Test Definition: B190R

BCR/ABL1, p190, 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 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 e1-a2 (p190) *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
Collection 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.

Test Definition: B190R

BCR/ABL1, p190, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Reflex, Varies

Specimen Type: Bone marrow
Collection 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 (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 e1-a2 (p190) type mRNA, the reflex test provides a corresponding p190 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 (PCR) 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.

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. Radich JP, Gooley T, Bryant E, et al. The significance of *BCR-ABL* molecular detection in chronic myeloid leukemia patients "late," 18 months or more after transplantation. Blood. 2001;98(6):1701-1707. doi:10.1182/blood.v98.6.1701
3. Olavarria E, Kanfer E, Szydlo R, et al. Early detection of *BCR-ABL* transcripts by quantitative reverse transcriptase-polymerase chain reaction predicts outcome after allogeneic stem cell transplant for chronic myeloid leukemia. Blood. 2001;97(6):1560-1565
4. Tefferi A. The classic myeloproliferative neoplasms: Chronic myelogenous leukemia, polycythemia vera, essential thrombocythemia, and primary myelofibrosis. In: Valle DL, Antonarakis S, Ballabio A, Beaudet AL, Mitchell GA, eds. The Online Metabolic and Molecular Bases of Inherited Disease. McGraw-Hill; 2019, Accessed December 27, 2023. Available at https://ommbid.mhmedical.com/content.aspx?sectionid=225078035&bookid=2709

Performance

Method Description

Total RNA is extracted and reverse transcribed to complementary DNA. Quantitative real time polymerase chain reaction is performed and p190/*ABL1* relative quantitative levels are determined using TaqMan-type probe technology.

The data is analyzed using the supplied software for relative quantification with calibrator normalization. The reference gene, *ABL1,* is used to control for RNA degradation in the sample and the calibrator is used to control for inter-run variations. A normalized ratio of *BCR/ABL1* (p190) mRNA:*ABL1* mRNA is obtained and reported in the form of percentage.(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
81207