Test Definition: SMPU

Monoclonal Protein Screen, 24 Hour, Urine

Overview

Useful For

Monitoring patients with monoclonal gammopathies

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
MPTU	M-protein Mass-Fix, 24 HR, U	No	Yes
PTU3	Protein, Total, 24 HR, U	Yes, (order PTU)	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
PEU	Protein Electrophoresis, 24 Hr, U	No	No

Testing Algorithm

Testing for urine monoclonal proteins (M-proteins) with MASSFIX alone is not considered adequate screening for monoclonal gammopathies.

The laboratory will evaluate the urine for M-proteins using the Mayo Clinic MASSFIX method, and if positive for M-protein, protein electrophoresis will be performed at an additional charge.

Special Instructions

- Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens
- Amyloidosis: Laboratory Approach to Diagnosis
- Multiple Myeloma: Laboratory Screening

Method Name

PTU3: Turbidimetry
PEU: Agarose Gel Electrophoresis
MPTU: Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS)

NY State Available

Yes

Specimen

Specimen Type

Urine

Shipping Instructions

Send refrigerated.

Necessary Information

24-Hour volume (in milliliters) is required.

Specimen Required

Supplies: Urine Container, 60 mL (T313)
Submission Container/Tube: Plastic, 60-mL urine bottle
Specimen Volume: 50 mL
Collection Instructions:
1. Collect urine for 24 hours and refrigerate specimen during collection.
2. Aliquot between 30 mL and 50 mL of urine into a plastic, 60-mL urine bottle.
Additional Information: See Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens 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

Preservatives must be added or temperature controls applied within 4 hours of completion of the collection.

Ambient (no additive)	OK
Refrigerate (no additive)	Preferred
Frozen (no additive)	OK
50% Acetic Acid	No
Boric Acid	No
Diazolidinyl Urea	OK
6M Hydrochloric Acid	No
6M Nitric Acid	No
Sodium Carbonate	No
Toluene	No

Specimen Minimum Volume

30 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	
	Ambient	24 hours	
	Frozen	5 days	

Clinical & Interpretive

Clinical Information

Urine proteins can be grouped into 5 fractions by protein electrophoresis:
-Albumin
-Alpha-1
-Alpha-2
-Beta-globulin
-Gamma-globulin
One or more quantifiable monoclonal proteins may be present and reported as M spike.

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:
-Amyloidosis: Laboratory Approach to Diagnosis
-Multiple Myeloma: Laboratory Screening

Reference Values

PROTEIN, TOTAL
<229 mg/24 hours

Reference values have not been established for patients younger than 18 years.

ELECTROPHORESIS, PROTEIN
The following fractions, if present, will be reported as mg/24 h:
Albumin
Alpha-1-globulin
Alpha-2-globulin
Beta-globulin
Gamma-globulin

MASSFIX M-PROTEIN ISOTYPE
M-protein Isotype MS:
No monoclonal protein detected

Flag M-protein Isotype MS:
Negative

Interpretation

The presence of a monoclonal immunoglobulin light chain in the urine is seen in multiple myeloma, macroglobulinemia, primary systemic amyloidosis and light-chain deposition disease, monoclonal gammopathy of undetermined significance, and idiopathic Bence-Jones proteinuria. The presence of a monoclonal light chain can produce renal insufficiency, may be deposited as amyloid fibrils, may damage the proximal tubes producing Fanconi syndrome, or light chains may deposit in the glomerulus and cause light-chain deposition disease.

Heavy-chain fragments as well as light chains may be seen in the urine of patients with multiple myeloma or amyloidosis.

Cautions

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

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

Penicillin may split the albumin band.

Radiographic agents may produce an uninterpretable pattern.

Clinical Reference

1. 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
2. Sykes E, Posey Y. Immunochemical characterization of immunoglobulins in serum, urine, and cerebrospinal fluid. In: Detrick B, Hamilton RG, Schmitz JL, eds. Molecular and Clinical Laboratory Immunology. 8th ed. Wiley; 2016:chap 9

Performance

Method Description

Protein:
The sample is preincubated in an alkaline solution containing EDTA, which denatures the protein and eliminates interference from magnesium ions. Benzethonium chloride is then added, producing turbidity.(Package insert: Total Protein Urine/CSF. Roche Diagnostics; V13.0, 11/2018)

Electrophoresis:
Urine proteins are separated in an electric field according to their size, shape, and electric charge (Helena SPIFE Touch). The separation is performed on agarose gels. 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 converts the percentage of protein in each fraction into urine concentration.(Instruction manual: Helena SPIFE Touch. Helena Laboratories, Corp; 11/2016; package insert: Helena SPIFE Touch SPE Pro 277. Helena Laboratories, Corp; 06/2018; 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)

Mayo Clinic MASSFIX:
The Mayo Clinic MASSFIX M-protein isotype by matrix-assisted laser desorption/ionization time-of-flight mass

spectrometry (MALDI-TOF MS) is performed with immunoaffinity purification followed by MALDI-TOF MS analysis. For the immunoaffinity purification, patient sample is applied to 5 separate immunoaffinity resins (CaptureSelect, Life Sciences) specific to immunoglobulin G, A, M, K, and L. Unbound protein is washed away and the isolated immunoglobulins are reduced to separate the heavy and light chains subunits to be analyzed via MALDI-TOF MS. The 5 separate spectra from each patient immunopurification are overlaid and investigated for an overabundance of immunoglobulin and immunoglobulin light chain.(Milani P, Murray DL, Barnidge DR, et al. The utility of MASS-FIX to detect and monitor monoclonal proteins in the clinic. Am J Hematol. 2017;92(8):772-779. doi:10.1002/ajh.24772)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
4 to 6 days

Specimen Retention Time
See Individual Test IDs

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
84156
84166 Electrophoresis, protein (if appropriate)
0077U

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SMPU	M-protein Screen, 24 HR, U	In Process

Result ID	Test Result Name	Result LOINC® Value

617117	M-protein Isotype MS, 24 HR, U	In Process
617118	Flag M-protein Isotype MS, 24 HR, U	No LOINC Needed
VL92	Urine Volume	3167-4
TP6	Total Protein, 24 HR, U	2889-4
TM24	Collection Duration	13362-9
CONCU	Total Protein Concentration	21482-5