ImmunoCAP™ Specific IgE

Fluoroenzymeimmunoassay

Rx only

Calibrator Range 0-100 kU/l

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

In patients suffering from extrinsic asthma, hay fever or atopic eczema, symptoms develop immediately after exposure to specific allergens. This immediate (atopic or anaphylactic) type of allergy is a function of a special type of serum antibodies belonging to the IgE class of immunoglobulins (1, 2).

PRINCIPLE OF THE PROCEDURE

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. Following incubation, unbound enzyme-anti-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 0-100** (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 0-100** (Art No 10-9463-02: for 6 x 96 determinations)
- **ImmunoCAP Specific IgE Calibrators 0-100** (Cal-xx) (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** (phad) (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 10-9202-01: 2 x 5 l)
  - Washing Solution Additive, 2 x 86 ml
  - Washing Solution Concentrate, 2 x 400 ml
- **ImmunoCAP Specific IgE Control L** (Art No 10-9528-01: for 6 x 4 determinations)
- **ImmunoCAP Specific IgE Control M** (Art No 10-9529-01: for 6 x 4 determinations)
- **ImmunoCAP Specific IgE Control H** (Art No 10-9530-01: for 6 x 4 determinations)
- **ImmunoCAP Specific IgE Negative Control** (Art No 10-9445-01: for 6 x 4 determinations)

Details of reagents

ImmunoCAP Specific IgE Conjugate	
ß-Galactosidase-anti-IgE Approximately 1 µg/ml (mouse monoclonal antibodies) Sodium azide 0.06%	Ready for use. Store at 2 – 8 °C until expiration date. **Do not freeze!**

ImmunoCAP Specific IgE Calibrators	
(human IgE in buffer) Conc. 0; 0.35; 0.7; 3.5; 17.5 and 100 kU/l Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Specific IgE Curve Controls	
(human IgE in buffer) Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Specific IgE Anti-IgE	
(mouse monoclonal antibodies) Preservative* <0.0015%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Allergen	
Preservative* <0.0015%	Ready for use. Store at 2 – 8 °C until expiration date.

ImmunoCAP Phadiatop	
Preservative* <0.0015%	Ready for use. Store at 2 – 8 °C until expiration date.

Development Solution	
4-Methylumbelliferyl-ß-D-galactoside 0.01% Preservative* <0.0010%	Ready for use. Store at 2 – 8 °C until expiration date. **Do not freeze!**

Stop Solution	
Sodium carbonate 4%	Ready for use. Store at 2 – 32 °C until expiration date.

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

ImmunoCAP Specific IgE Control L	
Sodium azide 0.05%	Ready for use. Store at 2 – 8 °C until expiration date.
ImmunoCAP Specific IgE Control L is prepared from selected pooled human samples and contains IgE antibodies to the allergen e1. Approximate value 3 kU_A/l. **Note:** Please refer to the vial labels for lot specific assayed target ranges.	

ImmunoCAP Specific IgE Control M	
Sodium azide 0.05%	Ready for use. Store at 2 – 8 °C until expiration date.
ImmunoCAP Specific IgE Control M is prepared from selected pooled human samples and contains IgE antibodies to the allergen t3. Approximate value 10 kU_A/l. **Note:** Please refer to the vial labels for lot specific assayed target ranges.	

ImmunoCAP Specific IgE Control H	
Sodium azide 0.05%	Ready for use. Store at 2 – 8 °C until expiration date.
ImmunoCAP Specific IgE Control H is prepared from selected pooled human samples and contains IgE antibodies to the allergen d1. Approximate value 25 kU_A/l. **Note:** Please refer to the vial labels for lot specific assayed target ranges.	

ImmunoCAP Specific IgE Negative Control	
Sodium azide 0.05%	Ready for use. Store at 2 – 8 °C until expiration date.
ImmunoCAP Specific IgE Negative Control is prepared from selected pooled human samples.	

ImmunoCAP IgE/ECP/Tryptase Sample Diluent	
(buffer solution with Bovine Serum Albumin) Preservative* <0.003%	Ready for use. Store at 2 – 8 °C until expiration date.

***Preservative:** Reaction mass of CMIT/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 HIV1, HIV2 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 CMIT/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 EN374. For more information see 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[(a)].

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 (RT) for shipping purposes only. Store 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).

Note: 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 5 to 6 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.

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

Handling of control specimen

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

ImmunoCAP Specific IgE Controls are ready for use and must not be further diluted. ImmunoCAP Specific IgE Controls should be treated in the same way as a patient sample in the procedure.

PROCEDURES

Procedural steps[a]

For procedural steps, see **Notes** a.

Parameters of the procedure

Patient samples are run in single determinations.

Volumes per determination:

Sample	40 µl
Conjugate	50 µl
Development Solution	50 µl
Stop Solution	600 µl

Incubations are performed at 37 °C by Phadia 100 instrument.

Total time for one assay is 2.5 hours.

Calibration[a]

ImmunoCAP Specific IgE Calibrators are run in duplicates to obtain a calibration curve. The curve can be stored. The software for Phadia instruments has built-in acceptance limits for the calibration curve and the curve controls. Use two curve controls, CC-1 and CC-2, each in single determination to evaluate subsequent assays against the stored curve.

Working range: 0-100 kU/l calibrator range (see Supplement, Linearity, for highest range tested for representative allergens).

Reference material: The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 2nd International Reference Preparation (IRP) 75/502, or the equivalent 3rd International Standard 11/234, of Human Serum Immunoglobulin E from World Health Organization (WHO) (12).

