510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212181

B Applicant

Phadia AB

C Proprietary and Established Names

ImmunoCAP Allergen f433, Allergen component rTri a 14 LTP, Wheat
ImmunoCAP Allergen f416, Allergen component rTri a 19 Omega-5 Gliadin, Wheat
ImmunoCAP Allergen f449, Allergen component rSes i 1 Sesame seed

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DHB	Class II	21 CFR 866.5750 - Radioallergosorbent (RAST) Immunological Test System	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

Addition of three new recombinant allergens to a cleared device

B Measurand:

Allergen-specific IgE for: f433, rTri a 14 LTP (Wheat)
f416, rTri a 19 Omega-5 Gliadin (Wheat)
f449, rSes i1 (Sesame seed)

C Type of Test:

Fluoroenzymeimmunoassay, Quantitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

ImmunoCAP Specific IgE 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 250, Phadia 1000, Phadia 2500 and Phadia 5000.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on the instruments Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000

IV Device/System Characteristics:

A Device Description:

The ImmunoCAP system is a fully integrated and automated system for the determination of specific IgE in human blood serum or plasma (EDTA or Na-Heparin) samples. It is comprised of general, and test- and method-specific reagents for Phadia test system modules, as well as instrument and data management software.

The general ImmunoCAP reagents include ImmunoCAP Specific IgE Conjugate, ImmunoCAP Specific IgE Curve Control, ImmunoCAP Specific IgE Calibrators, Specific IgE anti-IgE ImmunoCAP, Allergen ImmunoCAP carriers, ImmunoCAP development solution and stop solution. The method-specific reagents consist of individual purified allergens (native or recombinant) covalently coupled to a support in a plastic housing.

B Principle of Operation:

The allergen of interest, covalently coupled to ImmunoCAP solid phase, reacts with the specific IgE in the patient sample. After washing away nonspecific IgE, enzyme-labeled antibodies against IgE are added to form a complex. After 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 is present in the specimen. The fluorescence results are converted to 'kU_A/L' concentrations by the software with the use of a calibration curve.

V Substantial Equivalence Information:

A Predicate Device Name(s):

UniCAP system, UniCAP Specific IgE Assay and UniCAP Specific IgE Conjugate 100 and Conjugate 400

B Predicate 510(k) Number(s):

K051218

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K212181	Predicate K051218
Device Trade Name	ImmunoCAP Specific IgE • ImmunoCAP Allergen f433, Allergen component rTri a 14 LTP,Wheat • ImmunoCAP Allergen f416, Allergen component rTri a 19 Omega-5 Gliadin, Wheat • ImmunoCAP Allergen f449, Allergen component rSes i 1 Sesame seed	UniCAP Specific IgE • ImmunoCAP Allergen f4, Wheat (14-4113-01) • ImmunoCAP Allergen f10, Sesame (14-4175-01)
General Device Characteristic Similarities		
Intended Use/ Indications for Use	ImmunoCAP Specific IgE 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 instruments Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000.	Same
Type of Test	Quantitative	Same

Device & Predicate Device(s):	Device K212181	Predicate K051218
Test Principle	Fluoroenzyme-immunoassay	Same
Sample matrix	Serum and plasma	Same
Analyte	Allergen specific IgE	Same
Detection antibody	β-Galactosidase-anti-human IgE (mouse monoclonal antibody)	Same
Sample volume	40 µL	Same
Analytical Sensitivity (LoD/LoQ)	0.1 kU_A/L	Same
Software	Phadia Information Data Manager or Phadia Prime	Same
General Device Characteristic Differences		
Allergen-containing reagent	Purified recombinant allergen components: f433, rTri a 14 LTP (Wheat); f416, rTri a 19 Omega-5 Gliadin (Wheat); f449, rSes i 1 (Sesame seed)	Allergenic extracts: wheat (f4); sesame (f10)
Number of calibrators	Six levels at 0, 0.35, 0.7, 3.5, 17.5, 100 kU_A/L	Six levels at 0.35, 0.7, 3.5, 17.5, 50, and 100 kU_A/L
Instruments	Phadia 250, Phadia 1000, Phadia 2500, Phadia 5000	UniCAP 250

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline -Third Edition
- CLSI EP06, 2nd Evaluation of Linearity of Quantitative Measurement Procedures
- CLSI EP07, 3rd Edition, Interference Testing in Clinical Chemistry
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition
- CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
- CLSI I/LA20-Ed3: Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergy Specificities; Approved Guidelines – Second Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

i) Within-laboratory imprecision:

