510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K242531

B Applicant

Hycor Biomedical

C Proprietary and Established Names

NOVEOS Specific IgE (sIgE), Capture Reagent Johnson Grass - G010, *Sorghum halepense*
NOVEOS Specific IgE (sIgE), Capture Reagent Oak - T007, *Quercus alba*
NOVEOS Specific IgE (sIgE), Capture Reagent Bermuda Grass - G002, *Cynodon dactylon*
NOVEOS Specific IgE (sIgE), Capture Reagent Common Ragweed - W001, *Ambrosia artemisiifolia*
NOVEOS Specific IgE (sIgE), Capture Reagent Dog Dander - E005, *Canis familiaris*
NOVEOS Specific IgE (sIgE), Capture Reagent Common Silver Birch - T003, *Betula verrucosa*
NOVEOS Specific IgE (sIgE), Capture Reagent Egg White - F001, *Gallus gallus*
NOVEOS Specific IgE (sIgE), Capture Reagent Cow's Milk - F002, *Bos taurus*

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:

Eight new devices

B Measurand:

Allergen specific IgE to Johnson Grass - G010, *Sorghum halepense*
Allergen specific IgE to Oak - T007, *Quercus alba*

Allergen specific IgE to Bermuda Grass - G002, *Cynodon dactylon*
Allergen specific IgE to Common Ragweed - W001, *Ambrosia artemisiifolia*
Allergen specific IgE to Dog Dander - E005, *Canis familiaris*
Allergen specific IgE to Common Silver Birch - T003, *Betula verrucosa*
Allergen specific IgE to Egg White - F001, *Gallus gallus*
Allergen specific IgE to Cow's Milk - F002, *Bos taurus*

C Type of Test:

Chemiluminescent, Quantitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The NOVEOS Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE Assay is to be used with the NOVEOS Immunoassay Analyzer. It is intended for use as an *in vitro* diagnostic aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings and is to be used in clinical laboratories.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on the NOVEOS Immunoassay Analyzer

IV Device/System Characteristics:

A Device Description:

The NOVEOS specific IgE (sIgE) Assay consists of the following reagents:

- IgE Common Kit:
  - Diluent A (human serum albumin in buffer with preservative)
  - Conjugate IgE (horse radish peroxidase labeled mouse monoclonal anti-IgE antibody with preservative)
  - Substrate A
  - Substrate B
  - Fluo Beads (streptavidin coated magnetic particles with preservative)

- Capture Reagent Pack
  - Johnson Grass - G010, *Sorghum halepense*
  - Oak - T007, *Quercus alba*
  - Bermuda Grass - G002, *Cynodon dactylon*
  - Common Ragweed - W001, *Ambrosia artemisiifolia*
  - Dog Dander - E005, *Canis familiaris*
  - Common Silver Birch - T003, *Betula verrucosa*
  - Egg White - F001, *Gallus gallus*
  - Cow's Milk - F002, *Bos taurus*

- IgE Calibrator Set (six levels: 0.07, 0.35, 0.70, 3.5, 17.5, 100 kU/L)
- IgE Calibrator Antibody Pack (mouse monoclonal anti-human IgE with preservative)
- IgE Positive Control Pack (known to be >0.35 kU/L)
- IgE Negative Control Packs (known to be <0.35 kU/L)

- Others:
  - Probe Wash Pack (phosphate buffered citric acid solution with preservative)
  - Wash Buffer Concentrate Pack (10X phosphate buffer saline solution with preservative)
  - Cuvette Wash Pack (citric acid solution with preservative)

B Principle of Operation:

