Overview

Useful For
Providing diagnostic information and guiding treatment primarily for patients with mammary analogue secretory carcinoma, secretory carcinoma of the breast, and infantile fibrosarcoma

Reflex Tests

<table>
<thead>
<tr>
<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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<tr>
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<td>Interphases, 25-99</td>
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<tr>
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<td>Interphases, &gt;=100</td>
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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
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

**Container/Tube:** Formalin-fixed, paraffin-embedded tumor tissue block

**Specimen Type:** 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**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Tissue</td>
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<td></td>
<td>Refrigerated</td>
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**Clinical and Interpretive**

**Clinical Information**

*ETV6* rearrangement is a recurrent abnormality in mammary analogue secretory carcinoma, secretory carcinoma of the breast, and infantile fibrosarcoma, but is not observed in tumors that share clinical and pathologic similarities.

**Reference Values**

An interpretive report will be provided.

**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 *ETV6* locus, which can be useful for diagnosis. A negative result suggests no rearrangement of the *ETV6* gene region at 12p13.2.

**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 36 paraffin-embedded tissue samples and 25 noncancerous lymph node control specimens. Rearrangement of *ETV6* was identified in 19 samples. The normal controls were used to generate a normal cutoff for this assay.

**Clinical Reference**


**Performance**

**Method Description**

The test is performed using a laboratory-developed *ETV6* (12p13.2) 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**
Test Definition: ETV6F
ETV6 (12p13.2), FISH, Ts

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

LOINC® Information

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