Imprecision of each ImmunoCAP Allergen Component was evaluated by testing five (f433, rTri a 14) or six (f416, rTri a 19 and f449, rSes i 1) positive samples (> 0.1 kU_A/L) with concentrations of allergen-specific IgEs spanning the analytical measuring range (AMR). Each sample was tested in four replicates in one assay run per day for a total of 20 operating days (yielding a total of 80 replicates per sample) except Sample 6 for f416, rTri a 19, which was tested in three replicates in 11 runs over 20 days (yielding a total of 33 replicates). One lot of each ImmunoCAP Allergen Component was used for testing each sample. The assay was performed according to the ImmunoCAP Specific IgE Directions for Use using a Phadia 250 instrument. Mean concentrations of allergen-specific IgEs, standard deviation (SD), and coefficients of variance (%CV) were calculated for each sample separately. Results for all three ImmunoCAP Allergen Components are shown in the table below:

Sample	N	Mean (kU_A/L)	Within-run (Repeatability)		Between-run		Total (Within-laboratory)	
			SD	%CV	SD	%CV	SD	%CV
ImmunoCAP Allergen Component f433, rTri a 14 LTP (Wheat)								
1	80	0.18	0.01	6.05	0.01	6.10	0.02	8.59
2	80	0.34	0.03	7.43	0.02	7.14	0.03	10.30
3	80	2.24	0.08	3.35	0.10	4.41	0.12	5.53
4	80	14.83	0.48	3.27	0.70	4.75	0.85	5.76
5	80	82.81	4.91	5.93	5.20	6.27	7.15	8.63
ImmunoCAP Allergen Component f416, rTri a 19 Omega-5 Gliadin								
1	80	0.15	0.01	8.88	0.01	6.63	0.02	11.09
2	80	0.28	0.02	6.47	0.01	4.94	0.02	8.14
3	80	2.72	0.09	3.20	0.08	3.06	0.12	4.42
4	80	18.49	0.53	2.86	0.96	5.17	1.09	5.91
5	80	37.50	1.00	2.66	2.05	5.46	2.28	6.08
6	33	71.52	5.56	7.77	3.16	4.42	6.40	8.95
ImmunoCAP Allergen Component f449, rSes i 1 (Sesame seed)								
1	80	0.16	0.01	7.22	0.01	5.42	0.01	9.03
2	80	0.35	0.01	2.43	0.01	2.36	0.01	3.39
3	80	2.23	0.06	2.59	0.04	1.69	0.07	3.09
4	80	14.27	0.38	2.68	0.22	1.53	0.44	3.09
5	80	56.25	2.58	4.59	2.06	3.67	3.30	5.87
6	80	71.85	4.95	6.89	2.48	3.45	5.53	7.70

ii) Lot-to-lot imprecision:

Three different lots of each ImmunoCAP Allergen Component were tested using four (f433, rTri a 14 and f416, rTri a 19) or five (f449, rSes i 1) positive samples and one negative sample (< 0.1 kU_A/L). For each lot, the samples were tested in 12 replicates in one assay run. Each lot represented a different preparation of the allergen from routine production. The assay was performed according to the ImmunoCAP Specific IgE, Directions for Use, using the Phadia 250 instrument. Negative samples results were all below 0.1 kU_A/L and only positive results are included in the table below. Mean concentrations of allergen-specific IgEs and %CV) were calculated for the positive samples and are presented in the tables below for each ImmunoCAP Allergen Component:

ImmunoCAP Allergen Component f433, rTri a 14 LTP (Wheat)								
Lot	**Sample Panel**							
	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**	
	Mean (kU_A/L)	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**
1	0.35	4.03	2.12	2.45	17.30	2.32	78.46	4.29
2	0.33	2.50	2.07	2.33	16.80	3.53	75.30	3.95
3	0.34	2.98	2.10	2.29	17.25	4.15	79.93	6.09

ImmunoCAP Allergen Component f416, rTri a 19 Omega-5 Gliadin (Wheat)								
Lot	**Sample Panel**							
	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**	
	Mean (kU_A/L)	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**
1	0.40	9.20	2.03	2.93	12.78	4.09	55.32	6.10
2	0.34	5.93	2.02	2.02	11.93	2.27	55.89	3.36
3	0.31	9.97	2.03	2.51	12.02	2.08	55.63	6.48

ImmunoCAP Allergen Component f449, rSes i 1 (Sesame seed)										
Lot	**Sample Panel**									
	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**		**Sample 5**	
	Mean (kU_A/L)	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**	**Mean (kU_A/L)**	**%CV**
1	0.38	3.33	2.34	5.77	16.15	3.80	50.56	3.17	95.54	6.46
2	0.37	2.15	2.02	10.06	14.77	4.07	48.40	5.91	100.25	6.30
3	0.35	2.70	1.94	9.50	14.26	5.61	44.32	6.22	90.78	7.90