QUALITY CONTROL

Record keeping for each assay

It is good laboratory practice to record the lot numbers of the components used, the dates when they were first opened and the remaining volumes.

Control specimen

Good laboratory practice requires that quality control specimen should be included in every run. Any material used should be assayed repeatedly to establish mean values and acceptable ranges.

Controls available from Phadia AB for day to day quality control:

- ImmunoCAP Specific IgE Control L (10-9528-01)
- ImmunoCAP Specific IgE Control M (10-9529-01)
- ImmunoCAP Specific IgE Control H (10-9530-01)
- ImmunoCAP Specific IgE Negative Control (10-9445-01)

Intended use

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%).

This established target value is expected to fall within the range for the actual lot. The range is stated on the vial for:

- ImmunoCAP Specific IgE Control L (10-9528-01), to be used with ImmunoCAP Allergen e1, Cat dander (14-4109-01)
- ImmunoCAP Specific IgE Control M (10-9529-01), to be used with ImmunoCAP Allergen t3, Common silver birch (14-4102-01)
- ImmunoCAP Specific IgE Control H (10-9530-01), to be used with ImmunoCAP Allergen d1, House dust mite (14-4107-01)

The range for each specific lot is calculated as a mean ±2 SD using the expected long term variation. The mean value for each specific lot has been determined from at least 8 consecutive control assays, each in a minimum of 6 replicates using ImmunoCAP Specific IgE.

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 (14-4109-01)
- 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_A/l.

Proficiency testing

An external quality assessment program (proficiency 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[a].

Interpretation of results for individual ImmunoCAP Allergen tests

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

IgE calibrators traceable to the WHO preparation 75/502, or the equivalent 11/234, for Human IgE are used for determination of total IgE and values are expressed in kU/l. In ImmunoCAP Specific IgE assay these calibrators are used for determination of specific IgE antibodies, and values are expressed in kU_A/l, where A represents allergen-specific antibodies.

Values above limit of quantitation (0.1 kU_A/l) represent a progressive increase in the concentration of allergen-specific IgE antibodies and should be reported as quantitative results. Results above 0.1 kU_A/l are indicative of an allergen specific IgE sensitization (7).

ASM Evaluation and Class Numbers

ImmunoCAP Specific IgE ASM (Alternate Scoring Method) provides semi-quantitative result presentation in classes equivalent to those obtained in the Modified RAST procedure. The Phadia Information Data Manager software automatically performs this calculation. The concentrations of IgE antibodies in kU_A/l corresponding to the ASM classes are shown below.

ASM Classes

ASM class	Specific IgE antibody concentration (kU_A/l)	Level of allergen specific IgE antibody
0/1	0.22 - 0.31	Equivocal/very low
1	0.31 - 0.55	Low
2	0.55 - 1.4	Moderate
3	1.4 - 3.9	High
4	3.9 - 19	Very high
5	19 - 100	Very high
6	>100	Very high

Calculations and interpretation of results for other applications of specific IgE are provided with:

- ImmunoCAP Phadiatop (Art No 14-4338-35)

Interpretation of results for ImmunoCAP Allergen mixes

Results for ImmunoCAP Allergen mixes are qualitative values and 0.35 kU/l is recommended as a cut-off value.

Values ≥0.35 kU/l indicate specific IgE antibodies to one or more of the allergens coupled to ImmunoCAP Allergen mixes.

A value below 0.35 kU/l indicates undetectable levels or very low levels, of allergen specific IgE antibodies. Deviations from results obtained with single ImmunoCAP Allergen(s) may occur.

Reinvestigation with appropriate single ImmunoCAP Allergen(s) is recommended when there is a need to further identify and obtain a quantitative result for the specific allergen(s).

The interpretation of results obtained with ImmunoCAP Allergen mixes cannot be compared with the results with single ImmunoCAP Allergen. The degree of positivity of ImmunoCAP Allergen mixes cannot be considered the cumulative degree of positivity of the respective single ImmunoCAP Allergen.

LIMITATIONS OF THE PROCEDURE

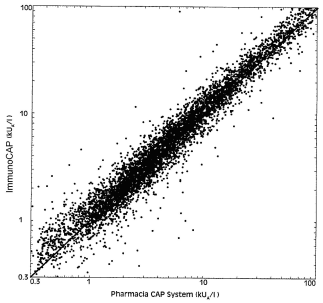
A definitive clinical diagnosis should be made by the physician after all clinical and laboratory findings have been evaluated. It should not be based on the results of any single diagnostic method.

