Test Definition: MSTF

Myeloid Sarcoma, FISH, Tissue

Overview

Useful For

Detecting, at diagnosis, recurrent common chromosome abnormalities associated with acute myeloid leukemia (AML)/myeloid sarcomas in paraffin-embedded specimens

Monitoring response to therapy by tracking known chromosome abnormalities in patients with AML or myeloid sarcoma

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
_I099	Interphases, 25-99	No, (Bill Only)	No
_I300	Interphases, >=100	No, (Bill Only)	No
_IL25	Interphases, <25	No, (Bill Only)	No
_PADD	Probe, +1	No, (Bill Only)	No
_PB02	Probe, +2	No, (Bill Only)	No
_PB03	Probe, +3	No, (Bill Only)	No
_PBCT	Probe, +2	No, (Bill Only)	No

Testing Algorithm

This test includes a charge for the probe application, analysis, and professional interpretation of results for one probe set (2 individual fluorescence in situ hybridization [FISH] probes). Additional charges will be incurred for all reflex or additional probe sets performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

This test may be ordered in 2 distinct ways allowing different combinations of probes to be analyzed based on the clinical question.
1. Standard (**diagnostic**) acute myeloid leukemia (AML)/myeloid sarcoma paraffin-embedded FISH panel
2. Individual AML/myeloid sarcoma paraffin-embedded FISH probes chosen, per **client request**, from probes listed below

If individual FISH probes are needed, the specific probes requested must be noted on the request form or in the reason for referral. If no FISH probes are indicated, the standard (diagnostic) panel will be performed.

The standard (**diagnostic**) panel includes testing for the following abnormalities, using the FISH probes listed:
t(8;21)(q21.3;q22) or *RUNX1::RUNX1T1* fusion, RUNX1T1/RUNX1 probe set
t(9;22)(q34;q11.2) or *BCR::ABL1* fusion, ABL1/BCR probe set
t(11q23;var) or *KMT2A* rearrangement, KMT2A break-apart probe set
t(15;17)(q24;q21) or *PML::RARA* fusion, PML/RARA probe set
inv(16) or t(16;16) or *CBFB::MYH11* fusion, MYH11/CBFB probe set

Appropriate ancillary probes may be performed at consultant discretion to render comprehensive assessment. Any additional probes will have the results included within the final report and will be performed at an additional charge.

Method Name
Fluorescence In Situ Hybridization (FISH)

NY State Available
Yes

Specimen

Specimen Type
Tissue

Ordering Guidance
This test does not include a pathology consultation. If a pathology consultation is requested, order PATHC / Pathology Consultation, and appropriate testing will be added at the discretion of the pathologist and performed at an additional charge.

Mayo Clinic Hematopathology consultants are involved in both the pre-analytic (tissue adequacy and probe selection, when applicable).

This test is **not appropriate** for testing blood and bone marrow from patients with acute myeloid leukemia/myeloid sarcoma. If a non-paraffin embedded bone marrow or blood sample is received for this test, the test will be canceled and automatically reordered by the laboratory as AMLFA / Adult Acute Myeloid Leukemia Panel, FISH, Varies or AMLFP / Pediatric Acute Myeloid Leukemia Panel, FISH, Varies depending on the age of the patient.

Shipping Instructions
Advise Express Mail or equivalent if not on courier service.

Necessary Information
1. A pathology report is required for testing to be performed. If not provided, appropriate testing and/or interpretation may be compromised or delayed. Acceptable pathology reports include working drafts, preliminary pathology, or surgical pathology reports.
2. The following information must be included in the report provided:
-Patient name
-Block number - must be on all blocks, slides, and paperwork
-Date of collection
-Tissue source
3. 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.
4. A list of probes is required if select probes are necessary or if the patient is being tracked for known abnormalities. See Table in Clinical Information.

Specimen Required
Submit only 1 of the following specimens:

Preferred
Specimen Type: Tissue block (fresh tissue is **not acceptable**)
Collection Instructions:
1. Submit a formalin-fixed, paraffin-embedded tumor tissue block.
2. Blocks prepared with alternative fixation methods (eg, Prefer, Bouin's) will be attempted but are less favorable for successful results. Provide fixation method used.
Additional Information:
1. Paraffin-embedded specimens can be from any anatomic location (skin, soft tissue, lymph node, etc).
2. Decalcified paraffin-embedded specimens will have testing attempted; however, the success rate is approximately 50%. **Testing may be canceled** if sufficient tumor tissue is not present.
3. **Submitted fresh tissue specimens will be canceled upon receipt**. If only fresh tissue is available, embed in paraffin prior to sending.