The NOVEOS Specific IgE Assay is an immunometric, chemiluminescent procedure for the quantitative determination of IgE of known specificity in human serum samples. It employs fluorescent labelled magnetic, streptavidin coated microparticles which are incubated with a biotinylated allergenic capture reagent, patient sample and monoclonal anti-human IgE antibody labeled with horseradish peroxidase (Conjugate IgE). The beads are collected by use of a magnetic field to remove the liquid, and then undergo a wash step to remove unbound biotinylated allergen prior to incubation with the sample. If present in the sample, sIgE binds to the captured biotinylated allergen. After incubation, the beads are washed and subsequently incubated with an HRP-labeled anti-IgE monoclonal antibody (Conjugate IgE) to form an antibody-conjugate complex that is bound to the captured biotinylated allergen. After washing away the non-bound conjugate, a chemiluminescent substrate is added to the assay mixture resulting in light generation in proportion to the amount of antibody-conjugate that has been bound to the beads. The fluorescence is used to correct for any bead loss during the assay, and the (corrected) chemiluminescence is compared to a calibration curve to provide quantification of bound sIgE. The higher the value of chemiluminescent signal detected by the instrument, the higher the amount of sIgE detected in the sample tested. The concentration of allergen specific IgE is determined from a standard curve, which is traceable to the World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ImmunoCAP Specific IgE Assay and ImmunoCAP Specific IgE Conjugate 100 and Conjugate 400

B Predicate 510(k) Number(s):

K051218

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K242531**	**K051218**
Device Trade Name	**NOVEOS sIgE Assay**	**ImmunoCAP Specific IgE**
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The NOVEOS Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE is to be used with the NOVEOS Immunoassay Analyzer. It is intended for use as an in vitro diagnostic 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 an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000. 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.
Assay Type	Quantitative	Same
Allergen	Whole extract of allergen material to: • G010, Johnson Grass • T007, Oak • G002, Bermuda Grass • W001, Common Ragweed • E005, Dog Dander • T003, Common Silver Birch • F001, Egg White • F002, Cow's Milk	Same
Traceability	World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234	Same
Calibrator levels	0, 0.35, 0.7, 3.5, 17.5 and 100 kU/L	Same
Reaction Temperature	37°C	Same

General Device Characteristic Differences		
Specimen Type	Serum	Serum and Plasma (EDTA, Na-Heparin)
Solid Phase	Magnetic microparticles	Cellulose derivative
Instrument(s)	NOVEOS Immunoassay Analyzer	Phadia 100 Phadia 250/1000/2500/5000
Assay Principle	Chemiluminescent assay	Fluoroenzyme-immunoassay
Detection Antibody	HRP conjugated mouse anti-human IgE monoclonal antibody	β-Galactosidase conjugated mouse anti-human IgE monoclonal antibody
Sample Volume	4 µL	40 µL
Detection Limit	• G010, Johnson Grass: LoB: 0.03 kU/L LoD: 0.06 kU/L LoQ: 0.10 kU/L • T007, Oak: LoB: 0.04 kU/L LoD: 0.05 kU/L LoQ: 0.10 kU/L • G002, Bermuda Grass: LoB: 0.03 kU/L LoD: 0.05 kU/L LoQ: 0.10 kU/L • W001, Common Ragweed: LoB: 0.03 kU/L LoD: 0.05 kU/L LoQ: 0.10 kU/L • E005, Dog Dander: LoB: 0.03 kU/L LoD: 0.06 kU/L LoQ: 0.16 kU/L • T003, Common Silver Birch: LoB: 0.04 kU/L LoD: 0.08 kU/L LoQ: 0.10 kU/L • F001, Egg White: LoB: 0.02 kU/L LoD: 0.04 kU/L LoQ: 0.14 kU/L • F002, Cow's Milk: LoB: 0.03 kU/L LoD: 0.05 kU/L LoQ: 0.10 kU/L	LoB: 0.001 kU/L LoD: 0.02 kU/L LoQ: 0.10 kU/L

Assay Duration	1 hour and 45 minutes	Phadia 100: 2 hours and 30 minutes Phadia 250/1000/2500/5000: 1 hour and 45 minutes
Assay Range	• G010, Johnson Grass: 0.10 – 100 kU/L • T007, Oak: 0.10 – 100 kU/L • G002, Bermuda Grass: 0.10 –100 kU/L • W001, Common Ragweed: 0.10 – 100 kU/L • E005, Dog Dander: 0.16 – 100 kU/L • T003, Common Silver Birch: 0.10 – 100 kU/L • F001, Egg White: 0.14 – 100 kU/L • F002, Cow's Milk: 0.10 – 100 kU/L	0.10 – 100 kU/L

