Overview

Useful For
Identifying monoclonal gammopathies using random urine specimens

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>RPEU</td>
<td>Protein Electrophoresis, Random, U</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>PTCON</td>
<td>Protein, Total, Random, U</td>
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<td>Yes</td>
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Reflex Tests

<table>
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<th>Reporting Name</th>
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<tbody>
<tr>
<td>RIFXU</td>
<td>Immunofixation, Random, U</td>
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</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
- Laboratory Approach to the Diagnosis of Amyloidosis
- Laboratory Screening Tests for Suspected Multiple Myeloma

Method Name
PTCON: Turbidimetry
RPEU: Agarose Gel Electrophoresis
RIFXU: Immunofixation

NY State Available
Yes

Specimen
Specimen Type
Urine

Advisory Information
Random urine specimens may be sufficient for identifying monoclonal proteins, but 24-hour specimens should be used to quantitate and monitor urinary abnormalities. See MPSU / Monoclonal Protein Study, 24 Hour, Urine.

Shipping Instructions
Refrigerate specimen after collection and send refrigerated.

Necessary Information
Random urine, no 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 random urine specimen.
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).

Specimen Minimum Volume
25 mL

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>Urine</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
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<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

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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

No reference values apply to random urine.

ELECTROPHORESIS, PROTEIN

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

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

No reference values apply to random urines.

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 chains and light chains.

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 primary systemic amyloidosis (AL) and 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. (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**

Total Protein: Monday through Sunday; Continuously
**Test Definition: REPU**
Electrophoresis, Protein, Random, U

Protein Electrophoresis: Monday through Saturday; 12 p.m.

**Analytic Time**
Same day/1 day

**Maximum Laboratory Time**
3 days

**Specimen Retention Time**
7 days

**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 or approved 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**

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<td>Alpha 1-Globulin</td>
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<td>Alpha 2-Globulin</td>
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