- Allergen specific IgE antibody levels as measured by *in vitro* assays are sometimes used as grounds for instituting immunotherapy; however the results of a Specific IgE test should not be the only consideration when selecting an initial dose for immunotherapy. Prior to implementing immunotherapy a skin test with the planned initial dilution of the immunotherapy solution should be performed to prove that the patient tolerates *in vivo* administration of this allergenic extract.
- Very low levels of allergen specific IgE antibodies should be evaluated with caution when:
  a. total IgE values are above 1000 kU/l
  b. total IgE values are above 500 kU/l when testing for specific IgE antibodies to beta-lactams (ImmunoCAP Allergen c1, c2, c5 & c6)[b]
- Samples with results below limit of quantitation obtained with ImmunoCAP Allergen Components are recommended to be tested with the corresponding extract based ImmunoCAP Allergen, if not already performed. Additional extract based testing will cover additional allergen components present in the allergen source material to which the patient may be sensitized.
- A result below limit of quantitation obtained with an extract based ImmunoCAP Allergen never excludes the possibility of obtaining measurable concentrations of specific IgE when testing with ImmunoCAP Allergen Components from the same allergen source. This is due to the fact that some components may be present in very low amounts in the natural extract.
- In food allergy, circulating IgE antibodies may remain undetectable despite a convincing clinical history because these antibodies may be directed towards allergens that are revealed or altered during industrial processing, cooking or digestion and therefore do not exist in the original food for which the patient is tested.
- False positive test results in persons who are tested for food allergies may lead to inappropriate dietary restrictions while false negative results in food sensitive persons may result in anaphylactic reactions of varying severity.
- Results below limit of quantitation obtained for a drug-specific IgE determination with ImmunoCAP Specific IgE indicates the absence of specific IgE antibodies to the drug. Such results are found in nonsensitized individuals. However, they can also be found in patients hypersensitive to drugs, for example when:
  a. The symptoms are mediated without IgE involvement.
  b. The blood sample has been collected a long time after the latest adverse reaction of a therapeutic treatment procedure. It has been shown that the concentration of IgE antibodies decreases with time after the allergic reactions (13).
  c. The blood sample has been collected very soon after the allergic reaction. An interval between the time of the allergic reaction and 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.
- Identical 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 cause symptoms in patients when 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 allergens, the 95 percentile was below 0.1 kU_A/l. In clinical practice, 0.35 kU_A/l has commonly been used as a cut off 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[b] between Pharmacia CAP System Specific IgE FEIA and ImmunoCAP Specific IgE have been performed with 6458 patient samples and 170 different single allergen ImmunoCAP, and 613 patient samples and 16 different ImmunoCAP Allergen mixes. Results for patient samples obtained with Pharmacia CAP System Specific IgE FEIA and ImmunoCAP Specific IgE Assay show good agreement, see figure. In the comparison studies done with 6458 samples, agreement in positive and negative results for the two systems was 99%.



PERFORMANCE CHARACTERISTICS

Precision[b]

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.

Sample level (kU$_A$/l)	Coefficients of variation (%)	
	Within assay	Between assay
0.7 – 3.5	5	11
3.5 – 17.5	6	10
17.5 – 100	5	10

Analytical sensitivity[b]

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

Analytical specificity[b]

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		Contains sufficient for <*n*> tests
LOT	Batch code	IVD	*In vitro* diagnostic medical device
	Date of manufacture		Temperature limit
REF	Catalogue number		Consult instructions for use
	Caution		Biological risks
	Manufacturer	**Rx only**	Prescription use only

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

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Notes

[a]For more information, see Phadia 100 User Manual.

[b]Studies performed at Phadia AB, Uppsala, Sweden.

