Test Definition: APLDF

Acute Promyelocytic Leukemia-PML::RARA fusion, Expedited Diagnostic FISH, Varies

Reporting Title: APL - PML::RARA fusion, FISH, BL/BM
Performing Location: Rochester

Ordering Guidance:

This test is intended for diagnostic samples only when PML::RARA fusion is presumed and targeted PML and RARA fluorescence in situ hybridization (FISH) probes are needed to diagnose acute promyelocytic leukemia (APL).

Complete acute myeloid leukemia (AML) diagnostic FISH panel tests for adults and pediatric patients are also available. AML panel tests will be automatically prioritized by the laboratory when PML::RARA fusion is present. Most often, AML panel tests found with PML::RARA fusion will be reported the next business day from receipt in the Genomics laboratory. Same day testing is not available for panel testing. If panel testing is warranted, order either AMLFA / Adult Acute Myeloid Leukemia Panel, FISH, Varies or AMLFP / Pediatric Acute Myeloid Leukemia Panel, FISH, Varies, as appropriate based on patient age.

This test should not be used to screen for residual AML or when the diagnosis of APL is not strongly suggested. Monitoring patients known to have PML::RARA fusion should be performed by quantitative reverse transcription-polymerase chain reaction (RT-PCR) testing and not FISH testing. If the specimen does not meet the criteria for RT-PCR, follow-up FISH testing for PML::RARA fusion should be ordered as AMLMF / Acute Myeloid Leukemia (AML), Specified FISH, Varies with a PML/RARA specific probe request.

If this test is received in the laboratory concurrently with an order for either AMLFA / Adult Acute Myeloid Leukemia Panel, FISH, Varies or AMLFP / Pediatric Acute Myeloid Leukemia Panel, FISH, Varies, panel testing will be held pending the results of this test. Ordering an AML panel test concurrently with this test will result in an approximate 1 business day delay of the panel test reporting. If PML::RARA fusion is detected, the AMLFA or AMLFP panel test will be cancelled by the laboratory. If no fusion is identified, the complete AML FISH panel test will be performed, except for the PML/RARA FISH probe set.

If the entire AML FISH panel is preferred for an adult patient (aged 31 years or older), order AMLFA / Adult Acute Myeloid Leukemia panel, FISH, Varies.

If the entire AML FISH panel is preferred for a pediatric patient (aged 30 years or younger), order AMLFP / Pediatric Acute Myeloid Leukemia panel, FISH, Varies.

If upfront break-apart RARA FISH testing is desired, order AMLMF / Acute Myeloid Leukemia (AML), Specified FISH, Varies. Results will be reported the next business day.

For more information see Acute Promyelocytic Leukemia: Guideline to Diagnosis and Follow-up

Additional Testing Requirements:

At diagnosis, PMLR / PML::RARA Quantitative, PCR, Varies should be performed in parallel with this test.
At follow-up, only PMLR / PML::RARA Quantitative, PCR, Varies should be performed.

Shipping Instructions:

Advise Express Mail or equivalent if not on courier service.

Necessary Information:
1. A reason for testing must be provided. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.
2. A flow cytometry and/or a bone marrow pathology report should be submitted with each specimen. The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be compromised or delayed.
3. If a result callback by phone is needed after finalized results are released, the ordering healthcare professional must supply the name and direct phone number of a licensed physician (MD or DO) at the time the order is received.
-Result callbacks are only available during regular business hours.
-Preliminary results or exact times the finalized report will be available will not be provided under any circumstances.

Specimen Requirements:
Submit only 1 of the following specimens:

Preferred
Specimen Type: Bone marrow
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin) or lavender top (EDTA)
Specimen Volume: 2 to 3 mL
Collection Instructions:
1. It is preferable to send the first aspirate from the bone marrow collection.
2. Invert several times to mix bone marrow.
3. Send bone marrow in original tube. Do not aliquot.

Acceptable
Specimen Type: Whole blood
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin) or lavender top (EDTA)
Specimen Volume: 6 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send whole blood in original tube. Do not aliquot.

Specimen Minimum Volume:
Bone marrow: 1 mL; Whole blood: 2 mL

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
APLDF	GC168	Reason for Referral	Plain Text	Yes
APLDF	GC169	Specimen: • Whole blood ACD • Bone marrow ACD • Whole blood Na Hep • Bone marrow Na Hep • Whole blood EDTA • Bone marrow EDTA	Answer List	Yes

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
622914	Result Summary	Alphanumeric		50397-9
622915	Interpretation	Alphanumeric		77031-3
622916	Result Table	Alphanumeric		93356-4
622917	Result	Alphanumeric		62356-1
GC168	Reason for Referral	Alphanumeric		42349-1
GC169	Specimen	Alphanumeric		31208-2
622918	Source	Alphanumeric		31208-2
622919	Method	Alphanumeric		85069-3
622920	Additional Information	Alphanumeric		48767-8
622921	Disclaimer	Alphanumeric		62364-5
622922	Released By	Alphanumeric		18771-6

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:
No

CPT Code Information:

88271x2, 88275x1, 88291x1- FISH Probe, Analysis, Interpretation; 1 probe set
88271x2, 88275x1-FISH Probe, Analysis; each additional probe set (if appropriate)

Reflex Tests:

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
APLDB	Probe, Each Additional (APLDF)	2 1	88271 88275	No	No (Bill Only)

Reference Values:

An interpretive report will be provided