Acceptable
Specimen Type: Tissue slides
Slides: 1 Hematoxylin and eosin-stained and 2 unstained for each probe set
Collection Instructions:
1. Include 1 hematoxylin and eosin-stained slide for the entire test order.
2. If individual probe sets are chosen: For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides.
3. If a complete myeloid sarcoma FISH panel is ordered, include 10 consecutive, unstained, 5 micron-thick sections placed on positively charged slides.
Additional Information: Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

Forms

If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Myeloid sarcomas are tumors made up of myeloblasts or immature myeloid cells that occur in extramedullary sites or in bone. They can occur concurrently with acute or chronic myeloid leukemia (AML or CML) or may precede the leukemia or other myeloid neoplasms. They may also be the initial manifestation of relapse of a previously treated primary AML in remission. Due to this extramedullary presentation, the bone marrow may have a low number of myeloblasts due to a lack of bone marrow involvement.

The most common chromosome abnormalities associated with myeloid sarcomas include t(8;21), t(9;22), t(15;17), inv(16) or t(16;16), and rearrangements of the *KMT2A* gene at 11q23.

In general, AML patients with an inv(16), t(8;21), t(9;22), or t(15;17) have a favorable prognosis, while AML patients with a rearrangement of t(11q23) have an unfavorable prognosis. Thus, the detection of these abnormalities in an extramedullary presentation of AML can be prognostically important.

Reference Values

An interpretive report will be provided.

Interpretation

A neoplastic clone is detected when the percent of cells with an abnormality exceeds the normal reference range for a given probe set.

A positive result is not diagnostic for myeloid sarcoma but may provide relevant prognostic information.

A negative result does not rule out the presence of a neoplastic disorder.

Cautions

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

This fluorescence in situ hybridization (FISH) assay does not rule out other chromosome abnormalities.

Fixatives other than formalin (eg, Prefer, Bouin's) may not be successful for FISH assays. Non-formalin fixed specimens will not be rejected.

Paraffin-embedded tissues that have been decalcified may not be successful for FISH analysis. The success rate of FISH studies on decalcified tissue is approximately 50%, but FISH will be attempted if sufficient tumor is present for analysis.

Fluorescence in situ hybridization studies will be attempted if sufficient tumor is present for analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing if insufficient tissue/tumor is available for testing.

If no FISH signals or a lack of sufficient tumor tissue are observed post-hybridization, the case will be released indicating a lack of FISH results.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

Clinical Reference

1. Slovak ML, Kopecky KJ, Cassileth PA, et al. Karyotypic analysis predicts outcome of preremission and postremission therapy in adult acute myeloid leukemia: a Southwest Oncology Group/Eastern Cooperative Oncology Group Study. Blood. 2000;96(13):4075-4083
2. Swerdlow SH, Campo E, Harris NL, et al, eds. WHO Classification of Tumour of Haematopoietic and Lymphoid Tissues. 4th ed. IARC Press; 2017
3. Grimwade D, Hills RK, Moorman AV, et al. Refinement of cytogenetic classification in acute myeloid leukemia: determination of prognostic significance of rare recurring chromosomal abnormalities among 5876 younger adult patients treated in the United Kingdom Medical Research Council trials. Blood. 2010;116(3):354-365

Performance

Method Description

This test is performed using commercially available and laboratory-developed fluorescence in situ hybridization (FISH) probes. Rearrangements involving *KMT2A* are detected using a dual-color break-apart strategy probe set. Dual-color, dual-fusion FISH (D-FISH) strategy probe sets are used to detect t(8;21), t(9;22), t(15;17), inv(16) or t(16;16).

Paraffin-embedded tissue samples are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the identification of target areas on the hematoxylin and eosin (H and E)-stained slide are performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped engraving tool on the back of the unstained slide to be assayed. Each probe set is hybridized to the appropriate target areas, as indicated on the H and E, and 100 interphase nuclei are scored within the targeted areas. The results are expressed as the percent of abnormal nuclei.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

7 to 10 days

Specimen Retention Time

Slides used for analysis are retained by the laboratory in accordance with regulatory requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88291
88271 x 2 (if appropriate)
88271 x 2 (if appropriate)
88271 (if appropriate)
88271 x 2 (if appropriate)
88271 x 3 (if appropriate)
88274 w/modifier 52 (if appropriate)
88274 (if appropriate)
88275 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MSTF	Myeloid Sarcoma, FISH, Ts	In Process

Result ID	Test Result Name	Result LOINC® Value
52084	Result Summary	50397-9
52086	Interpretation	69965-2
52085	Result Table	93356-4
54576	Result	62356-1
CG735	Reason for Referral	42349-1
CG736	Specimen	31208-2

52087	Source	31208-2
52088	Tissue ID	80398-1
52089	Method	85069-3
52090	Released By	18771-6
55121	Additional Information	48767-8
53839	Disclaimer	62364-5