



mammaPrint®

decoding breast cancer.

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CUSTOMER

Doctor:
Account:

Address:

City, St., Zip:

SPECIMEN

Requisition #:
Collection Date:
Date Received:
Report Date:
Specimen Type:
Customer Ref.:

PATIENT

Patient:

DOB:
Patient #:
Gender:
SSN:

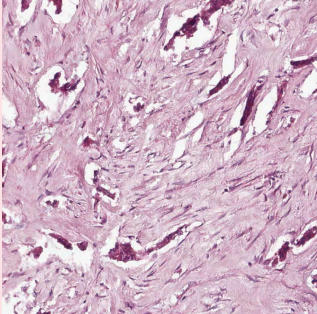
Gene Profile Test Result

LOW RISK

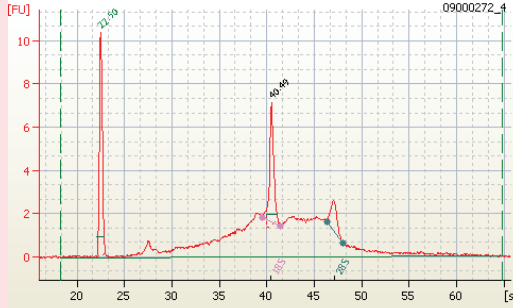
The breast cancer tissue sample submitted was analyzed by MammaPrint, an FDA Cleared IVDMA 70-Gene Profile of Breast Cancer for Metastatic Risk that has been validated to correlate with high or low outcome risk for distant metastases in women with invasive breast cancer. ¹ In a consecutive series of 131 patients, "Low Risk" means that a lymph node negative patient 61 years of age or older, has a 7% (95% CI 3-15) chance that her cancer will recur within 5 years without any additional adjuvant treatment, either hormonal therapy or chemotherapy.

Clinicopathologic Findings

Tumor Cell Percentage: 40%



RNA Integrity Score: 4.5

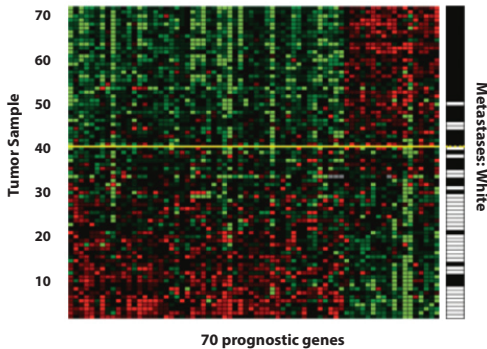


The reported tumor cell percentage and pathology comments serve as a quality control for Agendia's genomic assays and should not be viewed as a diagnosis of the presence or absence of malignancy.

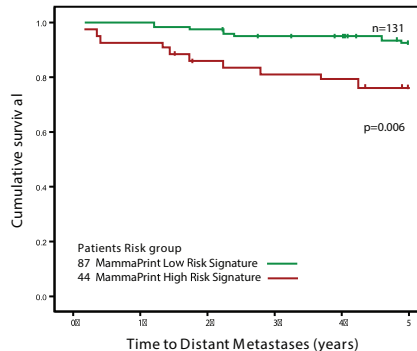
Assay Description

The U.S. Food and Drug Administration (FDA) has provided IVDMA clearance of MammaPrint for Stage I and II, lymph node negative, invasive breast cancer, for women of all ages who have a tumor of 5 cm or less, independent of estrogen receptor status (ER+/-), based upon the development and validation of the assay as reported in *Nature*, *New England Journal of Medicine*, *Journal of the National Cancer Institute* and *BMC Genomics*.²⁻⁵ The test is performed using a microarray-based gene expression profile that was independently validated on 10 year outcome data on an untreated patient cohort. ² An unbiased, supervised analysis of the entire human genome, ~25,000 genes, followed by a leave-one-out cross-validation procedure, revealed the 70 critical genes that distinguish patients at High Risk vs. Low Risk of metastasis. ³ Based on the analytical performance of MammaPrint, the accuracy of classifying a sample as High Risk or Low Risk is 98.9% with reproducibility of the measurement being 98.5%. ¹ MammaPrint has been validated in over 774 breast cancer patients and shown to provide information independent of clinicopathological risk assessment. ^{2,4,5}

MammaPrint® Breast Cancer Gene Profile³



Above 61 Years Validation Results





mammaprint®

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Patient #:
Gender:
SSN:

Pathology/Additional Comments:

This sample is created during the test procedure of the Agenda Report Generator. Unittest: test_107_MP_TP_BP_US_1_AD8DE97C-F0E7-0F2F-389A1A39F99621B0

References

- 1) FDA Label - USFDA Clearance; <http://www.accessdata.fda.gov> website.
- 2) Buyse M, Loi S, van 't Veer LJ, et. al., J Natl Cancer Inst 2006; 98(17):1183-1192
- 3) van 't Veer LJ, Dai H, van de Vijver MJ, et. al., Nature 2002; 415(31): 530-536
- 4) van de Vijver MJ, He YD, van 't Veer LJ, et. al., New Engl J Med 2002; 347(25): 1999-2009
- 5) Glas AM, Floore A, Delahaye LJ, et. al., BMC Genomics 2006; 7: 278

Sign Off

Chynel F. Henning, MD, PhD, FASCP, FCAP
Pathologist
Laboratory Director

For In Vitro Diagnostic Use

Caution: 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 is an aid in estimating the prognosis of patients diagnosed with breast cancer. Decisions regarding care and treatment should not be based on a single test such as this test. Rather, decisions on care and 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 can be found at www.agendia.com. Detailed information regarding methodology has been published previously ¹⁰. If you have any questions regarding this report, please contact Agendia Customer Care at 888-321-2732 or at customer care@agendia.com.