blueprint™

molecular subtyping profile

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:

Molecular Subtyping Test Result

Luminal-type

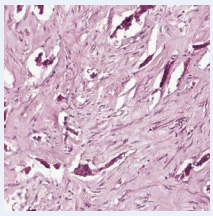
Luminal-type breast cancers are characterized by gene expression of luminal epithelial cells that line the breast ducts and glands. The Luminal-type cancers are typically hormone receptor positive tumors and therefore responsive to hormonal therapy. A Luminal-type molecular subtyping result means that the tumor phenotype most closely resembles the Luminal-type intrinsic subtype. Patients classified as MammaPrint ® 70-gene signature "Low Risk" and Luminal-type can be expected to have a clinical course similar to luminal A, usually treated with hormonal therapy, whereas those with a MammaPrint "High Risk" and Luminal-type, a clinical course similar to luminal B patients who usually benefit from more aggressive treatment which may include chemotherapy.

Assay Description

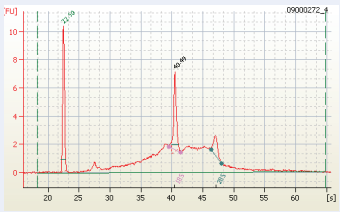
Gene expression analysis has confirmed the heterogeneity of breast cancer, revealing it to be a disease with intrinsic subgroups that can be uncovered by genomic profiling.[1] The BluePrint molecular subtyping profile was designed to distinguish the Basal-type, Luminal-type and ERBB2-type (HER2/neu positive) intrinsic subgroups of tumors.[2] The BluePrint signature determines the RNA levels of 80 genes that best discriminate among these three distinctive subtypes. Tumors from a cohort of 295 patients were used for the development of gene expression profiles specific for the Basal-type, Luminal-type and ERBB2-type breast cancers. Using state of the art bioinformatics tools, Agendia identified genes whose expression ratios best discriminate among the three subgroups. Subtype specific gene expression profiles were identified in a 3-fold cross-validation procedure. Optimal classification of the training samples in the corresponding Basal-type, Luminal-type and ERBB2-type subgroups was reached with a set of 80 genes. Next, a nearest-centroid classification procedure utilizing the 80-gene profile was developed that most accurately classified the breast cancer molecular subtypes on all samples. Based on the analytical performance of BluePrint, the reliability of the measurement is 99.2%. The BluePrint molecular subtyping profile was subsequently validated on 374 independent samples and demonstrated high concordance with the subgroups (excluding normal-like) described by Perou et al.[1,2]

Pathology Results

Tumor Cell Percentage: 0%



RNA Integrity Score: 0



Pathology/Additional Comments:

This sample is created during the test procedure of the Agenda Report Generator. Unittest: test_107_BP_US_LUMINAL_1_AD8D7A29-C0BC-22A9-D09B08200F56AC33

Sign Off

Chynel Henning, MD.

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

References

(1) Perou CM, Sørlie T, Eisen MB, et al., Nature. 2000; 406(6797): 747-52.
(2) Stork-Sloots L, Krijgsman O, Roepman P, et al., J Clin Oncol 2009; 27: 15s.

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 molecular subtyping profile 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.

This test was performed at Agendia's Irvine, California laboratory.

22 Morgan | Irvine | CA 92618 | ph: 888.321.2732 | fax: 866.756.7548
customercare@agendia.com | www.agendia.com

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