

Patient ID #: 2
Date Reported: September 21, 2016

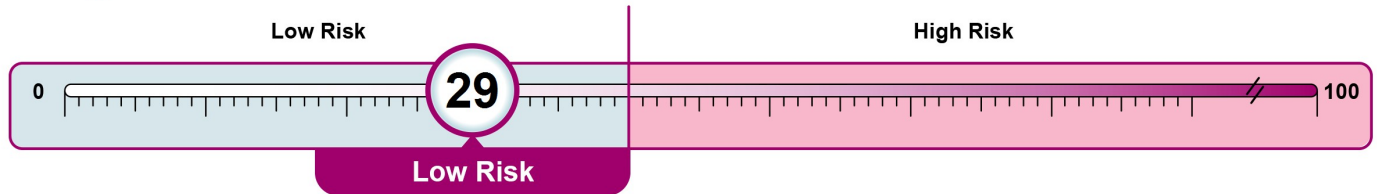
Specimen Tumor Size: <= 2cm
Lymph Nodes: node-positive (1-3 nodes)

Run Set ID: 11092020
Comments:



ID #: 2 Tumor Size: <= 2cm Lymph Nodes: node-positive (1-3 nodes)
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.

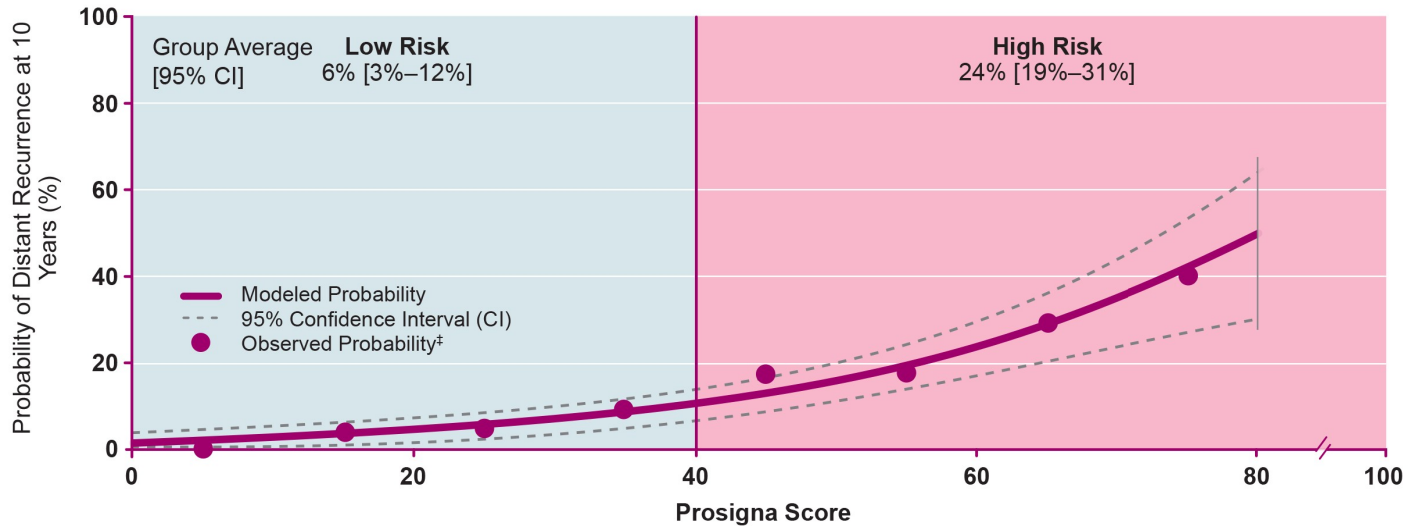
Patient Prosigna Score*:



* 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. Prosigna® Scores greater than 80 are considered high risk, and the score is not reported.

Clinical Trial Results: Probability of Distant Recurrence

In the clinical validation study, patients who were node-positive (1-3 nodes), with a Prosigna® Score of 29 were in the low risk group. The low risk population averaged a 6% 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-positive (1-3 nodes) patients in the ABCSG-8 study is displayed below.[†]



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Due to small sample size of patients with scores greater than 80 in the clinical validation study, the exact relationship of the Prosigna® Score to probability of DR could not be established with a retrospective model fitting.

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
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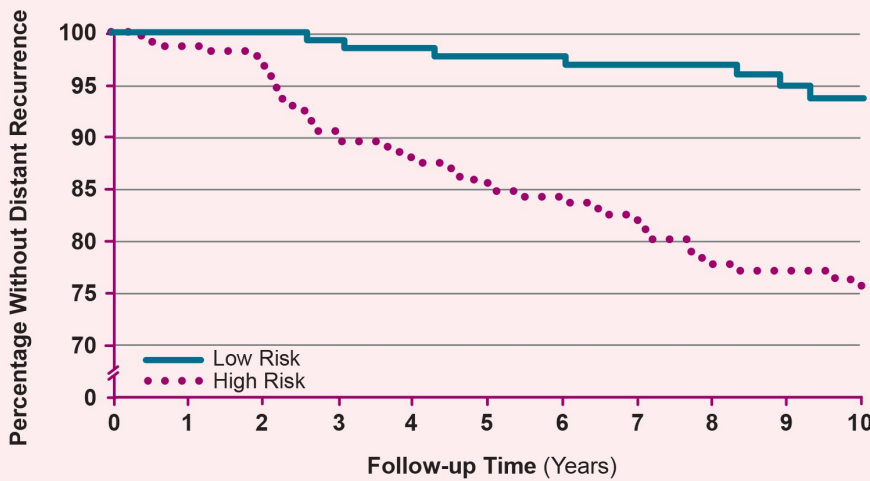
Run Set ID: 20140912AB
Comments:



ID #: Sample 00-000 Tumor Size: <= 2cm Lymph Nodes: node-positive (1-3 nodes)
Clinical Trial Results: Clinical Validation Study: Prognosis for node-positive (1–3 nodes) 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 382 node-positive (1–3 nodes) samples using a prospectively defined analysis plan. The data shown are for post-menopausal women with hormone receptor-positive, node-positive (1–3 nodes), Stage II breast cancer that received 5 years of endocrine therapy.*

Probability of DR for Node-Positive (1-3 Nodes) Patients	Prespecified Patient Risk Group	
	Low Risk [95% CI]	High Risk [95% CI]
ABCSG-8 ²	6% [3%–12%]	24% [19%–31%]

DRFS by Risk Group for Node-Positive (1-3 Nodes) Patients³



The Prosigna Score classifies node-positive (1-3 nodes) patients as low 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-positive (1-3 nodes) patients was 6% (95% CI: 3%-12%), while the probability of DR at 10 years for high-risk patients was 24% (95% CI: 19%-31%).

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

* 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.