2. Linearity:

The linearity of each ImmunoCAP Allergen Component was assessed following the CLSI guideline I/LA-20 3rd Edition. Three (f449, rSes i 1) or four (f433, rTri a 14 and f416, rTri a 19) positive samples were each diluted in negative sample matrix to generate at least six 2-fold consecutive dilutions. Samples were tested at a minimum of four replicates in one assay run on the Phadia 250 instrument according to the ImmunoCAP Specific IgE, Directions for Use, using one lot of each ImmunoCAP Allergen component. Results of the replicates from all samples were analyzed for linearity. Regression statistics comparing the observed results to expected results are presented in the table below for each ImmunoCAP Allergen Component:

ImmunoCAP Allergen Component f433, rTri a 14 LTP (Wheat)				
Sample	**Concentration range tested (kU_A/L)**	**r^2**	**Slope (95% CI)**	**Intercept (95% CI)**
1	0.48–30.49	1.00	1.00 (0.99; 1.01)	0.00 (-0.01; 0.01)
2	0.15–9.36	1.00	1.01 (1.00; 1.03)	0.00 (-0.01; 0.01)
3	0.07–75.87	1.00	1.00 (0.99; 1.01)	0.03 (0.02; 0.04)
4	0.05–100	1.00	1.02 (1.01; 1.03)	0.03 (0.02; 0.05)
Pooled	0.05–100	1.00	1.02 (1.00; 1.03)	0.02 (0.01; 0.03)

ImmunoCAP Allergen Component f416, rTri a 19 Omega-5 Gliadin (Wheat)				
Sample	**Concentration range tested (kU_A/L)**	**r^2**	**Slope (95% CI)**	**Intercept (95% CI)**
1	0.20–6.36	1.00	1.08 (1.06; 1.10)	–0.06 (-0.07; -0.05)
2	0.19–23.76	1.00	1.01 (1.00; 1.03)	0.00 (-0.01; 0.01)
3	0.06–62.47	1.00	1.02 (1.01; 1.03)	-0.01 (-0.03; 0.00)
4	0.07–68.44	1.00	1.00 (0.99; 1.01)	0.01 (0.00; 0.02)
Pooled	0.06–68.44	1.00	1.02 (1.00; 1.04)	-0.01 (-0.03; 0.00)

ImmunoCAP Allergen Component f449, rSes i 1 (Sesame seed)				
Sample	**Concentration range tested (kU_A/L)**	**r^2**	**Slope (95% CI)**	**Intercept (95% CI)**
1	0.08–85.59	1.00	1.05 (1.04; 1.05)	–0.06 (-0.07; -0.05)
2	0.17–43.10	1.00	1.04 (1.03; 1.05)	–0.06 (-0.07; -0.05)
3	0.24–7.83	1.00	1.09 (1.08; 1.11)	-0.08 (-0.09; -0.07)
Pooled	0.08–85.59	1.00	1.06 (1.04; 1.07)	–0.06 (-0.08; -0.05)

3. Analytical Specificity/Interference:

i) Inhibition studies:

Immunological specificity of each ImmunoCAP Allergen Component was verified through competitive inhibition. The studies were conducted in accordance with CLSI I/LA-20 3rd Edition. For each ImmunoCAP Allergen component, a positive sample was tested and the specific IgE concentration is shown in the table below:

ImmunoCAP Allergen Component	kU_A/L
f433, rTri a 14 LTP (Wheat)	2.94
f416, rTri a 19 Omega-5 Gliadin (Wheat)	1.55
f449, rSes I 1 (Sesame seed)	2.17

For each ImmunoCAP Allergen Component, three inhibitors from different allergen groups and one inhibitor from the same allergen group were included in the study (see table below).

ImmunoCAP Allergen Component	Unrelated Inhibitors
f433, rTri a 14 LTP (Wheat)	From different allergen groups: rVes v 5, rFel d 2, rOle e 1 From the same allergen group: rAra h 6
f416, rTri a 19 Omega-5 Gliadin (Wheat)	From different allergen groups: rCan f 4, rVes v 5, rAsp f 2 From the same allergen group: rPru p 1
f449, rSes I 1 (Sesame seed)	From different allergen groups: rCan f 4, rAsp f 1, rOle e 1 From the same allergen group: rCor a 8

Each inhibitor was added to positive samples at serial dilutions and the results from the dose-dependent inhibition was conducted and analyzed as follows. Equal volumes of the positive sample and varying serial dilutions of the three specific allergen components were premixed. The mixture was incubated in a sample tube at room temperature for 2 hours before being analyzed with each ImmunoCAP Allergen Component on the Phadia 250 instrument according to the ImmunoCAP Specific IgE Directions for Use. The testing was performed in duplicate in one assay run. Mean values were calculated.

