Overview

Useful For
Identifying patients with chronic myelomonocytic leukemia and other hematologic disorders who may be responsive to imatinib mesylate

Identifying and tracking chromosome abnormalities and response to therapy

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>I300</td>
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Testing Algorithm
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.

Method Name
Fluorescence In Situ Hybridization (FISH)

NY State Available
Yes

Specimen

Specimen Type
Varies

Specimen Required
Provide a reason for referral with each specimen. The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be compromised or delayed.

Advise Express Mail or equivalent if not on courier service.

Submit only 1 of the following specimens:
Specimen Type: Blood

Container/Tube: Green top (sodium heparin)

Specimen Volume: 7-10 mL

Collection Instructions:
1. Invert several times to mix blood.
2. Other anticoagulants are not recommended and are harmful to the viability of the cells.

Specimen Type: Bone marrow

Container/Tube: Green top (sodium heparin)

Specimen Volume: 1-2 mL

Collection Instructions:
1. Invert several times to mix bone marrow.
2. Other anticoagulants are not recommended and are harmful to the viability of the cells.

Forms
If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

Specimen Minimum Volume
Blood: 2 mL
Bone Marrow: 1 mL

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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<tr>
<td>Varies</td>
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<td></td>
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Clinical and Interpretive

Clinical Information
Platelet-derived growth factor receptor-beta (PDGFRB) produces a tyrosine kinase involved in cell proliferation. Translocation-ets-leukemia protein (encoded by the gene ETV6) is a gene transcription protein that is frequently rearranged in leukemias. A 5;12 translocation, t(5;12)(q33;p13), results in a fusion product (PDGFRB/ETV6) that is
seen in approximately 1% to 2% of patients diagnosed with chronic myelomonocytic leukemia. Patients with this translocation often have associated hypereosinophilia.

Imatinib mesylate is an inhibitor of tyrosine kinases, including PDGFRB. Patients with the 5;12 translocation are reportedly responsive to imatinib mesylate; upon treatment, they usually go into complete remission.

**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.

The presence of a positive clone supports a diagnosis of malignancy.

The absence of an abnormal clone does not rule out the presence of neoplastic disorder.

**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.

**Supportive Data**
A blinded study using the PDGFRB/ETV6 dual-color, dual-fusion (D-FISH) strategy probe was performed on 12 samples from patients identified with a t(5;12) by chromosome analysis and a series of normal control specimens. Translocation of PDGFRB and ETV6 was identified in the neoplastic specimens but was not detected in any of the 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 PDGFRB/ETV6 dual-color, dual-fusion (D-FISH) strategy probe. The probe set is hybridized to the sample and 2 technologists each analyze 250 interphase nuclei (500 total) with the results expressed as the percent 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. to 5 p.m. CST.

**Analytic Time**
5 days

**Maximum Laboratory Time**
7 days
Specimen Retention Time
Four weeks

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 Ąćà,−ąćœ DNA probe, each (first probe set), Interpretation and report

88271x2 Ąćà,−ąćœ DNA probe, each; each additional probe set (if appropriate)

88271x1 Ąćà,−ąćœ DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2 Ąćà,−ąćœ DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3 Ąćà,−ąćœ DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52 Ąćà,−ąćœ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274 Ąćà,−ąćœ Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

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

LOINC® Information

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