

Patient Name TEST,IMPLEMENTATION TESTING	Patient ID 321	Age 61	Gender F	Order # V6672926
Ordering Phys TESTING				DOB 12/07/1950
Client Order # V6672926	Account Information			Report Notes
Collected 08/31/2012 06:00	C7028846-DLMP ROCHESTER 3050 SUPERIOR DRIVE ROCHESTER,MN 55901			
Printed 09/07/2012 14:08				

Test	Flag	Results	Unit	Reference Value	Perform Site*
HER2, Breast IHC, Automated			REPORTED	08/31/2012 15:26	
Accession Number		HR12-40545			MCR
Referring Pathologist/Physician		Doctor Test Jr., M.D.			MCR
Ref Path/Phys Address		Methodist Hospital 200 1st Street SW Rochester, MN 55905 507-266-0740			MCR
Material:		1 Block			MCR
Tissue:		A:HER2 Auto			MCR
Interpretation:		HER2, Immunostain: Fixation: HER2 protein immunohistochemical (IHC) 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 48 hours. Delay to fixation, under fixation or over fixation fall outside of CAP/ASCO guidelines and may affect these results. Fixation conditions for this specimen were indicated to be within the CAP/ASCO guidelines for HER2 testing. Method: Testing is performed using FDA approved Ventana Pathway HER2 (4B5) rabbit monoclonal primary antibody and a proprietary detection system. Negative (HER2 score of 0), moderate 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 CAP/ASCO guidelines. The Aperio data and corresponding slide are reviewed by a pathologist for final interpretation. Fixation conditions for this specimen were indicated as falling outside of CAP/ASCO guidelines for HER2 testing. Fixation: HER2 protein immunohistochemical (IHC) 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 48 hours. Delay to fixation, under fixation or over fixation fall outside of CAP/ASCO guidelines and may affect these			MCR

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Cold ischemia time has not been established for body fluids for HER2 testing.

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SP Signing Pathologist:

See Below

Result: 8/31/2012 15:25 Interpreted by: Pathologist X. Test, M.D.
Report electronically signed by Melissa L. Skjeveland

MCR

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Transcribed by: amp 8/31/2012 15:10:13

* Performing Site:

MCR	Mayo Clinic Laboratories - Rochester Main Campus 200 First St SW Rochester, MN 55905	Lab Director:
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