Patents/Trademarks

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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, Penicilloyl G
ImmunoCAP Allergen c2, Penicilloyl V
ImmunoCAP Allergen c5, Ampicilloyl
ImmunoCAP Allergen c6, Amoxicilloyl
ImmunoCAP Allergen c73, 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 rDer p 1, House dust mite
ImmunoCAP Allergen d203, Allergen component rDer p 2, House dust mite
ImmunoCAP Allergen d205, Allergen component rDer 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 rCan f 1 Dog
ImmunoCAP Allergen e102, Allergen component rCan f 2 Dog
ImmunoCAP Allergen e2, Dog epithelium
ImmunoCAP Allergen e201, Canary bird feathers
ImmunoCAP Allergen e213, Parrot feathers
ImmunoCAP Allergen e220, Allergen component rFel d 2 Cat serum albumin
ImmunoCAP Allergen e221, Allergen component nCan f 3 Dog serum albumin
ImmunoCAP Allergen e226, Allergen component rCan f 5 Dog
ImmunoCAP Allergen e227, Allergen component rEqu c 1, Horse
ImmunoCAP Allergen e228, Allergen component rFel d 4, Cat
ImmunoCAP Allergen e229, Allergen component rCan f 4 Dog
ImmunoCAP Allergen e230, Allergen component rCan f 6 Dog
ImmunoCAP Allergen e231, Allergen component rFel d 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, Budgerigar droppings
ImmunoCAP Allergen e78, Budgerigar feathers
ImmunoCAP Allergen e79, Budgerigar serum proteins
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 rFel 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, Soyabean
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, Clam
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 nGal d 2 Ovalbumin, Egg
ImmunoCAP Allergen f233, Allergen component nGal d 1 Ovomucoid, Egg
ImmunoCAP Allergen f235, Lentil
ImmunoCAP Allergen f236, Cow's milk whey
ImmunoCAP Allergen f237, Apricot
ImmunoCAP Allergen f24, Shrimp
ImmunoCAP Allergen f242, Cherry
ImmunoCAP Allergen f244, Cucumber
ImmunoCAP Allergen f245, Egg
ImmunoCAP Allergen f25, Tomato
ImmunoCAP Allergen f254, Plaice
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 f299, 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 rPen a 1 Tropomyosin, Shrimp
ImmunoCAP Allergen f352, Allergen component rAra h 8 PR-10, Peanut
ImmunoCAP Allergen f353, Allergen component rGly m 4 PR-10, Soy
ImmunoCAP Allergen f354, Allergen component rBer e 1 Brazil nut
ImmunoCAP Allergen f36, Coconut
ImmunoCAP Allergen f37, Blue mussel
ImmunoCAP Allergen f4, Wheat
ImmunoCAP Allergen f40, Tuna
ImmunoCAP Allergen f41, Salmon
ImmunoCAP Allergen f419, Allergen component rPru p 1 PR-10, Peach
ImmunoCAP Allergen f420, Allergen component rPru p 3 LTP, Peach
ImmunoCAP Allergen f421, Allergen component rPru p 4 Profilin, Peach
ImmunoCAP Allergen f422, Allergen component rAra h 1 Peanut
ImmunoCAP Allergen f423, Allergen component rAra h 2 Peanut
ImmunoCAP Allergen f424, Allergen component rAra h 3 Peanut
ImmunoCAP Allergen f425, Allergen component rCor a 8 Hazel nut
ImmunoCAP Allergen f427, Allergen component rAra h 9 LTP, Peanut
ImmunoCAP Allergen f428, Allergen component rCor a 1 PR-10, Hazel nut
ImmunoCAP Allergen f431, Allergen component nGly m 5 Beta-conglycinin, Soy
ImmunoCAP Allergen f432, Allergen component nGly m 6 Glycinin, Soy
ImmunoCAP Allergen f439, Allergen component rCor a 14, Hazelnut
ImmunoCAP Allergen f44, Strawberry
ImmunoCAP Allergen f440, Allergen component nCor a 9, Hazelnut
ImmunoCAP Allergen f441, Allergen component rJug r 1, Walnut
ImmunoCAP Allergen f442, Allergen component rJug r 3, LTP, Walnut
ImmunoCAP Allergen f443, Allergen component rAna o 3, Cashew nut
ImmunoCAP Allergen f447, Allergen component rAra h 6, Peanut
ImmunoCAP Allergen f45, Yeast
ImmunoCAP Allergen f47, Garlic
ImmunoCAP Allergen f48, Onion
ImmunoCAP Allergen f49, Apple
ImmunoCAP Allergen f5, Rye
ImmunoCAP Allergen f50, Chub mackerel
ImmunoCAP Allergen f51, Bamboo shoot
ImmunoCAP Allergen f54, Sweet potato
ImmunoCAP Allergen f55, Common millet
ImmunoCAP Allergen f56, Foxtail millet
ImmunoCAP Allergen f57, Japanese millet
ImmunoCAP Allergen f58, Pacific squid
ImmunoCAP Allergen f59, Octopus
ImmunoCAP Allergen f6, Barley
ImmunoCAP Allergen f60, Jack mackerel, Scad
ImmunoCAP Allergen f61, Sardine, Pilchard
ImmunoCAP Allergen f7, Oat
ImmunoCAP Allergen f75, Egg yolk
ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk
ImmunoCAP Allergen f77, Allergen component nBos d 5 Beta-lactoglobulin, Milk
ImmunoCAP Allergen f78, Allergen component nBos d 8 Casein, Milk
ImmunoCAP Allergen f79, Gluten
ImmunoCAP Allergen f8, Maize, Corn
ImmunoCAP Allergen f80, Lobster
ImmunoCAP Allergen f81, Cheese, cheddar type
ImmunoCAP Allergen f82, Cheese, mold type
ImmunoCAP Allergen f83, Chicken
ImmunoCAP Allergen f84, Kiwi fruit
ImmunoCAP Allergen f85, Celery
ImmunoCAP Allergen f86, Parsley
ImmunoCAP Allergen f87, Melon
ImmunoCAP Allergen f88, Mutton
ImmunoCAP Allergen f89, Mustard
ImmunoCAP Allergen f9, Rice
ImmunoCAP Allergen f90, Malt
ImmunoCAP Allergen f91, Mango
ImmunoCAP Allergen f92, Banana
ImmunoCAP Allergen f93, Cacao
ImmunoCAP Allergen f94, Pear
ImmunoCAP Allergen f95, Peach

