### ImmunoCAP™ Specific IgE

Fluoroenzymeimmunoassay

Rx only

Calibrator Range 0-100 kUA

CLIA Complexity Category = Moderately Complex

Directions for Use 52-5255-US/28

### INTENDED USE

ImmunoCAP Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). 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, and is to be used in clinical laboratories.

ImmunoCAP Specific IgE is to be used with the instrument Phadia 100.

### SUMMARY AND EXPLANATION OF THE TEST

**INTENDED USE**

- ImmunoCAP Specific IgE Control M
- Washing Solution
- Stop Solution
- Development Solution
- ImmunoCAP Allergen
- ImmunoCAP Specific IgE Curve Controls
- ImmunoCAP Specific IgE Conjugates 0-100
- ImmunoCAP Specific IgE 0-100
- Reagents for Phadia 100 beyond the expiration date.

Reagents are packaged as described below, each purchased separately.

Samples are transformed to concentrations with the use of a calibration curve (3).

### PRINCIPLE OF THE PROCEDURE

The allergen of interest, coated on a bead, is then added to the sample well. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. Following incubation, unbound enzyme-ant-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE present in the sample.

To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve (3).

### REAGENTS AND MATERIAL

Reagents are packaged as described below, each purchased separately.

The expiration date and storage temperature are stated on the labels. Do not use reagents beyond their expiration dates.

Note: It is not recommended to pool any reagents.

Keep the ImmunoCAP carrier closed to avoid evaporation of buffer.

Reagents for Phadia 100

- ImmunoCAP Specific IgE 6-100 (Art No 10-9462-02; for 96 determinations)
- Specific IgE Conjugate (1 vial)
- Specific IgE Curve Control 1 (CC-1) (2 single dose vials)
- Specific IgE Curve Control 2 (CC-2) (2 single dose vials)
- ImmunoCAP Specific IgE Conjugate 9-100 (Art No 10-9463-02; for 96 determinations)
- ImmunoCAP Specific IgE Calibrators 6-100 (Cal-xc) (Art No 10-9460-01; for 1 calibration curve)
- ImmunoCAP Specific IgE Curve Controls (CC-1 and CC-2) (Art No 10-9408-01; 3 single dose vials)
- ImmunoCAP Specific IgE Anti-IgE (a-IgE) (Art No 14-4417-01; carriers of 16 ImmunoCAP)
- ImmunoCAP Allergen (See Product catalogue: carriers of 16 or 10 ImmunoCAP)
- ImmunoCAP Phadiatop (phd) (Art No 14-4338-35; for 48 determinations)
- Development Solution (Art No 10-9478-01; for 600 determinations)
- Stop Solution (Art No 10-9479-01; for 600 determinations)
- Washing Solution (Art No 10-9422-01; 6 x 1 l):
  - Washing Solution Additive, 6 x 17.2 ml
  - Washing Solution Concentrate, 6 x 80 ml
  - Washing Solution (Art No 10-9602-01; 2 x 5 l)
  - Washing Solution Additive, 2 x 88 ml
  - Washing Solution Concentrate, 2 x 400 ml
- ImmunoCAP Specific IgE Control L (Art No 10-9554-01; for 6 x 4 determinations)
- ImmunoCAP Specific IgE Control M (Art No 10-9553-01; for 6 x 4 determinations)
- ImmunoCAP Specific IgE Control H (Art No 10-9552-01; for 6 x 4 determinations)
- ImmunoCAP Specific IgE Control Negative Control (Art No 10-9445-01; for 6 x 4 determinations)

**Details of reagents**

**ImmunoCAP Specific IgE Conjugates**

- 6-Galactosidase-anti-IgE
- Approximately 1 µg/ml
- (mouse monoclonal antibodies)
- Sodium azide 0.06%

**ImmunoCAP Specific IgE Calibrators**

- (human IgE in buffer)
- Conc.: 0, 30, 0.7, 3.5, 17.5 and 100 kUA
- Preservative* <0.003%

**ImmunoCAP Specific IgE Curve Controls**

- (human IgE in buffer)
- Preservative* <0.003%

**ImmunoCAP Specific IgE Anti-IgE**

- (mouse monoclonal antibodies)
- Preservative <0.0015%

**ImmunoCAP Allergen**

- Preservative <0.0015%

**ImmunoCAP Phadiatop**

- Preservative <0.0015%

**Development Solution**

- 4-Methylumbelliferyl-D-Galactoside 0.01%
- Preservative* <0.0010%

**Stop Solution**

- Sodium carbonate 4%

**Washing Solution**

For information, see separate Directions for Use for Washing Solution.

