MAYO CLINIC LABORATORIES

# Test Definition: FRMH

Formaldehyde, IgE, Serum

## Overview

### Useful For

Establishing the diagnosis of an allergy to formaldehyde

Defining the allergen responsible for eliciting signs and symptoms

Identifying allergens:
-Responsible for allergic response and/or anaphylactic episode
-To confirm sensitization prior to beginning immunotherapy
-To investigate the specificity of allergic reactions to insect venom allergens, drugs, or chemical allergens

Testing for IgE antibodies is **not useful** in patients previously treated with immunotherapy to determine if residual clinical sensitivity exists or in patients in whom the medical management does not depend upon identification of allergen specificity.

### Special Instructions

- Allergens - Immunoglobulin E (IgE) Antibodies

### Method Name

Fluorescence Enzyme Immunoassay (FEIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

For a listing of allergens available for testing, see Allergens - Immunoglobulin E (IgE) Antibodies

### Specimen Required

**Collection Container/Tube:**
**Preferred:** Serum gel
**Acceptable:** Red top
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 0.5 mL for every 5 allergens requested
**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

## Forms

If not ordering electronically, complete, print, and send an Allergen Test Request (T236) with the specimen.

## Specimen Minimum Volume

For 1 allergen: 0.3 mL

For more than 1 allergen: (0.05 mL x number of allergens) + 0.25 mL dead space

## Reject Due To

| | |
|---|---|
| Gross hemolysis | OK |
| Gross lipemia | OK |

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Serum | Refrigerated (preferred) | 14 days | |
| | Frozen | 90 days | |

# Clinical & Interpretive

## Clinical Information

Clinical manifestations of immediate hypersensitivity (allergic) diseases are caused by the release of proinflammatory mediators (histamine, leukotrienes, and prostaglandins) from IgE-sensitized effector cells (mast cells and basophils) when cell-bound IgE antibodies interact with an allergen.

In vitro serum testing for IgE antibodies provides an indication of the immune response to allergens that may be associated with allergic disease.

The allergens chosen for testing often depend upon the age of the patient, history of allergen exposure, season of the year, and clinical manifestations. In individuals predisposed to develop allergic disease, the sequence of sensitization and clinical manifestations proceed as follows: eczema and respiratory disease (rhinitis and bronchospasm) in infants and children younger than 5 years due to food sensitivity (milk, egg, soy, and wheat proteins) followed by respiratory disease (rhinitis and asthma) in older children and adults due to sensitivity to inhalant allergens (dust mite, mold, and pollen inhalants).

## Reference Values

| Class | IgE kU/L | Interpretation |
|---|---|---|
| 0 | <0.10 | Negative |
| 0/1 | 0.10-0.34 | Borderline/equivocal |
| 1 | 0.35-0.69 | Equivocal |
| 2 | 0.70-3.49 | Positive |
| 3 | 3.50-17.4 | Positive |

| | | |
|---|---|---|
| 4 | 17.5-49.9 | Strongly positive |
| 5 | 50.0-99.9 | Strongly positive |
| 6 | > or =100 | Strongly positive |

Reference values apply to all ages.

Concentrations of 0.70 kU/L or more (class 2 and above) will flag as abnormally high.

### Interpretation

Detection of IgE antibodies in serum (class 1 or greater) indicates an increased likelihood of allergic disease as opposed to other etiologies and defines the allergens that may be responsible for eliciting signs and symptoms.

The level of IgE antibodies in serum varies directly with the concentration of IgE antibodies expressed as a class score or kU/L.

### Cautions

Some individuals with clinically insignificant sensitivity to allergens may have measurable levels of IgE antibodies in serum, and test results must be interpreted in the clinical context.

False-positive results for IgE antibodies may occur in patients with markedly elevated serum IgE (>2500 kU/L) due to nonspecific binding to allergen solid phases.

### Clinical Reference

Homburger HA, Hamilton RG: Allergic diseases. In: McPherson RA, Pincus MR, eds. Henry's Clinical Diagnosis and Management by Laboratory Methods. 24th ed. Elsevier; 2022:chap 56

## Performance

### Method Description

Specific IgE from the patient's serum reacts with the allergen of interest, which is covalently coupled to an ImmunoCAP. After washing away nonspecific IgE, enzyme-labeled anti-IgE antibody is added to form a complex. After incubation, unbound anti-IgE is washed away, and the bound complex incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. Fluorescence is proportional to the amount of specific IgE present in the patient's sample (ie, the higher the fluorescence value, the more IgE antibody is present).(Package insert: ImmunoCAP System Specific IgE FEIA. Phadia; Rev 02/2024)

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time
14 days

### Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

## 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

### CPT Code Information
86003

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| FRMH | Formaldehyde, IgE | 6119-2 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| FRMH | Formaldehyde, IgE | 6119-2 |