immunoCAP® Rapid
Asthma/Rhinitis Adult

Directions for Use 52-5257-01/06

INTENDED USE
ImmunoCAP® Rapid is an in vitro assay for qualitative determination of allergen specific IgE antibodies in human whole blood. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Several diseases have the same or similar symptoms as IgE-mediated allergy and the diagnosis of clinical allergy is thus not easy to make (1,2). Eczema, wheezing, sneezing and a runny nose are common in small children but need not have an allergic background (3). Viral infections are often underlying causes to upper and lower respiratory problems (4). In adult patients a common problem is to assess whether asthma-like symptoms and rhinitis are related to allergy. Determination of allergen-specific IgE antibodies combined with patient’s history and physical examination contributes to a more correct diagnosis (5-7). A rapid test is a useful tool for the physician to identify an allergic patient for subsequent proper treatment and correct referral to a specialist. (8-10).

PRINCIPLE OF THE TEST
ImmunoCAP® Rapid is a lateral flow test. The blood sample is applied to the Sample well and the separated plasma portion flows onto the test strips. IgE antibodies present in the sample, specific to any of the allergens in the test, bind to the relevant areas on the strip. The Developer Solution is then added to the Developer Solution well, releasing the dried gold-anti-IgE conjugate. The conjugate forms a complex with the already bound IgE antibodies, visible as pink-red lines in the Test windows. The remaining conjugate continues to migrate, forming pink-red lines in the Control windows. The control line will appear regardless of whether the sample is positive or not, indicating that the test has performed correctly.

REAGENTS AND MATERIAL
The expiry date and storage temperature for the kit is stated on the outer label. However, each component is stable until the date stated on each individual component’s label. It is not recommended to pool any reagents. Note: The Assay Device must always be stored in the sealed foil pouch.

For 10 determinations

<table>
<thead>
<tr>
<th>Assay Device</th>
<th>Asthma/Rhinitis Adult</th>
<th>1 device/foil pouch</th>
<th>Gold Anti-IgE Conjugate (mouse monoclonal)</th>
<th>10 pieces</th>
<th>Ready to use</th>
<th>Store at 2-8°C until expiry date</th>
</tr>
</thead>
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<table>
<thead>
<tr>
<th>Developer Solution</th>
<th>Phosphate buffer, Surfactant Sodium Azide &lt;0.1%</th>
<th>1 vial, 6 ml</th>
<th>Ready to use</th>
<th>Store at 2-8°C until expiry date</th>
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<table>
<thead>
<tr>
<th>Pipette</th>
<th>10 pieces</th>
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<table>
<thead>
<tr>
<th>Blood Sampling Device</th>
<th>Heparinized</th>
<th>10 pieces</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Result and ID sticker</th>
<th>10 pieces</th>
</tr>
</thead>
</table>

Allergens in the Assay Device

<table>
<thead>
<tr>
<th>Code and full name</th>
</tr>
</thead>
<tbody>
<tr>
<td>e1 Cat epithelium and dander</td>
</tr>
<tr>
<td>e2 Common silver birch (Pollon) (Betula verrucosa)</td>
</tr>
<tr>
<td>e3 Common grass (Poaceae) (Phleum pratense)</td>
</tr>
<tr>
<td>e4 Dog dander</td>
</tr>
<tr>
<td>e5 Olive (Pollon) (Olea europaea)</td>
</tr>
<tr>
<td>e6 Hymenoptera (Vespidae) (Vespula germanica)</td>
</tr>
<tr>
<td>d1 House dust mite (Dematophagoides pteronyssinus)</td>
</tr>
<tr>
<td>d2 Canine (Pollon) (Canis lupus familiaris)</td>
</tr>
<tr>
<td>d3 House dust mite (Dematophagoides pteronyssinus)</td>
</tr>
<tr>
<td>d4 Dog dander</td>
</tr>
<tr>
<td>d5 Cat epithelium and dander</td>
</tr>
<tr>
<td>m1 Timothy (Phleum pratense)</td>
</tr>
<tr>
<td>m2 Common ragweed (Asteraceae) (Ambrosia artemisiifolia)</td>
</tr>
<tr>
<td>m3 Common birch (Betula verrucosa)</td>
</tr>
<tr>
<td>m4 Common grass (Poaceae) (Phleum pratense)</td>
</tr>
<tr>
<td>m5 Cat epithelium and dander</td>
</tr>
<tr>
<td>m6 Common silver birch (Pollon) (Betula verrucosa)</td>
</tr>
</tbody>
</table>

1. Precautions
- For in vitro diagnostic use. Not for internal or external use in humans or animals.
- Do not use reagents beyond their expiration dates.
- The Assay Device, Blood Sampling Device and Pipettes are for single use only.
- Precautions for the handling of human blood specimen and safe waste disposal of used components (containing blood) must be observed. Please refer to local/national guidelines on safety procedures.
- Reagents that contain sodium azide as a preservative must be handled with care. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Safety data sheet is available from Phadia AB on request.