VI Standards/Guidance Documents Referenced:

The following Clinical and Laboratory Standards Institute (CLSI) guidelines were used:

- CLSI I/LA20-A3: Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies and Defined Allergen Specificities, Approved Guideline – Third Edition
- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP06, 2nd ed.: Evaluation of Linearity of Quantitative Measurement, Approved Guideline – Second Edition
- CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents, Approved Guideline
- CLSI EP07, 3rd ed.: Interference Testing in Clinical Chemistry; Approved Guideline –Third Edition
- CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

All results presented below met the manufacturer's pre-determined acceptance criteria**.**

1. Precision/Reproducibility:

   a. Within-laboratory imprecision

   The within-laboratory precision study was conducted per the CLSI EP05-A3 for each of eight NOVEOS Specific IgE Assay. A panel of four to five human sera that include two negative samples were tested in duplicate per run, two runs per day for 20 days using one reagent lot on one NOVEOS Immunoassay Analyzer (for a total of 80 measurements per sample). The standard deviation (SD) and %CV of the within-run, between-run, between-day, and total within-laboratory imprecision were calculated for each sample. The results for each NOVEOS Specific IgE Assay are summarized in the following tables:

NOVEOS Specific IgE Assay, G010, Johnson's Grass										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.20	80	0.02	8.9	0.01	6.9	0.04	19.0	0.05	22.1
2	0.36	80	0.01	4.0	0.02	6.0	0.03	9.4	0.04	11.8
3	7.76	80	0.35	4.6	0.16	2.0	0.61	7.8	0.72	9.3
4	34.56	80	1.19	3.5	1.07	3.1	3.09	8.9	3.48	10.1
5	43.17	84*	2.07	4.8	0.67	1.6	1.46	3.4	2.62	6.1
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with exclusion of 2 outliers for Day 21 and only 1 run at Day 22										

NOVEOS Specific IgE Assay, T007, Oak										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.20	80	0.01	5.8	0.01	4.7	0.01	6.3	0.02	9.8
2	0.25	80	0.01	4.5	0.02	8.2	0.00	0.0	0.02	9.4
3	1.72	80	0.07	4.2	0.13	7.8	0.12	6.9	0.19	11.2
4	11.80	80	0.46	3.9	0.70	6.0	0.84	7.1	1.19	10.1
5	96.20	84*	4.74	4.9	4.35	4.5	4.40	4.6	7.79	8.1
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with exclusion of 2 outliers for Day 21 and only 1 run at Day 22										

NOVEOS Specific IgE Assay, G002, Bermuda Grass										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.14	80	0.01	7.5	0.01	4.0	0.01	7.4	0.02	11.3
2	0.22	80	0.01	6.0	0.01	5.6	0.02	8.0	0.02	11.4
3	9.14	80	0.38	4.1	0.53	5.8	0.64	7.0	0.91	10.0
4	51.34	80	2.14	4.2	4.07	7.9	4.70	9.2	6.58	12.8

NOVEOS Specific IgE Assay, W001, Common Ragweed										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.17	80	0.01	8.1	0.01	8.2	0.02	10.7	0.03	15.7
2	0.29	80	0.02	7.4	0.01	3.8	0.02	6.5	0.03	10.6
3	1.28	80	0.07	5.5	0.06	4.4	0.08	6.7	0.12	9.7
4	6.28	80	0.22	3.5	0.22	3.5	0.37	5.9	0.48	7.7
5	70.33	86*	4.15	5.9	2.90	4.1	1.36	1.9	5.25	7.5
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with only 1 run at Day 22										

NOVEOS Specific IgE Assay, E005, Dog Dander										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.16	80	0.01	6.7	0.00	3.0	0.01	5.5	0.01	9.2
2	0.34	80	0.01	3.9	0.02	6.0	0.01	4.2	0.03	8.3
3	0.86	80	0.04	4.4	0.05	5.8	0.03	3.8	0.07	8.2
4	9.14	80	0.40	4.4	0.69	7.5	0.31	3.4	0.85	9.3
5	81.48	86*	4.68	5.7	2.62	3.2	2.60	3.2	5.96	7.3
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with only 1 run at Day 22										

