PML/RARA t(15;17) Analysis (Quantitative)

Detection of the presence of PML/RARA fusion transcripts associated with t(15;17) abnormality seen in AML-M3 (promyelocytic leukemia). Clinical use includes: Diagnosis, Minimal Residual Disease monitoring, Effectiveness of therapy, Prediction of early relapse and Response to all-*trans*-retinoic acid or arsenic trioxide therapy.

Testing Method and Background

Acute promyelocytic leukemia (APL or AML-M3) is a subtype of acute myeloid leukemia with distinct clinical and histopathologic features. APL is one of the most lethal forms of acute myeloid leukemia. A majority of cases harbor a t(15;17) translocation. This rearrangement results in the fusion of the PML and retinoic acid receptor alpha (RARA) genes located on chromosomes 15 and 17 respectively. Three breakpoint regions within the PML gene can be involved, resulting in three possible PML/RARA fusion types: bcr1 (long), bcr2 (variable), and bcr3 (short). Testing for PML/RARA can assist in the diagnosis, clinical management, prediction of response to all-*trans*-retinoic acid or arsenic trioxide therapy and monitoring of minimal residual disease (MRD).

This test utilizes reverse transcription followed by **Quantitative Real-Time Polymerase Chain Reaction (PCR)** using RNA extracted from white blood cells in bone marrow and/or peripheral blood samples. This test will detect three possible PML/RARA isoforms, bcr1 (long), bcr2 (intermediate) and bcr3 (short). The sensitivity of the assay is approximately 1/10,000 total cells carrying the fusion. Mutations may not be detected in samples with a neoplastic burden below this level. Control gene transcripts are amplified in parallel for normalization.

Highlights of PML/RARA t(15;17) Analysis

Targeted Region

PML/RARA : t(15;17)(q22;q21)

- **Accurate Results with established standard limit of detection**
  This assay has a limit of detection verified to 1/10,000 cells carrying the fusion.
- **Coverage of 3 Isoforms with Interpretive Report**
  Assessment detects three possible PML/RARA isoforms, bcr1 (long), bcr2 (intermediate) and bcr3 (short)

Ordering Information

Get started (non-HFHS): Print a Molecular Hematologic Testing requisition form online at www.HenryFord.com/HFCPD

Get started (HFHS): Order through Epic using test "PML/RARA t(15;17)" (MOL80371 Blood, MOL80372 Bone Marrow)

Specimen requirements:

- Peripheral Blood - 3ml in lavender top tube (EDTA) **Specimen stability: Ambient - 72 hours; Refrigerated - 1 week, PAXgene tube (RNA stabilization) for up to 48 hours room temp or longer periods cold**
- Bone Marrow - 1-3ml, anticoagulated with either heparin or EDTA, **Specimen stability: Refrigerated - 1 week** (ship cold)
- Extracted RNA or cDNA - from a CLIA-certified Laboratory

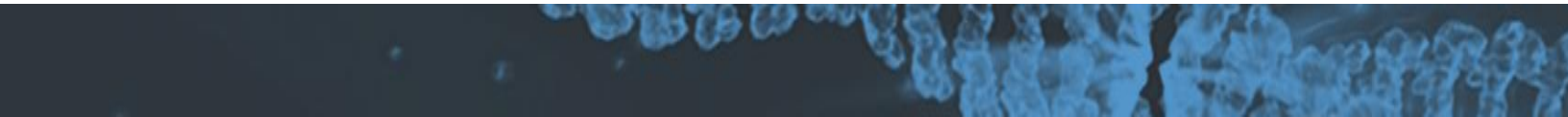
Cause for Rejection: Clotted, hemolyzed, or frozen specimens, improper anticoagulant, tubes not labeled with dual patient identification, non-dedicated tubes.

TAT: 5-7 business days (after Prior Authorization obtained)

Mail test material to:
Henry Ford Center for Precision Diagnostics
Pathology and Laboratory Medicine
Clinic Building, K6, Core Lab, E-655
2799 W. Grand Blvd., Detroit, MI 48202

CPT Codes: 81305, G0452

Contact us: Client Services, Account and Billing Set-up, and connect with a Molecular Pathologist at (313) 916-4DNA (4362)

For more information on Comprehensive Molecular Services, visit our website www.HenryFord.com/HFCPD

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