

# Prosigna Breast Cancer Prognostic Gene Signature Test

## Indications for Ordering

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Assess risk of distant recurrence in postmenopausal women with early stage (I or II), hormone receptor-positive (ER+ and/or PR+) breast cancer

- Useful in both node-negative and node-positive (1-3 nodes) disease

## Test Description

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### Test methodology

- Probe hybridization/gene expression
- Prosigna test
  - Received a European CE Mark
  - FDA 510(k) cleared for use in the U.S.
  - Utilizes PAM50 gene signature
- Prosigna score
  - Continuous risk score (0-100)
  - Associated with a patient's risk of recurrence at 10 years in women with hormone receptor-positive breast cancer given endocrine therapy alone

### Clinical validation

Two independent clinical trials in women with early-stage, hormone receptor-positive breast cancer accurately predicted distant recurrences in patients given adjuvant endocrine therapy alone (eg, tamoxifen or aromatase inhibitor)

- Trans-ATAC study (1,007 individuals) (Dowsett. J Clin Oncol. 2013)
  - Improved prognostic accuracy when compared to Oncotype Dx
- ABCSG8 study (1,478 individuals) (Gnant M. Ann Oncol. 2014)

## Test to Consider

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[Prosigna Breast Cancer Prognostic Gene Signature 2010248](#)

## Disease Overview

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### Incidence/prevalence of breast cancer

- High incidence and relatively low mortality
- Most prevalent cancer in the world

### Biology

Prosigna test uses the following to determine a woman's risk of relapse (risk estimates)

- Molecular subtype of breast cancer
- Proliferation status of tumor
- Tumor size and node status

### Treatment issues

Many women with breast cancer are overtreated with chemotherapy

- Often associated with unnecessary side effects (including risk of death or severe morbidity)
- Prosigna risk score may help decrease overtreatment

## Results

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Women with node-negative breast cancer

- 0-40 – low risk
- 41-60 – intermediate risk
- 61-100 – high risk

Women with node-positive (1-3 nodes) breast cancer

- 0-40 – low risk
- 41-100 – high risk (in node-positive cases, scores 81-100 are reported as >80)

### Limitations

- Minimum 10% tumor required
- Test is intended for women with hormone receptor-positive breast cancer only
- Not intended to provide information about what chemotherapy regimen should be given if at high risk for distant recurrence