

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	Yes	No
	Epsilon, S		

## **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



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## Reject Due To

Gross	OK
hemolysis	
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. 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



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- 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**

Mayo Clinic Jacksonville Clinical Lab

## **Fees & Codes**



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## **Fees**

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

### **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

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