Overview

Useful For
Supporting the diagnosis of low-grade fibromyxoid sarcoma when used in conjunction with an anatomic pathology consultation

Reflex Tests

<table>
<thead>
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<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
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</table>

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 application of 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.

See the Method Description for specific details.

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
A reason for referral and pathology report are required in order for testing to be performed. Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology.
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 by Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

<table>
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<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Tissue</td>
<td>Ambient (preferred)</td>
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<td></td>
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<tr>
<td></td>
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Clinical and Interpretive

Clinical Information
Low-grade fibromyxoid sarcoma (LGFMS) is a rare malignant soft tissue tumor characterized by a bland fibroblastic spindle cell proliferation arranged in alternating fibrous and myxoid areas, with or without giant collagen rosettes. These tumors are characterized by the chromosome translocation t(7;16)(q33-34;p11), which results in the fusion of FUS (also called TLS) on chromosome 16 to CREB3L2 (also called BBF2H7) on chromosome 7. Greater than 70% of LGFMS are cytogenetically characterized by this translocation. In rare cases, a variant t(11;16)(p11;p11) has been described in which FUS is fused to CREB3L1 (OASIS), a gene structurally related to CREB3L2. Testing of FUS locus rearrangement should be concomitant with histologic evaluation, and positive results may support the diagnosis of LGFMS.

Reference Values
Test Definition: FUSF
FUS (16p11.2), FISH, Ts

An interpretative report will be provided.

Interpretation
A neoplastic clone is detected when the percent of cells with an abnormality exceeds the normal cutoff for the FUS probe set.

A positive result is consistent with the diagnosis of low-grade fibromyxoid sarcoma (LGFMS).

A negative result suggests that a FUS gene rearrangement is not present, but does not exclude the diagnosis of LGFMS.

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.

Fixatives other than formalin (eg, Prefer, Bouin) 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 47 formalin-fixed, paraffin-embedded tissue samples including 13 low-grade fibromyxoid sarcoma (LGFMS) tumors, 8 histologic mimics of LGFMS, and 26 noncancerous control specimens. The normal controls were used to generate a normal cutoff for this assay. Rearrangement of FUS was identified in 8 of 13 (62%) LGFMS specimens.

Clinical Reference
1. Fletcher CDM, Unni K, Mertens F: World Health Organization Classification of Tumours. Pathology and Genetics of Tumours of Soft Tissue and Bone. IARC: Lyon 2002, pp 104-105

Performance
Method Description
This test is performed using a commercially available FUS 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) and Time(s) Test Performed**

Samples processed Monday through Sunday.

Results reported Monday through Friday: 8 a.m.-5 p.m.

**Analytic Time**

7 days

**Maximum Laboratory Time**

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 and 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 Regional Manager. 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 U.S. Food and Drug Administration.

**CPT Code Information**

88271x2, 88291  Açä–åèœ DNA probe, each (first probe set), Interpretation and report

88271x2  Açä–åèœ DNA probe, each; each additional probe set (if appropriate)

88271x1  Açä–åèœ DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2  Açä–åèœ DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3  Açä–åèœ DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52  Açä–åèœ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274  Açä–åèœ Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)
Test Definition: FUSF
FUS (16p11.2), FISH, Ts

Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

**LOINC® Information**

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