MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 9, 2021
Effective Date: December 13, 2021

Acute Myeloid Leukemia (AML), FISH, Adult, Varies

Test ID: AMLAF

Useful for:

Detecting a neoplastic clone associated with recurrent chromosome abnormalities seen in adult patients with acute myeloid leukemia (AML) or other myeloid malignancies

An adjunct to conventional chromosome studies in patients with AML

Evaluating specimens in which standard cytogenetic analysis is unsuccessful

Testing Algorithm:

This test includes a charge for the probe application, analysis, and professional interpretation of results for 4 probe sets (8 individual fluorescence in situ hybridization [FISH] probes). Additional charges will be incurred for all reflex or additional probe sets performed.

The initial panel includes testing for the following abnormalities using the probes listed:

inv(16), [M4, Eos], MYH11/CBFB
t(8;21), [M2], RUNX1T1/RUNX1
t(15;17), [M3], PML/RARA
11q23 rearrangement, [M0-M7], MLL (KMT2A)

Based on the results from the initial panel, if testing was ordered concurrently with a chromosomal study (CHRBM / Chromosome Analysis, Hematologic Disorders, Bone Marrow or CHRHB / Chromosome Analysis, Hematologic Disorders, Blood), testing will be held pending the results of the chromosome test. If the chromosome results are complete and informative, only appropriate secondary FISH probes will be selected and performed. If testing was NOT ordered concurrently with a chromosomal study each of the secondary probes will be performed. The secondary panel includes testing for the following abnormalities using the probes listed:

t(6;9), [M2,M4], DEK/NUP214
inv(3) or t(3;3), [M1,2,4,6,7], RPN1/MECOM
-5/5q-, D5S630/EGR1
-7/7q-, D7Z1/D7S486
17p-, TP53/D17Z1
t(9;22), ABL1/BCR

When an MLL (KMT2A) rearrangement is identified, reflex testing will be performed to identify the translocation partner. Probes include identification of t(4;11)(q21;q23) AFF1/MLL, t(6;11)(q27;q23) MLLT4(AFDN)/MLL, t(9;11)(p22;q23) MLLT3/MLL, t(10;11)(p12;q23) MLLT10/MLL, t(11;16)(q23;p13.3) MLL/CREBBP, t(11;19)(q23;p13.1) MLL/ELL or t(11;19)(q23;p13.3) MLL/MLLT1.

In the absence of RPN1/MECOM and RUNX1/RUNX1T1 fusion, when an extra MECOM signal and an extra RUNX1 signal are identified, reflex testing using the MECOM/RUNX1 probe set will be performed to identify a potential t(3;21)(q26.2;q22) rearrangement.

In the absence of RPN1/MECOM fusion, when an extra RPN1 signal is identified, reflex testing using the PRDM16/RPN1 probe set will be considered to identify a potential t(1;3)(p36;q21).

In the absence of MYH11/CBFB fusion, when an extra CBFB signal is identified, reflex testing will be performed using the CBFB break-apart probe set to evaluate for the presence or absence of an CBFB rearrangement.

In the absence of PML/RARA fusion, when an extra or atypical RARA signal is identified, testing using the 5'RARA/3'RARA rearrangement probe set will be performed to identify a potential variant translocation involving RARA. example: t(17;var)(q21;?).

In the absence of BCR/ABL1 fusion, when an extra ABL1 signal is identified, reflex testing will be performed using the ABL1 break-apart probe set to evaluate for the presence or absence of an ABL1 rearrangement.

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
AMLAB	Probe, Each Additional (AMLAF)	No (Bill Only)	No

Methods:

Fluorescence In Situ Hybridization (FISH)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

Preferred Specimen Type: Bone marrow

Preferred Container/Tube: Yellow top (ACD)

Acceptable Container/Tube: Green top (heparin) or lavender top (EDTA)

Specimen Volume: 2-3 mL

Minimum Volume: 1 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.

Acceptable Specimen Type: Blood

Preferred Container/Tube: Yellow top (ACD)

Acceptable Container/Tube: Green top (heparin) or lavender top (EDTA)

Specimen Volume: 6 mL

Minimum Volume: 2 mL

Collection Instructions:

1. Invert several times to mix blood.

Note:

A reason for testing and a flow cytometry and/or a bone marrow pathology report (if available) 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. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Refrigerated	

Cautions:

This test is not approved by the US Food and Drug Administration, and it is best used as an adjunct to existing clinical and pathologic information.

Fluorescence in situ hybridization (FISH) is not a substitute for conventional chromosome studies because the latter detects many chromosome abnormalities associated with other hematological disorders that would be missed by this FISH panel test.

Bone marrow is the preferred specimen type for this FISH test. If bone marrow is not available, a blood specimen may be used if there are malignant cells in the blood specimen (as verified by a hematopathologist).

CPT Code:

88271 x8, 88275 x4, 88291 x1- FISH Probe, Analysis, Interpretation; 4 probe sets

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

Day(s) Performed: Monday through Friday **Report Available:** 7 to 10 days

Questions

Contact Joshua Couchene Laboratory Technologist Resource Coordinator at 800-533-1710.