NOVEOS Specific IgE Assay, T003, Common Silver Birch										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.21	80	0.02	10.6	0.00	0.0	0.02	9.9	0.03	14.5
2	0.29	80	0.01	4.2	0.01	5.0	0.03	8.7	0.03	10.9
3	1.31	80	0.10	7.7	0.02	1.5	0.06	4.6	0.12	9.1
4	10.37	80	0.38	3.7	0.61	5.9	0.38	3.6	0.81	7.8
5	92.31	86*	7.05	7.6	5.01	5.4	1.70	1.8	8.82	9.6
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with only 1 run at Day 22										

NOVEOS Specific IgE Assay, F001, Egg White										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.14	80	0.01	4.2	0.01	4.8	0.00	0.0	0.01	6.4
2	0.31	80	0.01	2.9	0.01	3.1	0.00	1.5	0.01	4.5
3	1.21	80	0.03	2.4	0.04	3.6	0.02	1.8	0.06	4.7
4	1.49	80	0.05	3.4	0.04	2.4	0.03	2.0	0.07	4.7
5	78.75	83*	4.30	5.5	1.95	2.5	3.33	4.2	5.77	7.3
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with exclusion of 1dropped test on Day 20 and only 1 run at Day 22										

NOVEOS Specific IgE Assay, F002, Cow's Milk										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Run**		**Between-Day**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.18	80	0.02	9.7	0.00	2.6	0.01	3.4	0.02	10.6
2	0.33	80	0.01	3.4	0.01	3.1	0.01	4.1	0.02	6.2
3	3.91	80	0.11	2.9	0.14	3.6	0.10	2.6	0.21	5.3
4	22.51	80	0.72	3.2	0.73	3.2	0.23	1.0	1.05	4.7
5	59.43	86*	3.34	5.6	2.02	3.4	4.93	8.3	6.29	10.6
* Sample 5 was done with 2 replicates/run x 2 runs/day x 22 days with 1 run at Day 22										

b. Lot-to-lot imprecision:

A panel of four samples were tested with two to three different lots of each NOVEOS Specific IgE Assay. For F001 (Egg White), F002 (Cow's Milk), and G002 (Bermuda Grass), the samples were tested in two replicates per run, two runs per day for 20 days with three lots, to yield a total of 240 replicates per sample. For E005 (Dog Dander), T003 (Common Silver Birch), T007 (Oak) and W001 (Common Ragweed), the samples were tested in replicates of five per run, one run per day, over five days, to generate a total of at least 75 replicates per sample per lot. For G010 (Johnson Grass), the samples were tested in duplicate for two runs per day, over 5 days for a total of 60 replicates per sample. The results for each NOVEOS Specific IgE Assay are summarized in the following tables:

NOVEOS Specific IgE Assay, G010, Johnson's Grass										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.18	60	0.02	11.6	0.03	14.9	0.01	6.3	0.04	19.9
2	0.37	60	0.02	6.6	0.01	1.7	0.01	3.2	0.03	7.5
3	8.15	60	0.46	5.7	0.14	1.7	0.00	0.0	0.48	5.9
4	38.12	60	1.86	4.6	0.57	1.5	0.00	0.0	1.95	5.1

NOVEOS Specific IgE Assay, T007, Oak										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.20	75	0.02	8.2	0.03	14.5	0.00	0.0	0.03	16.7
2	0.44	75	0.02	5.6	0.04	8.2	0.00	0.0	0.04	9.9
3	1.46	75	0.06	4.4	0.14	9.5	0.08	5.2	0.17	11.7
4	10.07	75	0.37	3.7	0.51	5.1	0.38	3.7	0.73	7.3