**ImmunoCAP Specific IgE Control L**

- Sodium azide 0.05%

**ImmunoCAP Specific IgE Control M**

- Sodium azide 0.05%

**ImmunoCAP Specific IgE Control H**

- Sodium azide 0.05%

**ImmunoCAP Specific IgE Control Negative**

- Sodium azide 0.05%

**ImmunCAP Specific IgE Diluent**

(buffer solution with Bovine Serum Albumin)

Preservative* <0.003%

*Preservative: Reaction mass of CMI/MIT (3:1). (CAS No: 55965-84-9).

**Additional material**

- Additional products available from Phadia AB.
  - ImmunoCAP IgE/ECP/tryptase Sample Diluent (10-9256-01)
- Materials required but not provided by Phadia AB.
  - Measuring cylinder 1000 ml
  - Purified water (4, 5) or Clinical Laboratory Reagent Water (CLRW) (6)

**Precautions**

- For in vitro diagnostic use. Not for internal or external use in humans or animals.
- Some reagents are manufactured from human blood components. The source materials have been tested by immunoassay for hepatitis B surface antigen, for antibodies to HIV 1, HIV 2 and Hepatitis C virus and found to be negative. Nevertheless, all recommended precautions for the handling of blood derivatives should be observed.
- Please refer to Human Health Service (HHS) Publication No. (CDC)93-8395 or other local/national guidelines on laboratory safety procedures.
- Reagents containing >0.0015% reaction mass of CMI/MIT (3:1) (CAS No: 55965-84-9) may cause an allergic skin reaction (H317). Wear protective gloves/protective clothing/eye protection (P280). Gloves: Nitrile rubber EN274. For more information refer to Safety Data Sheet.
- 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 large volume of water to prevent azide build-up. For more information refer to the Safety Data Sheet and other local/national guidelines.

**INSTRUMENTS**

Phadia 100 processes all steps of the assay and prints results automatically after the assay is completed.

Phadia 100 has no provisions for on board reagent storage.

**SPECIMEN COLLECTION AND PREPARATION**

Serum and plasma (EDTA or Na-Heparin) samples from venous or capillary blood can be used. Collect blood samples using standard procedures. Keep specimens at room temperature (46°C). Sample at 2°C to 8°C up to one week, or else at <20°C. Avoid repeated freezing and thawing (7). For further reading on interfering substances see reference (8).

Blood samples for testing with drugs and venom ImmunoCAP should be collected during or close to the event, preferably not later than 6 months after exposure. If the test result is negative and an IgE-mediated reaction is still strongly suspected, it is advisable to draw a new sample and repeat the test at least 6 to 8 weeks (9, 10).

**Note:** It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. In general, laboratories should perform validation studies before implementing a change in specimen acceptance criteria (11).

**Preparation of samples**

Sample dilution is usually not required.

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Qualitative control specimens are ready for use and should not be further diluted.

Phadia 100 is programmed to automatically calculate all results (13).

Expected values for ImmunoCAP Specific IgE Negative Control

The negative control will give results representative for non-atopic blood donors using any of the following ImmunoCAP Allergens:

• ImmunoCAP Allergen e1, Cat dander (14-409-01)
• ImmunoCAP Allergen t3, Common silver birch (14-4102-01)
• ImmunoCAP Allergen d1, House dust mite (14-4107-01)

Expected values are below 0.1 kU/l.

Profitability testing

An external quality assessment program (profitability testing) is available from various independent organizations. Available from Phadia AB for quality assurance purposes (Quality Club):

• Quality Club Specific IgE (10-9298-01)

RESULTS

Phadia 100 is programmed to automatically calculate all results (13).

Quantitative evaluation of Specific IgE antibody concentration (kU/l)

ImmunoCAP Specific IgE Controls are ready for use and must not be further diluted.

Hen’s egg (14-4103-01), horse dander (14-4108-01), and yellow jacket (14-4139-01)

ImmunoCAP Specific IgE Controls are used for monitoring ImmunoCAP Specific IgE measurements performance in Phadia instruments.

