Overview

Useful For
Supporting the diagnosis of plasmacytoma when coordinated with a surgical pathology consultation

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
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<tbody>
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<td>_I099</td>
<td>Interphases, 25-99</td>
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<td>_PBCT</td>
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</table>

Testing Algorithm

This test does not include a pathology consult. 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. Indicate if the entire panel is to be performed. If the patient is being tracked for known abnormalities, indicate which probes should be used.

Panel includes testing for the following abnormalities using the probes listed:

17p-, TP53/D17Z1
1q gain, TP73/1q22
t(14;16)(q32;q23), IGH/MAF
t(4;14)(p16.3;q32), FGFR3/IGH
8q24.1 rearrangement, MYC
-13/13q-, RB1/LAMP1
+9/+15, D9Z1/D15Z4
+3/+7, D3Z1/D7Z1
14q32 rearrangement, IGH
t(11;14), \textit{CCND1/IGH}

t(14;20)(q32;q12), \textit{IGH/MAFB}

t(6;14)(p21;q32), \textit{CCND3/IGH}

If no probes are specified, probes will be selected based on disease risk stratification, pathologic review, and history (if applicable).

\textbf{Method Name}

Fluorescence In Situ Hybridization (FISH)

\textbf{NY State Available}

Yes

\textbf{Specimen}

\textbf{Specimen Type}

Tissue

\textbf{Advisory Information}

- For fresh bone marrow specimens, order PCPDS / Plasma Cell Proliferative Disorder, FISH, Bone Marrow.

- For fixed cell pellet specimens, order MFCF / Myeloma, FISH, Fixed Cells.

- Testing will be changed to the appropriate test if this test is ordered on either of the previous specimens or if bone marrow specimens are received greater than 96 hours from collection.

\textbf{Shipping Instructions}

Advise Express Mail or equivalent if not on courier service.

\textbf{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.

\textbf{Specimen Required}

Submit only 1 of the following specimens:

\textbf{Specimen Type:} Tissue

\textbf{Preferred:} Tissue block

\textbf{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.

\textbf{Acceptable:} Slides

\textbf{Collection Instructions:} For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.
Test Definition: PLASF
Plasma Cell Prolif, FISH, Ts

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

Specimen Minimum Volume
See Specimen Required

Reject Due To
All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

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

Clinical Information
A plasmacytoma is a localized proliferation of plasma cells that are cytologically and immunophenotypically identical to the plasma cell clones seen in myeloma. There are 2 primary types of plasmacytomas; solitary plasmacytoma of bone (SPB) and extramedullary plasmacytoma (EP).

SPBs are a localized bone tumor comprised of plasma cells and account for about 5% of all plasma cell neoplasms. Common sites for SPBs are the vertebrae, ribs, skull, pelvis, femur, clavicle, and scapula. Patients often present with pathological fracture and/or bone pain near the lesion. Treatment is typically radiation therapy; at 10 years, 35% of patients appear to be cured, 55% develop myeloma, and 10% have local recurrence.

EPs are tumors of plasma cells that form in areas away from the bone and account for 3% to 5% of all plasma cell neoplasms. Approximately 80% of EPs occur in the upper respiratory tract. Less common locations include the gastrointestinal tract, bladder, testis, central nervous system, and skin. Treatment consists of radiation therapy. Regional recurrence develops in about 25% of patients, but development of myeloma is less frequent, occurring in only about 15% of patients.

Genetics of both types of plasmacytomas, while not extensively studied, appears to be the same as plasma cell myeloma.

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 reference range for a given probe set.

A positive result supports the diagnosis of a plasmacytoma.

A negative result does not exclude the diagnosis of a plasmacytoma.
Cautions
This test is not approved by the US Food and Drug Administration and 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. 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
Each probe was independently tested and verified on paraffin-embedded tissue specimens. Normal cutoffs were calculated based on the results of at least 25 normal specimens. For each probe set a series of chromosomally abnormal specimens were evaluated to confirm each probe set detected the anomaly it was designed to detect.

Clinical Reference


Performance
Method Description
This test is performed using both commercially available and laboratory-developed probes. Deletion or monosomy of chromosomes 13 and 17 and copy number gain of 1q are detected using enumeration strategy probes. Centromere probes are used to detect chromosomal aneusomy of chromosomes 3, 7, 9, and 15. Translocations involving IGH with FGFR3, CCND1, CCND3, MAF, and MAFB are detected using dual-color, dual-fusion (D-FISH) strategy probes. Rearrangement of MYC is detected using a break-apart strategy (BAP) probe. 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. Each probe set is hybridized to the appropriate target areas and 2 technologists analyze 50 interphase nuclei each (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.-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-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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