HOTLINE: Effective November 14, 2022

New Test **3005839** **Diagnostic Qualitative BCR-ABL1 Assay with Reflex to p190 or p210 Quantitative Assays** **DX BCR RFX**

Time Sensitive

Additional Technical Information

Methodology: Reverse Transcription Polymerase Chain Reaction
Performed: **RNA isolation:** Sun-Sat
Assay: Varies
Reported: 4-10 days
If reflexed: TAT may be extended by 3-7 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.
Remarks: **This qualitative test is intended as a screening test only for initial diagnosis**. For those patients with an established diagnosis, please order **3005840 Quantitative Detection of *BCR-ABL1*, Major Form (p210) or (ARUP Test code 2005016) *BCR-ABL1*, Minor (p190), Quantitative.**
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 reflex assay is recommended when the BCR-ABL1 fusion form is not known or unclear. This reflex assay detects the presence of either the p210 (major breakpoint), p190 (minor breakpoint), or p230 (micro breakpoint). If the presence of either the common p210 or p190 BCR-ABL1 fusion is detected, then the appropriate quantitative test will be performed. Additional charges apply.

If the fusion form is known, refer to Quantitative Detection of BCR-ABL1, Major Form (p210) (ARUP test code 3005840) or BCR-ABL1, Minor (p190), Quantitative (ARUP test code 2005016).

CPT Code(s): 81206; 81207; 81208; If reflexed, add 81206 or 81207

New York DOH approval pending. Call for status update.

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