PML-RARα Translocation t(15;17) by RT-PCR

Clinical Indication and Relevance

- Can confirm an initial diagnosis of acute promyelocytic leukemia (AML-M3) carrying the *PML-RARα* t(15;17) translocation.
- May be used to monitor minimal residual disease in follow-up samples.

Methodology

RNA is isolated from peripheral blood or bone marrow and reverse transcribed. RT-PCR is performed using specific primers amplifying *PML-RARα* fusion transcripts. Results are reported as positive or negative for *PML-RARα* fusion transcripts.

Sensitivity

This assay can detect *PML-RARα* fusion transcripts to a sensitivity of 1 in 10,000.

Turn-around Time

- 24 hours for initial diagnosis case
- Five to seven working days for follow-up samples

Sample Requirements

Collect

- Peripheral blood (PB): 3-5 mL, in purple top (sodium EDTA) tube; yellow top (ACD) tube acceptable
- Bone marrow (BM): 1-3 mL, in 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 Samples

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

CPT Code(s)

81315: *PML/RARalpha*, (t(15; 17)), (promyelocytic leukemia/retinoic acid receptor alpha) translocation analysis; common breakpoints, qualitative or quantitative
G0452-26: Molecular pathology procedure; physician interpretation and report

References

1. Reiter A et al. Genes Chromosomes Cancer. 36:175, 2003
2. Rennert H et al. Molecular Diagnosis. 4:195, 1999