Quantitative p210 BCR-ABL by Real-Time Quantitative (RQ) PCR and Report on International Scale (IS)

**Methodology:** Reverse Transcription/Real-Time Quantitative Polymerase Chain Reaction using TaqMan Technology

**Performed:** Mon - Friday

**Reported:** Within 5-7 working days of sample receipt in the laboratory

**Specimen Required:**
- **Collection:** 5ml peripheral blood in a lavender top (EDTA) or yellow top (ACD) tube, or 3ml bone marrow in a lavender or yellow top tube (1ml minimum).
- **Transport:** Peripheral blood or bone marrow specimens collected as indicated above should be placed on ice or at 4°C and then delivered immediately to the Molecular Diagnostics Laboratory. If absolutely necessary, specimens may be stored for a maximum of 48 hours after collection at 4°C. Longer-term storage (>48 hours) of the specimen may compromise the quality of the RNA required for testing and/or produce a false negative result. Do not freeze whole blood or bone marrow specimens.

**Unacceptable Conditions:** Serum, frozen whole blood, clotted blood, or severely hemolyzed samples.

**Stability:** Ambient: 1 hour; refrigerated: 48 hours; Frozen: unacceptable.

**Reference Interval:**
Undetectable p210 BCR-ABL transcripts.

**Method:** RNA is isolated from patient samples; reverse transcribed, and amplified with specific primers targeting the p210 BCR-ABL and ABL genes region using a quantitative real-time RT-PCR assay. Quantitative results are obtained by comparing relative levels of p210 BCR-ABL and ABL gene expression to standard curves. P210 BCR-ABL results are reported as a percentage based on an international scale (IS). The assay is sensitive to 0.001% IS and can detect p210 BCR-ABL transcripts ranges from 0.001% IS to 20% IS.

**Clinical indications:** RQ-PCR for BCR-ABL transcript detection during therapy is becoming the standard for monitoring minimal residual disease in CML due to correlation of progression-free survival with transcript levels. p210 BCR-ABL RQ-PCR may be used to confirm the initial diagnosis of CML or Ph’ positive ALL and for monitoring minimal residual disease in follow-up samples.

**Test request form:** Please include the following information with the test request form:
1. Clinical history and diagnosis
2. Whether the sample was drawn at primary diagnosis or after treatment for monitoring minimal residual disease
3. A recent complete blood count (CBC) with white cell differential results
4. Whether or not the patient has previously undergone quantitative testing for p210 BCR-ABL in the UTHSCSA Molecular Diagnostic Laboratory.

**Applicable CPT Code(s):** 83891 RNA Isolation; 83902 Reverse transcription; 83896 Nucleic acid probe x 2; 83898 Amplification x 2; 83912 Interpretation and report.