Expected values for ImmunoCAP Specific IgE Control

As with all immunoassays the results are affected by the testing procedures and equipment used by different laboratories. It is therefore recommended that each laboratory establishes its own target value for each actual lot of control together with criteria of acceptance (recommended range ±30%).

Such results are found in nonsensitized individuals. However, they can also be found in patients hypersensitive to drugs, for example when:

• The symptoms are mediated without inflammation.
• The blood sample has been collected a long time after the last apparent reaction of a therapeutic treatment. It has been shown that the concentration of specific IgE antibodies falls time with time (13)
• The blood sample has been collected very soon after the allergic reaction. An interference of the time of the allergic reaction with the appearance of measurable specific IgE antibodies has been observed in some cases (14). This can lead to negative results for drug-specific IgE determinations with ImmunoCAP Specific IgE. Such results can be checked by collecting a new blood sample and repeating the test 5 to 6 weeks after the allergic reaction.

With ImmunoCAP venoms results below limit of quantitation indicate absent or undetectable levels of circulating venom-specific IgE antibodies. Such results do not preclude existence of current or future clinical hypersensitivity to insect sting.

Inappropriate results for different allergens may not be associated with clinically equivalent manifestations, due to differences in patient sensitivities.

IgE antibodies may be species specific or cross-reactive. Cross-reactivity between allergens, due to protein homologies across species, is common and is widely described in the scientific literature (15, 16). Cross reactive specific IgE antibodies often have clinical significance, since they may be revealed during the follow-up of patients who were exposed to allergens that did not originally induce the specific IgE response. For specific cross-reactivity information on closely related allergens, see Supplement to ImmunoCAP Specific IgE Directions for Use.

EXPECTED VALUES

Good practice recommends that each laboratory establishes its own expected range of values.

When a pool from 31 healthy non-allergic blood donors was tested against the existing panel of ImmunoCAP Specific IgE Controls, the 95 percentiles was below 0.1 kU/l. In clinical practice, 0.35 kU/l has commonly been used as a cut-off level and a large number of studies have been performed in which the clinical performance of ImmunoCAP Specific IgE tests in allergy diagnosis has been evaluated. Clinical performance expressed as sensitivity, ranging from 84-95%, and specificity, ranging from 85-94%, has been reported from multi-center studies including several hundred patients tested for a range of different allergens (17, 18, 19). Comparison studies between Pharmacia CAP System Specific IgE FEIA and ImmunoCAP Specific IgE have been performed with 6458 patient samples and 170 different single allergens. Newman et al. (14) compared the results with 106 ImmunoCAP Allergens. 77% of the patients tested had a specific IgE level above 0.1 kU/l.

For determination of values higher than 100 kU/l IgE, dilute the samples with ImmunoCAP IgE/DEP/ Tryptase Sample Diluent.

Handling of control specimen

To avoid evaporation, it is recommended to remove and replace the control vials from the instrument as soon as the pipetting of the sample is finished and the sample incubation is started. It is also recommended to gently stir the vial before use.

ImmunoCAP Specific IgE Controls are used for monitoring ImmunoCAP Specific IgE measurements performance in Phadia instruments.

Expected values for ImmunoCAP Specific IgE Negative Control

The negative control will give results representative for non-atopic blood donors using any of the following ImmunoCAP Allergens:

• ImmunoCAP Allergen e1, Cat dander (14-409-01)
• ImmunoCAP Allergen t3, Common silver birch (14-4102-01)
• ImmunoCAP Allergen d1, House dust mite (14-4107-01)

Expected values are below 0.1 kU/l.

Profitability testing

An external quality assessment program (profitability testing) is available from various independent organizations. Available from Phadia AB for quality assurance purposes (Quality Club):

• Quality Club Specific IgE (10-9298-01)
PERFORMANCE CHARACTERISTICS

Precision

The following mean coefficients of variation (CV) have been obtained when testing representative allergens from seven allergen groups. Each sample has been assayed in 4 replicates on 18 different occasions using stored calibration curves.

<table>
<thead>
<tr>
<th>Sample level (kU/l)</th>
<th>Coefficients of variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within assay</td>
</tr>
<tr>
<td>0.7 – 3.5</td>
<td>5</td>
</tr>
<tr>
<td>3.5 – 17.5</td>
<td>6</td>
</tr>
<tr>
<td>17.5 – 100</td>
<td>5</td>
</tr>
</tbody>
</table>

Analytical sensitivity

The overall limit of quantitation (20) for allergen specific IgE antibodies is 0.1 kU/l.

