Test Definition: B210R

BCR/ABL1, p210, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Reflex, Varies

Overview

Useful For

Diagnostic workup of patients with a high probability of *BCR-ABL1*-positive hematopoietic neoplasms, particularly chronic myeloid leukemia and Ph+ acute lymphoblastic leukemia (B-lymphoblastic leukemia), to provide a pretreatment quantitative level of *BCR-ABL1* mRNA transcript if the initial diagnostic reverse transcription polymerase chain reaction screen is positive

When positive, the reflex test provides a quantitative value for the corresponding e13-a2 or e14-a2 (p210) *BCR-ABL1* mRNA fusion variant

Method Name

Only orderable as a reflex. For more information see BCRFX /*BCR*/*ABL1* Qualitative Diagnostic Assay with Reflex to *BCR*/*ABL1* p190 Quantitative Assay or *BCR*/*ABL1* p210 Quantitative Assay, Varies.

Quantitative Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Specimen Required

Only orderable as a reflex. For more information see BCRFX /*BCR*/*ABL1* Qualitative Diagnostic Assay with Reflex to *BCR*/*ABL1* p190 Quantitative Assay or *BCR*/*ABL1* p210 Quantitative Assay, Varies.

Submit only 1 of the following specimens:

Specimen Type: Whole blood
Container/Tube:
Preferred: Lavender top (EDTA)
Acceptable: Yellow top (ACD)
Specimen Volume: 10 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send whole blood specimen in original tube. **Do not aliquot**.

3. Label specimen as blood.

Specimen Type: Bone marrow
Container/Tube:
Preferred: Lavender top (EDTA)
Acceptable: Yellow top (ACD)
Specimen Volume: 4 mL
Collection Instructions:
1. Invert several times to mix bone marrow.
2. Send bone marrow specimen in original tube. **Do not aliquot**.
3. Label specimen as bone marrow.

Specimen Minimum Volume
8 mL

Reject Due To

Gross hemolysis	Reject
Moderately to severely clotted	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	72 hours	PURPLE OR PINK TOP/EDTA
	Ambient	72 hours	PURPLE OR PINK TOP/EDTA

Clinical & Interpretive

Clinical Information
The t(9;22)/*BCR-ABL1* abnormality is associated with chronic myeloid leukemia (CML) and "Philadelphia positive" acute lymphoblastic leukemia of B-cell lineage (Ph ALL). Very rarely, this abnormality has also been identified in cases of acute myeloid leukemia and T-lymphoblastic leukemia/lymphoma. The fusion gene on the derivative chromosome 22q11 produces a chimeric *BCR-ABL1* messenger RNA (mRNA) transcript and corresponding translated oncoprotein. Despite substantial breakpoint heterogeneity at the DNA level, a consistent set of *BCR-ABL1* mRNA transcripts are produced that can be readily and sensitively detected by reverse transcription polymerase chain reaction (RT-PCR) technique. In CML, breakpoints in *BCR* nearly always result in either exons 13 or 14 (e13, e14) joined to exon 2 of *ABL1* (a2). The corresponding e13-a2 or e14-a2 *BCR-ABL1* mRNAs produce a 210 kDa protein (p210). Rare cases of CML are characterized by an e19-a2 type mRNA with a corresponding p230 protein. In Ph ALL, the majority of cases harbor an e1-a2 *BCR-ABL1* mRNA transcript, producing a p190 protein, although some ALL patients may alternatively present with

the e13/e14-a2 or p210 type fusion.

This assay provides information at the time of diagnosis regarding the presence (and specific mRNA type) or absence of the *BCR-ABL1* mRNA. If positive, the reflex test will follow to provide an initial quantitative level of the specific *BCR-ABL1* transcript. For example, when positive for the e13/e14-a2 (p210) type mRNA, the reflex test provides a corresponding p210 quantitative value. Results from this test are also useful to determine the correct quantitative assay for subsequent monitoring of transcript levels (ie, p190 or p210) during tyrosine kinase inhibitor therapy.

Reference Values

Only orderable as a reflex. For more information see BCRFX / *BCR*/*ABL1* Qualitative Diagnostic Assay with Reflex to *BCR*/*ABL1* p190 Quantitative Assay or *BCR*/*ABL1* p210 Quantitative Assay, Varies.

Interpretation

An interpretive report will be provided.

Cautions

In general, the results of this assay cannot be directly compared with results generated from other polymerase chain reaction assays, including identical assays performed in other laboratories. Monitoring should be performed using the same method and laboratory for each subsequent specimen.

If a rare alternative *BCR-ABL1* mRNA transcript (eg, e19-a2/p230, or other) is identified by diagnostic reverse-transcription polymerase chain reaction (RT-PCR), a reflex test cannot be performed as quantitative testing for these rare transcripts is not currently available.

For diagnostic reflex testing to quantitative RT-PCR for the p210 type mRNA, only normalized *BCR-ABL1/ABL1* values greater than or equal to 1% (IS) will be numerically reported. The reflex test is intended for use at diagnosis, when relatively high levels of *BCR-ABL1* p210 mRNA are present, and to establish the initial baseline prior to tyrosine kinase inhibitor therapy. Levels below 1% will be most likely consistent with posttherapy samples and will, therefore, only be reported qualitatively for this assay (eg, "a low level of BCR-ABL1 p210 mRNA is present"). In this case, a recommendation will be provided for submission of a new EDTA anticoagulated peripheral blood or bone marrow specimen to determine and report a more accurate quantitative value using BCRAB / *BCR*/*ABL1*, p210, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Monitoring Chronic Myeloid Leukemia (CML), Varies. Given the nature of the reflex test, normalized *BCR-ABL1/ABL1* mRNA levels below 1% are not considered reliable and accurate quantification will require submission of a new blood or marrow specimen for the specific BCRAB test.

Clinical Reference

1. Hughes TP, Kaeda J, Branford S, et al. Frequency of major molecular responses to imatinib or interferon alfa plus cytarabine in newly diagnosed chronic myeloid leukemia. N Engl J Med. 2003;349(15):1423-1432
2. Baccarani M, Deininger MW, Rosti G, et al. European LeukemiaNet recommendations for the management of chronic myeloid leukemia: 2013. Blood. 2013;122(6):872-884
3. Press RD, Kamel-Reid S, Ang D. BCR-ABL1 RT-qPCR for monitoring the molecular response to tyrosine kinase inhibitors in chronic myeloid leukemia. J Mol Diagn. 2013;15(5):565-576
4. Cross NC, White HE, Muller MC, Saglio G, Hochhaus A. Standardized definitions of molecular response in chronic myeloid leukemia. Leukemia. 2012;26(10):2172-2175

5. National Comprehensive Cancer Network Practice Guidelines in Oncology: Chronic Myeloid Leukemia 2015. Accessed December 27, 2023. Available at www.nccn.org

Performance

Method Description
The assay is performed using an automated platform, GeneXpert (Cepheid). All subsequent reactions are performed within the cartridge and the results are processed and calculated by the instrument. Quantitative, reverse transcription polymerase chain reaction (PCR) is performed with a nested PCR reaction Lot-to-lot variation in the cartridges is corrected using a calibration calculation to reference standard curve data to the IS provided by the manufacturer.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 10 days

Specimen Retention Time
Whole blood, Bone marrow: 2 weeks; Extracted RNA: 3 months

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

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

CPT Code Information
81206

Test Definition: B210R

BCR/ABL1, p210, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Reflex, Varies