MAYO CLINIC LABORATORIES

Test Definition: IMTF

Inflammatory Myofibroblastic Tumors (IMT), 2p23 (ALK) Rearrangement, FISH, Tissue

Overview

Useful For

Supporting the diagnosis of inflammatory myofibroblastic tumor when used in conjunction with an anatomic pathology consultation

Reflex Tests

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

Testing Algorithm

This test does not include a pathology consult. If a pathology consultation is requested, PATHC / Pathology Consultation should be ordered and the appropriate FISH test will be ordered and performed at an additional charge.

This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results.

Additional charges will be incurred for all reflex probes 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.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

Necessary Information

1. A pathology report is required in order for testing to be performed. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.
2. 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.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue
Preferred: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides
Collection Instructions: Four consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Forms

If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume

Two consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Inflammatory myofibroblastic tumor (IMT) is a distinctive lesion composed of myofibroblastic spindle cells accompanied by an inflammatory infiltrate of plasma cells, lymphocytes, and eosinophils which occur primarily in the soft tissue and viscera of children and young adults. They may arise in any anatomical site including lung, soft tissue, retroperitoneum, and bladder.

The genetic mechanisms underlying IMT pathogenesis are only partially known, but cytogenetic analyses have disclosed

chromosomal rearrangements involving the *ALK* gene at 2p23. Studies support that identification of *ALK* gene rearrangement is useful to differentiate IMTs from other spindle cell neoplasms of soft tissue and viscera.

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 cutoff for the *ALK* probe set.

A positive result is consistent with a subset of inflammatory myofibroblastic tumor (IMT).

A negative result suggests that an *ALK* gene rearrangement is not present but does not exclude the diagnosis of IMT.

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

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

Paraffin-embedded tissues that have been decalcified are generally unsuccessful for FISH analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

Supportive Data
FISH analysis was performed on 76 formalin-fixed, paraffin-embedded tissue samples. These included 26 inflammatory myofibroblastic tumors (IMT) (21 bladder and 5 soft tissue), 33 non-IMT spindle tumors, and 50 noncancerous control specimens (25 bladder and 25 soft tissue). The normal controls were used to generate a normal cutoff for this assay. Rearrangement of *ALK* was identified in 18 of 26 IMT specimens. Immunohistochemical staining confirmed these were negative for ALK-1. The remaining spindle cell tumors were also negative for *ALK* rearrangement and ALK-1 staining.

Clinical Reference
1. Coffin CM, Fletcher JA: Chapter II: Inflammatory myofibroblastic tumour. In World Health Organization Classification of Tumors. Pathology and Genetics of Tumours of Soft Tissue and Bone. Edited by CDM Fletcher, KK Unni, F Mertens. Lyon, IARC Press, 2002, pp 91-93
2. Sukov WR, Cheville JC, Carlson AW: Utility of ALK-1 protein expression and *ALK* rearrangements in distinguishing inflammatory myofibroblastic tumor from malignant spindle cell lesions of the urinary bladder. Mod Pathol 2007 May;20(5):592-603
3. Tsuzuki T, Magi-Galluzzi C, Epstein JI: ALK-1 expression in inflammatory myofibroblastic tumor of the urinary bladder. Am J Surg Pathol 2004;28:1609-1614
4. Li XQ, Hisaoka M, Shi DR: Expression of anaplastic lymphoma kinase in soft tissue tumors: an immunohistochemical and molecular study of 249 cases. Hum Pathol 2004 Jun;35(6):711-721
5. Griffin CA, Hawkins AL, Dvorak C, et al: Recurrent involvement of 2p23 in inflammatory myofibroblastic tumours. Cancer Res 1999;59:2776-2780

Performance

Method Description

The test is performed using a commercially available *ALK* dual-color break-apart strategy probe (BAP). Formalin-fixed, paraffin-embedded tissues 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 is performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. The probe set is hybridized to the appropriate target areas and 2 technologists each analyze 50 interphase nuclei (100 total) with the results expressed as the percent of abnormal nuclei.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

7 to 10 days

Specimen Retention Time

Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location

Rochester

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

88271x2, 88291-DNA probe, each (first probe set), Interpretation and report

88271x2-DNA probe, each; each additional probe set (if appropriate)
88271x1-DNA probe, each; coverage for sets containing 3 probes (if appropriate)
88271x2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)
88271x3-DNA probe, each; coverage for sets containing 5 probes (if appropriate)
88274 w/modifier 52-Interphase in situ hybridization, <25 cells, each probe set (if appropriate)
88274-Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
IMTF	ALK, (2p23), IMT, FISH, Ts	78205-2

Result ID	Test Result Name	Result LOINC® Value
52171	Result Summary	50397-9
52173	Interpretation	69965-2
54587	Result	62356-1
CG747	Reason for Referral	42349-1
52174	Specimen	31208-2
52175	Source	31208-2
52176	Tissue ID	80398-1
52177	Method	85069-3
55029	Additional Information	48767-8
52178	Released By	18771-6
53828	Disclaimer	62364-5