The inhibition test was evaluated with inhibition values in %, calculated according to the formula below:

$$\left(1-\left(\frac{r-b}{t-b}\right)\right)\times 100 = i\%$$

r = response [RU]
b = background response (100% inhibition) [RU]
t = total response (0% inhibition) [RU]
I = inhibition

Any negative percent inhibition values are shown as 0% inhibition.

The f433, rTri a 14 LTP (Wheat) dose-dependent inhibition study using inhibitor concentrations up to 279 µg/mL showed that >50% inhibition was achieved with rTri a

14 at a final concentration of 27.9 ng/mL. The inhibition studies, using four unrelated inhibitors, including three from the unrelated group (rVes v 5, rFel d 2, and rOle e 1) and one from the same group (rAra h 6), did not show any significant inhibition at 930 µg/mL. The inhibition studies indicate that the ImmunoCAP Allergen f433, rTri a 14 LTP (Wheat) solid phase contains the immunologically relevant allergen.

The f416, rTri a 19 Omega-5 Gliadin (Wheat) dose-dependent inhibition study using inhibitor concentrations up to 450 µg/mL showed that >50% inhibition was achieved with rTri a 19 at a final concentration of 30 µg/mL. The inhibition studies, using four unrelated inhibitors, including three from the unrelated group (rCan f 4, rVes v 5, and rAsp f 2) and one from the same group (rPru p 1), did not show any significant inhibition at 4.5 mg/mL. The inhibition studies indicate that the ImmunoCAP Allergen f416, rTri a 19 Omega-5 Gliadin (Wheat) solid phase contains the immunologically relevant allergen.

The f449, rSes I 1 (Sesame seed) dose-dependent inhibition study using inhibitor concentrations up to 166 µg/mL showed that >50% inhibition was achieved with the rSes I 1 at a final concentration of 83 ng/mL. The inhibition studies, using four unrelated inhibitors, including three from the unrelated group (rCan f 4, rAsp f 1, and rOle e 1) and one from the same group (rCor a 8), did not show any significant inhibition at 1.66 mg/mL. The inhibition studies indicate that the ImmunoCAP Allergen f449, rSes I 1 (Sesame seed) solid phase contains the immunologically relevant allergen.

ii) Interference:

a) Endogenous Substance Interference:

Interferences by endogenous substances were assessed by testing two positive samples and one negative sample following the CLSI guideline EP07, 3rd Edition. Each sample was spiked with the interfering substances or substance-specific diluents and analyzed in four replicates in one assay run using the Phadia 250 instrument according to the ImmunoCAP Specific IgE Directions for Use. The data demonstrated that ImmunoCAP Allergen Component: f433, rTri a 14 LTP (Wheat); f416, rTri a 19 Omega-5 Gliadin (Wheat); and f449, rSes I 1 (Sesame seed) were not adversely affected (ln (sample spiked with interferents/sample spiked with blank solution < ± 0.1)) by high levels of the following substances tested up to the concentrations listed in the table below:

Interferant	**No inhibition up to concentration tested**
Bilirubin C	20.2 mg/dL
Bilirubin F	18.5 mg/dL
Hemoglobin	490 mg/dL
Chyle	1,630 FTU-Formazine Turbidity Units
Rheumatoid Factor	500 IU/mL

b) Exogenous Substance Interference:

Two literature references were provided to support the claim that commonly prescribed allergy medications do not interfere with ImmunoCAP Specific IgE. The

references included: *(i)* Robert G. Hamilton, Accuracy of US Food and Drug Administration-cleared IgE antibody assays in the presence of anti-IgE (omalizumab), J. Allergy Clin. Immunol. 2006; 759-766, and *(ii)* Linda Cox *et al*., Pearls and pitfalls of allergy diagnostic testing: report from the American College of Allergy, Asthma and Immunology/ American Academy of Allergy, Asthma and Immunology Specific IgE Test Task Force, Annals of Allergy, Asthma & Immunology, 2008; 101:580-592.

4. Assay Reportable Range:

The claimed measuring range of each ImmunoCAP Allergen Components shown in the table below.

