

Patient ID #: 1
Date Reported: November 03, 2020

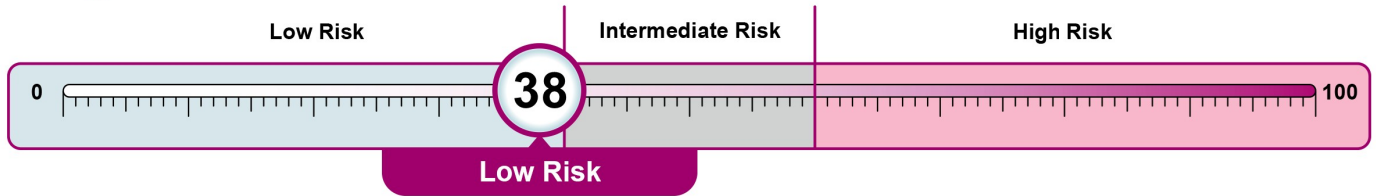
Specimen
Tumor Size: > 2cm
Lymph Nodes: node-negative

Run Set ID: 10222020np1
Comments:



ID #: 1 Tumor Size: > 2cm Lymph Nodes: node-negative
Assay Description: The Prosigna® breast cancer gene signature assay measures the expression of 58 different genes to report the Prosigna® Score, which is used along with the patient's nodal status to assign a risk classification defined by prespecified Prosigna® Score cutpoints. The Prosigna® Score is derived from a proprietary algorithm based on the PAM50 gene signature¹, and includes information on the correlation of the tumor's gene expression with four prototypical PAM50 molecular profiles, as well as proliferation and the pathologic tumor size.

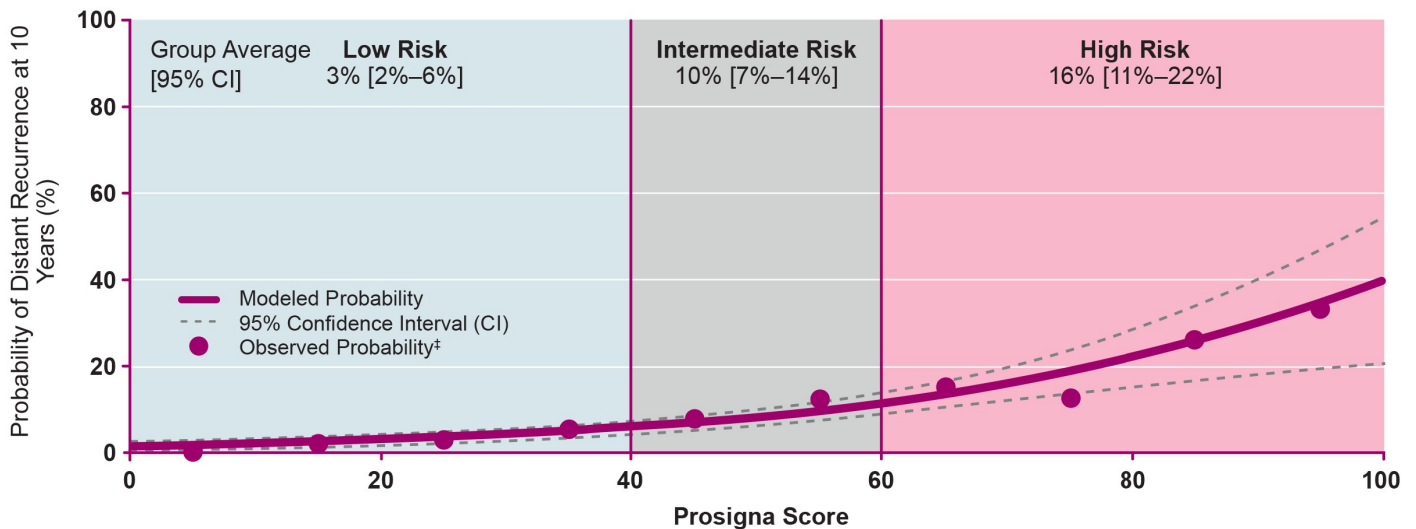
Patient Prosigna® Score*:



