Test Definition: IMFX

Immunofixation, Serum

Overview

Useful For

Aids in diagnosis of monoclonal gammopathies when used in conjunction with urine monoclonal studies

Identification and isotyping 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

Only orderable as part of a profile. For more information see MPSS / Monoclonal Protein Study, Serum.

Immunofixation

NY State Available

No

Specimen

Specimen Type

Serum

Specimen Required

Only orderable as part of a profile. For more information see MPSS / Monoclonal Protein Study, Serum.

Patient Preparation:
Fasting: 8 hours, 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

1 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK
Other	3 freeze/thaw cycles

Specimen Stability Information

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

Reference Values

Only orderable as part of a profile. For more information see MPSS / Monoclonal Protein Study, Serum.

Immunofixation: No monoclonal protein detected
Flag, Immunofixation: Negative

Interpretation

If present, a characteristic monoclonal band (M-spike) is most often found in the gamma region on serum protein electrophoresis (PEL) and, occasionally, in the beta or alpha-2 regions. The finding of an M-spike, restricted migration, or hypogammaglobulinemic PEL pattern is suggestive of a possible monoclonal protein. Immunofixation electrophoresis is primarily performed to identify and characterize the presence of any monoclonal immunoglobulin heavy or light chains. Immunofixation impression comments are made based on visual interpretation of gels.

Cautions

Serum protein electrophoresis (PEL) alone is not considered an adequate screen for monoclonal gammopathies.

Very large IgG M-spikes (>4 g/dL) may saturate the protein stain. In these situations, quantitative IgG assays more accurately determine M-spike concentrations for monitoring disease progression or response to therapy.

Although the PEL M-spike is the recommended method of monitoring monoclonal gammopathies, IgA and IgM proteins that are contained in the beta fraction may be more accurately monitored by quantitative immunoglobulins.

Fibrinogen will migrate as a distinct band in the beta-gamma fraction but will be negative on immunofixation electrophoresis.

Hemolysis may augment the beta fraction.

Penicillin may split the albumin band.

Radiographic agents may produce an uninterpretable pattern.

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

Performance

Method Description

Immunofixation electrophoresis is performed in four stages: 1) separation of proteins by electrophoresis on an agarose gel; 2) immunofixation (immunoprecipitation) and fixation of the electrophoresed proteins; 3) removal of unprecipitated soluble proteins by blotting and washing; and 4) staining of the precipitated proteins for visualization. Immunofixation is performed with Sebia reagent sets and are specific for gamma, alpha, mu, kappa, and lambda immunoglobulin heavy and light chains.(Package insert: Sebia HYDRAGEL 1, 2, 4 and 9 IF kit. Sebia Inc; 07/2020)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

3 to 7 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
IMFX	Immunofixation	74665-1

Result ID	Test Result Name	Result LOINC® Value
81653	Immunofixation	74665-1
606977	Flag, Immunofixation	No LOINC Needed