ImmunoCAP Allergen f96, Avocado
ImmunoCAP Allergen fx1, Food
ImmunoCAP Allergen fx13, Vegetables
ImmunoCAP Allergen fx14, Vegetables
ImmunoCAP Allergen fx15, Fruits
ImmunoCAP Allergen fx16, Fruits
ImmunoCAP Allergen fx18, Food
ImmunoCAP Allergen fx2, Food
ImmunoCAP Allergen fx20, Food
ImmunoCAP Allergen fx24, Food
ImmunoCAP Allergen fx25, Food
ImmunoCAP Allergen fx3, Food
ImmunoCAP Allergen fx5, Food
ImmunoCAP Allergen fx7, Food
ImmunoCAP Allergen fx73, Meat
ImmunoCAP Allergen fx8, Food
ImmunoCAP Allergen fx9, Food
ImmunoCAP Allergen g1, Sweet vernal grass
ImmunoCAP Allergen g10, Johnson grass
ImmunoCAP Allergen g11, Brome grass
ImmunoCAP Allergen g12, Cultivated rye
ImmunoCAP Allergen g13, Velvet grass
ImmunoCAP Allergen g14, Cultivated oat
ImmunoCAP Allergen g15, Cultivated wheat
ImmunoCAP Allergen g16, Meadow foxtail
ImmunoCAP Allergen g17, Bahia grass
ImmunoCAP Allergen g2, Bermuda grass
ImmunoCAP Allergen g201, Barley
ImmunoCAP Allergen g202, Maize, Corn
ImmunoCAP Allergen g205, Allergen component rPhl p 1 Timothy
ImmunoCAP Allergen g206, Allergen component rPhl p 2 Timothy
ImmunoCAP Allergen g209, Allergen component rPhl p 6 Timothy
ImmunoCAP Allergen g210, Allergen component rPhl p 7 Timothy
ImmunoCAP Allergen g212, Allergen component rPhl p 12 Profilin, Timothy
ImmunoCAP Allergen g215, Allergen component rPhl p 5b Timothy
ImmunoCAP Allergen g216, Allergen component nCyn d 1 Bermuda grass
ImmunoCAP Allergen g3, Cocksfoot
ImmunoCAP Allergen g4, Meadow fescue
ImmunoCAP Allergen g5, Rye-grass
ImmunoCAP Allergen g6, Timothy
ImmunoCAP Allergen g7, Common reed
ImmunoCAP Allergen g70, Wild rye grass
ImmunoCAP Allergen g71, Canary grass
ImmunoCAP Allergen g8, Meadow grass, Kentucky blue
ImmunoCAP Allergen g9, Redtop, Bentgrass
ImmunoCAP Allergen gx1, Grass pollen
ImmunoCAP Allergen gx2, Grass pollen
ImmunoCAP Allergen gx3, Grass pollen
ImmunoCAP Allergen gx4, Grass pollen
ImmunoCAP Allergen h1, House dust (Greer Labs. Inc.)
ImmunoCAP Allergen h2, House dust (Hollister-Stier Labs.)
ImmunoCAP Allergen hx2, House dust
ImmunoCAP Allergen i1, Honey bee venom
ImmunoCAP Allergen i2, White-faced hornet venom
ImmunoCAP Allergen i201, Horse bot fly
ImmunoCAP Allergen i208, Allergen component rApi m 1 Phospholipase A2, Honey bee
ImmunoCAP Allergen i209, Allergen component rVes v 5 Common wasp
ImmunoCAP Allergen i210, Allergen component rPol d 5 European Paper wasp
ImmunoCAP Allergen i211, Allergen component rVes v 1 Phospholipase A1, Common wasp
ImmunoCAP Allergen i214, Allergen component rApi m 2, Honey bee
ImmunoCAP Allergen i215, Allergen component rApi m 3, Honey bee
ImmunoCAP Allergen i216, Allergen component rApi m 5, Honey bee
ImmunoCAP Allergen i217, Allergen component rApi m 10, Honey bee
ImmunoCAP Allergen i3, Common wasp venom (Yellow jacket)
ImmunoCAP Allergen i4, Paper wasp venom
ImmunoCAP Allergen i5, Yellow hornet venom
ImmunoCAP Allergen i6, Cockroach, German
ImmunoCAP Allergen i70, Fire ant
ImmunoCAP Allergen i71, Mosquito
ImmunoCAP Allergen i72, Green nimitti
ImmunoCAP Allergen i73, Blood worm
ImmunoCAP Allergen i75, European hornet venom
ImmunoCAP Allergen i76, Berlin beetle
ImmunoCAP Allergen i8, Moth
ImmunoCAP Allergen k70, Green coffee bean
ImmunoCAP Allergen k71, Castor bean
ImmunoCAP Allergen k72, Ispaghula
ImmunoCAP Allergen k73, Silk waste
ImmunoCAP Allergen k74, Silk
ImmunoCAP Allergen k75, Isocyanate TDI
ImmunoCAP Allergen k76, Isocyanate MDI
ImmunoCAP Allergen k77, Isocyanate HDI
ImmunoCAP Allergen k78, Ethylene oxide
ImmunoCAP Allergen k79, Phthalic anhydride
ImmunoCAP Allergen k81, Ficus spp.
ImmunoCAP Allergen k82, Latex
ImmunoCAP Allergen k84, Sunflower seed
ImmunoCAP Allergen k87, Allergen component nAsp o 21 Alpha-amylase, Aspergillus oryzae
ImmunoCAP Allergen m1, Penicillium chrysogenum
ImmunoCAP Allergen m10, Stemphylium herbarum
ImmunoCAP Allergen m11, Rhizopus nigricans
ImmunoCAP Allergen m12, Aureobasidium pullulans
ImmunoCAP Allergen m13, Phoma betae
ImmunoCAP Allergen m14, Epicoccum purpurascens
ImmunoCAP Allergen m15, Trichoderma viride
ImmunoCAP Allergen m16, Curvularia lunata
ImmunoCAP Allergen m2, Cladosporium herbarum
