Test Definition: IGE

Immunoglobulin E (IgE), Serum

Overview

Useful For

Evaluating patients with suspected diseases associated with elevations in total IgE, including allergic disease, primary immunodeficiencies, infections, malignancies, or other inflammatory diseases

Diagnostic evaluation of patients with suspected allergic bronchopulmonary aspergillosis

Identifying candidates for omalizumab (anti-IgE) therapy

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

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

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

Immunoglobulin E (IgE) is one of the 5 immunoglobulin classes 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 helminths.

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

0-5 months: < or =13 kU/L
6-11 months: < or =34 kU/L
1 and 2 years: < or =97 kU/L
3 years: < or =199 kU/L
4-6 years: < or =307 kU/L
7 and 8 years: < or =403 kU/L

9-12 years: < or =696 kU/L
13-15 years: < or =629 kU/L
16 and 17 years : < or =537 kU/L
18 years or older: < or =214 kU/L

Interpretation

Elevated concentrations of total 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 (IgE is not diagnostic for allergic disease and must be interpreted in the clinical context of the patient including age, sex, 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;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;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;13(2):100080. doi:10.1016/j.waojou.2019.100080

Performance

Method Description

Anti-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. Phadia; revised 04/2019)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
Same day/1 day 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 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
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