

Patient ID 321	Patient Name TESTREFLABONESTTX, IMPLEMENTATION LABELS	Birth Date 1968-02-19	Sex M	Age 55
Order Number X100447682	Client Order Number X100447682	Ordering Physician TESTING	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 21 Nov 2023 05:00		

HER Breast SemiQuant IHC + Reflex

Case Number CR-23-929

Interpretation

1 MCR

Breast, Left, original accession: WR-123, block: WR-123A1

SPECIAL PROCEDURE REPORT

Breast Biomarker(s) for:

Invasive or metastatic breast carcinoma

Result(s):

HER2 by Immunohistochemistry (IHC):
Negative (Score 0)

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. WR-123: Breast, Left
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



Patient ID 321	Patient Name TESTREFLABONESTTX, IMPLEMENTATION LABELS	Birth Date 1968-02-19	Sex M	Age 55
Order Number X100447682	Client Order Number X100447682	Ordering Physician TESTING	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 21 Nov 2023 05:00		

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 09:04	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.

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