**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**

2. Rennert H et al. Molecular Diagnosis. 4:195, 1999