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

Specimen Required
Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
</tr>
</tbody>
</table>

Specimen Stability 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 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 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>Results Reported in kU/L</th>
<th>Age</th>
<th>Reference interval</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0-5 months</td>
<td>&lt; or =13</td>
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<tr>
<td></td>
<td>6-11 months</td>
<td>&lt; or =34</td>
</tr>
<tr>
<td></td>
<td>1 and 2 years</td>
<td>&lt; or =97</td>
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<tr>
<td></td>
<td>3 years</td>
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<tr>
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<td>4-6 years</td>
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<td>7 and 8 years</td>
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<td>9-12 years</td>
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<td></td>
<td>13-15 years</td>
<td>&lt; or =629</td>
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Test Definition: IGE
Immunoglobulin E (IgE), S

<table>
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<th>Age</th>
<th>Cut-off Value</th>
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<tbody>
<tr>
<td>16 and 17 years</td>
<td>&lt; or =537</td>
</tr>
<tr>
<td>18 years and older</td>
<td>&lt; or =214</td>
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**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 IgEs may be warranted.

**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. issued August 2000, revised June 2010)

**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.
**Test Definition: IGE**
Immunoglobulin E (IgE), S

**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 or approved 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**

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<tbody>
<tr>
<td>IGE</td>
<td>Immunoglobulin E (IgE), S</td>
<td>19113-0</td>
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