

Overview

Useful For

Monitoring patients with monoclonal gammopathies using 24-hour urine specimens

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
PTU	Protein, Total, U	Yes	Yes
PEU	Protein Electrophoresis, U	No	Yes
IFXU	Immunofixation, U	No	Yes

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

- [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

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.

Ambient	OK
Refrigerate	Preferred
Frozen	OK
50% Acetic Acid	No
Boric Acid	No
Diazolidinyl Urea	No
6M Hydrochloric Acid	No
6M Nitric Acid	No
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

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	14 days	
	Frozen	5 days	
	Ambient	72 hours	

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

<229 mg/24 hours

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 is followed by immunofixation to identify the immunoglobulin heavy chain and/or light chain.

Immunoglobulin free light chains as well as heavy chain fragments 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) or light chain deposition disease (LCDD).

Because patients with AL or 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

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

1. Kyle RA, Katzmann JA, Lust JA, Dispenzieri A: Clinical indications and applications of electrophoresis and immunofixation. In: Rose NR, Hamilton RG, Detrick B, eds. Manual of Clinical Laboratory Immunology. 6th ed. ASM Press; 2002:71-91

2. Keren DF, Humphrey RL: Clinical indications and applications of serum and urine protein electrophoresis. In: Detrick BD, Hamilton RG, Schmitz JL eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. 2016:chap 8

Performance

Method Description

Electrophoresis:

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)

Immunofixation:

Urine proteins are separated in an electric field according to their size, shape, and electric charge. The separation is performed on agarose gels (Helena SPIFE Immunofix-15). The proteins are anchored in situ following electrophoresis. Antisera specific for gamma, alpha, mu, kappa, and lambda immunoglobulin heavy and light chains are applied to the gel forming insoluble complexes with any immunoglobulin present. The proteins are visualized by staining with acid violet. (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.

Immunofixation: Monday through Friday; 8 a.m.

Analytic Time

Same day/1 day

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

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
MPSU	Monoclonal Protein Study, U	In Process

Result ID	Test Result Name	Result LOINC Value
82025	Immunofixation, U	33042-3
2776	Albumin	13986-5
TP2	Total Protein	2889-4
TM23	Collection Duration	13362-9
2777	Alpha 1-Globulin	13984-0
2779	Alpha 2-Globulin	13987-3
VL21	Urine Volume	19153-6
CONC1	Concentration	57369-1
2780	Beta-Globulin	13988-1
2781	Gamma-Globulin	13989-9
2833	A/G Ratio	44294-7
21446	M spike	42482-0
22307	M spike	42482-0
21447	Impression	32210-7