Overview

Useful For
Aiding in the diagnosis of new cases of multiple myeloma or other plasma cell proliferative disorders
Identifying prognostic markers based on the abnormalities found
This test should not be used to track the progression of disease.

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>Interphases, &gt;=100</td>
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Testing Algorithm
This test is designed for diagnostic specimens from patients with multiple myeloma or other plasma cell proliferative disorders.

This test includes a charge for application of the first probe set (2 fluorescence in situ hybridization: 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.

For diagnostic samples, all probes in the initial panel will be evaluated. The initial panel includes testing for the following abnormalities using the probes listed:

17p-, TP53/D17Z1
1q gain, TP73/1q22
14q32 rearrangement, IGH
t(11;14), CCND1/IGH
8q24.1 rearrangement, MYC
-13/13q-, RB1/LAMP1
+9/+15, D9Z1/D15Z4
Based on the results from the initial panel, reflex testing may be performed to identify the following abnormalities using the probes listed:

- **t(14;16)(q32;q23)**  \textit{IGH/MAF}  
- **t(4;14)(p16.3;q32)**  \textit{FGFR3/IGH}  
- **t(14;20)(q32;q12)**  \textit{IGH/MAFB}  
- **t(6;14)(p21;q32)**  \textit{CCND3/IGH}

For follow-up samples, only  \textit{TP73/1q22, TP53/D17Z1} and \textit{MYC} probes, along with a single probe that was abnormal in a previous study, will be tested. If a previous sample was uninformative due to an insufficient number of plasma cells, analysis will begin with the initial panel.

If the standard algorithm is not desired, please indicate which probes should be used.

**Method Name**  
Fluorescence In Situ Hybridization (FISH)

**NY State Available**  
Yes

**Specimen**

**Specimen Type**  
Fixed Cell Pellet Bone Marrow

**Advisory Information**

- For fresh bone marrow specimens, order PCPDS / Plasma Cell Proliferative Disorder, FISH, Bone Marrow.  
- For paraffin-embedded tissue specimens, order PLASF / Plasma Cell Proliferative Disorder, FISH, Tissue.  
- 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.

**Shipping Instructions**

Advise Express Mail or equivalent if not on courier service.

**Necessary Information**

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.

A pathology and/or flow cytometry report may be requested by the laboratory if a reason for referral is not provided with the specimen.

**Specimen Required**

**Container/Tube:** Sterile container
Specimen Volume: 1 fixed cell pellet

Collection Instructions: Place specimen in a sterile container with a 3:1 methanol:glacial acetic acid (or similar) fixative.

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

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>Fixed Cell Pellet Bone Marrow</td>
<td>Ambient (preferred)</td>
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Clinical and Interpretive

Clinical Information
Multiple myeloma is a hematologic neoplasm that generally originates in the bone marrow and develops from malignant plasma cells. There are 4 main categories of plasma cell proliferative disorders (PCPD): monoclonal gammopathy of undetermined significance (MGUS), monoclonal immunoglobulin deposition diseases ( amyloidosis), plasmacytoma, and multiple myeloma. MGUS, which occurs in 3% to 4% of individuals over 50 years of age, represents the identification of an asymptomatic monoclonal protein, yet approximately 1% per year will progress to multiple myeloma. Amyloidosis represents a rare group of deposition disorders including primary amyloidosis vs. light chain and heavy chain disease. Plasmacytomas represent isolated collections of bone or extramedullary plasma cells with a risk for development of multiple myeloma. Generalized bone pain, anemia, limb numbness, or weakness, symptoms of hypercalcemia, and recurrent infections are all symptoms that may indicate multiple myeloma.

As myeloma progresses, the malignant plasma cells interfere with normal blood product formation in the bone marrow resulting in anemia and leukopenia. Myeloma also causes an overstimulation of osteoclasts, causing excessive breakdown of bone tissue without the normal corresponding bone formation. These bone lesions are seen in approximately 66% of myeloma patients. In advanced disease, bone loss may reach a degree where the patient suffers fractures easily.

Multiple myeloma is increasingly recognized as a disease characterized by marked cytogenetic, molecular, and proliferative heterogeneity. This heterogeneity is manifested clinically by varying degrees of disease aggressiveness. Multiple myeloma patients with more aggressive disease experience suboptimal responses to some therapeutic approaches; therefore, identifying these patients is critically important for selecting appropriate treatment options.

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
any given probe.

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.

Supportive Data
Each probe was independently tested and verified on unstimulated peripheral blood and bone marrow 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, CCND3, CCND1, 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. For the enumeration and BAP probe sets, 200 interphase nuclei are scored and for the D-FISH probe sets, 500 interphase nuclei are scored. Results are 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.-5 p.m.

**Analytic Time**
7 days

**Maximum Laboratory Time**
10 days

**Specimen Retention Time**
4 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 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)

88271-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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