Patient Name	Patient ID	Age	Gender	Order #
TESTINGRNV,BAKDM	SA00060853	16	M	SA00060853
Ordering Phys CLIENT,CLIENT				**DOB** 11/11/1996
Client Order # SA00060853	**Account Information**			**Report Notes**
Collected 08/20/2013 06:00	C7028846-DLMP Rochester SDSC 2 - Client Support Rochester, MN 55901			
Printed 10/15/2013 14:46				

Test	Flag	Results	Unit	Reference Value	Perform Site*

BCR/ABL Mutation, ASPE
RECEIVED: 08/20/2013 09:23 **REPORTED:** 08/20/2013 09:32

Specimen Type — Peripheral blood — MCR

Supplemental PDF Report available at:
https://test.mmlaccess.com/Reports/C7028846-UBh4upwhCA.ashx

BCRABL Fusion Form — p210 — MCR

Final Diagnosis: — MCR

, BCR/ABL Kinase Domain Mutation Analysis:

Negative. No mutations in the ABL kinase domain region are identified at the specific loci evaluated.

This patient has a previously documented p210 BCR/ABL transcript type.

Signing Pathologist: Melissa Tricker-Klar
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

Performing Site Legend on Last Page of Report

Patient Name	Patient ID	Age	Gender	Order #
TESTINGRNV,BAKDM	SA00060853	16	M	SA00060853
Ordering Phys CLIENT,CLIENT				**DOB** 11/11/1996
Client Order # SA00060853	**Account Information**			**Report Notes**
Collected 08/20/2013 06:00	C7028846-DLMP Rochester SDSC 2 - Client Support Rochester, MN 55901			
Printed 10/15/2013 14:46				

Test	Flag	Results	Unit	Reference Value	Perform Site*

by the U.S. Food and Drug Administration.
Laboratory developed test.

* Performing Site:

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

MAYO CLINIC
Mayo Medical Laboratories

Performing Site:
Mayo Clinic Laboratories - Rochester Main Campus
200 First Street SW, Rochester MN 55905
Franklin R. Cockerill, M.D. Lab DirectorCampus
Phone: 800-533-1710
http://www.mayomedicallaboratories.com

TESTINGRNV, BAKDM MEDICAL RECORD # (PATIENT ID) SA00060853

DOB	11/11/1996	CLIENT ID/WARD	7028846	ORDER #	B320000265
SEX	Male	CLIENT/NAME WARD	DLMP Rochester	CLIENT ORDER #	SA00060853
CLIENT MRN	SA00060853	CITY, ST, ZIP	Rochester	DATE COLLECTED	8/20/2013 6:00 AM
REQUESTED BY	CLIENT CLIENT		MN 55901	DATE RECEIVED	8/20/2013 9:23 AM
				DATE REPORTED	8/20/2013 9:32 AM

Test Report

BCR/ABL Mutation, ASPE

Specimen Type	Peripheral blood
BCRABL Fusion Form	p210

Interpretation
, BCR/ABL Kinase Domain Mutation Analysis:

Negative. No mutations in the ABL kinase domain region are identified at the specific loci evaluated.

This patient has a previously documented p210 BCR/ABL transcript type.

Signing Pathologist: Melissa Tricker-Klar

Method:

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.

Disclaimer:

Laboratory developed test.

Site ID: C7028846
Accession Number: SA00060853
FileName: SA00060853-7WKfNO+py219z9P11FbY351Lp9EyZZf2gYo_tJABi9nxMlNer6Qv_XL5j2NdHbEJgteRp+PB3LBD+dOOt6n2Q==.pdf
Reported Date & Time: 08/20/13 09:35
Test Name: BCR/ABL Mutation, ASPE
Result Name: Specimen Type