BCR-ABL p210 QN- IS-MMR

CERNER ORDERABLE
BCR-ABL p210 QN PCR
BCR-ABL p210 Translocation
BCR/ABL Evaluation

CPT CODE
81206

CLINICAL UTILITY
BCR-ABL transcript level correlates with the number of leukemic cells present in blood and can be used to monitor response to therapy. Serial analysis of BCR-ABL levels by real-time quantitative (RQ-PCR) accurately reflects the level of leukemic inhibition induced by treatment. It provides an appropriate monitoring strategy for patients with chronic myeloid leukemia (CML). Molecular monitoring of BCR-ABL levels in conjunction with hematologic and cytologic findings provides correlative information to monitor response, remission, relapse/progression, and resistance to treatment—particularly imatanib mesylate (Gleevec).

Indiana University Health Molecular Pathology Laboratory BCR-ABL p210 transcript level is standardized to the International Scale, allowing the conversion of normal copy number (NCN) results to the International Scale, a more specific standard for determination of major molecular response (MMR) level of 0.1%. Values on the IS will allow comparison of response rates, including clinical trials for laboratories using the IS developed by the World Health Organization (WHO).[1]

METHODOLOGY
The qRT-PCR assay tests for p210 BCR-ABL fusion forms (b2a2 and/or b3a2 BCR-ABL fusion gene transcripts). The copy number of p210 BCR-ABL fusion gene transcripts is expressed relative to the copy number of ABL reference gene transcripts with conversion to a percentage on the International Scale (BCR-ABL as a percentage of total ABL relative to the IS). The IS-MMR kit is compliant with the updated international recommendations. Monitoring should be performed using the same method and laboratory for each subsequent specimen. Significant changes during monitoring should be verified with a subsequent specimen if the results are being used to make major therapeutic decisions.

SPECIMENS
Whole blood collected in a lavender-top (EDTA) tube(s) is the preferred specimen. EDTA whole blood should be received in the original VACUTAINER(S).
Minimum acceptable sample volume is 5 mL whole blood.

- Specimens are accepted M-F, until noon on Friday due to extraction requirements.

SPECIMEN STABILITY and SHIPPING
Specimens must arrive within 24 hours of collection due to stability of RNA!!!
Whole blood may be transported to the laboratory at 2-25^{o}C. DO NOT FREEZE specimens.

CAUSES FOR REJECTION
Specimen not received within 24 hours of the collection time.

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.

Specimen not collected in EDTA tubes.
Frozen specimens.

SPECIFICITY
Only b2a2 and/or b3a2 BCR-ABL fusion gene transcripts are detected. p230 and p190 transcripts are not detected. Achievement of MMR is a goal of CML therapy and testing with the IS-MMR kits will assess treatment of patients at the level of MMR with improved standardization and accuracy of BCR-ABL quantification.

ASSAY RANGE
BCR-ABL p210 transcripts not detected.
BCR-ABL p210 transcripts detected 0.002 to 100%-IS.
BCR-ABL p210 transcripts detected <0.002%-IS.

TURNAROUND TIME
7-10 days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.