

***BCR/ABL*, Tyrosine Kinase Inhibitor Resistance, Kinase Domain  
Mutation Screen  
#89609**

**USEFUL FOR:**

- Evaluating patients with CML and Ph+ ALL receiving TKI therapy, who are apparently failing treatment.
- This is the preferred initial test to identify the presence of acquired *BCR-ABL* mutations associated with TKI-resistance.

**METHODOLOGY:** Reverse Transcription-Polymerase Chain Reaction (RT-PCR) with Fluorescent-Bead Array Analysis Allele-specific primer extension (ASPE) and detection by Luminex Bead array (PCR is utilized pursuant to a license agreement with Roche Molecular Systems, Inc.)

**REFERENCE VALUES:** An interpretive report will be provided.

**SPECIMEN REQUIREMENTS:**

**Specimen must arrive within 72 hours of collection**

**NOTE: If patient's *BCR/ABL* fusion type (p210 or p190) is not provided #89006/ *BCR/ABL*, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay will be performed at an additional charge to get this information.**

**Submit only 1 of the following specimens:**

**Blood (Preferred)**

Draw blood in a lavender-top (EDTA) tube(s), and send 3 mL of EDTA whole blood in original VACUTAINER(S). Invert several times to mix blood. Forward unprocessed whole blood promptly at ambient temperature.

**Bone Marrow**

Place 2 mL of bone marrow in a lavender-top (EDTA) tube(s) and send in original VACUTAINER(S). Invert several times to mix bone marrow. Forward unprocessed bone marrow promptly at ambient temperature.

**NOTE: 1. The following information is required** on request form for processing:

- A. Patient's fusion type (p210 or p190) is required for performing this assay.
  - B. Pertinent clinical history
  - C. Clinical or morphologic suspicion
  - D. Collection date
  - E. Specimen source (blood or bone marrow)
2. Label specimen appropriately (blood or bone marrow).

3. If ordering electronically, please complete and submit a "MayoConnect Additional Test Information Form" (Supply T357) with the specimen. If not ordering electronically, please complete and submit "Hematopathology/Molecular Oncology Request Form" (Supply T241) with the specimen.

**CAUTIONS:**

- This assay does not detect all possible kinase domain mutations; thus, a negative result by this assay does not exclude the presence of a rare, less well characterized or unknown mutation that could be associated with some degree of TKI resistance. The clinical significance of such rarely occurring mutations may, however, be uncertain.
- The quantitative level of BCR-ABL transcript is critical for a successful assay mutation analysis. If the BCR-ABL quantitative PCR level is too low, RT-PCR amplification of BCR-ABL may be unsuccessful. Although laboratory standards are yet to be developed, a BCR-ABL/ABL quantitative level above 0.1% is generally considered to be required in order to detect KD mutations by this assay.
- EDTA blood specimens are preferred for testing. Bone marrow specimens are acceptable; there occasionally are sample failures from bone marrow RNA, for reasons that are not completely understood. Heparin anticoagulant also cannot be used because of PCR inhibition.
- Assay precision does not appear to be significantly affected by sample transport or moderate delays in processing. However, in samples with lower levels of BCR-ABL, these conditions may cause sufficient RNA degradation to produce false-negative results. Thus, samples should be shipped as quickly as possible and specimens > 3 days old at the time of receipt are unacceptable.

**NOTE:** When #89609, *BCR/ABL*, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen is ordered, #81481/Interpretation and Report will always be added at an additional charge.

**LIST FEE:**     \$ 400.00 for #89609  
                   \$ 79.30 for #81481

**CPT CODES:**

83891/Isolation or extraction of highly purified nucleic acid  
83894/x2 Gel electrophoresis  
83896/x8 Nucleic acid probe  
83898/x2 Amplification, target, each nucleic acid sequence  
83902/Reverse transcription  
83909 Separation and identification  
83914/x8 ASPE  
83912/ Interpretation and Report

**ANALYTIC TIME:**     3 days

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

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager  
Julie Breider, Mayo Medical Laboratories' Technologist Support  
Telephone: 800-533-1710

# TEST DEFINITION

5/8/2009

CODE    NAME  
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89609    BCR/ABL MUTATION, ASPE