Analytical specificity

The cross-reactivity with other human immunoglobulins is non-detectable at physiological concentrations of IgA, IgD, IgM and IgG.

WARRANTY

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 expressed, 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.

SYMBOLS

- Use-by date
- Batch code
- Date of manufacture
- Catalogue number
- Caution
- Manufacturer
- Contains sufficient for <x> tests
- In vitro diagnostic medical device
- Temperature limit
- Consult instructions for use
- Biological risks
- Prescription use only

Full symbol glossary is available at: https://symbols_glossary.phadia.com.

REFERENCES


Notes

For more information, see Phadia 100 User Manual.

Patents/Trademarks

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

Trademark change: Phadia AB has changed the trademarks of the instrument platforms from "UniCAP™" and "ImmunoCAP™" to "Phadia™". The new name has been applied to the instrument systems and related items, e.g. Software and User Manuals. The trademark "ImmunoCAP™" has been removed from the System Reagents. This is a trademark change only; the change has no impact on performance or safety.

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Supplement to
ImmunoCAP™ Specific IgE
Directions for Use 52-5255-US and 52-5256-US

ImmunoCAP Specific IgE Allergens with Representative Individual Allergen Performance
Listed below are ImmunoCAP Specific IgE Allergens for In Vitro Diagnostic Use.

Note:
1. Allergen codes containing an "x" (as in ex1, Animal proteins) are made from a mixture of multiple whole extract allergen sources.
2. ImmunoCAP Allergen Components are produced from purified proteins found in the source material.
3. All other ImmunoCAP Allergens listed below are derived from whole extracts of stated source material.

ImmunoCAP Allergen c1, Penicilliy G
ImmunoCAP Allergen c2, Penicilliy V
ImmunoCAP Allergen c5, Amapcilliy
ImmunoCAP Allergen c6, Amoxicilliy
ImmunoCAP Allergen c75, Insulin human
ImmunoCAP Allergen c74, Gelatin bovine
ImmunoCAP Allergen d1, House dust mite
ImmunoCAP Allergen d2, House dust mite
ImmunoCAP Allergen d201, House dust mite
ImmunoCAP Allergen d202, Allergen component dPer p 1, House dust mite
ImmunoCAP Allergen d203, Allergen component dPer p 2, House dust mite
ImmunoCAP Allergen d205, Allergen component dPer p 10 Tropomyosin, House dust mite
ImmunoCAP Allergen d3, House dust mite
ImmunoCAP Allergen d70, Storage mite
ImmunoCAP Allergen d71, Storage mite
ImmunoCAP Allergen d72, Storage mite
ImmunoCAP Allergen d73, Storage mite
ImmunoCAP Allergen d74, House dust mite
ImmunoCAP Allergen e1, Cat dander
ImmunoCAP Allergen e101, Allergen component eCan f 1 Dog
ImmunoCAP Allergen e102, Allergen component eCan f 2 Dog
ImmunoCAP Allergen e2, Dog epithelium
ImmunoCAP Allergen e201, Canary bird feathers
ImmunoCAP Allergen e213, Parrot feathers
ImmunoCAP Allergen e220, Allergen component ef el 2 Cat serum albumin
ImmunoCAP Allergen e221, Allergen component eCan f 3 Dog serum albumin
ImmunoCAP Allergen e226, Allergen component eCan f 15 Dog
ImmunoCAP Allergen e227, Allergen component eGou c 1, Horse
ImmunoCAP Allergen e228, Allergen component ef el 4, Cat
ImmunoCAP Allergen e229, Allergen component eCan f 14 Dog
ImmunoCAP Allergen e230, Allergen component eCan f 1, Dog
ImmunoCAP Allergen e231, Allergen component ef el 7 Cat
ImmunoCAP Allergen e3, Horse dander
ImmunoCAP Allergen e4, Cow dander
ImmunoCAP Allergen e5, Dog dander
ImmunoCAP Allergen e6, Guinea pig epithelium
ImmunoCAP Allergen e7, Pigeon droppings
ImmunoCAP Allergen e70, Goose feathers
ImmunoCAP Allergen e71, Mouse epithelium
ImmunoCAP Allergen e72, Mouse urine proteins
ImmunoCAP Allergen e73, Rat epithelium
ImmunoCAP Allergen e74, Rat urine proteins
ImmunoCAP Allergen e75, Rat serum proteins
ImmunoCAP Allergen e76, Mouse serum proteins
ImmunoCAP Allergen e77, Bird droppings
ImmunoCAP Allergen e78, Bird droppings
ImmunoCAP Allergen e79, Bird droppings
ImmunoCAP Allergen e80, Goat epithelium
ImmunoCAP Allergen e81, Sheep epithelium
ImmunoCAP Allergen e82, Rabbit epithelium
ImmunoCAP Allergen e83, Swine epithelium
ImmunoCAP Allergen e84, Hamster epithelium
ImmunoCAP Allergen e85, Chicken feathers