ImmunoCAP Allergen m202, Acremonium kiliense (Cephalosporium acremonium)
ImmunoCAP Allergen m205, Trichophyton rubrum
ImmunoCAP Allergen m207, Aspergillus niger
ImmunoCAP Allergen m229, Allergen component rAlt a 1, Alternaria alternata
ImmunoCAP Allergen m3, Aspergillus fumigatus
ImmunoCAP Allergen m4, Mucor racemosus
ImmunoCAP Allergen m5, Candida albicans
ImmunoCAP Allergen m6, Alternaria alternata
ImmunoCAP Allergen m7, Botrytis cinerea
ImmunoCAP Allergen m70, Pityrosporum orbiculare
ImmunoCAP Allergen m8, Setomelanomma rostrata (Helminthosporium halodes)
ImmunoCAP Allergen m80, Staphylococcal enterotoxin A
ImmunoCAP Allergen m81, Staphylococcal enterotoxin B
ImmunoCAP Allergen m9, Fusarium proliferatum
ImmunoCAP Allergen mx1, Moulds
ImmunoCAP Allergen mx2, Moulds
ImmunoCAP Allergen o1, Cotton, crude fibers
ImmunoCAP Allergen o214, Allergen component MUXF3 CCD, Bromelain
ImmunoCAP Allergen p1, Ascaris
ImmunoCAP Allergen p2, Echinococcus
ImmunoCAP Allergen p4, Anisakis
ImmunoCAP Allergen pax1
ImmunoCAP Allergen pax3
ImmunoCAP Allergen pax5
ImmunoCAP Allergen t1, Box-elder
ImmunoCAP Allergen t10, Walnut
ImmunoCAP Allergen t11, Maple leaf sycamore, London plane
ImmunoCAP Allergen t12, Willow
ImmunoCAP Allergen t14, Cottonwood
ImmunoCAP Allergen t15, White ash
ImmunoCAP Allergen t16, White pine
ImmunoCAP Allergen t17, Japanese cedar
ImmunoCAP Allergen t18, Eucalyptus, Gum-tree
ImmunoCAP Allergen t19, Acacia
ImmunoCAP Allergen t2, Grey alder
ImmunoCAP Allergen t20, Mesquite
ImmunoCAP Allergen t208, Linden
ImmunoCAP Allergen t21, Melaleuca, Cajeput-tree
ImmunoCAP Allergen t210, Privet
ImmunoCAP Allergen t212, Cedar
ImmunoCAP Allergen t215, Allergen component rBet v 1 PR-10, Birch
ImmunoCAP Allergen t216, Allergen component rBet v 2 Profilin, Birch
ImmunoCAP Allergen t22, Pecan, Hickory
ImmunoCAP Allergen t220, Allergen component rBet v 4 Birch
ImmunoCAP Allergen t222, Arizona Cypress
ImmunoCAP Allergen t224, Allergen component rOle e 1, Olive
ImmunoCAP Allergen t225, Allergen component rBet v 6 Birch
ImmunoCAP Allergen t227, Allergen component nOle e 7 LTP, Olive
ImmunoCAP Allergen t23, Italian/Mediterranean/Funeral cypress
ImmunoCAP Allergen t240, Allergen component rOle e 9, Olive
ImmunoCAP Allergen t3, Common silver birch
ImmunoCAP Allergen t4, Hazel
ImmunoCAP Allergen t5, American beech
ImmunoCAP Allergen t6, Mountain juniper
ImmunoCAP Allergen t7, Oak
ImmunoCAP Allergen t70, Mulberry
ImmunoCAP Allergen t72, Queen palm
ImmunoCAP Allergen t73, Australian pine
ImmunoCAP Allergen t8, Elm
ImmunoCAP Allergen t9, Olive
ImmunoCAP Allergen tx1, Tree pollen
ImmunoCAP Allergen tx2, Tree pollen
ImmunoCAP Allergen tx3, Tree pollen
ImmunoCAP Allergen tx4, Tree pollen
ImmunoCAP Allergen tx5, Tree pollen
ImmunoCAP Allergen tx6, Tree pollen
ImmunoCAP Allergen tx7, Tree pollen
ImmunoCAP Allergen tx8, Tree pollen
ImmunoCAP Allergen tx9, Tree pollen
ImmunoCAP Allergen w1, Common ragweed
ImmunoCAP Allergen w10, Goosefoot, Lamb's quarters
ImmunoCAP Allergen w11, Saltwort (prickly), Russian thistle
ImmunoCAP Allergen w12, Goldenrod
ImmunoCAP Allergen w13, Cocklebur
ImmunoCAP Allergen w14, Common pigweed
ImmunoCAP Allergen w15, Scale, Lenscale
ImmunoCAP Allergen w16, Rough marshelder
ImmunoCAP Allergen w17, Firebush (Kochia)
ImmunoCAP Allergen w18, Sheep sorrel
ImmunoCAP Allergen w19, Wall pellitory
ImmunoCAP Allergen w2, Western ragweed
ImmunoCAP Allergen w20, Nettle
ImmunoCAP Allergen w21, Wall pellitory
ImmunoCAP Allergen w230, Allergen component nAmb a 1 Ragweed
ImmunoCAP Allergen w231, Allergen component nArt v 1 Mugwort
ImmunoCAP Allergen w233, Allergen component nArt v 3 LTP, Mugwort
ImmunoCAP Allergen w3, Giant ragweed
ImmunoCAP Allergen w4, False ragweed
ImmunoCAP Allergen w5, Wormwood
ImmunoCAP Allergen w6, Mugwort
ImmunoCAP Allergen w7, Marguerite, Ox-eye daisy
ImmunoCAP Allergen w8, Dandelion
ImmunoCAP Allergen w9, Plantain (English), Ribwort
ImmunoCAP Allergen wx1, Weed pollen
ImmunoCAP Allergen wx2, Weed pollen
ImmunoCAP Allergen wx3, Weed pollen
ImmunoCAP Allergen wx5, Weed pollen
ImmunoCAP Allergen wx6, Weed pollen
ImmunoCAP Allergen wx7, Weed pollen

