

1-800-533-1710

<b>PATIENT NAME</b> TESTING, 81504		<b>PATIENT NUMBER</b> L3MRNG9151909		<b>AGE</b> 39	<b>SEX</b> F	<b>ACCESSION #</b> G9151909
<b>ORDERING PHYSICIAN</b> TEST,D		<b>CLIENT ORDER #</b>				<b>ACCOUNT #</b> LIAISONS
<b>COLLECTION</b> 06/16/10 11:00 A	<b>RECEIVED</b> 06/16/10 11:07 A	<b>REPORT PRINTED</b> 06/22/10 08:52 A		<b>SPECIMEN INFORMATION</b> DATE OF BIRTH: 6/19/1970		
<b>DATE</b> <b>TIME</b>	<b>DATE</b> <b>TIME</b>	<b>DATE</b> <b>TIME</b>				
Test Client Attn: Mayo Liaisons 200 First Street SW Rochester, MN 55905 507-284-8202						

<b>TEST REQUESTED</b>	<b>HI</b>	<b>LO</b>	<b>REF RANGE</b>	<b>PERFORM SITE *</b>
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**HER2, Breast IHC, Automated**

<b>Accession Number</b>	<b>HR10-149</b>	<b>MCR</b>
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<b>Referring Pathologist/Physician</b>		<b>MCR</b>
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Doctor Test Jr., M.D.

<b>Ref Path/Phys Address</b>		<b>MCR</b>
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 Methodist Hospital  
 200 1st Street SW  
 Rochester, MN 55905  
 507-266-0740

<b>Material:</b>		<b>MCR</b>
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1 block (X10-123) for testing 81504 - HER2 reporting title change

<b>Tissue:</b>		<b>MCR</b>
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A:TESTING 81504-HER2 REPORTING TITLE CHANGE

<b>Interpretation:</b>		<b>MCR</b>
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HER2, Immunostain:

Source: Breast left, core biopsy: block X10-123

Results: 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: HER2 protein immunohistochemical (IHC) test results are only valid for non-decalcified paraffin embedded specimens fixed in 10% neutral buffered formalin. Under or over fixation may affect these results. Per CAP/ASCO guidelines, specimen fixation time should be between 6 and 48 hours. Fixation conditions for this specimen was/were indicated as falling outside of the guidelines. The results of this test should be interpreted accordingly.

Method: Testing is performed using FDA approved Dako HercepTest(TM) employing a polyclonal antibody and a polymer-based detection system. Separate positive (3+ and 1+) and negative (0) controls are

\* Perform Site Legend on last page of report

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provided with, tested, and evaluated in accordance with HercepTest(TM) kit instructions. All controls show appropriate reactivity. Immunohistochemical stained slides are examined by the ACIS(R) III automated immunostain analysis instrument. Membrane staining for HER2 protein in breast carcinoma is scored on a 0 to 3+ scale. A pathologist reviews the ACIS data and corresponding slide to verify accuracy of regions scored. The scoring method was developed and validated in Department of Laboratory Medicine and Pathology, Molecular Cytology Laboratory. ACIS(R) III HercepTest(TM) Application Software is an FDA 510(k) cleared application for precise measurement for assessing the level of HER2 protein on cell membranes of breast tumor cells.

SP Signing Pathologist:

6/17/2010 11:28

MCR

Interpreted by:

Pathologist X. Test, M.D.

Report electronically signed by Angie S. Beckel

Transcribed by: asa05 6/17/2010 11:27:54

## \* PERFORMING SITE

MCR	Mayo Clinic Dpt of Lab Med & Pathology 200 First Street SW Rochester, MN 55905	Lab Director: Franklin R. Cockerill, III, M.D.
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