**PML-RARα 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-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. Real-time 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 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/RARalpha, (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**