

See the difference with **Prosigna**[®]



THE PROSIGNA BREAST CANCER PROGNOSTIC GENE SIGNATURE

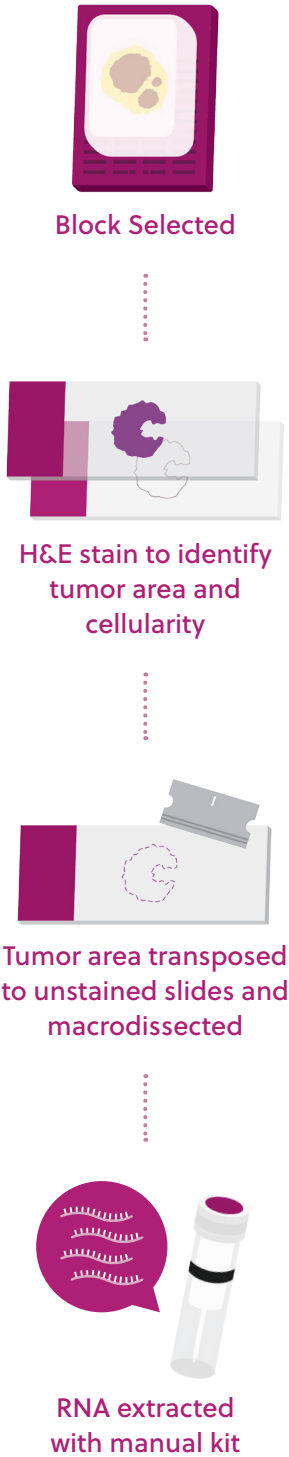
- ▶ The only PAM50-based breast cancer genomic signature
- ▶ The only genomic breast cancer assay that can be run in your pathology lab
- ▶ FDA 510(k) cleared for FFPE breast tumor tissue on the nCounter[®] Dx Analysis System

US Product Data Sheet

The Prosigna Breast Cancer Prognostic Gene Signature Assay is a qualitative in vitro diagnostic tool that 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 at 10 years in postmenopausal

women with node-negative (Stage I or II) or node-positive (Stage II), hormone receptor-positive (HR+) breast cancer. The Prosigna Assay measures gene expression levels of RNA extracted from formalin-fixed paraffin-embedded (FFPE) breast tumor tissue previously diagnosed as invasive breast carcinoma.

Prosigna Sample Requirements



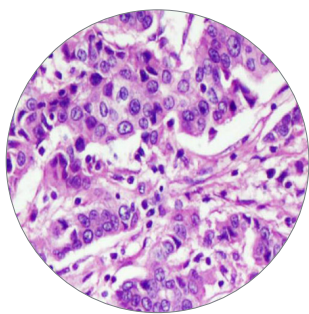
The Prosigna assay is performed on RNA isolated from FFPE breast tumor tissue. A pathologist examines a hematoxylin and eosin (H&E) stained slide and identifies (and marks) the area of invasive breast carcinoma suitable for the test. The pathologist also measures the tumor surface area, which determines the number of unstained slides required for the test, and the tumor cellularity to ensure the presence of sufficient tumor tissue for the test. A trained technologist macrodissects the area on the unstained slides corresponding to the marked tumor area on the H&E-stained slide and isolates RNA from the tissue. The isolated RNA is then tested on the NanoString nCounter® DX Analysis System to provide test results including the Prosigna Score and risk category.

SPECIMEN ATTRIBUTE	REQUIREMENT						
Tissue input	Viable invasive breast carcinoma (ductal, lobular, mixed, or NOS)						
Tissue input format	Macro-dissected 10-micron-thick slide-mounted tissue sections						
Minimum tumor size	4 mm ² tumor area						
Minimum tumor cellularity	10% within tumor area						
Minimum RNA amount	125 ng (12.5 ng/μL)						
Tumor area	<table border="0"> <tr> <td>≥100 mm²</td> <td>1 slide</td> </tr> <tr> <td>20 – 99 mm²</td> <td>3 slides</td> </tr> <tr> <td>4 – 19 mm²</td> <td>6 slides</td> </tr> </table>	≥100 mm ²	1 slide	20 – 99 mm ²	3 slides	4 – 19 mm ²	6 slides
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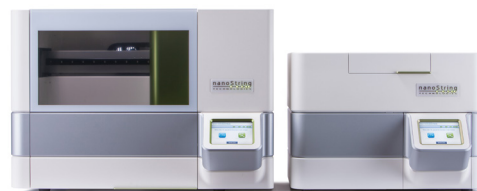
Prosigna Algorithm and Output*

The test is based on PAM50, the 50-gene classifier algorithm, and is performed on the nCounter® DX Analysis system using RNA extracted from formalin fixed paraffin embedded (FFPE) breast tumor tissue samples. The algorithm uses a 50-gene expression profile to assign breast cancer to one of four PAM50 molecular subtypes determined by the tumor's molecular profile. The prototypical gene expression profiles (e.g. centroids) of the four PAM50 molecular subtypes were retrained on the nCounter Dx Analysis System using FFPE breast tumor samples collected from multiple clinical sites. After performing the assay on a patient test sample, a computational algorithm based on a Pearson's correlation compares the normalized 50-gene expression profile of the patient test sample to the four PAM50 centroids.

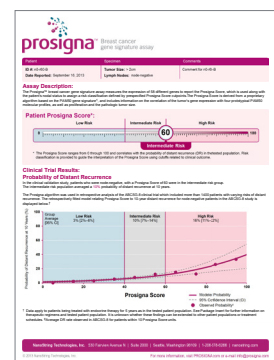
The algorithm reports a risk category based on both Prosigna Score and nodal status. The Prosigna Score is reported on a 0 -100 scale (referred to as ROR Score or Risk of Recurrence Score in the literature), which is correlated with the probability of distant recurrence at ten years for post-menopausal women with hormone receptor positive, early stage breast cancer. The Prosigna Score is calculated using coefficients from a Cox model that includes the Pearson correlation of a 46-gene subset of the 50 genes to each PAM50 centroid, a proliferation score, and gross tumor size. The test variables are multiplied by the corresponding coefficients from the Cox Model to generate the score, which is then adjusted to a 1-100 scale based on coefficients generated from the training set of FFPE breast tumor samples. Risk categories are reported based on cut-offs by nodal status for Prosigna Score which were validated in a clinical validation study.



Extract RNA from FFPE tumor sample



Run RNA and Prosigna CodeSet on nCounter DX Analysis System



Patient-specific Risk category and numerical score

*Intrinsic subtype is not reported by the Prosigna Assay in the United States. PAM50 molecular subtypes are utilized by the Prosigna algorithm to calculate Prosigna Score and risk category.

Ordering Information

PRODUCT DESCRIPTION

CATALOG NUMBER

UNIT

Prosigna® Gene Signature Assay

Complete kit for running Prosigna tests. Includes all CodeSet and Master Kit components; does not include RNA Isolation Kit.

PROSIGNA-001

One kit of 1 patient assay

PROSIGNA-002

One kit of 2 patient assays

PROSIGNA-003

One kit of 3 patient assays

PROSIGNA-004

One kit of 4 patient assays

PROSIGNA-010

One kit of 10 patient assays

Roche FFPET RNA Isolation Kit

Includes 25 isolations per kit.

Roche-FFPET-025

Each

CONTACT

For more information and details on how to offer Prosigna from your institution, please contact **NanoString Technologies, Inc:**

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