Overview

Useful For
Monitoring patients with monoclonal gammopathies

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTU</td>
<td>Protein, Total, U</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PEU</td>
<td>Protein Electrophoresis, U</td>
<td>No</td>
<td>Yes</td>
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</table>

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFXU</td>
<td>Immunofixation, U</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
Urine protein electrophoresis alone is not considered an adequate screening for monoclonal gammopathies.

If a discrete electrophoresis band is identified, the laboratory will evaluate the urine protein electrophoresis and, if necessary, perform immunofixation at an additional charge.

The following algorithms are available in Special Instructions:

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

Special Instructions

- Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens
- Laboratory Approach to the Diagnosis of Amyloidosis
- Laboratory Screening Tests for Suspected Multiple Myeloma

Method Name
PTU: Turbidimetry
PEU: Agarose Gel Electrophoresis
IFXU: Immunofixation

NY State Available
Yes
Specimen Type
Urine

Shipping Instructions
Refrigerate specimen during collection and send refrigerated.

Necessary Information
24-Hour volume is required.

Specimen Required

Supplies:

Urine Container, 60 mL (T313)
Aliquot Tube, 5 mL (T465)

Submission Container/Tube: Plastic, 60-mL urine bottle and plastic, 5-mL tube

Specimen Volume: 50 mL

Collection Instructions:

1. Collect urine for 24 hours.
2. Aliquot at least 25-mL specimen in plastic, 60-mL urine bottle and at least 1-mL of specimen in plastic, 5-mL tube.
3. Label specimens appropriately (60-mL bottle for protein electrophoresis and 5-mL tube for protein, total).

Additional Information: See Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens in Special Instructions for multiple collections.

Forms
If not ordering electronically, complete, print, and send a Renal Diagnostics Test Request (T830) with the specimen.

Urine Preservative Collection Options

Note: The addition of preservative or application of temperature controls must occur within 4 hours of completion of the collection.

<table>
<thead>
<tr>
<th>Preservative</th>
<th>Acceptable Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient</td>
<td>OK</td>
</tr>
<tr>
<td>Refrigerate</td>
<td>Preferred</td>
</tr>
<tr>
<td>Frozen</td>
<td>OK</td>
</tr>
<tr>
<td>50% Acetic Acid</td>
<td>No</td>
</tr>
<tr>
<td>Boric Acid</td>
<td>No</td>
</tr>
<tr>
<td>Diazolidinyl Urea</td>
<td>No</td>
</tr>
<tr>
<td>6M Hydrochloric Acid</td>
<td>No</td>
</tr>
<tr>
<td>6M Nitric Acid</td>
<td>No</td>
</tr>
</tbody>
</table>
Sodium Carbonate | No
---|---
Thymol | OK
Toluene | No

**Specimen Minimum Volume**

25 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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</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>5 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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**Clinical and Interpretive**

**Clinical Information**

Urine proteins can be grouped into 5 fractions by protein electrophoresis:

- Albumin
- Alpha-1
- Alpha-2
- Beta-globulin
- Gamma globulin

The urine total protein concentration, the electrophoretic pattern, and the presence of a monoclonal immunoglobulin light chain may be characteristic of monoclonal gammopathies such as multiple myeloma, primary systemic amyloidosis, and light chain deposition disease.

The following algorithms are available in Special Instructions:

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

**Reference Values**

PROTEIN, TOTAL
Reference values have not been established for patients <18 years of age.
Reference value applies to 24-hour collection.

ELECTROPHORESIS, PROTEIN

The following fractions, if present, will be reported as a percent of the protein, total:

- Albumin
- Alpha-1-globulin
- Alpha-2-globulin
- Beta-globulin
- Gamma-globulin

**Interpretation**

A characteristic monoclonal band (M-spike) is often found in the urine of patients with monoclonal gammopathies. The initial identification of an M-spike or an area of restricted migration should be followed by immunofixation to identify the immunoglobulin heavy chain and/or light chain.

Immunoglobulin heavy chain fragments as well as free light chains may be seen in the urine of patients with monoclonal gammopathies. The presence of a monoclonal light chain M-spike of greater than 1 g/24 hours is consistent with a diagnosis of multiple myeloma or macroglobulinemia.

The presence of a small amount of monoclonal light chain and proteinuria (total protein >3 g/24 hours) that is predominantly albumin is consistent with amyloidosis (AL) or light chain deposition disease (LCDD).

Because patients with AL and LCDD may have elevated urinary protein without an identifiable M-spike, urine protein electrophoresis is not considered an adequate screen for these disorders and immunofixation is also recommended.

**Cautions**

Patients suspected of having a monoclonal gammopathy may have a normal urine protein electrophoretic pattern, and these patients should have immunofixation performed.

Monoclonal gammopathies are rarely seen in patients younger than 30 years of age.

Hemolysis may cause a discrete band on protein electrophoresis, which will be negative on immunofixation.

Penicillin may split the albumin band.

Radiographic agents may produce an uninterpretable pattern.

**Clinical Reference**


**Performance**

**Method Description**

Urine proteins are separated in an electric field according to their size, shape, and electric charge (Helena SPIFE 3000). The separation is performed on agarose gels (Helena SPIFE SPE Vis Gel). The proteins are visualized by staining with acid blue and the intensity of staining is quantitated by densitometry (Helena Quick Scan Touch). Multiplying by the urine protein concentration (Benzethonium Chloride) converts the percentage of protein in each fraction into urine concentration. (Instruction manual: Helena SPIFE 3000; package insert: Helena SPIFE SPE Vis Gel, 2001; Abraham RS, Barnidge DR: Protein analysis in the clinical immunology laboratory. In: Detrick BD, Hamilton RG, Schmitz JL eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. 2016:chap 4)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Protein, total: Monday through Sunday; Continuously

Electrophoresis, protein: Monday through Friday; 12 p.m.

**Analytic Time**

2 days

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

See Individual Unit Codes

**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 has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with
CLIA requirements.

**CPT Code Information**
84156
84166
86335-Immunofixation (if appropriate)

**LOINC® Information**

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>EPU</td>
<td>Electrophoresis, Protein, U</td>
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<table>
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<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<td>Albumin</td>
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<td>TP2</td>
<td>Total Protein</td>
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<td>Collection Duration</td>
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<td>2777</td>
<td>Alpha 1-Globulin</td>
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<td>2779</td>
<td>Alpha 2-Globulin</td>
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<td>VL21</td>
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<td>Beta-Globulin</td>
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<td>2781</td>
<td>Gamma-Globulin</td>
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<td>21446</td>
<td>M spike</td>
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<tr>
<td>22307</td>
<td>M spike</td>
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<td>21447</td>
<td>Impression</td>
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