Test Definition: MAMLF

MAML2 (11q21), FISH, Ts

Overview

Useful For

Supporting a diagnosis of mucoepidermoid carcinoma

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,	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 consultation. 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.

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

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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

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 reports.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Container/Tube: Formalin-fixed, paraffin-embedded (FFPE) tumor tissue block.

Collection Instructions: Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides

Specimen Volume: 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 and Interpretive

Clinical Information

Mucoepidermoid carcinoma (MEC) is the most common malignant salivary gland neoplasm, representing over 30% of all malignant salivary gland tumors. The diagnosis of MEC can be quite challenging due to the degree of histologic overlap with other glandular, clear cell, or oncocytic salivary gland tumors. *MAML2* rearrangements are detectable in 80% to 85% of MEC, but not in morphologic mimics such as oncocytic cystadenoma, Warthin tumor, oncocytoma, oncocytic carcinoma, acinic cell carcinoma, and metastatic renal cell carcinoma.

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 *MAML2* probe.

A positive result is consistent with a diagnosis of mucoepidermoid carcinoma (MEC).

A negative result suggests no rearrangement of the *MAML2* gene region at 11q21. However, this result does not exclude the diagnosis of MEC.

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 28 mucoepidermoid carcinoma (MEC) formalin-fixed paraffin-embedded tissue samples and 51 control specimens. The normal controls were used to generate a normal cutoff for this assay. A rearrangement of *MAML2* was identified in 26 of 28 (93%) MEC cases.

Clinical Reference

1. Stewart FW, Foote FW, Becker WF: Mucoepidermoid tumors of salivary glands. Ann Surg 1945;122:820-844

2. Spiro RH, Huvos AG, Berk R, Strong EW: Mucoepidermoid carcinoma of salivary gland origin. A clinicopathologic study of 367 cases. Am J Surg 1978;136:461-468

3. Seethala RR, Dacic S, Cieply K, et al: A reappraisal of the MECT1/MAML2 translocation in salivary mucoepidermoid carcinomas. Am J Surg Pathol 2010 Aug;34(8):1106-1121

4. Behboudi A, Enlund F, Winnes M, et al: Molecular classification of mucoepidermoid carcinomas-prognostic significance of the MECT1-MAML2 fusion oncogene. Genes Chromosomes Cancer 2006 May;45(5):470-481

Performance

Method Description

The test is performed using a laboratory-developed *MAML2* (11q21) 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. CST.

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 and its performance characteristics 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 Ã¢â‚¬â€œ DNA probe, each (first probe set), Interpretation and report

88271x2 Ã¢â‚¬â€œ DNA probe, each; each additional probe set (if appropriate)

88271x1 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52 Ã¢â‚¬â€œ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274 Ã¢â‚¬â€œ Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275 Ã¢â‚¬â€œ Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
MAMLF	MAML2 (11q21), FISH, Ts	74034-0

Test Definition: MAMLF

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Result ID	Test Result Name	Result LOINC Value
54689	Result Summary	50397-9
54692	Interpretation	69965-2
54691	Result	62356-1
CG930	Reason For Referral	42349-1
54918	Specimen	31208-2
54694	Source	31208-2
54695	Tissue ID	80398-1
55136	Method	49549-9
55137	Additional Information	48767-8
53394	Disclaimer	62364-5
54696	Released By	18771-6