PML-RARA (PRAM1) Translocation, t(15;17) by RT PCR, qualitative and quantitative

CPT Code(s): 81316

Service Code (IU Health): 53053054

Ordering Recommendation: PML-RARA (PRAM1) qRT-PCR is recommended to: be a genetic confirmation of acute promyelocytic leukemia (APL); to access therapeutic response and monitor for minimal residual disease (MRD).

Synonyms: PML-RARA translocation; t(15;17) by RT PCR, qualitative and quantitative, PRAM1

Methodology: Quantitative real-time RT-PCR.

Performed: Mon-Fri

Reported: 6-9 days

Specimen Requirements

Patient Preparation: None required for whole blood

Collect: Blood: Lavender (EDTA) tubes

Specimen Volume: Blood: 2-6 mL whole blood

Storage/Transport: Refrigerated

Unacceptable Conditions: Grossly hemolyzed or clotted

Stability: 1 month refrigerated

Reference Interval: by report

Interpretive Data
Department of Medical and Molecular Genetics  
Division of Diagnostic Genomics

**Characteristics:** APL is a distinct group of acute myeloid leukemia (AML-M3), representing about 5% to 10% of AML. APL generally has a good prognosis with standard all-trans retinoic acid and chemotherapy treatments. Definitive diagnosis of APL requires testing for the PML/RARA fusion gene, resulting from the t(15;17)(q24.1;q21.1) translocation. Three fusion transcript isoforms, bcr1, bcr2 and bcr3 are generated as a result of different breakpoint cluster regions (bcr) within the PML gene. bcr1 (45% to 55%) results from a break within intron 6 of the PML gene. bcr3 (37% to 45%) indicates a breakpoint within intron 3 of the PML gene. bcr2 (8% to 10%) represents variable breakpoint sites within exon 6 of the PML gene. The PML-RARA fusion gene transcripts are diagnostic for acute promyelocytic leukemia.

**Incidence:** representing about 5% to 10% of AML.

**Analytical sensitivity and specificity:**

**Limitations:** The detection limit of this assay is from 0.01% to 0.1%. Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data.