

Patient ID SA00118852	Patient Name TESTING, JESSICA	Birth Date 1981-12-26	Gender F	Age 37
Order Number SA00118852	Client Order Number SA00118852	Ordering Physician CLIENT, CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 17 Mar 2019 00:00		

HER Breast IHC Automated NO Reflex

Case Number CR-19-163

Interpretation

MCR

Right Breast, original accession: SA-19-346, block: SA-19-346-A1

SPECIAL PROCEDURE REPORT

Breast Biomarker(s) for:

Invasive or metastatic breast carcinoma

Result(s):

This assay has not been validated on tissues subjected to the decalcification process and/or use of alternative fixatives for bone/bone marrow specimens. Results should be interpreted with caution given the likelihood of false negativity on decalcified specimens.

HER2 by Immunohistochemistry (IHC) Negative (Score 0)

METHOD AND SCORING

Fixation: Test results are only valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin within 1 hour of acquisition and fixed between 6 and 72 hours. Delay to fixation, under fixation or over fixation fall outside of ASCO/CAP guidelines and may affect these results.

Fixation conditions for this specimen were indicated to be within the ASCO/CAP guidelines.

HER2 Breast Cancer Automated Scoring Method: Testing is performed using FDA approved Ventana Pathway HER2 (4B5) rabbit monoclonal primary antibody and a proprietary detection system. No expression (HER2 score of 0), low expression (HER2 score of 1+) and high expression (HER2 score of 3+) controls are used. All controls show appropriate reactivity. Immunohistochemical stained slides are scanned using the Aperio ScanScope instrument. A technologist views the captured digital image and traces around areas of cancer to include at least 75% of the total invasive cancer within the image. The traced areas are analyzed using Aperio software, an FDA 510(k) cleared application for precise measurement of the level of HER2 protein on cell membranes of breast tumor cells. Membrane staining for HER2 protein in breast carcinoma is scored on a 0 to 3+ scale in accordance with ASCO/CAP guidelines. The Aperio data and corresponding slide are reviewed by a pathologist for final interpretation.

HER2 References: Wolff AC, Hammond ME, Hicks DG, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. [published online ahead of print May 30, 2018]. J Clin Oncol. doi: 10.1200/JCO.2018.77.8738.

Material Received

MCR

A. SA-19-346: Right Breast
1 block

Report electronically signed by

MCR

JESSICA PHILLIPS

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292



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Fixed in 10% NB formalin w/in 1 hr

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Yes

Fixed in 10% NB formalin 6-72 hrs

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Yes

Tumor type

MCR

Primary invasive breast carcinoma

Tumor classification

MCR

Invasive breast carcinoma

Tissue was decalcified

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Yes

Received: 18 Mar 2019 11:40

Reported: 18 Mar 2019 11:44

Performing Site Legend

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MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292