BCR-ABL P210 Quantitation by Real-Time PCR and Report by IS

Clinical Indication and Relevance

- Can confirm the initial diagnosis of chronic myelogenous leukemia (CML) or p210 *BCR-ABL* positive acute lymphoblastic leukemia (ALL).
- Recommended for monitoring minimal residual disease in follow-up samples.

Methodology

RNA is isolated, reverse transcribed and amplified by real-time PCR using specific primers targeting the p210 *BCR-ABL* and *ABL* genes. Quantitative results are obtained by comparing relative levels of p210 *BCR-ABL* and *ABL* transcripts to standard curves. P210 *BCR-ABL* results are reported as a percentage based on an international scale (IS).

Sensitivity

This assay can detect p210 *BCR-ABL* transcripts to a sensitivity of 0.001% international scale (IS).

Turn-around Time

Five to seven working days

Sample Requirements

Collect

- Peripheral blood (PB): 3-5 mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- Bone marrow (BM): 1-3 mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

Transport

Deliver immediately at 2-8°C (wet ice or cold packs). Do not freeze.

Stability

Ambient - 1 hour; refrigerated – 48 hours.
Note: for RNA based assays, samples should be transported to the laboratory within 8 hours of collection (optimal), or up to a maximum of 48 hours after collection to avoid RNA degradation. RNA integrity is critical, especially for samples used for monitoring minimal residual disease.

Unacceptable Conditions

Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

CPT Code(s)

81206: *BCR/ABL1* (t(9;22))translocation analysis; major breakpoint, qualitative or quantitative
G0452-26: Molecular pathology procedure; physician interpretation and report

References

1. Beillard E et al. Leukemia. 17:2474, 2003
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4. Hughes T et al. Blood. 108:28, 2006
5. Hughes T. Blood Rev. 20:29, 2006
6. Müller MC et al. Leukemia. 23:1957, 2009