ImmunoCAP Allergen Component	**Claimed assay range (kU_A/L)**
f433, rTri a 14 LTP (Wheat)	0.10-100.00
f416, rTri a 19 Omega-5 Gliadin (Wheat)	0.10-68.44
f449, rSes i 1 (Sesame seed)	0.10-85.59

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

i) Traceability:

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).

ii) Kit Stability:

A real-time stability study was performed at 2–8°C to test two positive and one negative sample using three lots of each ImmunoCAP Allergen Component in accordance with the CLSI guideline EP25-A to demonstrate shelf-life stability. The real-time stability data support unopened shelf-life stability of 19 months for f433, rTri a 14 LTP (Wheat) and f416, rTri a 19 Omega-5 Gliadin (Wheat), and 6 months for f449, rSes i 1 (Sesame seed). The real-time stability study for f449 is ongoing.

The studies to determine the stability of the calibration curve, real-time, and on-board stability of ImmunoCAP IgE calibrator are described in K100999.

6. Detection Limit:

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined on the Phadia 250 instrument according to the CLSI guideline EP17-A2 using two lots of each ImmunoCAP Allergen Component.

The LoB was based on determinations of five blank samples in five replicates in one run per day for three days (n=75 replicates) for each lot and was estimated as the 95% percentile of the distribution. Results from maximum LoB of the two lots were used in the calculation of LoB.

LoD was calculated according to the equation: LoD = LoB + cß • SD_{LoD}, where SD_{LoD} is the pooled SD for each of five low positive samples using two lots measured in five replicates in three runs (n=15 replicates) for each lot. LoQ was determined and calculated at 20% CV of the test results from LoD study.

The results from the higher LoB, LoD and LoQ of the two lots are presented in the table below.

ImmunoCAP Allergen Component	LoB (kU_A/L)	LoD (kU_A/L)	LoQ (kU_A/L)
f433, rTri a 14 LTP (Wheat)	0.014	0.019	0.058
f416, rTri a 19 Omega-5 Gliadin (Wheat)	0.007	0.029	0.068
f449, rSes i 1 (Sesame seed)	0.000	0.014	0.041

The precision profile provided supports the claimed LoQ of 0.1 kUA/L at ≤20% CV.

7. Assay Cut-Off:

Limit of Quantitation for ImmunoCAP Specific IgE is 0.10 kU_A/L. All results > 0.1 kU_A/L are interpreted as being analytically positive.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Refer to clinical studies

2. Matrix Comparison:

Refer to K101251

C Clinical Studies:

1. Clinical Sensitivity and specificity:

The performance of each ImmunoCAP Allergen Component was compared to a clinical diagnosis of allergy. The objectives of this study were: *(i)* to show the linkage between specific IgE antibodies to ImmunoCAP Allergen Component and the corresponding extract based ImmunoCAP Allergen, using clinical samples, and *(ii)* to demonstrate that samples

from healthy, non-atopic donors with no reported clinical reaction to the allergen have undetectable or very low levels of specific IgE to the individual ImmunoCAP Allergen Components.

A total of 35 to 133 clinical samples from individuals with a clinical history of allergy-like symptoms upon exposure to the allergens, as diagnosed by a physician, were tested in the study. Information about clinical symptoms and manifestations was available for all clinical samples. Non-atopic samples (<0.35 kU_A/L) from 100 healthy non-atopic donors were also tested. Clinical sensitivity and specificity for each ImmunoCAP Allergen Component are summarized in the following tables:

ImmunoCAP Allergen Component		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
f433, rTri a 14 LTP (Wheat)	**Positive**	25	0	25
	Negative	108	100	208
	Total	133	100	233
Sensitivity = 18.8 % (25/133), 95% CI (12.5%; 26.5%) Specificity = 100.0% (100/100), 95% CI (96.4%; 100%)				

ImmunoCAP Allergen Component		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
f416, rTri a 19 Omega-5 Gliadin (Wheat)	**Positive**	41	0	41
	Negative	88	100	188
	Total	129	100	229
Sensitivity = 31.8 % (41/129), 95% CI (23.9%; 40.6%) Specificity =100% (100/100), 95% CI (96.4%; 100%)				

ImmunoCAP Allergen Component		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
f449, rSes i 1 (Sesame seed)	**Positive**	28	0	28
	Negative	7	100	107
	Total	35	100	135
Sensitivity = 80.0% (28/35), 95% CI (63.1%; 96.1%) Specificity =100% (100/100), 95% CI (96.4%; 100%)				

2. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The expected value determined in healthy, non-sensitized, individuals is < 0.35 kU_A/L. Each laboratory is recommended to establish its own expected range of values.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.