

PATIENT NAME: **Doe, Jane**DOB: **15-Jun-1951**

GENDER: Female
SPECIMEN ID: SID 123-A6
PATIENT/MRN:
CUSTOMER REF:

ORDERED BY: Doc Last Name, Doc First Name
ACCOUNT: Agendia Hospital
 12345 Main St Suite 456 Irvine CA
 92618 US

REQUISITION #: RPR VAL 64
SPECIMEN TYPE: FFPE, Excision
SPECIMEN SOURCE: Right Breast
COLLECTED DATE: 18-Jan-2015
RECEIVED DATE: 19-Jan-2015
REPORTED DATE: 24-Feb-2015

MammaPrint[®] FFPE Result**High Risk**

The breast cancer tissue sample submitted was analyzed by MammaPrint FFPE, an IVDMA 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 (RASTER) study have a 2.3% chance (95% CI 0.1-4.5), and "High Risk" patients have an 11.5% chance (95% CI 6.0-17.0) that their cancer will recur within 5 years (not accounting for any covariates other than the patient's MammaPrint FFPE status).

**Additional Comments:**

Changed Pt. Name.

Assay Description

The U.S. FDA has provided IVDMA 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 If a FFPE sample's MammaPrint Index (MPI) falls within a pre-defined area around the classification cut-off between -0.0575 and +0.0575, the classification accuracy is less than 90%. See MammaPrint Physician's Brochure found on www.agendia.com for more information.

Sign Off


Sign Off
 Jia-Peng 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.