

**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 RT-PCR 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.

**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.

**Specimen Minimum Volume**

1 mL

**Reject Due To**

Gross hemolysis	Reject
Other	Moderately to severely clotted

**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 and 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* 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 PCR (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 kD 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 under the BCRFX / *BCR/ABL1* Qualitative Diagnostic Assay with Reflex to *BCR/ABL1* p190 Quantitative Assay or *BCR/ABL1* p210 Quantitative Assay, Varies.

### Cautions

In general, the results of this assay cannot be directly compared with results generated from other 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 RT-PCR, a reflex test cannot be performed as quantitative testing for these rare transcripts is not currently available.

### Performance

#### Method Description

Total RNA is extracted and reverse transcribed to cDNA. Quantitative real time PCR 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) and Time(s) Test Performed

Monday through Friday

#### Analytic Time

7 days

**Maximum Laboratory Time**

10 days

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**

81207