ImmunoCAP Allergen e86, Duck feathers
ImmunoCAP Allergen e87, Rat epithelium, serum and urine proteins
ImmunoCAP Allergen e88, Mouse epithelium, serum and urine proteins
ImmunoCAP Allergen e89, Turkey feathers
ImmunoCAP Allergen e94, Allergen component ef el d 1 Cat
ImmunoCAP Allergen ex1, Animal proteins
ImmunoCAP Allergen ex2, Animal proteins
ImmunoCAP Allergen ex70, Rodents
ImmunoCAP Allergen ex71, Feathers
ImmunoCAP Allergen ex73, Feathers
ImmunoCAP Allergen f1, Egg white
ImmunoCAP Allergen f10, Sesame seed
ImmunoCAP Allergen f11, Buckwheat
ImmunoCAP Allergen f12, Pea
ImmunoCAP Allergen f13, Peanut
ImmunoCAP Allergen f14, Soybean
ImmunoCAP Allergen f15, White bean
ImmunoCAP Allergen f17, Hazel nut
ImmunoCAP Allergen f18, Brazil nut
ImmunoCAP Allergen f2, Milk
ImmunoCAP Allergen f20, Almond
ImmunoCAP Allergen f201, Pecan nut
ImmunoCAP Allergen f202, Cashew nut
ImmunoCAP Allergen f203, Pistachio
ImmunoCAP Allergen f204, Trout
ImmunoCAP Allergen f205, Herring
ImmunoCAP Allergen f207, Cian
ImmunoCAP Allergen f208, Lemon
ImmunoCAP Allergen f209, Grapefruit
ImmunoCAP Allergen f210, Pineapple
ImmunoCAP Allergen f213, Rabbit
ImmunoCAP Allergen f214, Spinach
ImmunoCAP Allergen f215, Lettuce
ImmunoCAP Allergen f216, Cabbage
ImmunoCAP Allergen f218, Paprika, Sweet pepper
ImmunoCAP Allergen f225, Pumpkin
ImmunoCAP Allergen f23, Crab
ImmunoCAP Allergen f231, Milk boiled
ImmunoCAP Allergen f232, Allergen component fNal d 2 Ovalbumin, Egg
ImmunoCAP Allergen f233, Allergen component fNal d 1 Ovomucoid, Egg
ImmunoCAP Allergen f235, Lentil
ImmunoCAP Allergen f236, Cow's milk whey
ImmunoCAP Allergen f237, Agaricus
ImmunoCAP Allergen f24, Shrimp
ImmunoCAP Allergen f242, Cherry
ImmunoCAP Allergen f244, Cucumber
ImmunoCAP Allergen f245, Egg
ImmunoCAP Allergen f25, Tomato
ImmunoCAP Allergen f254, Placie
ImmunoCAP Allergen f255, Plum
ImmunoCAP Allergen f256, Walnut
ImmunoCAP Allergen f259, Grape
ImmunoCAP Allergen f26, Pork
ImmunoCAP Allergen f260, Broccoli
ImmunoCAP Allergen f27, Beef
ImmunoCAP Allergen f280, Black pepper
ImmunoCAP Allergen f284, Turkey meat
ImmunoCAP Allergen f290, Oyster
ImmunoCAP Allergen f294, Sweet chestnut
ImmunoCAP Allergen f3, Fish (cod)
ImmunoCAP Allergen f309, Chick pea
ImmunoCAP Allergen f31, Carrot
ImmunoCAP Allergen f33, Orange
ImmunoCAP Allergen f338, Scallop
ImmunoCAP Allergen f35, Potato
ImmunoCAP Allergen f351, Allergen component fPer a 1 Tropomyosin, Shrimp
ImmunoCAP Allergen f355, Allergen component fPer a 9 PR-10, Peanut
ImmunoCAP Allergen f356, Allergen component nGly m 4 PR-10, Soy
ImmunoCAP Allergen f357, Allergen component fPer a 1 Brazil nut
ImmunoCAP Allergen f358, Beeswax
ImmunoCAP Allergen f359, Blue mussels
ImmunoCAP Allergen f4, Wheat
ImmunoCAP Allergen f40, Tuna
ImmunoCAP Allergen f41, Salmon
ImmunoCAP Allergen f419, Allergen component fPrn p 1 PR-10, Peach
ImmunoCAP Allergen f420, Allergen component fPrn p 3 LTP, Peach
ImmunoCAP Allergen f421, Allergen component fPrn p 4 Profilin, Peach
ImmunoCAP Allergen f422, Allergen component fPrn a 1 Hazel nut
ImmunoCAP Allergen f423, Allergen component fPrn a 2 Peanut
ImmunoCAP Allergen f424, Allergen component fPrn a 3 Peanut
ImmunoCAP Allergen f425, Allergen component fOc a 8 Hazel nut
ImmunoCAP Allergen f427, Allergen component fOc a 9 LTP, Peanut
ImmunoCAP Allergen f428, Allergen component fOc a 1 PR-10, Hazel nut
ImmunoCAP Allergen f431, Allergen component fDer p 1 Cat
ImmunoCAP Allergen f432, Allergen component fDer p 5 Beta-conglycinin, Soy
ImmunoCAP Allergen f433, Allergen component fDer p 6 Mung bean
ImmunoCAP Allergen f434, Allergen component fDer p 7 Adh-1, Asparagine
ImmunoCAP Allergen f435, Allergen component fDer p 8 Amylo-1, Myo-inositol

