Overview

Useful For
Identifying TFEB gene rearrangements in patients with renal cell carcinoma (RCC)

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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<td>_PBCT</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: 4 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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<tr>
<td></td>
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Clinical and Interpretive

Clinical Information
The TFEB gene may be altered in some patients with renal cell carcinoma (RCC). Identification of rearrangement of the TFEB gene region by FISH analysis can aid in the diagnosis of RCC.

Reference Values
An interpretive report will be provided.

Interpretation
A positive result with the TFEB probe is detected when the percent of cells with an abnormality exceeds the normal cutoff for the probe set. A positive result of TFEB suggests promotor substitution caused by structural alterations of the TFEB gene region at 6p21.1. A negative result suggests no structural alterations of the locus.

Cautions
This test is not approved by the FDA and should be used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin) may not be successful for FISH assays. Although FISH testing will not be rejected due to nonformalin fixation, results may be compromised.
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 27 formalin-fixed paraffin-embedded specimens including 25 renal cell carcinoma (RCC) tissue samples, 2 RCC specimens from Johns Hopkins known positive for TFEB rearrangement, and 25 noncancerous control specimens. The normal controls were used to generate the normal cutoff values. Structural alterations resulting in the rearrangement of the TFEB gene region were identified and results correlated with pathology findings.

**Clinical Reference**


**Performance**

**Method Description**

This test uses a laboratory developed TFEB (6p21.1) dual-color break-apart probe (BAP) strategy. 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 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 probes are hybridized to the appropriate target areas and 2 technologists analyze each probe set. Using the TFEB probe set, each technologist analyzes 50 interphase nuclei (100 total) and the results are 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 and E used for analysis are retained by the laboratory. 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
88271 x 2, 88291-DNA probe, each (first probe set), Interpretation and report
88271 x 2-DNA probe, each; each additional probe set (if appropriate)
88271 x 1-DNA probe, each; coverage for sets containing 3 probes (if appropriate)
88271 x 2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)
88271 x 3-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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