Overview

Useful For
Detecting peripheral blood involvement by plasma cell proliferative disorders
Establishing the diagnosis of and determining prognosis for plasma cell proliferative disorders

Testing Algorithm
The following algorithms are available in Special Instructions:

- Laboratory Approach to the Diagnosis of Amyloidosis
- Laboratory Screening Tests for Suspected Multiple Myeloma

Special Instructions

- Laboratory Approach to the Diagnosis of Amyloidosis
- Laboratory Screening Tests for Suspected Multiple Myeloma

Method Name
Six Color Flow Cytometry

NY State Available
Yes

Specimen

Specimen Type
Whole blood

Shipping Instructions
Specimen must arrive within 72 hours of draw.

Necessary Information
Date and time of draw are required.

Specimen Required
Container/Tube:

Preferred: Green top (sodium heparin)
Acceptable: Lavender top (EDTA)

Specimen Volume: 10 mL

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

Specimen Minimum Volume
Test Definition: PBLI
Plasma Cell Assessment, B

4 mL

Reject Due To

| Gross hemolysis | Reject |

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>Whole blood</td>
<td>Ambient (preferred)</td>
<td>72 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
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Clinical and Interpretive

Clinical Information

Plasma cell proliferative disorders are a group of hematologic neoplasms, all of which are derived from clonal plasma cells. These disorders exhibit a wide range of biologic activity ranging from monoclonal gammopathy of uncertain significance (MGUS), a usually indolent disorder with a low rate of disease progression, to multiple myeloma, a disease that most often is aggressive with poor long-term survival. Detecting plasma cell immunoglobulin (Ig) light chain restriction (ie, the presence of either predominately kappa or predominately lambda light chains) is an important element in assessing plasma cell clonality and, hence, establishing the diagnosis. Furthermore, a greater degree of peripheral blood involvement by these disorders is associated with more aggressive disease types and, therefore, is an adverse prognostic indicator.

Flow cytometric immunophenotyping (FCIP) is a recognized method for detecting plasma cell Ig light chain restriction. However, shortcomings of this technique, as traditionally performed, include its relative insensitivity and its consistent underestimation of the number of clonal plasma cells present. Both of these short-comings are likely attributable to limitations of the instruments and antibodies used, as well as the presence of intraclonal phenotypic heterogeneity, which created difficulties in accurately detecting and enumerating all of the clonal plasma cells. For this reason, the FCIP plasma cell clonality assessment previously performed in our laboratory was supplemented with a slide-based immunofluorescence technique.

However, recent advances in flow cytometry have led to the development of more powerful instruments and antibody reagents that allow for the use of greater antibody combinations and increased resolution of the data. With these tools, the ability of FCIP to detect and enumerate plasma cell clones has been greatly enhanced, allowing us to discontinue the supplemental, labor-intensive, slide-based plasma cell evaluation in peripheral blood specimens.

The following algorithms are available in Special Instructions:

- Laboratory Screening Tests for Suspected Multiple Myeloma
- Laboratory Approach to the Diagnosis of Amyloidosis

Reference Values

CD38+/CD138+ plasma cells=0.0

Interpretation

In normal peripheral blood specimens, no clonal plasma cells are present (polytypic or too few to detect).
Plasma cells are CD38 and CD138 positive.

Normal (polyclonal, nonneoplastic) plasma cells are typically CD19-positive, whereas neoplastic (clonal) plasma cells typically are CD19-negative. CD19 expression is especially helpful in distinguishing clonal from nonclonal plasma cells when few analyzable cells are present.

CD45 may be expressed by both normal and neoplastic plasma cells. In some plasma cell proliferative disorders there are both CD45-positive and CD45-negative subsets within the clonal cell population.

The evaluation of these antigens aids in the identification of abnormal plasma cells, however, they will not be reported independently.

Cautions
No significant cautionary statements

Clinical Reference

Performance

Method Description
The plasma cell immunoglobulin (Ig) light chain restriction assessment is performed by 6-color flow cytometry using a single assay tube containing antibodies to kappa Ig light chain, lambda Ig light chain, CD19, CD38, CD45, and CD138. CD38 and CD138 are used to gate on the plasma cells and anti-kappa and anti-lambda are used to identify cytoplasmic Ig light chains. The flow cytometric screen will report the presence or absence of a detectable plasma cell population with Ig light chain restriction (clonality).(Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Specimens are processed Monday through Sunday.

Results reported Monday through Friday.

Analytic Time
1 day

Maximum Laboratory Time
2 days

Specimen Retention Time
Not retained

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

88184-Flow cytometry, cell surface, cytoplasmic

88185 x 5-Each additional marker

88187-Flow cytometry, interpretation; 2 to 8 markers

LOINC® Information

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<td>Plasma Cell Assessment, B</td>
<td>86900-8</td>
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