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 DfU. 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(observed concentration), x= log-transformed(expected concentration)

ImmunoCAP Allergen Component	Regression Equation	r2	95% CI Slope	95% CI Intercept	Highest concentration tested (kU_A/L)
d203, rDer p 2	y = 1.00x	1.00	0.99 – 1.01	-0.01 – 0.01	79
e94, rFel d 1	y = 0.97x + 0.03	0.99	0.95 – 0.98	0.02 – 0.04	56
f423, rAra h 2	y = 0.91x + 0.09	0.99	0.90 – 0.93	0.08 – 0.11	78
m229, rAlt a 1	y = 0.97x	0.99	0.96 – 0.99	-0.01 – 0.01	59
w230, nAmb a 1	y = 0.97x + 0.02	1.00	0.96 – 0.98	0.02 – 0.03	25
g205, rPhl p 1	y = 1.00x + 0.02	1.00	0.99 – 1.00	0.01 – 0.02	80
t215, rBet v 1	y = 0.99x + 0.02	1.00	0.99 – 1.00	0.02 – 0.03	97
f351, rPen a 1	y = 1.03 + (-0.03)	0.99	1.02 – 1.05	-0.04 – (-0.01)	71
k82, Latex	y = 0.99x + (-0.01)	1.00	0.97 – 1.00	-0.02 – 0.01	>100
t212, Cedar	y = 0.96x + 0.07	1.00	0.95 – 0.97	0.07 – 0.08	40
i3, Common wasp venom	y = 0.97 + 0.05	1.00	0.96 – 0.98	0.04 – 0.06	70
e101, rCan f 1	y = 0.99 + 0.01	1.00	0.98 – 1.00	0.00 – 0.02	74
f353, rGly m 4	y = 1.01x	1.00	1.00 – 1.01	-0.01 – 0.00	78
f441, rJug r 1	y = 1.00x	1.00	0.99 – 1.00	0 – 0	63
d202, rDep p 1	y = 1.00x + (-0.02)	1.00	0.99 – 1.01	-0.03 – (-0.02)	76
w1, Common ragweed	y = 0.99x + 0.04	1.00	0.98 – 1.00	0.02 – 0.07	92
f447, rAra h 6	y = 1.01x	1.00	1.00 – 1.01	-0.01 – 0.02	63
e229, rCan f 4	y = 1.00x	1.00	0.99 – 1.00	-0.01 – 0.01	97
e231, rFel d 7	y = 1.01x - 0.01	1.00	1.01 – 1.02	-0.01 – (-0.01)	52
o214, MUXF3 CCD	y = 0.98x + 0.04	1.00	0.97 – 0.99	0.03 – 0.05	67
i208, rApi m 1	y = 1.03x - 0.03	1.00	1.01 – 1.04	-0.04 – (-0.02)	51
i209, rVes v 5	y = 1.00x - 0.01	1.00	0.99 – 1.01	-0.02 – (-0.00)	78
i210, rPol d 5	y = 1.00x + 0.02	1.00	0.99 – 1.01	0.01 – 0.03	83
i211, rVes v 1	y = 0.99x + 0.02	1.00	0.98 – 0.99	0.01 – 0.02	67
i214, rApi m 2	y = 1.01x - 0.01	1.00	1.00 – 1.01	-0.01 – 0.00	40
i215, rApi m 3	y = 1.00x + 0.01	1.00	0.99 – 1.00	0.01 – 0.02	76
i216, rApi m 5	y = 1.01x - 0.01	1.00	1.00 – 1.01	-0.02 – (-0.01)	84
i217, rApi m 10	y = 1.02x - 0.01	1.00	1.01 – 1.02	-0.02 – (-0.01)	61

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.

ImmunoCAP Allergen d203, Allergen component rDer p 2, House dust mite

		Clinical Diagnosis to House dust mite		
		Atopic	Non-atopic	Total
d203, rDer p 2	Positive	53	0	53
	Negative	4	100	104
	Total	57	100	157

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

ImmunoCAP Allergen e94, Allergen component rFel d 1, Cat

		Clinical Diagnosis to Cat		
		Atopic	Non-atopic	Total
e94, rFel d 1	Positive	72	0	72
	Negative	1	100	101
	Total	73	100	173

Sensitivity = 99% (95% CI: 92.6 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmnuoCAP Allergen f423, Allergen component rAra h 2, Peanut

		Clinical Diagnosis to Peanut		
		Atopic	Non-atopic	Total
f423, rAra h 2	Positive	40	0	40
	Negative	53	100	153
	Total	93	100	193

Sensitivity = 43% (2, 3) (95% CI: 32.8 – 53.7%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen m229, Allergen component rAlt a 1, Alternaria alternata

		Clinical Diagnosis to Alternaria alternata		
		Atopic	Non-atopic	Total
m229, rAlt a1	Positive	45	0	45
	Negative	0	100	100
	Total	45	100	145

Sensitivity =100% (95% CI: 92.1 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen w230, Allergen component nAmb a 1, Ragweed

		Clinical Diagnosis to Ragweed		
		Atopic	Non-atopic	Total
w230, nAmb a 1	Positive	34	0	34
	Negative	0	100	100
	Total	34	100	134

Sensitivity = 100% (95% CI: 89.7 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen g205, Allergen component rPhl p 1, Timothy

		Clinical Diagnosis to Timothy		
		Atopic	Non-atopic	Total
g205, rPhl p 1	Positive	85	0	85
	Negative	0	100	100
	Total	85	100	185

Sensitivity = 100% (95% CI: 95.8 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen t215, Allergen component rBet v 1, PR-10, Birch

		Clinical Diagnosis to Birch		
		Atopic	Non-atopic	Total
t215, rBet v 1	Positive	94	0	94
	Negative	0	100	100
	Total	94	100	194

Sensitivity = 100% (95% CI: 96.2 – 100%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen f351, Allergen component rPen a 1, Shrimp

		Clinical Diagnosis to Shrimp		
		Atopic	Non-atopic	Total
f351, rPen a 1	Positive	40	0	40
	Negative	0	100	100
	Total	40	100	140

