Patient Name	Patient ID	Age	Gender	Order #
TEST,IMPLEMENTATION TESTING	321	61	F	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:					MCR

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

Performing Site Legend on Last Page of Report

Patient Name	Patient ID	Age	Gender	Order #
TEST,IMPLEMENTATION TESTING	321	61	F	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*

results.
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 are unknown 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 results.
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.
The decalcification process and/or use of alternative fixatives for boneone marrow specimens may affect the validity of 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

Performing Site Legend on Last Page of Report

Patient Name	Patient ID	Age	Gender	Order #
TEST,IMPLEMENTATION TESTING	321	61	F	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*

between 6 and 48 hours. Delay to fixation, under fixation or over fixation fall outside of CAP/ASCO guidelines and may affect these results.
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.
Cold ischemia time has not been established for body fluids 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 results.
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.
SP Signing Pathologist: See Below MCR
Result: 8/31/2012 15:25 Interpreted by: Pathologist X. Test, M.D.
Report electronically signed by Melissa L. Skjeveland

Performing Site Legend on Last Page of Report

MAYO CLINIC
Mayo Medical Laboratories

Laboratory Service Report

1-800-533-1710

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

Test	Flag	Results	Unit	Reference Value	Perform Site*

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: Franklin R. Cockerill, III, M.D.

* Report times for Mayo performed tests are CST/CDT