



CUSTOMER

Doctor:
Account:
Address:
City, St., Zip:

SPECIMEN

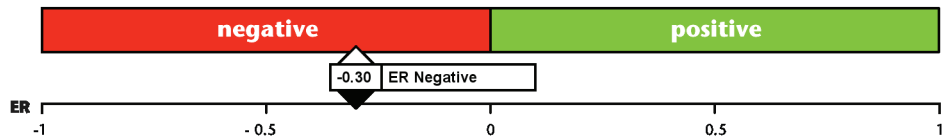
Requisition #:
Collection Date:
Date Received:
Report Date:
Specimen Type:
Customer Ref.:

PATIENT

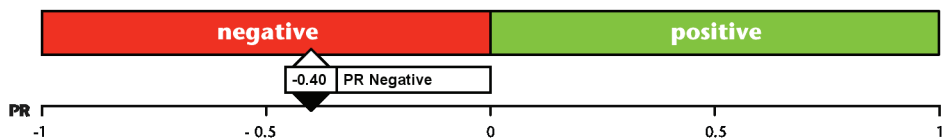
Patient:
DOB:
Patient #:
Gender:
SSN:

Quantitative Gene Expression Test Results

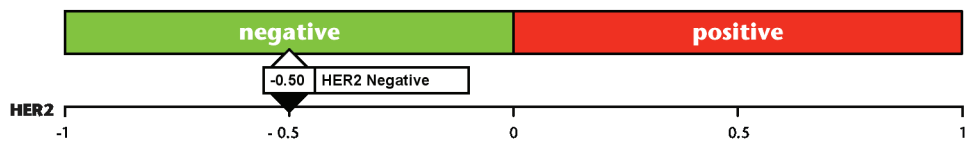
Estrogen Receptor
ER Negative



Progesterone Receptor
PR Negative



HER2/neu
HER2 Negative

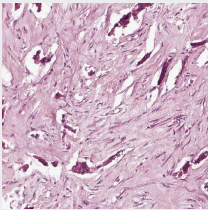


Assay Description

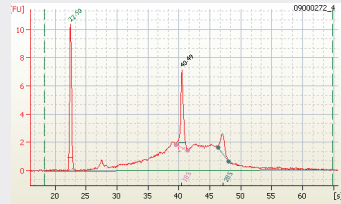
TargetPrint determines the mRNA levels of estrogen receptor (ER), progesterone receptor (PR) and HER2 using DNA microarray technology. The values of the DNA microarray read out for these three genes have been validated in over 600 breast cancer samples against conventional immunohistochemistry (IHC) and fluorescent in situ hybridization (FISH), allowing a conversion of the microarray values to IHC and FISH equivalence which are shown in the red and green. The ER, PR and HER2 microarray values were compared to IHC which was assessed at one central laboratory, indicating a 93% concordance (95CI: 91-95%) for ER, an 83% concordance (95CI: 80-86%) for PR and a 96% concordance (95CI: 94-98%) for HER2 respectively. ¹ For ER and PR a threshold of 1% IHC positively stained tumor cells was used to classify samples as positive; for HER2, an IHC score of 3+ was considered positive. In case of 2+ samples, FISH assessed final HER2 amplification status. ²

Pathology Results

Tumor Cell Percentage: 40%



RNA Integrity Score: 4.5



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

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.

Sign Off

References

- (1) Roepman et al, Clin Cancer Res 2009; 15(22): 7003-7011
- (2) Harris, et al, JCO 25 (33) 2007: 5287-5312

Regulatory Information

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. TargetPrint 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. TargetPrint was validated using FDA cleared test kits in a CLIA certified US reference laboratory.

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

Chynel Henning, MD.

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Pathologist
Laboratory Director