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

ImmunoCAP Allergen k82, Latex

		Clinical Diagnosis to Latex		
		Atopic	Non-atopic	Total
k82, Latex	Positive	75	0	75
	Negative	0	100	100
	Total	75	100	175

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

ImmunoCAP Allergen t212, Cedar

		Clinical Diagnosis to Pollen		
		Atopic	Non-atopic	Total
t212, Cedar	Positive	30	0	30
	Negative	0	100	100
	Total	30	100	130

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

ImmunoCAP Allergen i3, Common wasp venom (Yellow jacket)

		Clinical Diagnosis to Venoms		
		Atopic	Non-atopic	Total
i3, Common wasp venom (Yellow jacket)	Positive	31	0	31
	Negative	0	100	100
	Total	31	100	131

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

ImmunoCAP Allergen e101, Allergen component rCan f 1, Dog

		Clinical Diagnosis to Dog		
		Atopic	Non-atopic	Total
e101, rCan f 1	Positive	69	0	69
	Negative	0	100	100
	Total	69	100	169

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

		Clinical Diagnosis to Soy or foods		
		Atopic	Non-atopic	Total
f353, rGly m 4	Positive	30	0	30
	Negative	0	100	100
	Total	30	100	130

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

ImmunoCAP Allergen f441, Allergen component rJug r 1, Walnut

		Clinical Diagnosis to Walnut or foods		
		Atopic	Non-atopic	Total
f441, rJug r 1	Positive	37	0	37
	Negative	2	100	102
	Total	39	100	139

Sensitivity = 95% (95% CI: 82.7 – 99.4%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

ImmunoCAP Allergen d202, Allergen component rDer p 1, House dust mite

		Clinical Diagnosis to House dust mite		
		Atopic	Non-atopic	Total
d202, rDer p 1	Positive	28	0	28
	Negative	7	100	107
	Total	35	100	135

Sensitivity = 80% (95% CI: 63.1 – 91.6%)
Specificity = 100% (95% CI: 96.4 – 100%)

ImmunoCAP Allergen w1, Common ragweed

		Clinical Diagnosis to Common ragweed or pollen		
		Atopic	Non-atopic	Total
w1, Common ragweed	Positive	47	0	47
	Negative	3	112	115
	Total	50	112	162

Sensitivity = 94% (95% CI: 83.5 – 98.7%)
Specificity = 100% (95% CI: 96.8 – 100%)

ImmunoCAP Allergen f447, Allergen component rAra h 6, Peanut

		Clinical Diagnosis to Peanut or other foods		
		Atopic	Non-atopic	Total
f447, rAra h 6	Positive	28	0	28
	Negative	6	100	106
	Total	34	100	134

Sensitivity = 82% (95% CI: 65.5 – 93.2%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

ImmunoCAP Allergen e229, Allergen component rCan f 4, Dog

		Clinical Diagnosis to Dog		
		Atopic	Non-atopic	Total
e229, rCan f 4	Positive	26	0	26
	Negative	7	100	107
	Total	33	100	133

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

		Clinical Diagnosis to Cat		
		Atopic	Non-atopic	Total
e231 rFel d 7	Positive	32	0	32
	Negative	5	100	105
	Total	37	100	137

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

ImmunoCAP Allergen o214, Allergen component MUXF3 CCD, Bromelain

		Clinical Diagnosis to allergens containing CCD		
		Atopic	Non-atopic	Total
o214, MUXF3 CCD	Positive	34	0	34
	Negative	1	100	101
	Total	35	100	135

Sensitivity = 97% (95% CI: 85.1 – 99.9%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

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

		Clinical Diagnosis to Venoms		
		Atopic	Non-atopic	Total
i208, rApi m 1	Positive	98	0	98
	Negative	59	100	159
	Total	157	100	257

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

		Clinical Diagnosis to Venoms		
		Atopic	Non-atopic	Total
i209, rVes v 5	Positive	50	0	50
	Negative	17	100	117
	Total	67	100	167

Sensitivity = 75% (95% CI: 62.5 – 84.5%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

ImmunoCAP Allergen i210, Allergen component rPol d 5, European Paper wasp

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i210, rPol d 5	Positive	36	0	36
	Negative	19	100	119
	Total	55	100	155

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

ImmunoCAP Allergen i211, Allergen component rVes v 1 Phospolipase A1, Common wasp

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i211, rVes v 1	Positive	48	0	48
	Negative	16	101	117
	Total	64	101	165

Sensitivity = 75% (95% CI: 62.6 – 85.0%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

ImmunoCAP Allergen i214, Allergen component rApi m 2, Honey bee

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i214, rApi m 2	Positive	42	0	42
	Negative	94	100	194
	Total	136	100	236

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

ImmunoCAP Allergen i215, Allergen component rApi m 3, Honey bee

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i215, rApi m 3	Positive	43	0	43
	Negative	93	100	193
	Total	136	100	236

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

ImmunoCAP Allergen i216, Allergen component rApi m 5, Honey bee

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i216, rApi m 5	Positive	62	0	62
	Negative	72	100	172
	Total	134	100	234

Sensitivity = 46% (95% CI: 37.6 – 55.1%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

ImmunoCAP Allergen i217, Allergen component rApi m 10, Honey bee

		Clinical Diagnosis to Venoms		
		Atopic	**Non-atopic**	**Total**
i217, rApi m 10	Positive	87	0	87
	Negative	49	100	149
	Total	136	100	236

Sensitivity = 64% (95% CI: 55.3 – 72.0%)
Specificity = 100% (95% CI: 96.4 – 100.0%)

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