

HOTLINE: Effective November 14, 2022

**New Test** 

3005840

Quantitative Detection of BCR-ABL1, Major Form (p210)

ONT BCR MAJ



Time Sensitive



Additional Technical Information

**Methodology:** Reverse Transcription Polymerase Chain Reaction

Performed: RNA isolation: Sun-Sat

Assay: Varies

**Reported:** 5-9 days

Specimen Required: Collect: Whole blood or bone marrow in lavender (EDTA).

Specimen Preparation: Whole blood: Transport 5 mL whole blood. (Min: 3 mL)

Bone marrow: Transport 3 mL bone marrow. (Min: 1 mL)

Refrigerate immediately. Specimens must be received within 48 hours of collection due to lability of RNA.

Storage/Transport Temperature: Whole blood and bone marrow: CRITICAL REFRIGERATED. Separate specimens must be

submitted when multiple tests are ordered.

<u>Remarks:</u> This quantitative test is recommended for therapeutic monitoring and detection of minimal residual disease for patients with an established diagnosis. For patients with uncertain diagnoses or unknown forms of *BCR-ABL1* fusion transcripts,

please order 3005839 Diagnostic Qualitative BCR-ABL1 Assay with Reflex to p190 or p210 Quantitative Assays.

Unacceptable Conditions: Serum, plasma, ambient or frozen bone marrow or whole blood, CSF, or FFPE tissue. Specimens collected

in anticoagulants other than EDTA. Severely hemolyzed or clotted specimens.

Ambient whole blood and ambient bone marrow specimens past 7 days will be canceled. Refrigerated whole blood or bone marrow

past 7 days will be canceled.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 48 hours; Frozen: Unacceptable

## **Interpretive Data:**

Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

**Note:** This test does not detect the *BCR-ABL1* micro (p230) or minor (p190) fusion transcripts. This test does not detect rare *BCR-ABL1* major (p210) forms involving beyond *ABL1* exon 2.

For the p190 fusion form (minor breakpoint), order BCR-ABLI, Minor (p190), Quantitative (ARUP test code 2005016).

**CPT Code(s):** 81206

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.