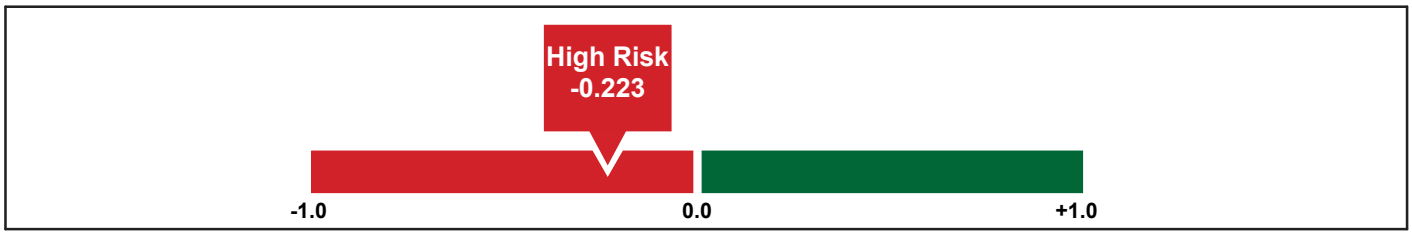
PATIENT NAME: **Test, First** DOB: **1-Jun-1950**

AGENDIA MAMMAPRINT

GENDER:	Female	**ORDERED BY:**	Doctor, Test	**REQUISITION #:**	04JAN23T5
SPECIMEN ID:	04JAN23T1-A1	**ACCOUNT:**	Agendia Hospital - *TEST*	**SPECIMEN TYPE:**	FFPE, Surgical
PATIENT/MRN:	MRN-12345		123 Fake Street	**SPECIMEN SOURCE:**	Right Breast
CUSTOMER REF:	CREF12345		Suite 456	**COLLECTED DATE:**	1-Dec-2024
			Anytown, CA 92618 US	**PERFORMED DATE:**	4-Dec-2024
				REPORTED DATE:	12-Dec-2024

MammaPrint® FFPE Result — High Risk

The breast cancer tissue sample submitted was analyzed by MammaPrint FFPE, an IVDMIA 70-Gene Profile of Breast Cancer for Metastatic Risk that has been validated to correlate with high or low outcome risk for distant metastases in patients with invasive breast cancer.[1] This risk assessment is based on a retrospective analysis of a prospective observational study that included 345 breast cancer patients treated and not treated with adjuvant therapy.[2] Treatment was selected according to clinical assessments that included MammaPrint test results. The risk for distant metastases in unselected patients who did not receive adjuvant treatment was not studied; therefore, MammaPrint FFPE should be used as a prognostic marker only. As a group, "Low Risk" patients like those in the MammaPrint FFPE clinical validation study (RASTER) have a 1.3% chance (95% CI 0-3.1), and "High Risk" patients have an 11.7% chance (95% CI 6.6-16.8) that their cancer will recur within 5 years (not accounting for any covariates other than the patient's MammaPrint FFPE status).



Additional Comments:

Assay Description

The U.S. FDA has provided IVDMIA clearance of MammaPrint with FFPE tissue for patients with Stage I and II invasive breast cancer, tumor size ≤ 5 cm, lymph node negative, based upon the development and validation of the MammaPrint assay as reported in Nature, New England Journal of Medicine, JNCI, BMC Genomics, Pers. Medicine, and Ann Oncol.[3-8] The test is performed using a microarray-based gene expression profile that was independently validated on 5-year outcome data on a patient cohort.[2] MammaPrint provides a qualitative result (high risk/low risk). The numerical index is provided to illustrate distance from the borderline region to establish accuracy of the result. If a FFPE sample's MammaPrint Index (MPI) falls within a pre-defined area around the classification cut-off between -0.050 and +0.050, the classification accuracy is less than 90%. See MammaPrint Physician's Brochure found on www.agendia.com for more information.

Manual Microdissection

Completed

Sign Off

Sign Off
Jia-Perng Jennifer Wei, MD, PhD
Laboratory Director

For In Vitro Diagnostic Use

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
Agendia, Inc (05D1089250) is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. MammaPrint FFPE is an aid in estimating the prognosis of patients diagnosed with breast cancer. Decisions on treatment should be based on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient's condition, including other pathological tests, in accordance with the standard of care in a given community. MammaPrint was developed using adjuvantly untreated, lymph node negative, mainly European, patients to capture the biology of the primary tumor in a gene expression profile. The metastasis free survival data is from an independent external patient group in Europe. This test was performed at Agendia's Irvine, California laboratory. General information about MammaPrint FFPE can be found at www.agendia.com.

References:

1) FDA label - USFDA Clearance; http://www.accessdata.fda.gov website.
2) Drukker CA et al. Int J Cancer 2013;133(4):929-36.
3) Van 't Veer LJ et al. Nature 2002;415(31):530-536.
4) Van de Vijver MJ et al. New Engl J Med 2002; 347(25):1999-2009.
5) Buyse M et. al. J Natl Cancer Inst 2006; 98(17):1183-1192.
6) Glas AM et al. BMC Genomics 2006;7:278.
7) Delahaye LJM et al. Pers Med 2013;10:801.
8) Mook S et al. Ann Oncol 2010;21(4):717-722.