NOVEOS Specific IgE Assay, G002, Bermuda Grass										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.14	240	0.02	13.9	0.01	6.9	0.01	6.9	0.02	17.1
2	0.23	240	0.03	11.8	0.02	9.0	0.02	7.4	0.04	16.8
3	9.14	240	0.38	4.2	0.64	7.0	0.00	0.0	0.88	9.6
4	51.00	240	2.46	4.8	4.67	9.1	0.00	0.0	6.43	12.6

NOVEOS Specific IgE Assay, W001, Common Ragweed										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.18	75	0.01	8.0	0.01	5.7	0.01	7.9	0.02	12.6
2	0.48	75	0.03	5.7	0.02	4.5	0.02	4.0	0.04	8.3
3	1.27	75	0.05	4.3	0.06	4.8	0.00	0.0	0.08	6.5
4	6.16	75	0.29	4.7	0.02	3.7	0.00	0.0	0.37	6.0

NOVEOS Specific IgE Assay, E005, Dog Dander										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.14	75	0.01	8.2	0.01	9.0	0.01	4.2	0.02	12.9
2	0.43	75	0.02	5.4	0.02	4.2	0.03	5.9	0.04	9.0
3	0.79	75	0.04	5.1	0.04	4.7	0.03	3.6	0.06	7.8
4	8.25	75	0.30	3.6	0.45	5.5	0.00	0.0	0.54	6.6

NOVEOS Specific IgE Assay, T003, Common Silver Birch										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.11	75	0.01	8.6%	0.01	10.6%	0.00	0.0%	0.01	13.6%
2	0.55	75	0.02	3.6%	0.05	9.2%	0.00	0.0%	0.05	9.9%
3	1.54	75	0.06	3.7%	0.05	3.2%	0.00	0.0%	0.08	4.9%
4	8.89	75	0.38	4.3%	0.1	1.1%	0.00	0.0%	0.39	4.4%

NOVEOS Specific IgE Assay, F001, Egg White										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.15	240	0.02	15.0	0.00	0.0	0.01	4.5	0.02	16.0
2	0.31	240	0.01	3.1	0.00	0.9	0.00	0.0	0.02	5.1
3	1.20	240	0.03	2.8	0.02	1.5	0.01	1.2	0.06	4.8
4	1.47	240	0.05	3.3	0.02	1.1	0.01	0.7	0.08	5.2

NOVEOS Specific IgE Assay, F002, Cow's Milk										
Sample	**Mean (kU/L)**	**N**	**Within-Run**		**Between-Day**		**Between-Lot**		**Total**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	0.18	240	0.01	6.4	0.00	1.6	0.00	0.3	0.01	7.5
2	0.35	240	0.01	3.1	0.01	2.7	0.01	4.2	0.02	6.4
3	4.05	240	0.10	2.4	0.16	4.0	0.11	2.8	0.24	5.9
4	22.35	240	0.62	2.8	0.76	3.4	0.04	0.2	1.04	4.7

2. Linearity:

Linearity of each NOVEOS Specific IgE Assay was evaluated in accordance with the CLSI guideline I/LA20-3rd Edition. Three sets of linearity dilution panels including five to six levels were prepared by using three human serum samples (low, mid, and high) diluted with one serum sample. Three dilution panels overlapped and created the full dilution panel.

Testing was performed using one lot of each NOVEOS Specific IgE Assay in four replicates of each sample. The linearity data analysis was performed individually for each NOVEOS Specific IgE Assay in accordance with the CLSI guideline EP06, 2nd Edition. For each sample level, the mean value of the measured values, the predicted value (that is the value of the calculated regression line at the point of the expected values) and the deviation from linearity (ADL), which is the difference of the mean value of the measured values minus the predicted value, were calculated. All sample levels were within the specification for ADL. The linear range for each NOVEOS Specific IgE Assay is shown in the table below:

NOVEOS Specific IgE Assay	Linear Range
G010, Johnson Grass	0.10 – 100.0 kU/L
T007, Oak	0.10 – 100.0 kU/L
W001, Common Ragweed	0.10 – 94.0 kU/L
G002, Bermuda Grass	0.10 – 100.0 kU/L
E005, Dog Dander	0.16 – 100.0 kU/L
T003, Common Silver Birch	0.10 – 92.2 kU/L
F001, Egg White	0.14 – 100.0 kU/L
F002, Cow's Milk	0.10 – 96.9 kU/L