ORDER CODE	EFF DATE	TC	TITLE	CHECKING NORMALS	PRINT NORMALS (# CODED)	PERFORM SITE *
89609	4/27/2009		BCR/ABL MUTATION, ASPE			MCR
			TRANSPORT TEMP : AMBIENT <72 HOURS\REFRIG <72 HOURS OK\FROZEN NO			
			19817    ACCESSION NUMBER			
			- - - - -			
			19818    REFERRING PATHOLOGIST/PHYSICIAN			
			- - - - -			
			19819    REF. PATH ADDRESS			
			- - - - -			
			19820    MATERIAL			
			- - - - -			
			19821    SPECIMEN			
			- - - - -			
			19822    MICROSCOPIC DESCRIPTION			
			- - - - -			
			19823    SPECIAL STUDIES :			
			- - - - -			
			19824    FINAL DIAGNOSIS :			
			- - - - -			
			19825    COMMENT :			
			- - - - -			
			19826    REVISION DESCRIPTION :			
			- - - - -			
			19827    SIGNING PATHOLOGIST			
			- - - - -			
			19828    SPECIAL PROCEDURES			
			- - - - -			
			19829    SP SIGNING PATHOLOGIST			
			- - - - -			
			19830    *PREVIOUS REPORT FOLLOWS*			
			- - - - -			

19831    ADDENDUM  
-   -   -   -   -

19832    ADDENDUM COMMENT:  
-   -   -   -   -

19833    ADDENDUM PATHOLOGIST:  
-   -   -   -   -

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\*PERFORMING SITE LEGEND

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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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# TEST DEFINITION

5/8/2009

CODE NAME  
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81481 INTERPRETATION AND REPORT

ORDER CODE	EFF DATE	TC	TITLE	CHECKING NORMALS	PRINT NORMALS (# CODED)	PERFORM SITE *
81481	5/8/2006		INTERPRETATION AND REPORT			MCR
			TRANSPORT TEMP : AMBIENT\REFRIG OK\FROZEN NO			
			81481 INTERPRETATION AND REPORT			

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\*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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LABORATORY SERVICE REPORT

1-800-533-1710

PATIENT NAME TESTING, DEBBIE		PATIENT NUMBER		AGE 51	SEX F	ACCESSION # G9125531
ORDERING PHYSICIAN		CLIENT ORDER #				ACCOUNT # LIAISONS
COLLECTION 04/28/09 08:00 A	RECEIVED 04/28/09 07:17 P	REPORT PRINTED 05/08/09 09:06 A		SPECIMEN INFORMATION DATE OF BIRTH: 1/22/1958		
<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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**Interpretation and Report**

Interpretation and Report

Performed

MCR

**BCR/ABL Mutation, ASPE**

Accession Number

BR09-50

MCR

Material

MCR

2 EDTA tube peripheral blood received.

SLIDE DISPOSITION:

Specimen

MCR

A:Peripheral Blood

Final Diagnosis:

MCR

Peripheral blood, BCR/ABL mRNA level analysis (p210 fusion form):

Negative. No BCR/ABL p210 mRNA transcripts were detected (% bcr/abl(p210):abl = 0). The detection limit for this sample was 0.00044%.

Method summary-BCR/ABL, p210 fusion: BCR/ABL p210 mRNA transcript level was evaluated using quantitative, reverse transcription PCR.

The assay detects the two most common fusion forms in chronic myelogenous leukemia: e13/a2 and e14/a2, which code for p210 proteins. It is intended for monitoring patients with neoplasms known to carry the p210 fusion form. The assay does not detect other fusions, including those for the p190 protein commonly present in acute lymphoblastic leukemia. Please contact the lab at 1-507-266-0489 with questions or if additional testing is required.

Signing Pathologist

4/28/2009 20:18

MCR

Interpreted by:

Pathologist X. Test, M.D.

Report electronically signed by Debbie A. Postier

Transcribed by: dap07 4/28/2009 20:18:26

\* Perform Site Legend on last page of report

PATIENT NAME TESTING, DEBBIE	ORDER STATUS Final	COLLECTION DATE AND TIME 04/28/09 08:00 A
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Specimen receipt and report times are in CST/CDT

REPRINT

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## LABORATORY SERVICE REPORT

1-800-533-1710

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TEST REQUESTED	HI LO	REF RANGE	PERFORM SITE *
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## \* PERFORMING SITE

MCR 200 First Street SW Rochester, MN 55905	Mayo Clinic Dpt of Lab Med & Pathology	Lab Director: Franklin R. Cockerill, III, M.D.
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PATIENT NAME TESTING, DEBBIE	ORDER STATUS Final	COLLECTION DATE AND TIME 04/28/09 08:00 A
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REPRINT

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