2. TEST PROCEDURE
- Capillary blood or heparinized whole venous blood can be used in this test.

3. Preparation
- Place the Assay Device on a flat surface and leave it horizontally during the whole assay. Label the Assay Device with the patient ID.

4. Specimen Collection – Capillary Blood Sample
- Capillary blood must be added immediately to the Assay Device and should not be stored in the Blood Sampling Device.
- Warm the fingertip. Clean and dry the puncture site. Prick the fingertip with a lancet according to manufacturer’s instructions (A).
- Collect the blood using the provided heparinized Blood Sampling Device (B).
- Angle the Blood Sampling Device slightly downwards so that the blood runs into it. Do not cover the hole in the Plunger.
- Make sure that the Blood Sampling Device is properly filled to the Blood stop.

5. Assay Procedure
- Carefully empty the Blood Sampling Device in the Sample well (C).
- Do this by gently pressing down the Plunger with a finger covering the hole in the Plunger (D).
- Set a timer and wait five minutes (D).
- Fill the provided pipette to the upper mark with 500 μl Developer Solution (E).
- Add the whole amount of solution into the Developer Solution well by gently squeezing the bulb of the Pipette (F).
- Set a timer and wait fifteen minutes (G).
- Read the result in the Test window (H).

6. QUALITY CONTROL
- Internal Control
- The Assay Device has a procedural control. Fifteen minutes after the Developer Solution is added, pink-red lines will appear in the Control windows, indicating that the test has performed correctly.
- Venous Blood Sample
- Heparinized whole venous blood can be used in this test. The volume added to the Assay Device must be 110 μl.
The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Phadia AB may affect the results, in which event Phadia AB disclaims all warranties, implied or statutory, including the implied warranty of merchantability and fitness for use. Phadia AB and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

**REFERENCES**


**NOTES**

(a) Studies performed at Phadia AB, Uppsala, Sweden.

**PATENTS**

ImmunoCAP® Rapid is patent pending.

The following designations are trademarks belonging to Phadia AB: ImmunoCAP.

**WARRANTY**

The results obtained with this kit are considered to be satisfactory. If the results are in doubt, further tests may be performed using control materials or testing additional samples. If the problem persists, consult Phadia AB for advice.

**INTERPRETATION OF RESULTS**

**Positive Test Result**

Any pink-red line in the Test window next to an allergen indicates the presence of specific IgE antibodies reacting with that allergen. Pink-red lines in the Control window indicate that the test has performed correctly. The colour indicating a positive test result may differ from slightly pink to darker red in intensity.

**Negative Test Result**

No visible pink-red line next to an allergen indicates that specific IgE antibodies are not detected for that particular allergen. Pink-red lines in the Control window indicate that the test has performed correctly.

**Invalid Test Result**

The test is considered invalid if the control lines do not turn pink-red fifteen minutes after Developer solution is added. If this occurs, the patient should be retested with a new Assay Device.

**LIMITATIONS OF THE PROCEDURE**

A definitive clinical diagnosis should not be based on the results of any single diagnostic method and should only be made by the physician after all clinical and laboratory findings have been evaluated.

Individuals that have problems perceiving colours (e.g., red-green colour-blindness) may have difficulty reading the test result. A positive result indicates the presence of specific IgE antibodies for that allergen in the patient’s sample. Sensitization to allergens other than those provided in the test should not be excluded.

**EXPECTED VALUES**

108 patients, above the age of 18 years, with symptoms of asthma and/or rhinitis were investigated in a study performed in Sweden and Spain. The patients were diagnosed as allergic or nonallergic per allergen by allergists. 291 positive allergen specific diagnoses and 590 negative diagnoses were made by the doctors. The agreement between ImmunoCAP® Rapid Asthma/Rhinitis Adult and the doctor’s positive diagnosis was 76%. The agreement with the negative diagnosis was 97%. The overall agreement was 90%.

**ANALYTICAL PERFORMANCE CHARACTERISTICS**

**Precision**

Upon repeated testing of both negative and positive samples, the classification of samples as positive or negative has been shown to be highly reproducible.

**Analytical specificity**

No measurable cross-reactivity of the IgE-Specific conjugate antibody was observed with human IgA, IgG, IgD or IgM.

No interference of haemoglobin, bilirubin, triglycerides and cholesterol was observed within normal concentration ranges. No influence on test results, due to different hematocrit levels in blood samples, was observed for values up to 48%.

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**SYMBOLS USED**

- **LOT**
- **Batch code**
- **IVC**
- **In Vitro Diagnostic**
- **Medical Device**
- **Caution, consult accompanying documents**
- **Use By**
- **Consult Instructions for Use**
- **Do not reuse**
- **Manufacturer**

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**REFERENCES**


**NOTES**

(a) Studies performed at Phadia AB, Uppsala, Sweden.