Published 2019-10-24
<table>
<thead>
<tr>
<th>ImmunoCAP Allergen</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>46, Avocado</td>
<td></td>
</tr>
<tr>
<td>47, Fennel</td>
<td></td>
</tr>
<tr>
<td>1, Food</td>
<td></td>
</tr>
<tr>
<td>13, Vegetables</td>
<td></td>
</tr>
<tr>
<td>15, Fruits</td>
<td></td>
</tr>
<tr>
<td>16, Fruits</td>
<td></td>
</tr>
<tr>
<td>2, Food</td>
<td></td>
</tr>
<tr>
<td>25, Fruits</td>
<td></td>
</tr>
<tr>
<td>3, Food</td>
<td></td>
</tr>
<tr>
<td>5, Food</td>
<td></td>
</tr>
<tr>
<td>5255, Yellow hornet venom</td>
<td></td>
</tr>
</tbody>
</table>
Representative individual allergen performance data

The data used to generate these tables were obtained from studies performed in support of the 510(k) submissions. Phadia has listed the overall ImmunoCAP Specific IgE system performance characteristics under the “Performance Characteristics” section in the main body of this DIU. For CLIA purposes, please continue to use these data to demonstrate that your laboratory can obtain similar results for ImmunoCAP Specific IgE. The allergen performance tables below are representative examples of individual allergen performance only, and are not target specifications to be verified by a laboratory.

