Test Definition: IFXED

Immunofixation Heavy Chain Type Delta and Epsilon, Serum

Overview

Useful For

Identification and isotyping of IgD or IgE monoclonal gammopathy

Documentation of complete response to therapy with established monoclonal gammopathy consisting of an IgD or IgE heavy chain

Method Name

Immunofixation

NY State Available

No

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation:

Fasting: 8 hours, preferred but not required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

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

0.5 mL

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	
	Ambient	14 days	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Monoclonal gammopathies indicate a clonal expansion of plasma cells or mature B lymphocytes that commonly consist of IgG, IgA, and IgM heavy chains. However, these monoclonal proteins may rarely consist of IgD or IgE immunoglobulin heavy chains. Diseases that are associated with monoclonal gammopathies include multiple myeloma, primary systemic amyloidosis, and light-chain deposition disease, as well as premalignant disorders such as smoldering multiple myeloma and monoclonal gammopathy of undetermined significance.

Routine isotyping or immunofixation identifies the monoclonal immunoglobulin heavy-chain (gamma, alpha, or mu) and/or light-chain type (kappa or lambda). Since IgD and IgE monoclonal gammopathies are rare, they are not part of the routine screening/isotyping.

Since the anti-sera against IgD and IgE are excluded from routine screening methods, this testing should only be ordered on patients with confirmed IgD or IgE monoclonal gammopathy or patients with only free monoclonal kappa or lambda light chains upon initial isotyping. Once the presence of an IgD or IgE heavy chain is excluded, there is no need to continue monitoring with this specialized isotyping assay; rather, continued monitoring via serum protein electrophoresis and traditional isotyping is more appropriate.

Reference Values

Immunofixation Delta and Epsilon: No monoclonal IgD or IgE protein detected.

Immunofixation Delta and Epsilon, Flag: Negative

Interpretation

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

Cautions

Immunofixation for only IgD and IgE will not provide information about the more common heavy chains associated with monoclonal gammopathies (IgG, IgA, or IgM). Order QMPSS / Monoclonal Protein Study, Quantitative, Serum to obtain this information.

Immunofixation is not a quantitative assay.

Clinical Reference

1. Willrich MAV, Murray DL, Kyle RA. Laboratory testing for monoclonal gammopathies: Focus on monoclonal gammopathy of undetermined significance and smoldering multiple myeloma. Clin Biochem. 2018;51:38-47

2. 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
3. Katzmann JA, Kyle RA. Immunochemical characterization of immunoglobulins in serum, urine, and cerebrospinal fluid. In: Detrick B, Hamilton RG, Folds JD eds. Manual of Molecular and Clinical Laboratory Immunology. 7th ed. ASM Press; 2006:88-100
4. 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. 2016:74-88
5. Katzmann JA, Keren DF. Strategy for detecting and following monoclonal gammopathies. In: Detrick BD, Hamilton RG, Schmitz JL, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:112-124

Performance

Method Description
Immunofixation is performed with Sebia reagent sets that are specific for delta and epsilon immunoglobulin heavy chains and kappa and lambda light chains. Immunofixation electrophoresis is performed in 4 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.(Package insert: Sebia HYDRAGEL 1, 2, 4 and 9 IF kit. Sebia Inc; 07/2021)

PDF Report
No

Day(s) Performed
Tuesday, Friday

Report Available
2 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.

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Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were 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

86334

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
IFXED	Immunofixation Delta and Epsilon, S	104672-1

Result ID	Test Result Name	Result LOINC® Value
606458	Immunofixation D and E	74665-1
606981	Flag, Immunofixation D and E	No LOINC Needed