

***PML-RAR α* Translocation t(15;17) by Real-time PCR**

Clinical Indication and Relevance

- Can confirm an initial diagnosis of acute promyelocytic leukemia (APL) carrying the *PML-RAR α* 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. Real-time PCR is performed using specific primers amplifying *PML-RAR α* fusion transcripts. Results are reported as positive or negative for *PML-RAR α* fusion transcripts.

Sensitivity

This assay can detect *PML-RAR α* fusion transcripts to a sensitivity of 1 in 1000 cells.

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 (EDTA) tube
- 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/RAR α* , (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), 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. Slack JL et al. *Journal of Molecular Diagnostics*. 3:141, 2001