Linearity
Data from samples in at least five 2-fold dilutions (1) y-log-transformed(expected concentration), x-log-transformed(expected concentration)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen Component</th>
<th>Allergen</th>
<th>Regression Equation</th>
<th>r²</th>
<th>95% CI Slope</th>
<th>95% CI Intercept</th>
<th>Highest concentration tested (kU/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>d203, rDer p 2</td>
<td>e94, rFel d 1</td>
<td>y = 0.97x + 0.03</td>
<td>0.99</td>
<td>0.96 – 0.98</td>
<td>0.02 – 0.04</td>
<td>56</td>
</tr>
<tr>
<td>f423, rAra h 2</td>
<td>m229, rAlt a 1</td>
<td>y = 0.97x + 0.09</td>
<td>0.99</td>
<td>0.96 – 0.99</td>
<td>-0.01 – 0.01</td>
<td>59</td>
</tr>
<tr>
<td>w230, rAmb a 1</td>
<td>g205, rPhl p 1</td>
<td>y = 1.00x + 0.02</td>
<td>0.99</td>
<td>1.00 – 0.01</td>
<td>-0.02 – 0.01</td>
<td>80</td>
</tr>
<tr>
<td>g215, rBet v 1</td>
<td>f351, rPen a 1</td>
<td>y = 0.99x + 0.02</td>
<td>0.99</td>
<td>1.00 – 0.01</td>
<td>-0.02 – 0.01</td>
<td>97</td>
</tr>
<tr>
<td>J62, Latex</td>
<td>f121, Cedar</td>
<td>y = 0.96x + 0.07</td>
<td>0.96</td>
<td>0.97 – 0.07</td>
<td>0.07 – 0.08</td>
<td>40</td>
</tr>
<tr>
<td>i3, Common wasp venom</td>
<td>e101, rCan f 1</td>
<td>y = 0.99 + 0.01</td>
<td>0.99</td>
<td>1.00 – 0.00</td>
<td>-0.02 – 0.00</td>
<td>74</td>
</tr>
<tr>
<td>f353, rGly m 4</td>
<td>f441, rAug r 1</td>
<td>y = 1.00x + 0.02</td>
<td>0.99</td>
<td>1.00 – 0.01</td>
<td>-0.01 – 0.00</td>
<td>63</td>
</tr>
<tr>
<td>d202, rDer p 1</td>
<td>w1, Common ragweed</td>
<td>y = 0.99x + 0.04</td>
<td>0.98</td>
<td>1.00 – 0.02</td>
<td>-0.02 – 0.07</td>
<td>92</td>
</tr>
<tr>
<td>f447, rAra h 6</td>
<td>e229, rCan f 4</td>
<td>y = 1.00x + 0.01</td>
<td>0.99</td>
<td>1.00 – 0.01</td>
<td>-0.01 – 0.01</td>
<td>97</td>
</tr>
<tr>
<td>e231, rFel d 7</td>
<td>e94, rFel d 1</td>
<td>y = 1.01x + 0.01</td>
<td>0.99</td>
<td>1.00 – 0.02</td>
<td>-0.01 – 0.01</td>
<td>52</td>
</tr>
</tbody>
</table>

Cross-reactivity
Based upon inhibition testing of the closely related tree allergens Cypress and Cedar, an appreciable degree of cross reactivity was demonstrated. The potential for cross reactivity with other tree allergens was not evaluated in these studies. Latex specific IgE antibodies may show cross reactivity with ragweed and certain food allergens such as banana, avocado, kiwi and chestnut (4, 5, 6).

Clinical data
Comparison studies between the ImmunoCAP Allergen Components and the corresponding extract based ImmunoCAP Allergen were performed using patient samples with clinical documentation of allergy to the extract based allergen (or allergen group) and 100 negative samples from healthy non-atopic donors.

Sensitivity and Specificity with 95% Confidence Intervals (CI) were calculated. Please note that sensitivity values may reflect the prevalence of sensitization to an Allergen Component within a population with allergy to the corresponding allergen extract.

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen</th>
<th>Allergen Component</th>
<th>Clinical Diagnosis to Peanut</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>d203, rDer p 2</td>
<td>Peanut</td>
<td>Positive</td>
<td>53</td>
<td>0</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>4</td>
<td>100</td>
<td>104</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>57</td>
<td>100</td>
<td>157</td>
</tr>
</tbody>
</table>

Sensitivity = 93% (95% CI: 83.0 – 98.1%)
Specificity = 100% (95% CI: 96.4 – 100%)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen</th>
<th>Allergen Component</th>
<th>Clinical Diagnosis to Cat</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>e94, rFel d 1</td>
<td>Cat</td>
<td>Positive</td>
<td>72</td>
<td>0</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>1</td>
<td>100</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>73</td>
<td>100</td>
<td>173</td>
</tr>
</tbody>
</table>

Sensitivity = 99% (95% CI: 92.6 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)
### ImmunoCAP Allergen f351, Allergen component rPen a 1, Shrimp

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Shrimp</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>40</td>
<td>0</td>
<td>40</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>100</td>
<td>140</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 91.2 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen k82, Latex

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Latex</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>75</td>
<td>0</td>
<td>75</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>100</td>
<td>175</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 95.2 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen i212, Cedar

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Pollen</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>30</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100</td>
<td>130</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 88.4 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen i3, Common wasp venom (Yellow jacket)

