ARUP LABORATORIES | aruplab.com
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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

PATIENT REPORT

Patient Age/Sex: [redacted] years Male

Specimen Collected: 1/30/2025 08:06 MST

X-PML::RARA Detection by RT-PCR, Quant | **Received: 1/30/2025 08:07 MST** | **Report/Verified: 1/30/2025 09:52 MST**

Procedure	Result	Units	Reference Interval
PML::RARA Translocation,Source	Whole Blood		
PML::RARA Translocation,Result	**Detected** * f1 i1		
PML::RARA Translocation,NCN	1.2345		

Result Footnote

f1: PML::RARA Translocation, Result

Please note that the method of transcript quantitation at ARUP Laboratories has been updated as of 3/4/2025, and this differs from that previously reported in send-out testing to Quest Diagnostics. A conversion factor of 10,000 is suggested when comparing the results. For example, a PML::RARA transcript NCN of 0.1 at ARUP Laboratories corresponds approximately to PML::RARA NCN of 1,000 reported by Quest Diagnostics.

PML::RARA fusion transcripts were detected by RT-PCR. This indicates the presence of t(15;17) positive cells in the sample. Use of the same assay is recommended for monitoring and comparison of quantitative results over time.

This result has been reviewed and approved by [redacted]

Test Information

i1: PML::RARA Translocation, Result

BACKGROUND INFORMATION: PML::RARA Translocation

This test is designed to detect t(15;17) PML::RARA, a recurrent genetic abnormality found in a subset of patients with acute myeloid leukemia. This test detects all three gene fusion patterns: type A (short, S-form, bcr-3), type B (long, L-form, bcr-1), and type B variant (variable, V-form, bcr-2).

Methodology:
Patient RNA is isolated, reverse transcribed into cDNA, and amplified using primers specific for the PML and RARA genes. Real time PCR is then performed to detect t(15;17). PML::RARA and ABL (control) transcripts are quantified. Results are reported as a normalized copy number (NCN) of PML::RARA fusion transcripts to ABL transcripts present in the sample.

Limitations:
Translocations involving other genes or gene partners and uncommon alternative transcripts will not be detected.

Limit of detection for this test is 1 in 10,000 cells. Limit of quantitation is greater than or equal to 0.0005 NCN.

Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data, and should not be used alone for a diagnosis of malignancy.

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This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.