

Patient ID 321	Patient Name TESTREFLABONESTTX, IMPLEMENTATION LABELS	Birth Date 1968-02-19	Sex M	Age 55
Order Number X100447683	Client Order Number X100447683	Ordering Physician TESTING	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 21 Nov 2023 05:01		

HER Breast SemiQuant IHC + Reflex

Case Number CR-23-930

Interpretation

1 MCR

Breast, Right, original accession: QR-123, block: QR-123B2

SPECIAL PROCEDURE REPORT

Breast Biomarker(s) for:

Invasive or metastatic breast carcinoma

Result(s):

HER2 by Immunohistochemistry (IHC):

Positive (Score 3+) Percent of cells with uniform intense complete membrane staining: >10%

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

Specimen fixation and processing: the specimen that was tested is 10% neutral buffered formalin-fixed paraffin-embedded sections. 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.

METHOD AND SCORING

HER2 Breast Cancer Manual Scoring Method: Testing is performed using a modified 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. Scoring is performed according to ASCO/CAP guidelines as follows: Score of 3+ is defined as circumferential membrane staining that is complete, intense and in greater than 10% of the invasive tumor cells; Score of 2+ is defined as weak to moderate complete membrane staining observed and in greater than 10% of the invasive tumor cells; or circumferential membrane staining that is complete, intense and in less than or equal to 10% of the invasive tumor cells; Score of 1+ is defined as incomplete membrane staining that is faint or barely perceptible and in greater than 10% of the invasive tumor cells; or weak to moderate complete membrane staining observed and in less than 10% of the invasive tumor cells; Score of 0 is defined as no staining observed or membrane staining that is incomplete and is faint or barely perceptible and in less than or equal to 10% of the invasive tumor cells.

HER2 References: Wolff AC, 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 <https://pubmed.ncbi.nlm.nih.gov/29846104/>

Material Received

MCR

A. QR-123: Breast, Right
1 block

Report electronically signed by

MCR

Saba Yasir, M.B.B.S.

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

MCR

Yes

Fixed in 10% NB formalin 6-72 hrs

MCR

Yes

Tumor type

MCR

Primary invasive breast carcinoma

Tumor classification

MCR

Invasive breast carcinoma

Tissue was decalcified

MCR

No

Received: 21 Nov 2023 09:08

Reported: 27 Nov 2023 14:56

Laboratory Notes

- 1 This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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