Prosigna®

Breast Cancer Assay

Accurate Results, Confident Choices

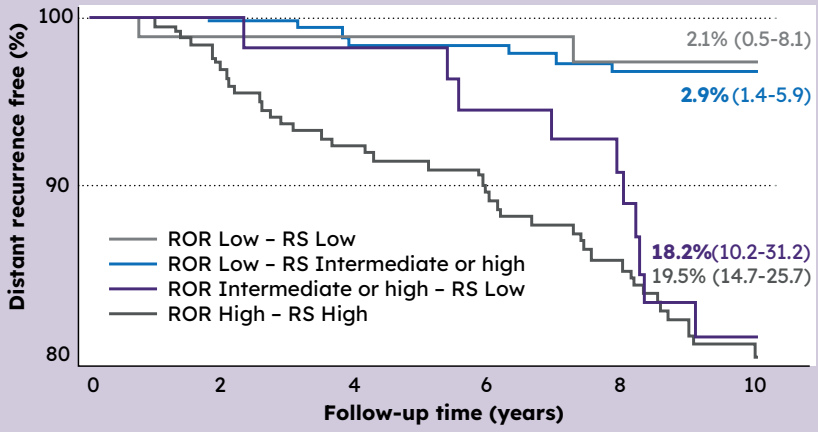
The Prosigna Breast Cancer Assay can help more accurately predict your patient's risk of recurrence

2nd generation breast cancer test that combines gene expression and clinical pathological factors to help better inform treatment decisions.

The Prosigna assay more accurately identifies patients as low-risk or intermediate-/high-risk for 10-year risk of distant recurrence.[1]

	Number of Women	10-year DR risk (%)
Prosigna ROR low and Oncotype Dx RS low	104	2.1%
Prosigna ROR low, but Oncotype Dx RS intermediate or high	**261**	**2.9%**
Prosigna ROR intermediate or high, but Oncotype Dx RS low	**62**	**18.2%**
Prosigna ROR high and Oncotype Dx RS high	55	19.5%

***ROR** = Prosigna®, **RS** = Oncotype Dx®
*This data is from the analysis using the TAILORx cut-offs



Data from the TransATAC study[1] which identifies patients' 10-year risk of distant recurrence, has shown that when results are discordant between Prosigna ROR and OncotypeDx RS, the Prosigna assay is more accurate.

Low Risk 10-year DR Outcome
2.9%

In a total cohort of 663 patients, **39.37% of patients assigned by Prosigna ROR to a low-risk group with a 10-year DR Risk of 2.9%**, were assigned by OncotypeDX as an intermediate- or high-risk group.

High Risk 10-year DR Outcome
18.2%

In addition, **9.35% of patients assigned by Prosigna ROR to an intermediate- or high-risk group with a 10-year Distant Recurrence (DR) Risk of 18.2%**, were assigned by OncotypeDX as low-risk group.

When the Prosigna assay reports a patient's risk category, the results can be trusted.

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Prosigna®

Breast Cancer Assay

2nd generation test that can help more comprehensively inform treatment decisions

Prosigna provides more accurate distant prognostic information than OncotypeDX[2,3].

Accurate prognosis is a foundation of treatment recommendations.

A patient's recurrence risk is a key consideration in deciding which treatment to recommend in ER+/HER2- breast cancer.[4]

Prosigna is an FDA cleared and CE-IVD marked assay, and the only gene expression profiling (GEP) test approved for use in many countries across the globe.

The Prosigna assay is included in leading international clinical guidelines.*

NCCN
Clinical Practice Guidelines in Oncology (NCCN Guidelines®)**

ASCO
Guidelines

ESMO
Guidelines

St. Gallen
Consensus Panel

NICE

The Prosigna Breast Cancer Assay is covered by Medicare and many commercial payers for patients meeting the indications for use.

Prosigna assay results may be available in as little as 24 hours

INTENT FOR USE:

The Prosigna® Breast Cancer Assay is an in vitro diagnostic assay which is performed on the nCounter® Analysis System using FFPE breast tumor tissue previously diagnosed as invasive breast carcinoma. This qualitative assay utilizes gene expression data, weighted together with clinical variables to generate a risk category and numerical score, to assess a patient's risk of distant recurrence of disease. The Prosigna Breast Cancer Assay is indicated in female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care, either as:

- A prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors.
- A prognostic indicator for distant recurrence-free survival at 10 years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1–3 positive nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. The device is not intended for patients with 4 or more positive nodes.

* ASCO and ESMO are trademarks of the American Society of Clinical Oncology and European Society for Medical Oncology. ASCO, ESMO, National Institute for Health and Care Excellence (NICE) and St Gallen International Consensus Panel do not endorse any product or therapy.

** NCCN recommends the 50 gene assay (Prosigna) as an option for appropriate patients with pN0 and pN1 breast cancers. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed [August 30, 2023]. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN=National Comprehensive Cancer Network® (NCCN®).

ASCO: American Society for Clinical Oncology; **ESMO**: European Society for Medical Oncology; **FFPE**: formalin fixed paraffin-embedded; **HR**: hormone receptor; **NICE**: National Institute for Health and Care Excellence.

1. Sestak, I, et al. Discordant classification and outcome between Prosigna ROR and Oncotype DX RS for ER-positive, HER2-negative, node-negative breast cancer: An exploratory analysis of the TransATAC study. Poster presented at: SABCS: December 10-14, 2019, San Antonio, TX.
2. Gnant M, et al. Ann Oncol. 2014;25(2):339-45.
3. Dowsett M, et al. J Clin Oncol. 2013;31(22):2783-2790.
4. Marie Alexandre et al. Cancer Manag Res. 2019.

Prosigna® Breast Cancer Assay (Prosigna assay) for use on the nCounter® Analysis System is 510(k) cleared for in vitro diagnostic use in prognosis and surgical resection. Please refer to region specific Package Inserts for the respective product claims. Intrinsic molecular subtypes are not reported by the Prosigna assay cleared by the FDA in the United States. However, intrinsic molecular subtypes identified by the gene signature are utilized by the algorithm to calculate the Prosigna Score (ROR) and risk category. Prosigna® in conjunction with the nCounter® Analysis System is 510(k) FDA cleared for in vitro diagnostic use in postmenopausal women with Hormone Receptor-Positive (HR+), lymph node-negative, Stage I or II breast cancer and post-menopausal women with Hormone Receptor-Positive (HR+), lymph node positive (1–3 positive nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy. See Package Insert for further details at prosigna.com.

Learn more:
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