

PATIENT NAME: **Test, First**DOB: **01-Jun-1950**

GENDER: Female
SPECIMEN ID: 04JAN23T1-A1
PATIENT/MRN: MRN-12345
CUSTOMER REF: CREF12345

ORDERED BY: Doctor, Test
ACCOUNT: Agendia Hospital - * TEST*
 123 Fake Street
 Suite 456
 Anytown, CA 92618 US

REQUISITION #: 04JAN23T1
SPECIMEN TYPE: FFPE, Surgical
SPECIMEN SOURCE: Right Breast
COLLECTED DATE: 30-Sep-2022
PERFORMED DATE: 01-Dec-2022
REPORTED DATE: 01-Jan-2023

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: +0.495**HER2-type: -0.222****Basal-type: -0.111****Additional Comments:**

Testing the BarTender report generation integration service.

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 fresh and 99.0% for FFPE.

Manual Microdissection

Completed

Sign Off


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

Disclaimer

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:

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