3. Analytical Specificity/Interference:

   a. Inhibition study:

   Immunological specificity of each NOVEOS Specific IgE Assay were verified through competitive inhibition study according to the CLSI guideline I/LA20-A3. Positive samples with specific IgE concentration used in the study include: 1.52 kU/L for G010, Johnson Grass; 12.12 kU/L for T007, Oak; 2.79 kU/L for G002, Bermuda Grass; 4.88 kU/L for W001, Common Ragweed; 3.65 kU/L for E005, Dog Dander; 2.27 kU/L for T003, Common Silver Birch; 2.04 kU/L for F001, Egg White; and 8.51 kU/L for F002, Cow's Milk.

   The allergen solution (inhibitor) was diluted 1:1 into the positive serum sample to achieve a starting concentration of 148.0 µg/mL for G010, 100 µg/mL for T007, 285.5 µg/mL for G002, 3.125 µg/mL for W001, 25 µg/mL for E005; 100 µg/mL for T003, 100 µg/mL for F001, and 100 µg/mL for F002. The sample solution was serially diluted five times in two-fold increments and each diluted sample was evaluated for dose-dependent inhibition in four replicates using three lots of NOVEOS sIgE Assays for G010, G002, F001, F002 and one lot of NOVEOS sIgE Assay for T007, W001, E005, T003. The results of the dose-dependent inhibition study showed that >50% inhibition was achieved at a final µg/mL inhibitor concentration of 18.5 µg/mL for G010, 3.125 µg/mL for T007, 17.8 µg/mL for G002, 0.78 µg/mL for W001, 0.78 µg/mL for E005, 6.25 µg/mL for T003, 3.125 µg/mL for F001, and 6.25 µg/mL for F002.

   For the NOVEOS Specific IgE Assays G010, T007, G002, W001, E005, T003, F001, and F002, the related and unrelated allergens tested were as follows:

- For G010, Johnson Grass, the related allergen G006, (timothy grass, *Phleum pretense*) and the unrelated allergens, E085, (chicken feathers); F203, (pistachio nut); T008, (elm) were tested as potential inhibitors at a final concentration of at least ten times the concentration of G010 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, G010. The results of the single-dose inhibition studies using one related allergen (G006) and at least three unrelated allergens (E085, F203 and T008) did not show inhibition at a test concentration of 1480 µg/mL for the related allergen and 1480 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, G010 contains the immunologically relevant allergen.

- For T007, Oak, the related allergen T006, (mountain cedar) and the unrelated allergens, E003, (horse epithelia); F004, (whole wheat); M003, (fungus, *Aspergillus fumigatus*) were tested as potential inhibitors at a final concentration of at least ten times the concentration of T007 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, T007. The results of the single-dose inhibition studies using one related allergen (T006) and three unrelated allergens (E003; F004; M003) did not show inhibition at a test concentration of 31.25 µg/mL for the related allergen and 31.25 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, T007 contains the immunologically relevant allergen.

- For G002, Bermuda Grass, the related allergen G202, (maize, corn, *Zia mays*) and the unrelated allergens, F203, (pistachio nut); T008, (elm); W001, (short ragweed, *Ambrosia artemisiifolia*) were tested as potential inhibitors at a final concentration of at least ten times the concentration of G002 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, G202. The results of the single-dose inhibition studies using one related allergen (G002) and three unrelated allergens (F203, T008 and W001) did not show inhibition at a test concentration of 2855 µg/mL for the related allergen and 2855 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, G002 contains the immunologically relevant allergen.

- For W001, Common Ragweed, the related allergen W014, (rough redroot pigweed) and the unrelated allergens, E003, (horse epithelia); F004, (whole wheat), T003, (white birch) were tested as potential inhibitors at a final concentration of at least ten times the concentration of W001 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, W001. The results of the single-dose inhibition studies using one related allergen (W014) and three unrelated allergens (E003; F004; T003) did not show inhibition at a test concentration of 7.8 µg/mL for the related allergen and 7.8 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, W001 contains the immunologically relevant allergen.

