Overview

Useful For

Diagnosing monoclonal gammopathies

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
RPEU	Protein Electrophoresis, Random, U	No	Yes
RIFXU	Immunofixation, Random, U	No	Yes
PTCON	Protein, Total, Random, 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

- 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

The use of a random urine specimen is sufficient for identifying the presence or absence of a monoclonal immunoglobulin, but a 24-hour specimen is preferred for quantitating and monitoring the abnormality. See MPSU / Monoclonal Protein Study, 24 Hour, Urine.

Shipping Instructions

Refrigerate specimen during 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 a 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).

Forms

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

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

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

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 chains and light chains.

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
RMPSU	Monoclonal Protein Study, Random, U	In Process

Result ID	Test Result Name	Result LOINC Value
33039	Albumin	13992-3
33040	Alpha 1-Globulin	13990-7
33041	Alpha 2-Globulin	13993-1
33042	Beta-Globulin	13994-9
33043	Gamma-Globulin	13995-6
33044	A/G Ratio	44293-9
33045	M spike	42483-8
33046	M spike	42483-8
33047	Impression	49299-1

Result ID	Test Result Name	Result LOINC Value
PTCON	Protein, Total, Random, U	2888-6
32526	Immunofixation, Random, U	74666-9