Test Definition: IGE

Immunoglobulin E (IgE), S

Overview

Useful For

Evaluation of patients with suspected diseases associated with elevations in total immunoglobulin E (IgE), including allergic disease, primary immunodeficiencies, infections, malignancies, or other inflammatory diseases

Diagnostic evaluation of patients with suspected allergic bronchopulmonary aspergillosis

Identification of candidates for omalizumab (anti-IgE) therapy

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

Specimen Minimum Volume

For total IgE: 0.3 mL
For total IgE and more than 1 allergen: 0.05 mL x number of allergen-specific IgEs + 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 and Interpretive

Clinical Information

Immunoglobulin E (IgE) is one of the 5 classes of immunoglobulins and is defined by the presence of the epsilon heavy chain. It is the most recently described immunoglobulin, having first been identified in 1966. IgE exists as a monomer and is present in circulation at very low concentrations, approximately 300-fold lower than that of IgG. The physiologic role of IgE is not well characterized, although it is thought to be involved in defense against parasites, specifically helminthes.

The function of IgE is also distinct from other immunoglobulins in that it induces activation of mast cells and basophils through the cell-surface receptor Fc epsilon RI. Fc epsilon RI is a high-affinity receptor specific for IgE that is present at a high density on tissue-resident mast cells and basophils. Because of this high-affinity interaction, almost all IgE produced by B cells is bound to mast cells or basophils, which explains the low concentration present in circulation. Cross-linking of the Fc epsilon RI-bound IgE leads to cellular activation, resulting in immediate release of preformed granular components (histamine and tryptase) and subsequent production of lipid mediators (prostaglandins and leukotrienes) and cytokines (interleukin-4 and interleukin-5).

Elevated concentrations of IgE are generally thought of in the context of allergic disease. However, increases in the amount of circulating total serum IgE can also be found in various other diseases, including primary immunodeficiencies, infections, inflammatory diseases, and malignancies. Total IgE measurements have limited utility for diagnostic evaluation of patients with suspected allergic disease, except for allergic bronchopulmonary aspergillosis (ABPA). ABPA is a hypersensitivity reaction against the fungi *Aspergillus* that occurs most frequently in patients with asthma or cystic fibrosis. An elevation of total IgE is part of the diagnostic criteria for ABPA, although the specific diagnostic concentration is dependent on certain patient characteristics.

For patients with an established diagnosis of allergic disease, measurement of total IgE is necessary for identification of candidates for omalizumab (anti-IgE) therapy and for determination of proper dosing. In addition to specific patient demographics and clinical presentations, candidates for omalizumab must have total IgE concentrations between 30 and 700 KU/L.

Reference Values

Results reported in kU/L	
Age	**Reference interval**
0-5 months	< or =13
6-11 months	< or =34
1 and 2 years	< or =97
3 years	< or =199
4-6 years	< or =307
7 and 8 years	< or =403
9-12 years	< or =696
13-15 years	< or =629
16 and 17 years	< or =537
18 years and older	< or =214

Interpretation

Elevated concentrations of total immunoglobulin E (IgE) may be found in a variety of clinical diseases including allergic disease, certain primary immunodeficiencies, infections, inflammatory diseases, and malignancies.

Elevated total IgE concentrations may be consistent with a diagnosis of allergic bronchopulmonary aspergillosis, provided other laboratory and clinical criteria are fulfilled.

Total IgE concentrations between 30 to 700 KU/L may identify candidates for omalizumab therapy and may help to determine proper therapeutic dosing.

Cautions

An elevated concentration of total immunoglobulin E (IgE) is not diagnostic for allergic disease and must be interpreted in the clinical context of the patient including age, gender, travel history, potential allergen exposure, and family history.

A normal concentration of total IgE does not eliminate the possibility of allergic disease. In patients with a high index of suspicion for allergic disease, testing for allergen-specific IgE may be warranted.

The probability of finding an increased level of total IgE in serum in a patient with allergic disease varies directly with the number of different allergens to which the patient is sensitized.

Normal levels of total IgE in serum occur in some patients with allergic disease, especially if there is sensitivity to a limited number of allergens and limited end organ involvement.

Clinical Reference

1. Homburger HA: Allergic diseases. In: Clinical Diagnosis and Management by Laboratory Methods. 21st ed. WB Saunders Company. 2007;961-971

2. Martins TB, Bandhauer ME, Bunker AM, Roberts WL, Hill HR: New childhood and adult reference intervals for total IgE. J Allergy Clin Immunol. 2014 Feb;133(2):589-591

3. Bernstein IL, Li JT, Bernstein DI, et al: Allergy diagnostic testing: An updated practice parameter. Ann Allergy Asthma Immunol. 2008 Mar;100(3 Suppl 3):S1-148

4. Ansotegui IJ, Melioli G, Canonica GW, et al: IgE allergy diagnostics and other relevant tests in allergy, a World Allergy Organization position paper. World Allergy Organ J. 2020 Feb;13(2):100080. doi: 10.1016/j.waojou.2019.100080

Performance

Method Description

Anti-immunoglobulin E (IgE), covalently coupled to ImmunoCAP, reacts with the IgE in a serum specimen. After washing, enzyme-labeled anti-IgE antibodies are added to form a complex. After incubation, unbound enzyme-labeled anti-IgE is washed away and the bound complex is incubated with a developing agent. After stopping the reaction, fluorescence of the eluate in the well is measured. The fluorescence is directly proportional to the concentration of IgE in the test specimen.(Package insert: Phadia CAP System IgE FEIA. Thermo Fisher Scientific, Inc; revised April 2014)

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

82785

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
IGE	Immunoglobulin E (IgE), S	19113-0

Result ID	Test Result Name	Result LOINC Value
IGE	Immunoglobulin E (IgE), S	19113-0