Patient	Specimen	Run Set ID: 20101118_StudyIdeal
ID #: Sample LumA	**Tumor Size:** <= 2cm	**Comments:**
Date Reported: February 06, 2023	**Lymph Nodes:** node-positive (1-3 nodes)	

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Breast Cancer Assay

Report Date: **February 06, 2023**

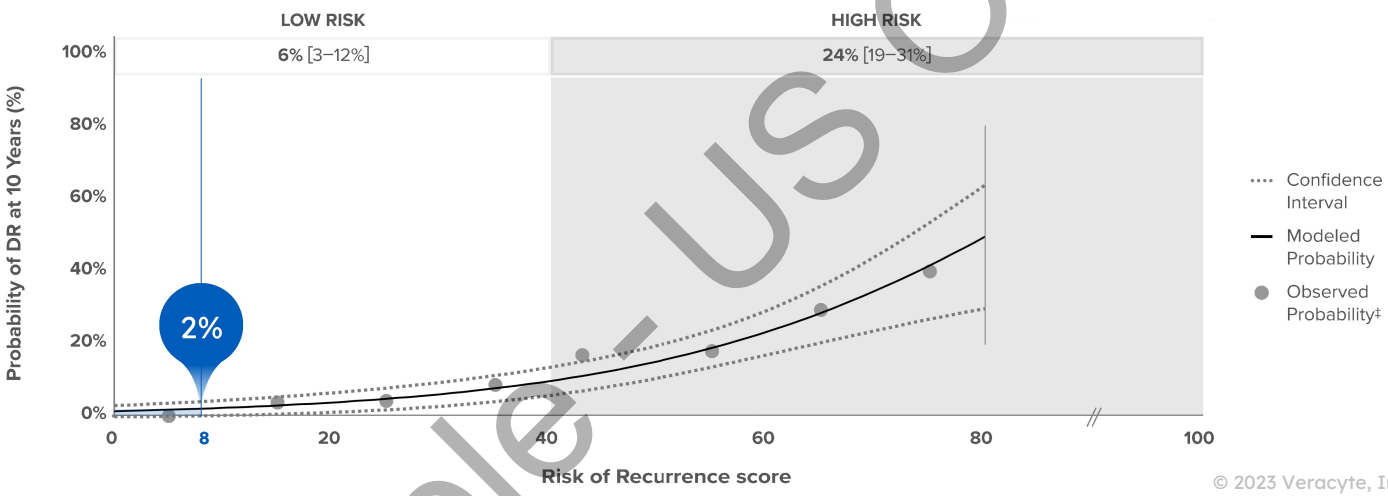
SPECIMEN SOURCE/ID:	TUMOR SIZE:	LYMPH NODES:
Sample LumA	**≤ 2cm**	**Node-positive**

SUBTYPE*:	PROLIFERATION SCORE**:
Luminal A	**-0.8**

Proliferation scores range from -2 (low proliferation) to 2 (high proliferation) and are calculated from a subset of 18 genes associated with proliferation[1]

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.

Patient	Specimen	Run Set ID: 20101118_StudyIdeal
ID #: Sample LumA	**Tumor Size:** <= 2cm	**Comments:**
Date Reported: February 06, 2023	**Lymph Nodes:** node-positive (1-3 nodes)	

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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.[2¶]

Probability of Distant Recurrence in the ABCSG-8[2] Clinical Validation Study

Prespecified Patient Risk Group	LOW RISK	HIGH RISK
	6% [3–12%]	**24%** [19–31%]

DRFS by Risk Group for Node-Positve (1-3 Nodes) Patients[3]

The ROR 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%).

