Patient	Specimen	
Tumor Size: <= 2cm	**ID #:** n0-l2-70-HR-LB	**Run Set ID:** Prosigna Sample 2
Lymph Nodes: node-negative	**Date Reported:** September 20, 2017	**Comments:** Comment for n0-l2-70-HR-LB

Prosigna
BREAST CANCER ASSAY

ID #: n0-l2-70-HR-LB **Tumor Size:** <= 2cm **Lymph Nodes:** node-negative

Clinical Validation Studies: Prognosis for node-negative, luminal B, high-risk breast cancer patients was determined based on the rate of distant recurrence (DR) of this population in 2 prospective-retrospective clinical studies. These studies analyzed more than 2400 samples from postmenopausal women with early stage, hormone receptor-positive breast cancer, using a prospectively defined analysis plan. The data shown are for postmenopausal women with early stage, hormone receptor-positive breast cancer who received 5 years of endocrine therapy after surgical resection of the primary tumor.

Rate of Distant Recurrence (DR) for Node-Negative Patients

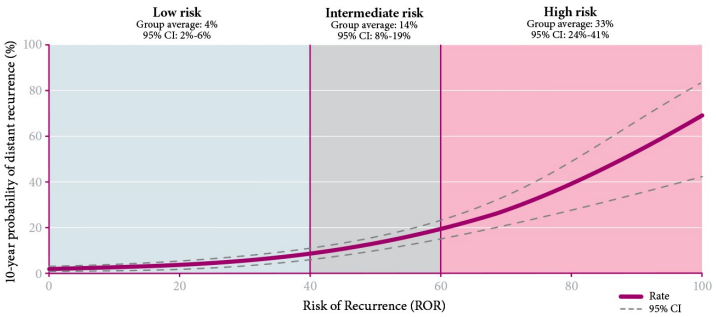
Subtype	Luminal A [95% CI]	Luminal B [95% CI]	HER2-enriched	Basal-like
Rate of DR	**5%** [4%-7%]	**18%** [15%-22%]	*	*

*There were insufficient numbers of basal-like and HER2-enriched patients in these studies to produce data.

Subtype and Prognosis:

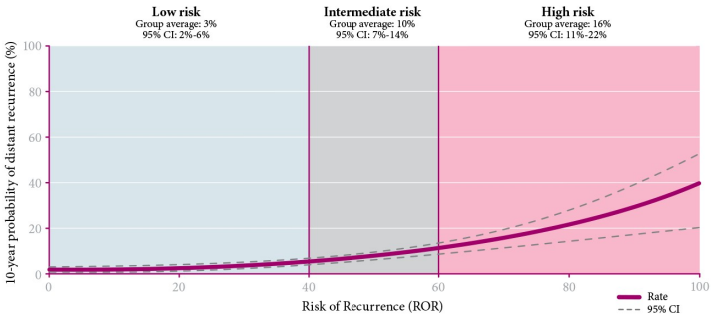
Intrinsic subtype is related to prognosis in the tested patient population. The most common subtypes of breast cancer are the luminal subtypes: luminal A and luminal B. In the combined analysis of 2 clinical validation studies of hormone receptor-positive patients, 68% of the tested patient population was found to be luminal A, and 27% was luminal B.[1] The gene expression pattern of these subtypes resembles the luminal epithelial component of the breast.[3] These tumors are characterized by high expression of estrogen receptor (ER), progesterone receptor (PR), and genes associated with ER activation.[3] Luminal A breast cancers exhibit low expression of genes associated with cell cycle activation and generally have a better prognosis than luminal B.

TransATAC clinical validation study[1]:



The TransATAC study analyzed 1007 samples using a prospectively defined analysis plan. Data shown are for postmenopausal stage I or II, node-negative, hormone receptor-positive breast cancer patients that received 5 years of endocrine therapy.*

ABCSG-8 clinical validation study[2]:



The ABCSG-8 study analyzed 1478 samples using a prospectively defined analysis plan. Data shown are for postmenopausal stage I or II, node-negative, hormone receptor-positive breast cancer patients that received 5 years of endocrine therapy.*

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.** Dowsett M, Lopez-Knowles E, Sidhu K, et al. Comparison of PAM50 risk of recurrence (ROR) score with Oncotype DX and IHC4 for predicting residual risk of RFS and distant-(D)RFS after endocrine therapy: A TransATAC Study. Program and abstracts of the 34th Annual San Antonio Breast Cancer Symposium; December 6-10, 2011; San Antonio, Texas. Abstract S4-5.

2. 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.

3. Parker JS, Mullins M, Cheang MC, et al. Supervised risk predictor of breast cancer based on intrinsic subtypes. *J Clin Oncol*. 2009;27(8):1160-1167