Prosigna®

Breast Cancer Assay

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® 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 on the PAM50 gene set to generate an intrinsic molecular subtype* (luminal A, luminal B, HER2-enriched, or basal-like) and a proliferation score* 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 receptorpositive (HR+) breast cancer. The Prosigna Assay measures gene expression levels of RNA extracted from formalin-fixed paraffinembedded (FFPE) breast tumor tissue previously diagnosed as invasive breast carcinoma.

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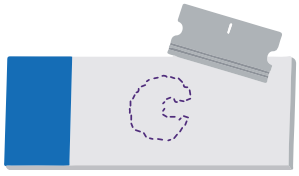
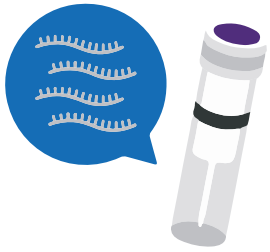
Prosigna Sample Requirements

Block Selected

H&E stain to identify tumor area and cellularity



Tumor area transposed to unstained slides and macrodissected



RNA extracted with manual kit

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.

SPECIMEN ATTRIBUTE	REQUIREMENT
Tissue input	Viable invasive breast carcinoma (ductal, lobular, mixed, or NOS)
Tissue input format	Macro-dissected 10-micronthick 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

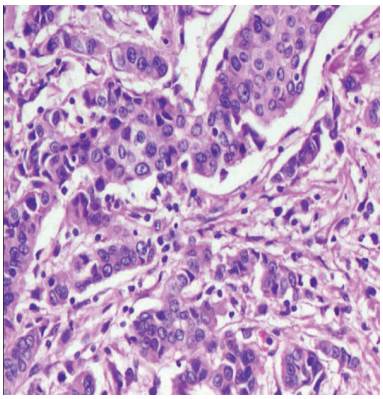
Prosigna Algorithm and Output

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 intrinsic molecular subtypes determined by the tumor's molecular profile.

The prototypical gene expression profiles (e.g. centroids) of the four PAM50 intrinsic molecular subtypes were retrained on the nCounter Analysis System using FFPE breast tumor samples collected from multiple clinical sites.

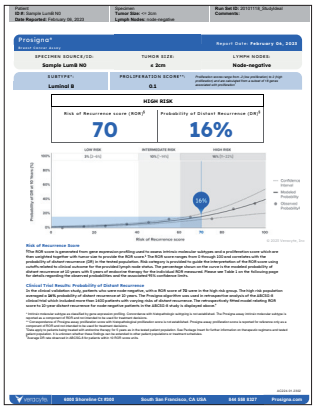
After performing the assay on a patient test sample, a computational algortithm based on a Pearson's correlation compares the normalized 50-gene expression profile of the patient test sample to the four PAM50 centroids.

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 Analysis System



Patient-specific Risk category and numerical score

Ordering Information

Prosigna® Gene Signature Assay

Product Description

Complete kit for running Prosigna tests. Includes all CodeSet and Master Kit components.
Does not include RNA Extraction Kit.

Catalog Number	Unit
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

Veracyte FFPE RNA Extraction Kit

Product Description

Includes 10 isolations per kit.

Catalog Number	Unit
550100	Each

Contact

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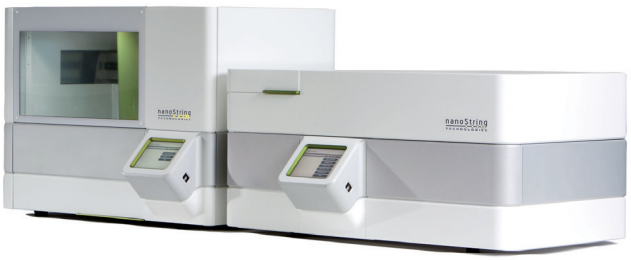

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*The intrinsic molecular subtype and proliferation score are only reported as constituent components of the ROR. Their correspondence with histopathological subtyping is not established.

Veracyte is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the US through our central laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally.

The Prosigna® Breast Cancer Prognostic Gene Signature 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.

Prosigna® in conjunction with the nCounter® Analysis System is 510(k) FDA cleared 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 breast cancer to be treated with adjuvant endocrine therapy. See Package Insert for further details at www.prosigna.com. ©2021 Veracyte, Inc. Prosigna and the Prosigna logo are trademarks and/or registered trademarks of Veracyte, Inc. in various jurisdictions. For more information, please visit www.prosigna.com.

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