MAYO CLINIC LABORATORIES

Test Definition: IMFXO

Immunofixation Only, Serum

Overview

Useful For

Identification of monoclonal immunoglobulin heavy and light chains

Documentation of complete response to therapy

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IFXED	Immunofixation Delta and Epsilon, S	Yes	No

Testing Algorithm

If a monoclonal light-chain is detected in the absence of an associated monoclonal heavy-chain, immunofixation electrophoresis specific for delta and epsilon chains is performed, if not previously performed, or at the discretion of the laboratory director reviewing the case.

Method Name

Immunofixation

NY State Available

No

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: Fasting preferred but not required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

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	14 days	

Clinical & Interpretive

Clinical Information

Monoclonal gammopathies indicate a clonal expansion of plasma cells or mature B lymphocytes. The monoclonal gammopathies include diseases such as multiple myeloma, Waldenstrom macroglobulinemia, lymphoproliferative disease, primary systemic amyloidosis, light-chain deposition disease, as well as the premalignant disorders of smoldering myeloma and monoclonal gammopathy of undetermined significance (MGUS). Monoclonal gammopathy patients may have a relatively small monoclonal protein abnormality or a large quantifiable peak (M-spike) on serum or urine protein electrophoresis. Abnormalities detected on serum protein electrophoresis (SPE) should have immunotyping performed to confirm and characterize the monoclonal protein. Immunotyping of monoclonal proteins is usually done by immunofixation electrophoresis (IFE) and identifies the monoclonal immunoglobulin heavy-chain (gamma, alpha, mu, delta, or epsilon) and/or light-chain type (kappa or lambda). It is generally recommended that both SPE and IFE be used as a screening panel. Because IFE is more sensitive than SPE, IFE is not only recommended as part of the initial screening process but also for confirmation of complete response to therapy.

Reference Values

Immunofixation: No monoclonal protein detected
Immunofixation Flag: Negative

Interpretation

Immunofixation electrophoresis (IFE) is primarily performed to identify and characterize the presence of any monoclonal immunoglobulin heavy and/or light chains.

Immunofixation impression comments are made based on visual interpretation of gels.

Cautions

Immunofixation is not a quantitative assay. If a monoclonal protein is identified, a serum protein electrophoresis assay is required for quantifying the abnormality.

Clinical Reference

1. Keren DF, Humphrey RL: Clinical indications and applications of serum and urine protein electrophoresis. In: Detrick B, Schmitz JL, Hamilton RG, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:74-88
2. Katzmann JA, Keren DF: Strategy for detecting and following monoclonal gammopathies. In: Detrick B, Schmitz JL, Hamilton RG, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:112-124
3. 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; 2002:66-70
4. Rifai N, Horvath AR, Wittwer CT, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018

Performance

Method Description

Immunofixation is performed with Sebia reagent sets and are specific for gamma, alpha, and mu immunoglobulin heavy-chains, and kappa, and lambda light-chains.(Package insert: Sebia Hydrasys Hydragel 1, 2, 4, and 9IF. Sebia, Inc; 09/2015)

Immunofixation electrophoresis is a 2-stage procedure using agarose gel high resolution electrophoresis in the first stage and immunoprecipitation in the second to detect monoclonal gammopathy.(Package insert: SPIFE ImmunoFix Procedure. Helena Laboratories; 08/2012)

If a monoclonal light chain is detected in the absence of an associated monoclonal heavy chain, immunofixation electrophoresis (IFE) specific for delta and epsilon chains is performed.(Sykes E, Posey Y: Immunochemical characterization of immunoglobulins in serum, urine, and cerebrospinal fluid. In: Detrick B, Schmitz JL, Hamilton RG, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:89-100)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 to 7 days

Specimen Retention Time

14 days

Performing Laboratory Location

Jacksonville

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 has been cleared, approved, or is exempt by the US 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

86334

86334-Immunofixation Delta and Epsilon (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
IMFXO	Immunofixation Only, S	74665-1

Result ID	Test Result Name	Result LOINC® Value
32436	Immunofixation	74665-1
606978	Flag, Immunofixation	No LOINC Needed