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
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 in Special Instructions

Specimen Required
Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Specimen Volume: 0.5 mL

Reject Due To
Gross hemolysis  OK
Gross lipemia  OK

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

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>90 days</td>
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</tbody>
</table>

Clinical & 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

<table>
<thead>
<tr>
<th>Age</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 months</td>
<td>&lt; or =13</td>
</tr>
<tr>
<td>6-11 months</td>
<td>&lt; or =34</td>
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<tr>
<td>1 and 2 years</td>
<td>&lt; or =97</td>
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<tr>
<td>3 years</td>
<td>&lt; or =199</td>
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<tr>
<td>4-6 years</td>
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</tbody>
</table>

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

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

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes
Test Definition: IGE
Immunoglobulin E (IgE), S

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