AGENDIA
PRECISION ONCOLOGY

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

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|---|---|---|---|---|---|
| **GENDER:** | Female | **ORDERED BY:** | Doc Last Name, Doc First Name | **REQUISITION #:** | RPR VAL 64 |
| **SPECIMEN ID:** | SID 123-A6 | **ACCOUNT:** | Agendia Hospital | **SPECIMEN TYPE:** | FFPE, Excision |
| **PATIENT/MRN:** | | | 12345 Main St Suite 456 Irvine CA | **SPECIMEN SOURCE:** | Right Breast |
| **CUSTOMER REF:** | | | 92618 US | **COLLECTED DATE:** | 18-Jan-2015 |
| | | | | **RECEIVED DATE:** | 19-Jan-2015 |
| | | | | **REPORTED DATE:** | 24-Feb-2015 |

## BluePrint® Result

Luminal-type

According to the 2013 St Gallen Consensus regarding the treatment of women with early breast cancer, identification of intrinsic subtypes is most precise using molecular technologies, such as gene expression profiling by microarray.[1] The BluePrint test result represents the numerical outputs of an 80-gene microarray-based signature that assesses a breast tumor for its molecular subtype by calculating the correlation scores between its gene expression patterns and a template for each of three molecular subtypes (Luminal-type, HER2-type, or Basal-type). Each tumor will have 3 individual scores, and the highlighted molecular subtyping classification of each tumor is determined by the molecular subtype with the highest correlation score. Luminal-type breast cancers can be sub-stratified into "Luminal A" and "Luminal B" using the MammaPrint categorical result of "Low Risk" and "High Risk", respectively, in combination with the BluePrint Luminal molecular subtype.

Luminal-type: +0.335

HER2-type: +0.210

Basal-type: -0.190


**Additional Comments:**

Results Updated.

## Assay Description

BluePrint, a microarray-based assay, has been developed to classify both fresh and formalin-fixed paraffin embedded (FFPE) breast tumor samples into one of three molecular subtypes (Luminal-type, HER2-type, or Basal-type) based on functional molecular pathways. The BluePrint molecular subtyping profile (MSP) contains 80 genes, and it was developed by evaluating early stage breast tumor samples with concordant ER, PR, and HER2 status by immunohistochemistry (IHC)/fluorescence in situ hybridization (FISH) and mRNA expression levels. BluePrint is a combination of 3 correlation-type scores to each of the three functional subtypes: Luminal-type (endocrine dependent), HER2-type (ERBB2 dependent), and Basal-type (triple negative). The BluePrint MSP has been shown to have high concordance with the subgroups (excluding normal-like) described by Perou et al. [2,3] Based on the analytical performance of BluePrint, the precision of classifying a sample as Luminal-type, HER2-type, or Basal-type is 99.3% for fresh and 98.3% for FFPE, and the repeatability is 99.6% for fresh and 98.7% for FFPE.



## Sign Off

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

### Disclaimer

Agendia, Inc (05D1089250) is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. BluePrint is a laboratory developed test regulated under CLIA by CMS. 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. This test was performed at Agendia's Irvine, California laboratory. General information about BluePrint can be found at www.agendia.com.

### References:

1) Goldhirsch A, Winer EP, Coates AS, et al., Ann Oncol. 2013; 24(9):2206-23.
2) Perou CM, Sørlie T, Eisen MB, et al., Nature. 2000; 406(6797):747-52.
3) Krijgsman O, Roepman P, Zwart W, et al., Breast Cancer Res Treat. 2012; 133(1):37-47.