Seminal Fluid IgE
Test Code: 87010A

Clinical and Procedure

Clinical Utility
This assay is used to detect allergen specific-IgE using the ImmunoCAP® FEIA method. In vitro allergy testing is the primary testing mode for allergy diagnosis.

Procedure
The ImmunoCAP® FEIA method uses as the solid phase a flexible, hydrophobic cellulosic polymer to which allergen has been covalently linked. The advantage of this system is that it has a very high antigen binding capacity when compared to other systems and it has minimal non-specific binding with high total IgE. Viracor Eurofins provides an optional low range calibrator at 0.1 kU/L and a 0/1 class. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Turnaround Time
1-2 business days from receipt of specimen

Specimen Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>87010A</td>
<td>86003</td>
<td>Yes</td>
<td>0.5 mL (min. 340uL)</td>
<td>See Scoring Guide</td>
</tr>
</tbody>
</table>

Special Instructions
- Collect 1-2 mL whole blood in red top tube.
- Centrifuge and transfer 0.5 mL serum into a transfer tube.
- Ship at ambient or frozen temperature Monday through Friday.
- Specimens are stable for 4 weeks refrigerated or ambient; freeze for longer storage.

ImmunoCAP® Quantitative Scoring Guide:

<table>
<thead>
<tr>
<th>Class</th>
<th>IgE (kU/L)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>&lt;0.10</td>
<td>Negative</td>
</tr>
<tr>
<td>0/1</td>
<td>0.10-0.34</td>
<td>Equivocal/Borderline</td>
</tr>
<tr>
<td>1</td>
<td>0.35-0.69</td>
<td>Low Positive</td>
</tr>
<tr>
<td>2</td>
<td>0.70-3.49</td>
<td>Moderate Positive</td>
</tr>
<tr>
<td>3</td>
<td>3.50-17.49</td>
<td>High Positive</td>
</tr>
<tr>
<td>4</td>
<td>17.50-49.99</td>
<td>Very High Positive</td>
</tr>
<tr>
<td>5</td>
<td>50.00-99.99</td>
<td>Very High Positive</td>
</tr>
<tr>
<td>6</td>
<td>&gt;99.99</td>
<td>Very High Positive</td>
</tr>
</tbody>
</table>

Note that Viracor Eurofins includes an extra calibrator at 0.10 kU/L and uses it to define an optional equivocal class.
Causes for Rejection
Lipemic samples may lead to rejection

Disclaimer
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

References
Position Statement 12 April 1990 published in Immunology and Allergy Practice.


Szeinbach S et al. Precision and accuracy of commercial laboratories ability to classify positive and/or negative allergen-specific IgE results. Ann Allergy, Asthma & Immunol 2001; 86: 373 - 381.

Valcour A. Allergy testing for the 21st century. Advance/Laboratory 2003; 12: 68 - 75.