

# ***PML-RAR $\alpha$* 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 $\alpha$*  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 $\alpha$*  fusion transcripts. Results are reported as positive or negative for *PML-RAR $\alpha$*  fusion transcripts.

## **Sensitivity**

This assay can detect *PML-RAR $\alpha$*  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 $\alpha$* , (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