

Patient Name SAMPLEREP,BAKDM N	Patient ID SA00060338	Age 47	Gender F	Order # SA00060338
Ordering Phys CLIENT,CLIENT				DOB 06/10/1966
Client Order # SA00060338	Account Information			Report Notes
Collected 07/25/2013 00:00	C7028846-DLMP Rochester 3050 Superior Drive Rochester, MN 55901			
Printed 07/30/2013 07:44				

Test	Flag	Results	Unit	Reference Value	Perform Site*
BCR/ABL Mutation, ASPE					
RECEIVED: 07/29/2013 08:00 REPORTED: 07/29/2013 10:56					
Specimen Type		Peripheral blood			MCR
BCRABL Fusion Form		p210			MCR
Final Diagnosis:					
Peripheral blood, BCR/ABL Kinase Domain Mutation Analysis:					
Negative. No mutations in the ABL kinase domain region are identified at the specific loci evaluated.					

Signing Pathologist: Jennifer Herman

This assay detects approximately 80% of the currently described and most frequently occurring ABL kinase domain mutations, which have been associated with significant clinical or in vitro resistance to tyrosine kinase inhibitor therapy (M351T, T315I, E255K, H396R, F359V, M244V, E355G, G250E, F317L, Y253H, Y253F, and Q252H). Additional mutations of potential or unknown significance are not covered by this test methodology and therefore cannot be excluded.

Method Summary: Total RNA was extracted and nested reverse transcription PCR was performed to detect the BCR/ABL transcript and ABL kinase domain (KD) region. Kinase domain mutations (KDM) were evaluated using a fluorescent multiplex allele-specific extension (ASPE) assay and analyzed for specific mutations using liquid bead array platform (see Mayo Medical Laboratories Interpretive Handbook for method details). The quantitative level of BCR-ABL transcript is related to optimal mutation analysis.

If the BCR-ABL quantitative PCR level is too low, RT-PCR amplification of BCR-ABL may be unsuccessful in this assay.

In general, a BCR-ABL/ABL quantitative level above 0.1% is considered to be required in order to detect KD Mutations by this assay.

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.
Laboratory developed test.

Performing Site Legend on Last Page of Report

Patient Name SAMPLEREP,BAKDM N	Collection Date and Time 07/25/2013 00:00	Report Status Final
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* Report times for Mayo performed tests are CST/CDT

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>> Accession SA00060338 - Continued From Previous Page <<
 >> Do Not Discard <<

* Performing Site:

MCR	Mayo Clinic Laboratories - Rochester Main Campus 200 First St SW Rochester, MN 55905	Lab Director:
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Patient Name SAMPLEREP,BAKDM N	Collection Date and Time 07/25/2013 00:00	Report Status Final
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