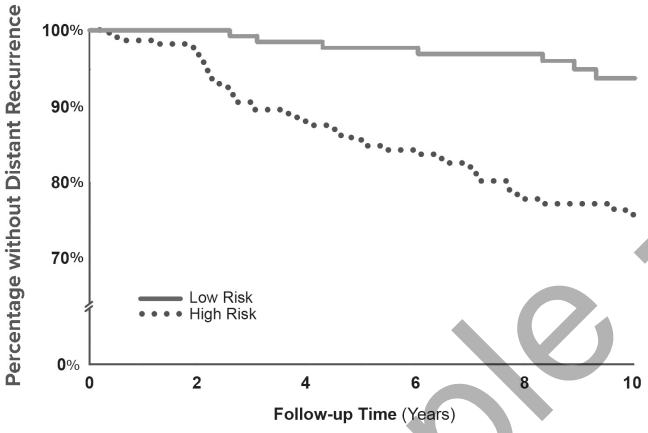

Table 1: Distribution of Node-Positive (1–3 nodes) patients by 10-unit ROR score Range

ROR score Range	Number of Patients	Percent of Patients	10-year DR Risk (Empirical) with 95% Confidence Limits
1–10	3	0.8%	0% [N/A]
11–20	34	8.9%	3.6% [0%–10.2%]
21–30	53	13.9%	4.1% [0%–9.6%]
31–40	68	17.8%	8.5% [0%–16.2%]
41–50	57	14.9%	16.7% [5.1%–27.0%]
51–60	71	18.6%	17.8% [6.8%–27.4%]
61–70	42	11.0%	28.9% [11.7%–42.7%]
71–80	34	8.9%	39.5% [18.9%–54.9%]
81–90	17	4.5%	33% [4.5%–53.0%]
91–100	3	0.8%	33.3% [0%–70.0%]
Total	*382*	*100%*	

1. Wallden B, Storhoff J, Nielsen N, et al. Development and verification of the PAM50-based Prosigna breast cancer gene signature assay.*BMC Medical Genomics* 2015 Vol. 8 Issue 1, DOI: 10.1186/s12920-015-0129-6
2. Prosigna Package Insert
3. Gnant M, et al., on behalf of the Austrian Breast and Colorectal Cancer Study Group. Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: using the PAM50 Risk of Recurrence score in 1478 postmenopausal patients of the ABCSG-8 trial treated with adjuvant endocrine therapy alone. *Annals of Oncology* 2014; 25(2):339-45

¶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.

Patient	Specimen	Run Set ID: 20101118_StudyIdeal
ID #: Sample LumB N0	**Tumor Size:** <= 2cm	**Comments:**
Date Reported: February 06, 2023	**Lymph Nodes:** node-negative	

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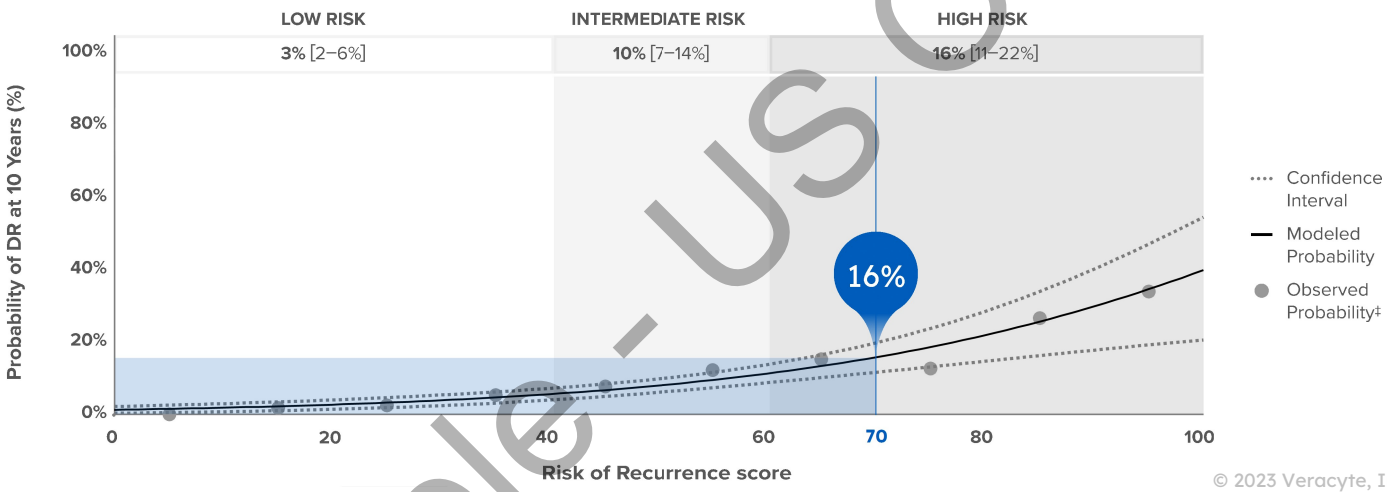
Report Date: **February 06, 2023**

