

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.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
MALDO	M-Protein Isotype Only, S	No	Yes
TMAB	Therapeutic Antibody Administered?	No	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IFXED	Immunofixation Delta and Epsilon, 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

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

[Renal Diagnostics Test Request \(T830\)](#)

[-Hematopathology/Cytogenetics Test Request \(T726\)](#)

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	28 days	
	Ambient	7 days	

Clinical & 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

1. 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 Oct;62(10):1334-1344
2. 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 Aug;92(8):772-779

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.(Kohlhagen M, Dasari S, Willrich M, et al: Automation and validation of a MALDI-TOF MS (Mass-Fix) replacement of immunofixation electrophoresis in the clinical lab. *Clin Chem Lab Med*. 2020 Aug 3;59(1):155-163. doi: 10.1515/cclm-2020-0581)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 5 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Definition: MALD

M-Protein Isotype, Matrix-Assisted Laser
Desorption-Ionization Time-of-Flight Mass
Spectrometry, Serum

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. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

0077U

86334 (if appropriate)

LOINC® Information

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

Result ID	Test Result Name	Result LOINC® Value
606982	Flag, M-protein Isotype	94400-9
606590	M-Protein Isotype MALDI-TOF MS	90990-3
TMAB	Therapeutic Antibody Administered?	98855-0