Product Data Sheet

The Prosigna™ Breast Cancer Prognostic Gene Signature

See the difference with Prosigna

- The only PAM50-based breast cancer genomic signature
- The only genomic breast cancer assay that can be run in your pathology lab
- The only test that is FDA 510(k) cleared for FFPE tissue

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.

Special conditions for use: Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients.

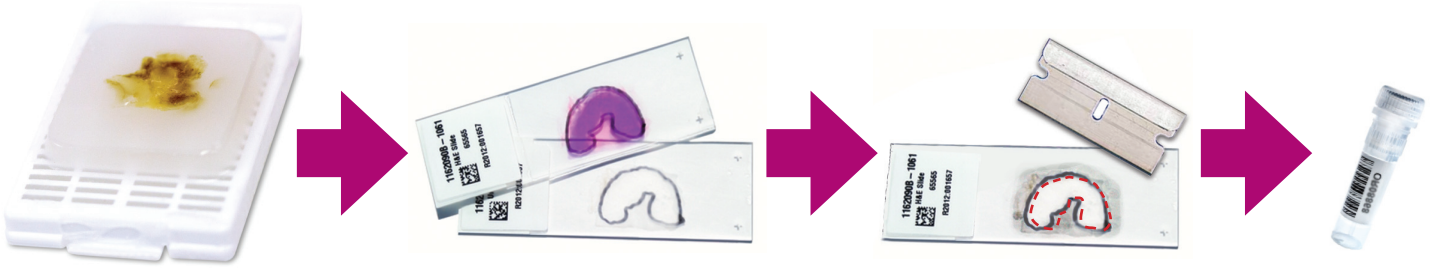
prosigna™
Breast cancer gene signature assay

nanoString® TECHNOLOGIES

For detail information see the Prosigna package insert or visit: www.PROSIGNA.com

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® Analysis System to provide test results including the Prosigna Score and risk category.



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H&E stain to identify tumor area and cellularity

Tumor area transposed to unstained slides and macrodissected

RNA extracted with manual kit

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	≥100 mm^2 1 slide 20 – 99 mm^2 3 slides 4 – 19 mm^2 6 slides

Prosigna™ Algorithm and Output

The test is based on PAM50, the 50-gene classifier algorithm, and is performed on the nCounter® 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 in North America. After performing the assay on a patient test sample, a computational algortithm based on a Pearson's correlation compares the normalized 50-gene expression profile of the patient test sample to the four PAM50 centroids.

Extract RNA from FFPE tumor sample

Run RNA and Prosigna CodeSet on nCounter Analysis System

Patient specific expression profile

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.

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prosigna™ Breast cancer gene signature assay

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Ordering Information

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

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Suite 2000
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(888-358-6266)

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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™ Breast cancer gene signature assay	PROSIGNA-004	One kit of 4 patient assays
	PROSIGNA-010	One kit of 10 patient assays
	PROSIGNA-020	One kit of 20 patient assays
	PROSIGNA-030	One kit of 30 patient assays
	PROSIGNA-040	One kit of 40 patient assays
Roche FFPET RNA Isolation Kit Includes 25 isolations per kit.	Roche-FFPET-025	Each

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