SPECIMEN SOURCE/ID:	TUMOR SIZE:	LYMPH NODES:
Sample LumB N0	**≤ 2cm**	**Node-negative**

SUBTYPE*:	PROLIFERATION SCORE**:	
Luminal B	**0.1**	*Proliferation scores range from -2 (low proliferation) to 2 (high proliferation) and are calculated from a subset of 18 genes associated with proliferation[1]*

HIGH RISK

Risk of Recurrence score (ROR)§	Probability of Distant Recurrence (DR)§
70	**16%**



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-negative, with a ROR score of **70** were in the high risk group. The high risk population averaged a **16%** 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-negative 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.
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‡Average DR rate observed in ABCSG-8 for patients within 10 ROR score units.

Patient	Specimen	
ID #: Sample LumB N0	**Tumor Size:** <= 2cm	**Run Set ID:** 20101118_StudyIdeal
Date Reported: February 06, 2023	**Lymph Nodes:** node-negative	**Comments:**

Prosigna®
Breast Cancer Assay

Report Date: **February 06, 2023**

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 post-menopausal women with hormone receptor-positive, node-negative, Stage I and II breast cancer that received 5 years of endocrine therapy.[2¶]

Probability of Distant Recurrence in the ABCSG-8[2] Clinical Validation Study

Prespecified Patient Risk Group	LOW RISK	INTERMEDIATE RISK	HIGH RISK
	3% [2–6%]	**10%** [7–14%]	**16%** [11–22%]

DRFS by Risk Group for Node-Negative Patients[3]

The ROR 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%).

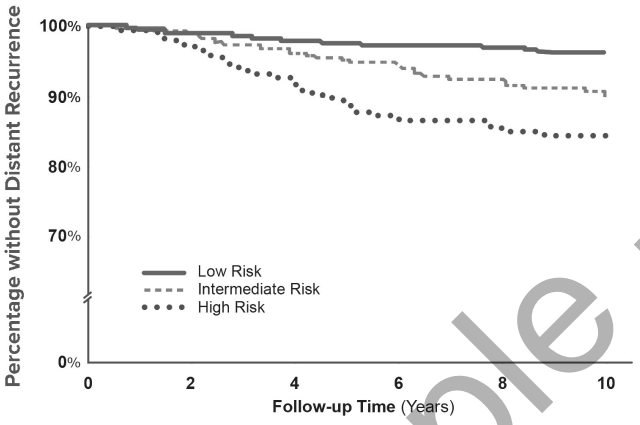

Table 1: Distribution of Node-Negative patients by 10-unit ROR score Range

ROR score Range	Number of Patients	Percent of Patients	10-year DR Risk (Empirical) with 95% Confidence Limits
1–10	7	0.7%	0% [N/A]
11–20	116	11.1%	1.8% [0%–4.3%]
21–30	155	14.8%	2.5% [0%–5.2%]
31–40	209	20.0%	5.1% [2.0%–8.1%]
41–50	183	17.5%	7.5% [3.3%–11.6%]
51–60	152	14.5%	12.1% [6.2%–17.6%]
61–70	116	11.1%	15% [7.6%–21.8%]
71–80	77	7.4%	12.3% [4.4%–19.6%]
81–90	28	2.7%	26.1% [7.3%–41.1%]
91–100	4	0.4%	33.3% [0%–70.0%]
Total	*1,047*	*100%*	

1. Wallden B, Storhoff J, Nielsen N, et al. Development and verification of the PAM50-based Prosigna breast cancer gene signature assay.*BMC Medical Genomics* 2015 Vol. 8 Issue 1, DOI: 10.1186/s12920-015-0129-6
2. Prosigna Package Insert
3. Gnant M, et al., on behalf of the Austrian Breast and Colorectal Cancer Study Group. Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: using the PAM50 Risk of Recurrence score in 1478 postmenopausal patients of the ABCSG-8 trial treated with adjuvant endocrine therapy alone. *Annals of Oncology* 2014; 25(2):339-45

¶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.