Prosigna® Breast Risk of Recurrence Test
PATIENT REPORT

PATIENT	SPECIMEN INFORMATION	ORDERING CLINICIAN
Name: Jane Doe	Order Date: 01/24/2026	Name: Dr. Jones
Date of Birth: 01/01/1964	Specimen ID: AB-12345-A	Practice: West Coast Oncology
Medical Record #: 8675309	Specimen Collection Date: 01/23/2026	Address: 123 Ocean Beach Way, Coastaltown, CA 92123
	Specimen Received Date: 01/27/2026	
	Order Number: 98765	

CLINICAL AND PATHOLOGY INFORMATION

SPECIMEN
Surgical Resection

TUMOR SIZE
> 2 cm

LYMPH NODE STATUS
Node-positive (4-9 nodes)

HORMONE RECEPTOR STATUS
ER+ / PR+

MENOPAUSAL STATUS
Postmenopausal

PROSIGNA TEST RESULT

Intrinsic Subtype
Luminal A

Risk of Recurrence (ROR) Score [1,2]
30
(Score ranges 0-100)

Predicted Chemotherapy Benefit [2,3]
No
Prosigna ROR score ≤60

Prosigna Test Result Summary
A risk of recurrence (ROR) score of 30 results in no 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.

Prosigna Risk of Recurrence (ROR) Score
The Prosigna 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 Prosigna ROR score ranges from 0 through 100 and correlates with the probability of distant recurrence (DR) in the tested population. A prognostic estimate for the 10-year distant recurrence-free survival when treated with standard of care locoregional management and adjuvant endocrine therapy has not been established for patients with 4-9 positive lymph nodes in the context of the Prosigna ROR score.

Intrinsic Subtype
The intrinsic subtype is based on the PAM50 classifier and determined by the biology of the breast cancer tumor. Classifications are: Luminal A, Luminal B, HER2 enriched, or Basal-like. Concordance with histopathologic subtyping is not established.

Predicted Chemotherapy Benefit
Patients with a Prosigna ROR score of ≤ 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 a Prosigna ROR score > 60; those with an ROR ≤ 60 were treated with endocrine therapy alone (including ovarian suppression in premenopausal women). With a demonstrated non-inferiority margin of 2%, the OPTIMA trial concluded that Prosigna-guided therapy was non-inferior for invasive breast cancer free survival (IBCFS), supporting the use of Prosigna ROR to guide chemotherapy decisions.

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

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

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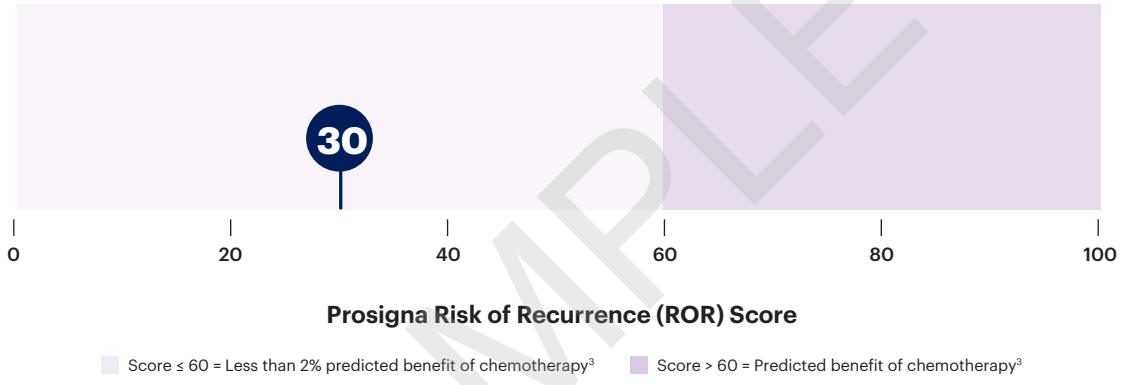
ADDITIONAL CLINICAL EVIDENCE

Prediction for node-positive patients was determined based on the OPTIMA phase III prospective randomized clinical trial. This trial analyzed 3826 node-positive samples using a prospectively defined analysis plan.[3]

Higher lymph node burden is associated with a worse prognosis for developing distant metastatic recurrence. A low ROR score in node-positive (1-3 nodes) breast cancer has been associated with better prognosis. In node-positive (4-9 nodes) breast cancer patients, the relationship between ROR score and the estimated 10-year probability for distant recurrence prognosis has not been established.[4]

Prosigna Personalized Results Summary[1,2,3]



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 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. The Prosigna Risk of Recurrence (ROR) score predicts the benefit of chemotherapy and guides treatment decisions in the intended use population.

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 (not available for patients with 4-9 positive lymph nodes), predictive chemotherapy benefit, and intrinsic subtype (Luminal A, Luminal B, HER2-Enriched, Basal-like).

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. For more information on the Prosigna test visit Veracyte.com.

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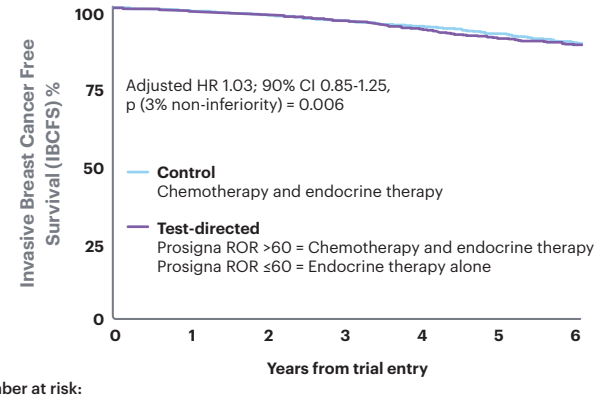
CLINICAL TRIAL RESULTS

PREDICTIVE EVIDENCE

OPTIMA Phase III Prospective Trial[3]

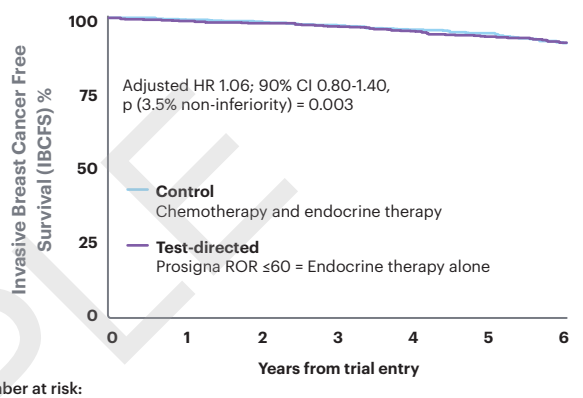
Complete per protocol population



Number at risk:							
Control	2059	1818	1563	1283	999	741	485
Test-directed	2094	1857	1591	1303	989	724	481

OPTIMA Phase III Prospective Trial[3]

Per protocol population: Prosigna ROR low score (ROR ≤60)



Number at risk:							
Control	1358	1207	1043	862	672	504	337
Test-directed	1421	1257	1086	905	694	503	342

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.** Laenkholm A, et al. PAM50 Risk of Recurrence Score Predicts 10-Year Distant Recurrence in a Comprehensive Danish Cohort of Postmenopausal Women Allocated to 5 Years of Endocrine Therapy for Hormone Receptor-Positive Early Breast Cancer. J Clin Oncology 2018 Vol. 36 Number 8, DOI:10.1200/JCO.2017.74.6586

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