

Overview

Useful For

Establishing a diagnosis of an allergy to gluten

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. Å

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. Å

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

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
GLT	Gluten, IgE	6125-9

Result ID	Test Result Name	Result LOINC Value
GLT	Gluten, IgE	6125-9