Helminthosporium sativum/Drechlera IgE
Test Code: 79510E

Clinical and Procedure

Clinical Utility
This assay is used to detect allergen specific-IgE using an enzyme immunoassay (EIA). In vitro allergy testing is the primary testing mode for allergy diagnosis.

Procedure
The test method is an enzyme immunoassay (EIA). Allergens are covalently coupled to the cellulose paper discs via the APT method. Alkaline phosphatase (AP) labelled anti-IgE is used to quantify the patient's specific IgE. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration.

Turnaround Time
2-3 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>79510E</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.

Scoring System for the Allergen-specific IgE EIA.

<table>
<thead>
<tr>
<th>Class</th>
<th>IgE (kU/L)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>&lt;0.35</td>
<td>Below Detection</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>Positive</td>
</tr>
<tr>
<td>4</td>
<td>17.50 - 49.99</td>
<td>Strong Positive</td>
</tr>
<tr>
<td>5</td>
<td>50.00 - 99.99</td>
<td>Very Strong Positive</td>
</tr>
<tr>
<td>6</td>
<td>&gt;99.99</td>
<td>Very Strong Positive</td>
</tr>
</tbody>
</table>

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.