 1,047 node-negative samples using a prospectively defined analysis plan. The data shown are for post-menopausal women with hormone receptor-positive, node-negative, Stage I and II breast cancer that received 5 years of endocrine therapy.[4]

Personalized Results Summary[1,2,3]



Prognostic Estimate

	ROR Score	Risk Estimate
Low	0-40	3% (2-6%)
Intermediate	41-60	10% (7-14%)
High	61-100	16% (11-22%)

Risk category is provided to guide the interpretation of the ROR score using cutoffs related to clinical outcome for the provided lymph node status.

Proliferation Score: 20

Proliferation scores range from 0 (low proliferation) to 100 (high proliferation) and are calculated from a subset of 18 genes associated with proliferation.[1] Correspondence of Prosigna test proliferation score with histopathological proliferation score is not established. The proliferation score is only reported as a constituent component of the Prosigna® test.

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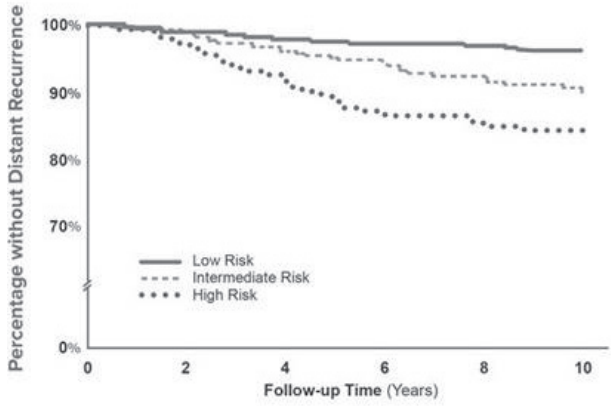
CLINICAL TRIAL RESULTS: CLINICAL VALIDATION STUDY

ABCSG-8 Clinical Validation Study[4]



DRFS Kaplan-Meier plot for prognostic risk groups.

Table 1: Distribution of Node-Negative Patients by 10-unit ROR Score Range[2,4]

ROR Score Range	Number of Patients	Percent of Patients	10-year DR Risk (Empirical) with 95% Confidence Limits
1–10	7	0.7%	0% [N/A]
11–20	116	11.1%	1.8% [0%–4.3%]
21–30	155	14.8%	2.5% [0%–5.2%]
31–40	209	20.0%	5.1% [2.0%–8.1%]
41–50	183	17.5%	7.5% [3.3%–11.6%]
51–60	152	14.5%	12.1% [6.2%–17.6%]
61–70	116	11.1%	15% [7.6%–21.8%]
71–80	77	7.4%	12.3% [4.4%–19.6%]
81–90	28	2.7%	26.1% [7.3%–41.1%]
91–100	4	0.4%	33.3% [0%–70.0%]
Total	**1,047**	**100%**	

TEST DESCRIPTION

The Prosigna Breast Cancer Gene Signature Assay, branded as the Prosigna Breast Risk of Recurrence test, is intended for use in early-stage Hormone Receptor positive (HR+) invasive breast cancer patients as a prognostic indicator for estimating the 10-year distant recurrence-free survival when treated with standard of care locoregional management and adjuvant endocrine therapy, applied with consideration of other clinicopathologic factors.

Whole transcriptome RNA sequencing analysis is utilized for gene expression profiling of the PAM50-based gene set on RNA extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue; data is collected from over 21,000 genes and over 425,000 probes across the transcriptome for each patient when the test is performed. The test provides Risk of Recurrence (ROR) score, probability of 10-year distant recurrence, predictive chemotherapy benefit, intrinsic subtype (Luminal A, Luminal B, HER2-Enriched, Basal-like), and proliferation score.

Results should be interpreted by a qualified healthcare professional in the context of the patient's clinical and pathological history. Test results are intended to aid clinical decision-making in alignment with professional guidelines alongside other clinicopathological factors.

REFERENCES: 1. Wallden B, Storhoff J, Nielsen N, et al. Development and verification of the PAM50-based Prosigna breast cancer gene signature assay. BMC Medical Genomics 2015 Vol. 8 Issue 1, DOI:10.1186/s12920-015-0129-6. **2.** Data on file. **3.** Stein RC, et al. First results from the OPTIMA phase III randomized non-inferiority trial of test-directed chemotherapy in patients with high clinical risk ER-positive HER2-negative early breast cancer. In: Proceedings from the American Society of Clinical Oncology; May 30, 2026; Chicago IL. Abstract 500. **4.** Gnant M, et al., on behalf of the Austrian Breast and Colorectal Cancer Study Group. Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: using the PAM50 Risk of Recurrence score in 1478 postmenopausal patients of the ABCSG-8 trial treated with adjuvant endocrine therapy alone. Annals of Oncology 2014; 25(2):339-45.

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