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Venoms</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>31</td>
<td>0</td>
<td>31</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>100</td>
<td>131</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 88.8 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen e101, Allergen component rCan f 1, Dog

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Dog</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>69</td>
<td>0</td>
<td>69</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>69</td>
<td>100</td>
<td>169</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 94.8 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen f353, Allergen component rGly m 4, PR-10, Soy

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Soy or foods</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>30</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100</td>
<td>130</td>
</tr>
</tbody>
</table>

**Sensitivity = 100% (95% CI: 88.4 – 100%)**  
**Specificity = 100% (95% CI: 96.4 – 100%)**

### ImmunoCAP Allergen e229, Allergen component rCan f 4, Dog

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Dog</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>26</td>
<td>0</td>
<td>26</td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
<td>100</td>
<td>107</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>100</td>
<td>133</td>
</tr>
</tbody>
</table>

**Sensitivity = 79% (95% CI: 61.1 – 91.0%)**  
**Specificity = 100% (95% CI: 96.4 – 100.0%)**

### ImmunoCAP Allergen e231, Allergen component rFel d 7, Cat

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Cat</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>32</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td>Negative</td>
<td>5</td>
<td>100</td>
<td>105</td>
</tr>
<tr>
<td>Total</td>
<td>37</td>
<td>100</td>
<td>137</td>
</tr>
</tbody>
</table>

**Sensitivity = 86% (95% CI: 71.2 – 95.5%)**  
**Specificity = 100% (95% CI: 96.4 – 100.0%)**

### ImmunoCAP Allergen o214, Allergen component MUXF3 CCD, Bromelain

<table>
<thead>
<tr>
<th>Clinical Diagnosis to allergens containing CCD</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>34</td>
<td>0</td>
<td>34</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>100</td>
<td>101</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100</td>
<td>135</td>
</tr>
</tbody>
</table>

**Sensitivity = 97% (95% CI: 85.1 – 99.0%)**  
**Specificity = 100% (95% CI: 96.4 – 100.0%)**

### ImmunoCAP Allergen i208, Allergen component rApi m 1 Phospholipase A2, Honey bee

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Venoms</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>98</td>
<td>0</td>
<td>98</td>
</tr>
<tr>
<td>Negative</td>
<td>59</td>
<td>100</td>
<td>159</td>
</tr>
<tr>
<td>Total</td>
<td>157</td>
<td>100</td>
<td>257</td>
</tr>
</tbody>
</table>

**Sensitivity = 62% (95% CI: 54.3 – 70.0%)**  
**Specificity = 100% (95% CI: 96.4 – 100.0%)**

### ImmunoCAP Allergen i209, Allergen component rVes v 5, Common wasp

<table>
<thead>
<tr>
<th>Clinical Diagnosis to Venoms</th>
<th>Atopic</th>
<th>Non-atopic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>50</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>Negative</td>
<td>17</td>
<td>100</td>
<td>117</td>
</tr>
<tr>
<td>Total</td>
<td>67</td>
<td>100</td>
<td>167</td>
</tr>
</tbody>
</table>

**Sensitivity = 75% (95% CI: 62.5 – 84.5%)**  
**Specificity = 100% (95% CI: 96.4 – 100.0%)**
<table>
<thead>
<tr>
<th>ImmunoCAP Allergen i210, Allergen component rPol d 5, European Paper wasp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis to Venoms</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>i210, rPol d 5</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Sensitivity = 65% (95% CI: 51.4 – 77.8%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen i211, Allergen component rVes v 1 Phospholipase A1, Common wasp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis to Venoms</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>i211, rVes v 1</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Sensitivity = 75% (95% CI: 62.8 – 85.0%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen i214, Allergen component rApi m 2, Honey bee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis to Venoms</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>i214, rApi m 2</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Sensitivity = 31% (95% CI: 23.2 – 39.4%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen i215, Allergen component rApi m 3, Honey bee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis to Venoms</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>i215, rApi m 3</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Sensitivity = 32% (95% CI: 23.9 – 40.1%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

<table>
<thead>
<tr>
<th>ImmunoCAP Allergen i216, Allergen component rApi m 5, Honey bee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis to Venoms</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>i216, rApi m 5</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Sensitivity = 46% (95% CI: 37.8 – 55.1%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

List of references cited in this Supplement

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