

## Overview

### Useful For

Aiding in the diagnosis of monoclonal gammopathies, when used in conjunction with free light chain studies

This test alone is **not considered** an adequate screen for monoclonal gammopathies.

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
IGD	Immunoglobulin D (IgD), S	Yes	No
IMMG	Immunoglobulins IgG,A,M, S	Yes	No
FLCP	Immunoglobulin Free Light Chains, S	Yes	No
IMFX	Immunofixation	Yes, (IMFXO)	No
IGE	Immunoglobulin E (IgE), S	Yes	No

### Testing Algorithm

This test includes M-protein isotyping. If a light chain is identified without a corresponding heavy chain during initial testing, immunofixation with IgD and IgE antisera will be performed at an additional charge.

### Method Name

Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Patient Preparation:** Fasting 12 hours preferred but not required

### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 1 mL

### Specimen Minimum Volume

See Specimen Required

### Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Frozen	14 days	
	Ambient	7 days	

## Clinical and Interpretive

### Clinical Information

Immunotyping of monoclonal (M-) proteins identifies the monoclonal immunoglobulin heavy chain type (gamma, alpha, mu, delta, or epsilon) and light chain type (kappa or lambda) in serum specimens.

### Reference Values

Negative: No monoclonal protein detected.

### Interpretation

A characteristic monoclonal band (M-spike) is often found on serum protein electrophoresis (SPE) in the gamma globulin region and, more rarely, in the beta or alpha-2 regions. The finding of an M-spike, restricted migration, or hypogammaglobulinemic protein electrophoresis pattern is suggestive of a possible monoclonal protein.

Immunoaffinity purification followed by matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) is performed to identify the immunoglobulin heavy and light chains.

### Cautions

No significant cautionary statements

### Clinical Reference

- Barnidge DR, Dasari S, Ramirez-Alvarado M, et al: Phenotyping polyclonal kappa and lambda light chain molecular mass distributions in patient serum using mass spectrometry. *J Proteome Res* 2014;13(11):5198-5205
- Mills JR, Kohlhagen MC, Dasari S, et al: Comprehensive assessment of M-proteins using nanobody enrichment coupled to MALDI-TOF mass spectrometry. *Clin Chem* 2016;62(10):1334-1344

## Performance

### Method Description

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 specific to immunoglobulin G, A, M, K, and L. Unbound protein is washed away and the isolated immunoglobulins are broken down in to their 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) and Time(s) Test Performed**

Monday through Friday

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

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

**CPT Code Information**

0077U

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
MALDO	M-Protein Isotype Only, S	90990-3

Result ID	Test Result Name	Result LOINC Value
606982	M-protein Isotype Flag, S	94400-9
606590	M-Protein Isotype MALDI-TOF MS	90990-3

