MAYO CLINIC LABORATORIES

# Test Definition: RSMPU

Monoclonal Protein Screen, Random, Urine

## Overview

### Useful For

Identifying monoclonal gammopathies using random urine specimens

### Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| MPTRU | M-protein Mass-Fix, Random, U | No | Yes |
| RPTU2 | Protein/Creatinine Ratio, Random, U | Yes, (RPTU1) | Yes |

### Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| RPEU | Protein Electrophoresis, Random, U | No | No |

### Testing Algorithm

Urine M-protein MASSFIX alone is not considered adequate screening for monoclonal gammopathies.

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

### Special Instructions

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

### Method Name

RPTU2: Turbidimetry/Enzymatic Colorimetric Assay
RPEU: Agarose Gel Electrophoresis
MPTRU: Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS)

### NY State Available

Yes

## Specimen

### Specimen Type

Urine

## Ordering Guidance

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

## Shipping Instructions

Send refrigerated.

## Specimen Required

**Supplies:** Urine Container, 60 mL (T313)
**Submission Container/Tube:** Plastic, 60-mL urine bottle
**Specimen Volume:** 50 mL
**Collection Instructions:**
1. Collect random urine specimen.
2. Aliquot between 30 mL and 50 mL of urine into a plastic, 60 mL urine bottle and refrigerate.

## Forms

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

## 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-globulin
-Alpha-2-globulin
-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

CREATININE:
> or =18 years old: 16-326 mg/dL
Reference values have not been established for patients younger than 18 years.

PROTEIN/CREATININE RATIO:
> or =18 years: <0.18 mg/mg creatinine
Reference values have not been established for patients younger than 18 years.

ELECTROPHORESIS, PROTEIN
The following fractions, if present, will be reported as mg/dL:
-Albumin
-Alpha-1-globulin
-Alpha-2-globulin
-Beta-globulin
-Gamma-globulin
No reference values apply to random urines.

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 B, Hamilton RG, Schmitz JL, eds. Molecular and Clinical Laboratory Immunology. 8th ed. Wiley; 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)

Creatinine:
The enzymatic method is based on the determination of sarcosine from creatinine with the aid of creatininase, creatinase, and sarcosine oxidase. The liberated hydrogen peroxide is measured via a modified Trinder reaction using a colorimetric indicator. Optimization of the buffer system and the colorimetric indicator enables the creatinine concentration to be quantified both precisely and specifically.(Package insert: Creatinine plus v2. Roche Diagnostics; V15.0, 03/2019)

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 serum 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)

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)

### 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
82570
84166 Electrophoresis, protein (if appropriate)
0077U

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| RSMPU | M-protein Screen, Random, U | In Process |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 617119 | M-protein Isotype MS, Random, U | In Process |
| 617120 | Flag M-protein Isotype MS, Random, U | No LOINC Needed |
| CRTR1 | Creatinine, Random, U | 2161-8 |
| PCRT1 | Protein/Creatinine Ratio | 2890-2 |
| PTCN1 | Protein, Total, Random, U | 2888-6 |