

## Overview

### Useful For

Establishing a diagnosis of an allergy to clam

Defining the allergen responsible for eliciting signs and symptoms

Identifying allergens:

-Responsible for allergic disease 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

### Special Instructions

- [Allergens - Immunoglobulin E \(IgE\) Antibodies](#)

### Method Name

FluorescenceEnzymeImmunoassay(FEIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Advisory Information

For a listing of allergens available for testing, see [Allergens - Immunoglobulin E \(IgE\) Antibodies](#) in Special Instructions

### Specimen Required

**Container/Tube:**

**Preferred:** Red top

**Acceptable:** Serum gel

**Specimen Volume:** 0.5 mL for every 5 allergens requested

### 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 deadspace

**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 and Interpretive**
**Clinical Information**

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

In vitro serum testing for IgE antibodies provides an indication of the immune response to allergen(s) 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(s), the sequence of sensitization and clinical manifestations proceed as follows: eczema and respiratory disease (rhinitis and bronchospasm) in infants and children less 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     | <0.35     | Negative          |
| 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.

**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**

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.

Some individuals with clinically insignificant sensitivity to allergens may have measurable levels of IgE antibodies in serum, and 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: Chapter 55: Allergic diseases. In Henry's Clinical Diagnosis and Management by Laboratory Methods. 23rd edition. Edited by RA McPherson, MR Pincus. Elsevier, 2017, pp 1057-1070

### **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 is then 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, Uppsala, Sweden Rev 06/2019)

#### **PDF Report**

No

#### **Day(s) and Time(s) Test Performed**

Monday through Friday; 9 a.m.-8 p.m.

Saturday; 8 a.m.-3 p.m.

#### **Analytic Time**

Same day/1 day

#### **Maximum Laboratory Time**

3 days

#### **Specimen Retention Time**

14 days

#### **Performing Laboratory Location**

Rochester

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**Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved or is exempt by the U.S. 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**

86003

**LOINC® Information**

| Test ID | Test Order Name | Order LOINC Value |
|---------|-----------------|-------------------|
| CLAM    | Clam, IgE       | 6076-4            |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|------------------|--------------------|
| CLAM      | Clam, IgE        | 6076-4             |