- For E005, Dog Dander, the related allergen E003 (horse epithelia), and the unrelated allergens, M003, (fungus, *Aspergillus fumigatus);* T006*, (Mountain Cedar)*; W006*, (Mugwort)* were tested as potential inhibitors at a final concentration of at least ten times the concentration of E005 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, E005. The results of the single-dose inhibition studies using one related allergen (E003) and three unrelated allergens (M003, T006 and W006) did not show inhibition at a test concentration of 7.8 µg/mL for the related allergen and 7.8 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, E005 contains the immunologically relevant allergen.

- For T003, Common Silver Birch, the related allergen T083, (mango blossoms) and the unrelated allergens, E003, (horse epithelia); F202, (cashew nut); W006, (common Mugwort); W012, (goldenrod); and W017, (firebush) were tested as potential inhibitors at a final concentration of at least ten times the concentration of T003 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, T003. The results of the single-dose inhibition studies using one related allergen (T083) and three unrelated allergens (E003; F202; W006; W012; W017) did not show inhibition at a test concentration of 62.5 µg/mL for the related allergen and 62.5 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, T003 contains the immunologically relevant allergen.

- For F001, Egg White, the related allergen F002, (cow's milk, *Bos taurus*), and the unrelated allergens, G010, (johnson grass, *Sorghum halepense*); M006, (*Alternaria alternata);* W006*, (*common mugwort) were tested as potential inhibitors at a final concentration of at least ten times the concentration of F001 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, F001. The results of the single-dose inhibition studies using one related allergen (F002) and three unrelated allergens (G010, M006 and W006) did not show inhibition at a test concentration of 125 µg/mL for the related allergen and 125µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, F001 contains the immunologically relevant allergen.

- For F002, Cow's Milk, the related allergen F001, (Egg white), and the unrelated allergens, E085, (chicken feathers); G002, (bermuda grass, *Cynodon dactylon*); T008, (elm) were tested as potential inhibitors at a final concentration of at least ten times the concentration of F002 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of NOVEOS Specific IgE Assay, F002. The results of the single-dose inhibition studies using one related allergen (F001) and three unrelated allergens (E085, G002 and T008) did not show inhibition at a test concentration of 62.5 µg/mL for the related allergen and 62.5 µg/mL for the three unrelated allergens. The inhibition studies indicate that the NOVEOS Specific IgE Assay, F002 contains the immunologically relevant allergen.

b. Interference:

i. Endogenous Substance Interference:

The effect of the presence of elevated level of human albumin, hemoglobin, triglyceride, conjugated bilirubin, and unconjugated bilirubin in serum samples was evaluated by testing three (one negative, one near the cut-off and one positive) serum sample pools spiked with varying levels of each interferent and analyzed in 12 replicates in one assay run with three lots of each NOVEOS sIgE Assay for G010, G002, F001 and F002, and in replicates of seven in one assay run with one lot of NOVEOS sIgE Assay for T007, W001, E005, and T003. The % recovery for each sample spiked with the potential interfering substance was calculated by comparing its result to that of the corresponding reference sample spiked with an equal volume of the solvent without the interfering substance. No interference was noted for samples containing human serum albumin up to 120 g/L, hemoglobin up to 200 mg/dL, intralipid up to 3002 mg/dL, conjugated bilirubin up to 30 mg/dL, and unconjugated bilirubin up to 20 mg/dL.

ii. Exogenous Substance Interference:

Refer to K200825.

c. Cross-reactivity:

The potential cross-reactivity of non-IgE (IgA, IgD, IgG, and IgM) to the NOVEOS sIgE Assays was evaluated in K200825.

4. Assay Reportable Range:

The assay reportable range is the same as the claimed analytical measuring range for each NOVEOS Specific IgE Assay as shown in the table below:

NOVEOS Specific IgE Assay	**Assay Reportable Range/ Analytical Measuring Range**
G010, Johnson Grass	0.10 – 100.0 kU/L
T007, Oak	0.10 – 100.0 kU/L
W001, