# Prosigna®

## Breast Cancer Assay

THE PROSIGNA BREAST CANCER TEST

# What is it and what does it mean for me?

How can I confidently choose the best treatment for my breast cancer?

Post-menopausal women with early-stage hormone receptor-positive (HR+)

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**The Prosigna test provides important and comprehensive information that helps breast cancer patients and their doctors choose the best treatment.**

# What happens after I'm diagnosed with breast cancer?

Breast cancer is the most common cancer in women, and numbers have increased in the last 5 years. In 2020, 2.3 million women worldwide were diagnosed, which represents one in 15 women who will develop breast cancer in their lifetime.[1]

Your treatment choice is an essential decision defining the ultimate outcome.

**Breast cancer diagnosis doesn't have to shorten your life anymore but it has to be treated.**

**Surgical tumor removal is a must but the choice of chemotherapy, hormone therapy, radiation or other treatment depends on multiple factors and is very individual.**

**The more you and your doctor know about your tumor, the more precise and effective the treatment can be.**

## Screening or symptomatic presentation

- Breast imaging
- Medical history
- Physical examination
- Biopsies

## Confirmed diagnosis


## Testing on tumor sample

Prosigna test result

- Tissue stays in the local laboratory
- Analysis is performed by hospital's own staff
- Your results are available in as little as 72 hours

## Discussion with your doctor about treatment options

- Local/regional treatment (surgery and radiotherapy directed where your cancer started)
- Systemic therapy (medical treatment directed to cancer cells that may have spread throughout your body)

**Knowing how likely is your cancer to come back can help you and your doctor choose the best treatment.**

In recent years, new diagnostic tests have been developed to help health care professionals choose the most efficient treatment for their patients.

# What is the Prosigna test?

Prosigna is a genomic test which identifies the likelihood this cancer may return over the next 10 years. This is known as distant recurrence. By assessing your risk, Prosigna can provide a more complete understanding of your breast cancer.

Prosigna utilizes the PAM50 gene signature to find the genomic fingerprint of your tumour, also referred to as intrinsic subtype. Using an automated process, your subtype is combined with other factors including tumour size and number of involved lymph nodes to help determine your risk of distant recurrence. Looking ahead 10 years may help you and your physician make more confident choices today.

## Am I eligible?

Prosigna is indicated for use in postmenopausal women with hormone receptor-positive, node-negative (Stage I or II) or node-positive (Stage II or IIIA) early-stage breast cancer.

See the Prosigna Package Insert for full intended use.

**The Prosigna test was developed to help your oncologist assess which treatment is the most suitable for you.**

## How does the Prosigna test work?

The Prosigna test provides a Risk of Recurrence (ROR) score, a number between 0 and 100. This number estimates the likelihood that your cancer will return in some other parts of your body if you only receive endocrine (hormone) therapy. This is based on:

- The size of your tumour
- The intrinsic subtype (different types of disease, which can respond to different treatments)
- How quickly your disease is growing
- And the nodal status (whether the disease has entered the lymph nodes)

The Prosigna test has been validated with 2400 postmenopausal women before being approved by regulatory authorities as providing accurate information.

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## The Prosigna test gives you and your doctor more information.

# Subtype-based analysis

**Not all breast cancers are the same. They can be classified by molecular subtype, stage, nodal involvement and other factors. Based on this information your doctor is able to tailor your treatment.**

### The Prosigna report provides an accurate assessment of your risk of recurrence

The Prosigna report is delivered directly to your oncologist in as little as 72 hours and includes three important results:

- **Your Intrinsic Subtype**, which assigns your cancer to one of four intrinsic molecular subtypes: Luminal A, Luminal B, HER2 enriched or Basal-like. Subtypes provide additional information about how your tumor might behave.[2]
- **Your Prosigna Score**, which is a numerical value on a 0-to-100 scale. A lower number indicates your cancer is less likely to return. A higher number indicates there is a higher chance your cancer may return.
- **Your Risk Category**, (Low, Intermediate, or High) indicates how likely your cancer will return within 10 years. In combination with other aspects, such as your age, other health issues, the size and grade of your tumour, and hormone receptors present in your breast cancer, your risk category will help you and your oncologist make the best treatment decision for you.

These results will help your doctor to recommend the best possible treatment options so you can choose with confidence.

# The Prosigna report

The Prosigna patient report is customised to contain test results and information specific to each patient.

### Prosigna test patient profile

**Mrs. B.M., 68**

**Surgery**: Breast conserving surgery (BCS) and sentinel lymph node biopsy (SLNB)

**Pathology**: Invasive ductal cancer (IDC) grade III 15mm

| | |
|---|---|
| ✓ | Female |
| ✓ | Post-menopausal |
| ✓ | Hormone receptor-positive |
| ✓ | Surgery + Local/regional treatment with surgery and radiation |
| ✓ | Lymph Node Negative + Stage I or II **OR** Lymph Node Positive (1-3) Stage II or IIIA |

**The Prosigna test provides more comprehensive information about your cancer, the risk of it returning in other parts of your body and enables your doctor to define a personalised and precise treatment plan.**

Thousands of patients around the world have already chosen to use the Prosigna test. This test has allowed them to adapt their treatment, choosing with their doctor what is right for them.

# When and how is my Prosigna test performed?

**After surgery, the Prosigna test does not require any additional steps on your part and is performed in local laboratories, allowing a quick result in as little as 72 hours.**

### Prosigna request

Oncologist (ordering provider) requests Prosigna Breast Cancer Assay

### Tissue sample

Samples from your tumour are sent to a local laboratory

### Tissue review

Pathologist confirms that there is enough tissue to do the Prosigna test

### Prosigna analysis

Sample is prepared and the Prosigna test is performed

### Prosigna report

Prosigna test results are provided to your doctor

**The Prosigna test is recommended by major guidelines such as ESMO, NCCN, NICE, ASCO, St Gallen.Please ask your doctor if you would like to get any further details about the test, or visit our website:**

**www.prosigna.com/patients**

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# EXAMPLE OF PATIENT REPORTS

| Patient | Specimen | |
|---|---|---|
| **Tumor Size:** <= 2cm<br>**Lymph Nodes:** node-negative | **ID #:** n0-l2-70-HR-LB<br>**Date Reported:** September 20, 2017 | **Run Set ID:** Prosigna Sample 2<br>**Comments:** Comment for n0-l2-70-HR-LB |

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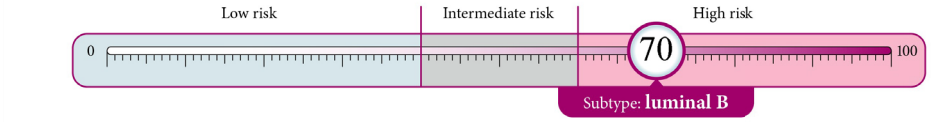
**ID #:** n0-l2-70-HR-LB **Tumor Size:** <= 2cm **Lymph Nodes:** node-negative

**Assay Description:** The Prosigna® breast cancer gene signature assay measures the expression of 50 different genes to identify subtype and report a Risk of Recurrence Score (ROR), which is used to assign the patient to a predefined risk group. These results are derived from a proprietary algorithm based on the PAM50 gene signature, intrinsic subtype, and clinical variables including tumor size and nodal status.

## Risk of Recurrence*:

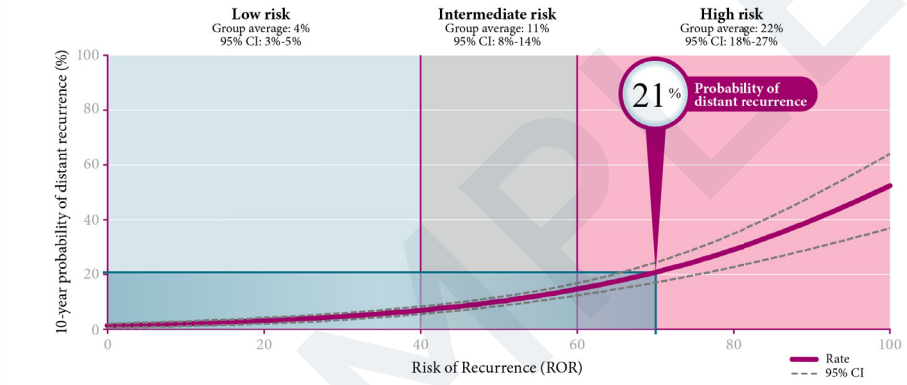



* The ROR ranges from 0 through 100 and correlates with the probability of distant recurrence (DR) in the tested patient population. The risk classification is provided to guide the interpretation of the ROR using cutoffs related to clinical outcome.

## Probability of Distant Recurrence:

**In the clinical validation studies, patients who were node-negative, luminal B subtype, with an ROR score of 70 were in the high-risk group. This group averaged a 22% probability of distant recurrence at 10 years.**

The Prosigna® algorithm has been validated by 2 randomized clinical trials including more than 2400 patients with varying rates of distant recurrence. An analysis of these 2 clinical validation studies shows that the probability of distant recurrence for the high-risk population is 22%.†




For more information, visit PROSIGNA.com or e-mail info@prosigna.com

†Data apply to patients being treated with hormone therapy for 5 years as in the tested patient population. See Package Insert for further information on therapy regimens and tested patient population. It is unknown whether these findings can be extended to other patient populations or treatment schedules.





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The patient's specific tumor size and nodal status and genomic expression profile are incorporated into calculation of the Risk of Recurrence (ROR) and risk group classification.

The test design has been assessed with data and outcomes of thousands of similar patients. The score is also reported as a percentage which is the probability of the disease coming back elsewhere in your body in 10 years time if you complete 5 years of endocrine therapy.

ROR is generated by a proprietary algorithm and is reported on a scale from 0 to 100. The risk groups are different if you are node positive.

| Patient | Specimen | |
|---|---|---|
| **Tumor Size:** <= 2cm<br>**Lymph Nodes:** node-positive (1-3 nodes) | **ID #:** n1-l2-8-LR-LA<br>**Date Reported:** September 20, 2017 | **Run Set ID:** Prosigna Sample 2<br>**Comments:** Comment for n1-l2-8-LR-LA |

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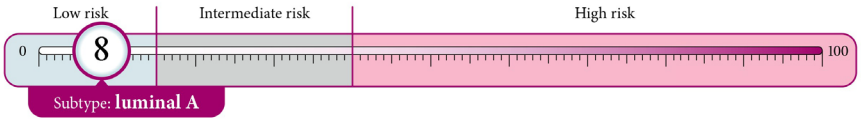
**ID #:** n1-l2-8-LR-LA **Tumor Size:** <= 2cm **Lymph Nodes:** node-positive (1-3 nodes)

**Assay Description:** The Prosigna® breast cancer gene signature assay measures the expression of 50 different genes to identify subtype and report a Risk of Recurrence Score (ROR), which is used to assign the patient to a predefined risk group. These results are derived from a proprietary algorithm based on the PAM50 gene signature, intrinsic subtype, and clinical variables including tumor size and nodal status.

## Risk of Recurrence*:

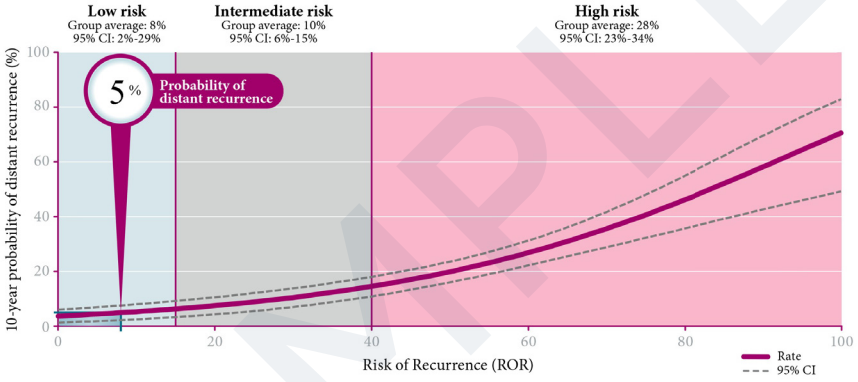



* The ROR ranges from 0 through 100 and correlates with the probability of distant recurrence (DR) in the tested patient population. The risk classification is provided to guide the interpretation of the ROR using cutoffs related to clinical outcome.

## Probability of Distant Recurrence:

**In the clinical validation studies, patients who were node-positive (1-3 nodes), luminal A subtype, with an ROR score of 8 were in the low-risk group. This group averaged an 8% probability of distant recurrence at 10 years.**

The Prosigna® algorithm has been validated by 2 randomized clinical trials including more than 2400 patients with varying rates of distant recurrence. An analysis of these 2 clinical validation studies shows that the probability of distant recurrence for the low-risk population is 8%, while the high-risk population has a significantly greater probability of distant recurrence.†

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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. We aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally.

**For more information,**
**call +1.650.243.6335**
**or send us an email at info@prosigna.com**

1. Breast cancer - WHO | World Health Organization
2. Perou C. et al. Molecular portraits of human breast tumours. Nature. 2000; 406: 747-752.



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