



**REPORTING NAME  
& METHOD CHANGE**

**NOTIFICATION DATE:** June 2, 2009

**EFFECTIVE DATE:** June 30, 2009

**HER2(HERCEPT), IMMUNOPEROXIDASE STAIN  
#81504**

**EXPLANATION:** Due to a change in methodology and instrumentation, a reporting name change will be implemented for the HER2 Immunostain assay. Reference values will not change. No other changes to this assay will be made at this time.

**CURRENT REPORTING NAME:** HER2, Immunostain

**CURRENT METHODOLOGY:** Immunohistochemical, Manual Analysis

**NEW REPORTING NAME:** HER2, Quantitative IHC, Automated

**NEW METHODOLOGY:** Immunohistochemical, ACIS<sup>®</sup> III Automated Immunostain Analysis

**CPT CODE:** 88361

**LIST FEE:** \$394.70

**DAY(S) SET UP:** Monday through Friday

**ANALYTIC TIME:** 2 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager  
Kim J. Baker, Mayo Medical Laboratories' Technical Support  
Telephone: 800-533-1710



# TEST DEFINITION

6/2/2009

MML NAME/ORDER CODE CROSS-REFERENCE

CODE NAME  
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81504 HER2, SEMI-QUANT IHC, MANUAL

MML MML TEST SETUP INFORMATION

ORDER CODE	EFF DATE	TC	TITLE	CHECKING NORMALS	PRINT NORMALS (# CODED)	PERFORM SITE *
81504	8/15/2003		HER2, SEMI-QUANT IHC, MANUAL			MCR
			TRANSPORT TEMP : AMBIENT\REFRIG OK\FROZEN OK			
		18930	ACCESSION NUMBER			
		18931	REFERRING PATHOLOGIST/PHYSICIAN			
		18932	REF PATH/PHYS ADDRESS			
		18933	MATERIAL:			
		18977	TISSUE:			
		18934	INTERPRETATION:			
		18978	COMMENT:			
		18935	SP SIGNING PATHOLOGIST:			
		18936	*PREVIOUS REPORT FOLLOWS*			
		18937	ADDENDUM:			
		19216	ADDENDUM COMMENT:			
		18938	ADDENDUM PATHOLOGIST:			





# TEST DEFINITION

2/16/2009

MML NAME/ORDER CODE CROSS-REFERENCE  
 CODE NAME  
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 81954 HER2 AMP, BREAST CANCER, FISH

MML		MML TEST SETUP INFORMATION				PERFORM	
ORDER CODE	EFF DATE	TC	TITLE	CHECKING NORMALS	PRINT NORMALS (# CODED)	SITE *	
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81954	5/6/2008		HER2 AMP, BREAST CANCER, FISH				MCR
		16878	TRANSPORT TEMP : AMBIENT\REFRIG OK\FROZEN NO SPECIMEN				
		16879	SPECIMEN ID				
		16880	SOURCE				
		16881	ORDER DATE				
		16883	REASON FOR REFERRAL				
		29636	FIXATIVE				
		16882	METHOD				
		16884	RESULTS				
		16885	INTERPRETATION				
		16886	AMENDMENTS				
		16887	CONSULTANT				
		16888	REPORT DATE				
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MML MML TEST SETUP INFORMATION

\*PERFORMING SITE LEGEND

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MCR	MAYO CLINIC DPT OF LAB MED & PATHOLOGY	LAB DIRECTOR:	FRANKLIN R. COCKERILL, III, M.D.
	200 FIRST STREET SW		
	ROCHESTER, MN 55905		

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MML MESSAGES USED AS NORMALS  
CODE TEXT

TOTAL OF 0 NORMALS CODES

\*\*\* END OF REPORT \*\*\*



LABORATORY SERVICE REPORT

1-800-533-1710

PATIENT NAME TESTING, 81504		PATIENT NUMBER		AGE 18	SEX F	ACCESSION # G9128189
ORDERING PHYSICIAN		CLIENT ORDER #				ACCOUNT # LIAISONS
COLLECTION 05/28/09 12:00 P	RECEIVED 05/29/09 02:26 P	REPORT PRINTED 06/02/09 02:00 P		SPECIMEN INFORMATION DATE OF BIRTH: 5/29/1990		
<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						

TEST REQUESTED	HI LO	REF RANGE	PERFORM SITE *
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**HER2, Semi-Quant IHC, Manual**

<b>Accession Number</b>	<b>HR09-84</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 (TEST09-123)

<b>Tissue:</b>		<b>MCR</b>
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A:Testing changes to HER2

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

Source: A, block TEST09-123

Results: HER2 protein overexpression is negative, score of 1+.

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. The fixation time for this specimen was indicated to be within the CAP/ASCO guidelines of between 6 and 48 hours.

Method: Testing is performed using FDA approved Dako HercepTest9 employing a polyclonal antibody and a polymer-based detection system. Separate positive (3+ and 1+) and negative (0) controls are provided with, tested, and evaluated in accordance with HercepTest9 kit instructions. Immunohistochemical stained slides are examined by the ACISe III automated immunostain analysis instrument. Membrane staining for HER2 protein in invasive carcinoma is scored on a 0 to 3+ scale. A pathologist review the ACIS data and corresponding

\* Perform Site Legend on last page of report

PATIENT NAME TESTING, 81504	ORDER STATUS Final	COLLECTION DATE AND TIME 05/28/09 12:00 P
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Specimen receipt and report times are in CST/CDT

REPRINT

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06/02/2009 2:01PM



## LABORATORY SERVICE REPORT

1-800-533-1710

PATIENT NAME TESTING, 81504		PATIENT NUMBER		AGE 18	SEX F	ACCESSION # G9128189
ORDERING PHYSICIAN		CLIENT ORDER #			ACCOUNT # LIAISONS	
COLLECTION 05/28/09 12:00 P	RECEIVED 05/29/09 02:26 P	REPORT PRINTED 06/02/09 02:00 P		SPECIMEN INFORMATION DATE OF BIRTH: 5/29/1990		
<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						

TEST REQUESTED	HI LO	REF RANGE	PERFORM SITE *
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slide to verify accuracy of regions scored. The scoring method was developed and validated in Department of Laboratory Medicine and Pathology, Molecular Cytology Laboratory.

ACISE III HercepTest9 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: 5/29/2009 14:36

MCR

Interpreted by:

Pathologist X. Test, M.D.

Report electronically signed by Angie S. Beckel

Transcribed by: asa05 5/29/2009 14:35:18

## \* 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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PATIENT NAME TESTING, 81504	ORDER STATUS Final	COLLECTION DATE AND TIME 05/28/09 12:00 P
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Specimen receipt and report times are in CST/CDT

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