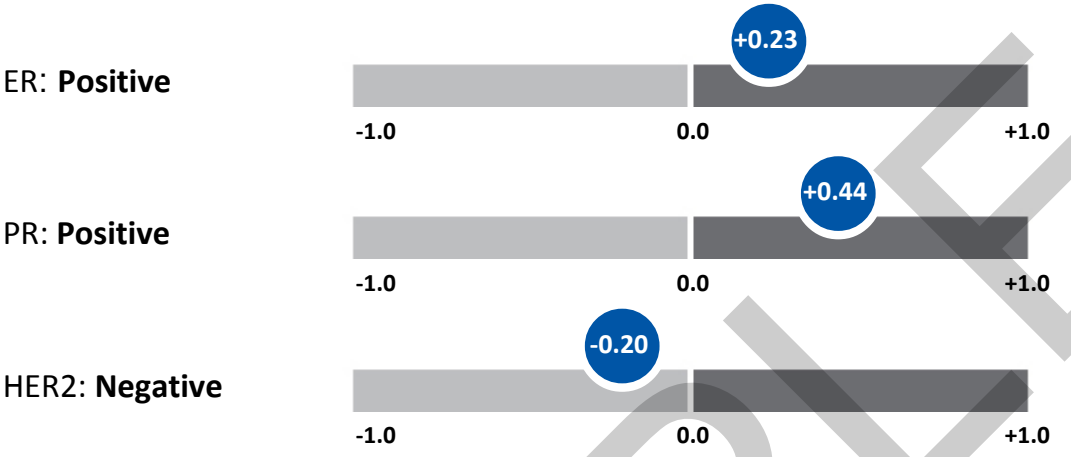
agendia®
decoding cancer

PATIENT NAME: **Doe, Jane** DOB: **21-Jan-1947**

GENDER:	Female	**ORDERED BY:**	AMS-StagingClient2, Physician1	**REQUISITION #:**	RPR VAL 2 ROW
SPECIMEN ID:	S# 98734	**ACCOUNT:**	AMS-Staging Client 2	**SPECIMEN TYPE:**	FFPE, Surgical
PATIENT/MRN:	1234-987			**SPECIMEN SOURCE:**	Left Breast
CUSTOMER REF:				**COLLECTED DATE:**	19-Jan-2015
				RECEIVED DATE:	20-Jan-2015
				REPORTED DATE:	13-Mar-2015

TargetPrint® Result

ER Positive, PR Positive, HER2 Negative



Additional Comments:

The TargetPrint Assay provides quantitative assessment of mRNA expression levels of ER, PR, and HER2, using a continuous scale between -1.0 and +1.0. A positive score in ER or PR corresponds to ≥1% tumor cells demonstrating positive nuclear staining with an immunohistochemistry (IHC) assay, while a positive score in HER2 correlates with a 3+ score by IHC or a HER2/CEP17 ratio of ≥2.0 by fluorescence in situ hybridization (FISH).

Assay Description

TargetPrint, a microarray-based assay, provides quantitative assessment of mRNA expression levels of the estrogen receptor (ESR1), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) genes. This assay was developed for both fresh[1] and formalin-fixed paraffin embedded (FFPE) breast tumor tissue, and its performance characteristics were determined by Agendia. Breast tumor samples with a microarray score ≥0 in ER, PR, and/or HER2 are considered to be positive for the respective biomarker(s). Based on the analytical performance TargetPrint scores for ER, PR, and HER2, the median precision is 99.1% for fresh and 95.6% for FFPE, and the median repeatability is 99.1% for fresh and 97.9% for FFPE. Comparison between TargetPrint and IHC/FISH assessments determined by a central pathology laboratory has been performed in over 600 fresh breast tumors in the EORTC 1004/BIG 03-04 MINDACT trial, with a concordance of 98% [95% confidence interval (CI): 96-99%] for ER, 85% [95% CI: 82-88%] for PR, and 96% [95% CI: 95-98%] for HER2.[2]

Sign Off

Sign Off
Prof. René Bernards, PhD
Laboratory Director

Disclaimer IVD

Agendia, NV (99D1030869) is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. TargetPrint 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 Amsterdam, NL laboratory. General information about TargetPrint can be found at www.agendia.com.

References:

1) Roepman P et al, Clin Cancer Res. 2009; 15(22):7003-7011.
2) Viale G et al, Ann Oncol. 2014; 25(4):816-23.