

Patient
ID #: Sample LumA
Date Reported: February 06, 2023

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

Run Set ID: 20101118_StudyIdeal
Comments:

Prosigna®
Breast Cancer Assay

Report Date: February 06, 2023

SPECIMEN SOURCE/ID:

Sample LumA

TUMOR SIZE:

≤ 2cm

LYMPH NODES:

Node-positive

SUBTYPE*:

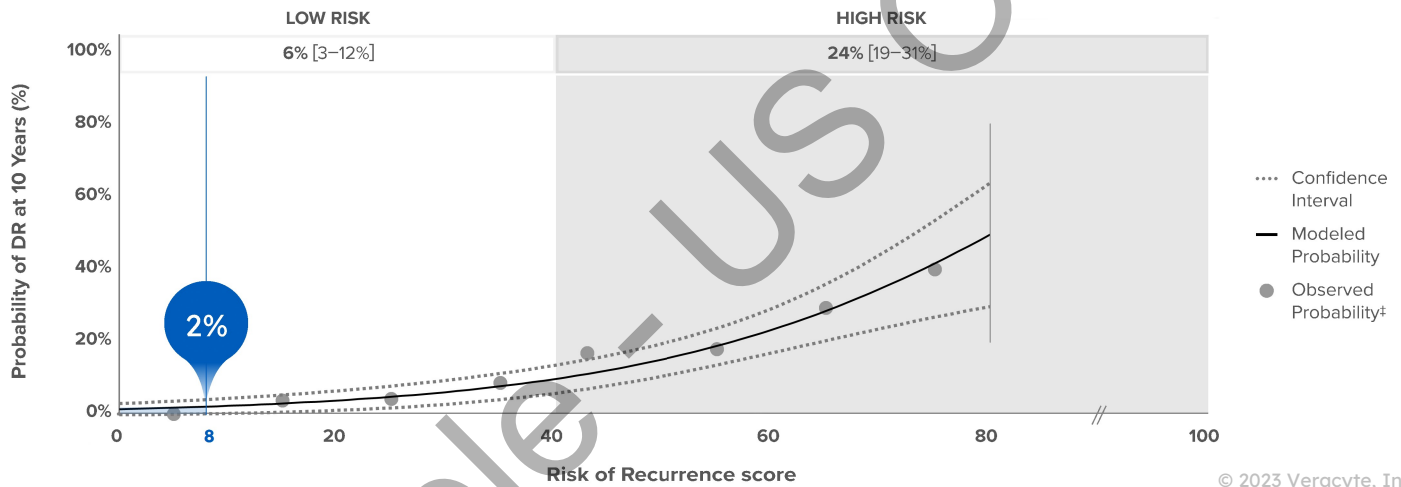
Luminal A

PROLIFERATION SCORE**:

-0.8

Proliferation scores range from -2 (low proliferation) to 2 (high proliferation) and are calculated from a subset of 18 genes associated with proliferation¹

LOW RISK	
Risk of Recurrence score (ROR) [§]	Probability of Distant Recurrence (DR) [§]
8	2%



Risk of Recurrence Score

[§]The ROR score is generated from gene expression profiling used to assess intrinsic molecular subtypes and a proliferation score which are then weighted together with tumor size to provide the ROR score.¹ The ROR score ranges from 0 through 100 and correlates with the probability of distant recurrence (DR) in the tested population. Risk category is provided to guide the interpretation of the ROR score using cutoffs related to clinical outcome for the provided lymph node status. The percentage shown on the curve is the modeled probability of distant recurrence at 10 years with 5 years of endocrine therapy for the individual ROR measured. Please see Table 1 on the following page for details regarding the observed probabilities and the associated 95% confidence limits.

Clinical Trial Results: Probability of Distant Recurrence

In the clinical validation study, patients who were node-positive (1-3 nodes), with a ROR score of **8** 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 ROR score to 10-year distant recurrence for node-positive (1-3 nodes) patients in the ABCSG-8 study is displayed above.[†]

* Intrinsic molecular subtype as classified by gene expression profiling. Concordance with histopathologic subtyping is not established. The Prosigna assay intrinsic molecular subtype is reported as a component of ROR and not intended to be used for treatment decisions.

** Correspondence of Prosigna assay proliferation score with histopathological proliferation score is not established. Prosigna assay proliferation score is reported for reference only as a component of ROR and not intended to be used for treatment decisions.

[†]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 ROR score units.