Patient Name	Patient ID	Age	Gender	Order #
SAMPLEREPORT,81504	C7028846-001884	42	F	R1057419,X100066209
Ordering Phys DOE,JANE				**DOB** 01/01/1971
Client Order # X100066209	**Account Information**			**Report Notes**
Collected 05/22/2013	C7028846-DLMP Rochester 3050 Superior Drive Rochester, MN 55901			
Printed 05/24/2013 07:47				

Test	Flag	Results	Unit	Reference Value	Perform Site*
HER2, Breast IHC, Automated		REPORTED 05/23/2013 08:51			
Accession Number		HR13-144			MCR
Material:					MCR
XR13-123					
Tissue:					MCR
A:Testing					
Interpretation:					MCR
HER2, Immunostain:					
HER2 protein overexpression is equivocal, score of 2+. Fluorescence in situ hybridization (FISH) for HER2 amplification will be performed and reported separately by the Division of Laboratory Genetics. 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. 1. Wolff AC, Hammond ME, Schwartz JN, et al. American Society of Clinical Oncology/College of American Pathologists guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer. Arch Pathol Lab Med 2007;131:18-43 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 CAP/ASCO guidelines. The Aperio data and corresponding slide are reviewed by a pathologist for final interpretation.					
SP Signing Pathologist:		See Below			MCR
Result: 5/23/2013 08:51 Interpreted by: Pathologist X. Test, M.D. Report electronically signed by Debbie A. Postier Transcribed by: dap07 5/23/2013 08:51:27					
HER2 Amp, Breast Cancer, FISH		REPORTED 05/24/2013 07:38			

Performing Site Legend on Last Page of Report

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Test	Flag	Results	Unit	Reference Value	Perform Site*
Specimen		Tissue-Paraffin			MCR
Specimen ID		1061996			MCR
Source		Breast XR13-123			MCR
Order Date		24 May 2013 07:31			MCR
Reason For Referral r/o HER2 gene amplification					MCR
Fixative		Formalin			MCR
Method FISH using probes for HER2 (17q12) and a chromosome 17 centromere (D17Z1) control probe (PathVysion, Abbott Molecular, Inc). Two technologists score signals in 60 total nuclei from invasive or metastatic tumor and concurrent controls.					MCR
Results nuc ish(D17Z1x2,ampHER2) The HER2:D17Z1 ratio is 10.3 Average HER2 signals per nucleus is 21.4. Average D17Z1 signals per nucleus is 2.1.					MCR
Interpretation The result is abnormal. The invasive tumor nuclei demonstrate HER2 gene amplification (per ASCO/CAP guidelines) in this breast excision specimen. The HER2:D17Z1 ratio is 10.3. Amplification of the HER2 gene is usually associated with HER2 overexpression in breast adenocarcinoma. ASCO/CAP reporting guidelines (Wolff et al., Arch Path Lab Med 131:18-43, 2007): A HER2:D17Z1 ratio less than 1.8 indicates absence of HER2 gene amplification. A HER2:D17Z1 ratio from 1.8-2.2 is equivocal for HER2 gene amplification. A HER2:D17Z1 ratio greater than 2.2 indicates HER2 gene amplification when there are greater than 6 HER2 signals per nucleus. DISCLAIMER: This test was developed and its performance characteristics determined by Laboratory Medicine and Pathology, Mayo Clinic, Rochester MN. It is intended as an adjunct to existing prognostic clinical and pathologic information for breast cancer patients. This test is not intended to diagnose or screen for breast cancer. Since					MCR

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Printed 05/24/2013 07:47				

Test	Flag	Results	Unit	Reference Value	Perform Site*
only a portion of the tumor was tested, it is possible that this result may not represent the entire tumor population. Per ASCO/CAP guidelines, HER2 FISH test results are valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin between 6 and 48 hours. Results from specimens fixed outside these parameters should be interpreted accordingly.					
Consultant		Christina M Radtke			MCR
Report Date		24 May 2013 07:36			MCR

* Performing Site:

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