Prosigna
BREAST CANCER ASSAY

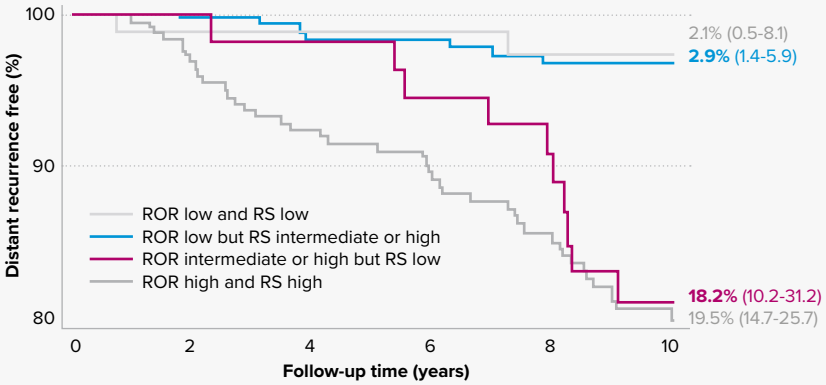
ACCURATE RESULTS, **CONFIDENT** CHOICES

THE PROSIGNA BREAST CANCER ASSAY **MORE ACCURATELY PREDICTS THE RISK OF RECURRENCE**

2nd generation breast cancer test that combines gene expression, clinical pathological factors and molecular subtypes to better inform treatment decisions

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

Patients identified as	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 which identifies patients' 10-year risk of distant recurrence prognosis, has shown that when results are discordant between Prosigna ROR and Oncotype Dx RS, the Prosigna assay is more accurate.[1]

LOW RISK
10-YEAR
DR OUTCOME
2.9%

Patients categorized as low risk by the Prosigna assay but intermediate or high risk by the Oncotype Dx test, had a low risk 10-year Distant Recurrence (DR) rate of 2.9%, with endocrine therapy alone. **With the Prosigna assay results, these patients could be appropriately treated and potentially avoid over treatment and the associated potential long-term consequences.**

HIGH RISK
10-YEAR
DR OUTCOME
18.2%

Patients classified as intermediate or high by the Prosigna assay but low risk by the Oncotype DX test, had a high risk 10-year DR outcome of 18.2%. **With the Oncotype Dx test results these patients would potentially not have received the correct treatment approach to lower their risk of recurrence.**

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

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2ND GENERATION TEST THAT MORE **COMPREHENSIVELY INFORMS TREATMENT DECISIONS**

Accurate prognosis is a foundation of treatment recommendations.

The recurrence risk is a key consideration in deciding which treatment to recommend in ER+/HER2- breast cancer.[2]

Prosigna is a CE-IVD marked and FDA cleared assay, and the only GEP test approved for use in laboratories across the globe.

Select the Prosigna assay based on internationally recommended guidelines*

The Prosigna Breast Cancer assay is covered by many public healthcare systems for patients meeting the indications for use.

INTENT FOR USE:

The Prosigna® Breast Cancer Assay is an in vitro diagnostic assay which uses the gene expression profile of cells found in breast cancer tissue to assess a patient's risk of distant recurrence. The assay measures the gene expression profile using RNA extracted from Formalin Fixed, Paraffin-Embedded (FFPE) breast tumor tissue. The gene expression data are weighted together with clinical variables to generate both a subtype (luminal A, luminal B, HER2-enriched, or basal-like) and a score indicative of the probability of distant recurrence of disease. The assay is performed on the nCounter® Analysis System using FFPE breast tumor tissue previously diagnosed as invasive breast carcinoma.

The Prosigna Breast Cancer Assay is indicated in female breast cancer patients who have undergone either mastectomy or breast-conserving therapy in conjunction with locoregional treatment consistent with standard of care, either as:

a. 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.

b. 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 or IIIA breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors.

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ASCO: American Society for Clinical Oncology; **ESMO:** European Society for Medical Oncology; **FFPE:** formalin fixed paraffin-embedded; **HR:** hormone receptor; **NCCN:** National Comprehensive Cancer Network; **NICE**: National Institute for Health and Care Excellence; **AGO:** German Gynecological Oncology Group; **SEOM:** Spanish Society of Medical Oncology.

Prosigna® Breast Cancer Prognostic Gene Signature Assay (Prosigna assay) for use on the nCounter® Analysis System is 510(k) cleared and CE-marked 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 CE marked for in vitro diagnostic use in post-menopausal 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 & IIIA breast cancer to be treated with adjuvant endocrine therapy. See Package Insert for further details at prosigna.com.

Learn more: www.prosigna.com
Contact us: info@prosigna.com

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. Marie Alexandre et al. Cancer Manag Res. 2019

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