Prosigna® Breast Risk of Recurrence Test

Test Requisition Form

Veracyte Labs SD
Fax: 1.650.763.4192
Email: customercare@veracyte.com

*Indicates a required field

PATIENT INFORMATION

First Name:* Last Name:*

Date of Birth:* (mm/dd/yyyy)

Address:

City: State: Zip:

Phone: Patient MRN:

E-mail:

Sex Assigned at Birth: ☐ Male ☐ Female

Race/Ethnicity: ☐ Prefer Not to Say

ORDERING CLINICIAN INFORMATION

Account #: Practice Name:

Address:

City: State: Zip:

Phone:* Fax:*

Ordering Clinician Name:*

Ordering Clinician NPI #:

Additional Result Recipient (Optional)

Clinician Name: NPI #:

Address:

City: State: Zip:

E-mail: Fax:

BILLING INFORMATION

ICD-10 Primary Diagnosis Code(s):* ☐ C50.411 ☐ C50.412 ☐ C50.511 ☐ C50.512 ☐ Other _____

Bill Type:* ☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Patient Self-Pay ☐ Client Bill

Secondary Insurance? ☐ Yes ☐ No

Specimen Collection Location: (Medicare patients only*)

☐ Non-Hospital Patient ☐ Hospital Outpatient

☐ Hospital Inpatient _____ Discharge Date (mm/dd/yyyy)

TEST INFORMATION

Formalin-fixed paraffin-embedded (FFPE) tumor tissue samples are required.

Select Specimen*

☐ Surgical Resection
☐ Core Needle Biopsy

FFPE TUMOR (Submit a block or slides — see FFPE Specimen Instructions.)

Specimen Collection Date:* _____ (mm/dd/yyyy)

Upon receipt of this requisition, Veracyte will procure the required FFPE sample if not already provided.

PATIENT HISTORY

Hormone Receptor Status:* (Select all that apply) ☐ ER+ ☐ PR+

Source of Tumor Information
☐ Clinical Data ☐ Pathology Report

Menopausal Status:* (Select one) ☐ Pre-menopausal ☐ Post-menopausal

Tumor Stage* (Select one): ☐ T1 ☐ T2 ☐ T3

Tumor Size* (Select one): ☐ ≤2 cm ☐ >2 cm

Lymph Node Status* (Select one): ☐ N0 (node -) ☐ pN1mic (micro metastatic) ☐ N1 (Clinical) ☐ N1 (1-3 nodes)

CLINICIAN SIGNATURE & STATEMENT OF MEDICAL NECESSITY

I confirm that I am a clinician authorized to order testing in the location that I practice, that this test is medically necessary for the prognosis and treatment selection of a cancer, that its results will be used in the medical management and treatment decisions for this patient, and that I am responsible for returning the results of testing to my patient and/or legal guardian. I confirm that I have the patient's assignment of benefits on file, authorizing benefits to be paid to ancillary service providers such as Veracyte, Inc. and its affiliates. I authorize Veracyte, Inc. and its affiliates to release information provided by me to process the claim for this service. I confirm that my patient and/or their legal guardian will receive appropriate counseling to understand the implications of this test. I hereby authorize the pathology laboratory, listed in the pathology section, to release the patient's FFPE tissue to Veracyte. For Medicare Beneficiaries, I certify that this patient meets the Medicare eligibility criteria provided on the reverse side of this form.

Ordering Clinician Signature:* Date* (mm/dd/yyyy)

THE FOLLOWING MUST BE PROVIDED:*

☐ Demographic/Face Sheet ☐ Copy of Insurance Card(s)
☐ Pathology Report

THIS FORM WAS COMPLETED BY:

Office Contact Name:	
Phone #:	E-mail:

Prosigna® Breast Risk of Recurrence Test

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SHIPPING INFORMATION

FFPE Tumor Slides or Blocks: Ship according to the "FFPE Specimen Instructions" provided in the Prosigna Tissue Specimen Collection Kit, along with the completed Test Requisition Form. If submitting slides, ensure they are unbaked, unstained, and positively charged.

CONTRAINDICATIONS / LIMITATIONS

- The assay is intended for use only on formalin-fixed, paraffin embedded (FFPE) breast cancer tissue specimens from surgical resection or core needle biopsy.
- The assay is not intended for use on fresh, frozen, non-breast cancer tissue, or breast cancers that have been treated with systemic therapy or radiation.
- The clinical or pathological assessment of the patient's primary tumor size and nodal status are required.
- No internal mammary, infraclavicular, or supraclavicular lymph nodes.
- If the tumor block or slides have insufficient tumor area or insufficient tumor cellularity, then a different block from the same tumor should be assessed.
- Macro-dissected slides for clinical sample testing will not be accepted.
- Test results should be interpreted within the clinical context by a licensed healthcare provider directly involved in the patient's care.

TEST DESCRIPTION

The Prosigna Breast Cancer Gene Signature Assay, branded as the Prosigna Breast Risk of Recurrence test, is intended for use in early-stage Hormone Receptor positive (HR+) invasive breast cancer patients as a prognostic indicator for estimating the 10-year distant recurrence-free survival when treated with standard of care locoregional management and adjuvant endocrine therapy, applied with consideration of other clinicopathologic factors.

Whole transcriptome RNA sequencing analysis is utilized for gene expression profiling of the PAM50-based gene set on RNA extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue; data is collected from over 21,000 genes and over 425,000 probes across the transcriptome for each patient when the test is performed.

Specimen Requirements:
Tumor Tissue: Formalin-Fixed Paraffin-Embedded (FFPE).

The Test Provides:
- Risk of recurrence (ROR) score
- Probability of 10-year distant recurrence
- Predictive chemotherapy benefit
- Intrinsic subtype
- Proliferation score

Results should be interpreted by a qualified healthcare professional in the context of the patient's clinical and pathological history. Test results are intended to aid in clinical decision-making in alignment with professional guidelines and alongside other clinicopathological factors.

Micro Metastatic Lymph Nodes:
Cases with pN1mic lymph node involvement are treated as LN+ disease when generating risk estimates and should be considered an upper bound estimate.

MEDICARE COVERAGE REQUIREMENTS

Post-menopausal female either:
- ER+, lymph node-negative, stage I or II breast cancer; or
- ER+, lymph node-positive (1-3 positive nodes), stage II breast cancer.

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