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

Clinical Trial Results: Probability of Distant Recurrence

In the clinical validation study, patients who were node-negative, with a Prosigna® Score of 38 were in the low risk group. The low risk population averaged a 3% probability of distant recurrence at 10 years. The Prosigna® algorithm was used in retrospective analysis of the ABCSG-8 clinical trial which included more than 1400 patients with varying risks of distant recurrence. The retrospectively fitted model relating Prosigna® Score to 10-year distant recurrence for node-negative patients in the ABCSG-8 study is displayed below.[†]



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

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

[‡]Average DR rate observed in ABCSG-8 for patients within 10 Prosigna® Score units.

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Specimen
Tumor Size: > 2cm
Lymph Nodes: node-negative

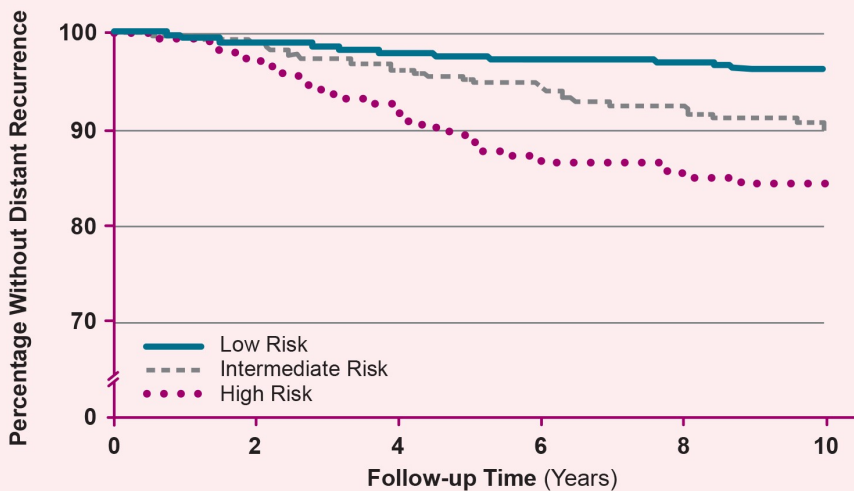
Run Set ID: 10222020np1
Comments:



ID #: 1 Tumor Size: > 2cm Lymph Nodes: node-negative
Clinical Trial Results: Clinical Validation Study: Prognosis for node-negative breast cancer patients was determined based on the probability of distant recurrence (DR) for this patient population in the validation study ABCSG-8. This study analyzed 1,047 node-negative samples using a prospectively defined analysis plan. The data shown are for postmenopausal women with hormone receptor-positive, node-negative, Stage I and II breast cancer that received 5 years of endocrine therapy.*

Probability of DR for Node-Negative Patients	Prespecified Patient Risk Group		
	Low Risk [95% CI]	Intermediate Risk [95% CI]	High Risk [95% CI]
ABCSG-8 ²	3% [2%–6%]	10% [7%–14%]	16% [11%–22%]

DRFS by Risk Group for Node-Negative Patients³



The Prosigna Score classifies node-negative patients as low, intermediate, or high-risk based on prespecified thresholds that indicate probability of DR at 10 years. In the ABCSG-8 clinical validation study, the probability of DR at 10 years for low-risk, node-negative patients was 3% (95% CI: 2%-6%), while the probability of DR at 10 years for high-risk patients was 16% (95% CI: 11%-22%).

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* 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.

- REFERENCES: 1. Parker JS, *et al.*, Supervised Risk Predictor of Breast Cancer Based on Intrinsic Subtypes. *Journal of Clinical Oncology*, v27 No. 8 (2009) 1160-1167
2. Prosigna[®] Package Insert
3. Gnant M, *et al.*, P2-10-02, Clinical Validation of the PAM50 risk of recurrence (ROR) score for predicting residual risk of distant recurrence (DR) after endocrine therapy in postmenopausal women with HR+ early breast cancer (EBC): An ABCSG study, SABCS 2012.