PATIENT NAME: **ADDR L3, ADDR F3** DOB: **16-Oct-1966**

AGENDIA PRECISION ONCOLOGY

GENDER:	Female	**ORDERED BY:**	AMS-StagingClient1, Physician2	**REQUISITION #:**	ROW ADDR3
SPECIMEN ID:	SID 3	**ACCOUNT:**	AMS-Staging Client 1 IN	**SPECIMEN TYPE:**	FFPE, Needle Core
PATIENT/MRN:	MRN 3			**SPECIMEN SOURCE:**	
CUSTOMER REF:	CREF 3			**COLLECTED DATE:**	05-Apr-2020
				RECEIVED DATE:	06-Apr-2020
				REPORTED DATE:	06-Apr-2020

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: +0.444

HER2-type: +0.333

Basal-type: -0.123

Additional Comments:

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 98.6% for FFPE, and the repeatability is 99.6% for FFPE.

Sign Off

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

Disclaimer IVD

BluePrint was developed and its performance characteristics determined by Agendia. It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This test was performed at Agendia, Inc (05D1089250), which is certified under the Clinical Laboratory Improvement Amendment (CLIA) as qualified to perform high-complexity clinical laboratory testing. It has also been CE-marked for use in Europe.

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.

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