Overview

Useful For
Assessing for MYB gene rearrangements in patients with primary salivary gland carcinoma to aid in confirming or excluding the diagnosis of primary salivary gland adenoid cystic carcinomas

Reflex Tests

<table>
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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 consultation. If a pathology consult 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
A reason for referral and pathology report are required in order for testing to be performed.
Test Definition: SGTF
MYB (6q23), FISH, Ts

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

**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 positive-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**

<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>
<td>Refrigerated</td>
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**Clinical and Interpretive**

**Clinical Information**
Salivary adenoid cystic carcinomas (ACC), although uncommon, are frequent among salivary gland malignancies. ACC is typically an aggressive tumor with a poor prognosis. Histologically, ACC show significant morphologic overlap with other salivary gland tumors, but have a much different clinical course. Because ACC requires a management distinct from histologically similar lesions, it is important to make an accurate diagnosis. Translocations between MYB (6q23.3) and NFIB (9p24) have been identified in a large proportion of primary salivary gland ACC. These alterations have not been identified in other salivary gland tumors. Therefore, separation of MYB, in the proper clinical and histologic context, is diagnostic for ACC and can be confirmed by FISH with MYB break-apart probes.

**Reference Values**
An interpretive report will be provided.
Test Definition: SGTF
MYB (6q23), FISH, Ts

Interpretation
A positive result is detected when the percent of cells with an abnormality exceeds the normal cutoff for the probe set.

A positive result suggests rearrangement of the MYB locus. The presence of a MYB rearrangement in conjunction with the proper clinical and histologic features is diagnostic of adenoid cystic carcinomas (ACC). A confirmed diagnosis of ACC results in specific clinical management that may be distinct from the management of other salivary gland neoplasms.

A negative result suggests no rearrangement of the MYB gene region at 6q23.3. The absence of a MYB rearrangement does not exclude the diagnosis of ACC, as a subset of ACCs do not show an MYB rearrangement.

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.

This test is only intended to be used in the diagnosis of salivary gland tumors. This test has not been validated on adenoid cystic carcinoma (ACC) arising from nonsalivary gland locations. The results of this test are intended to be interpreted in association with the pathologic and clinical findings. The absence of MYB rearrangement does not exclude the diagnosis of ACC.

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
The probe was independently validated in a blinded study on 48 paraffin-embedded adenoid cystic carcinoma tissue specimens and 25 noncancerous control specimens. The normal controls were used to generate a normal cutoff for this assay.

Clinical Reference

Performance

Method Description
This test is performed using a laboratory-developed MYB dual-color break-apart strategy probe (BAP). 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 are 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 is hybridized to the appropriate target areas and 2 technologists each analyze 50 interphase nuclei (100 total) with the results expressed as the percent abnormal nuclei.(Unpublished Mayo method)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Specimens are processed Monday through Sunday.

Results reported Monday through Friday, 8 a.m. to 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 Ąćą,ńåèœ DNA probe, each (first probe set), Interpretation and report

88271x2 Ąćą,ńåèœ DNA probe, each; each additional probe set (if appropriate)

88271x1 Ąćą,ńåèœ DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2 Ąćą,ńåèœ DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3 Ąćą,ńåèœ DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52 Ąćą,ńåèœ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)
Test Definition: SGTF
MYB (6q23), FISH, Ts

88274 ꞏInterphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275 ꞏInterphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

### LOINC® Information

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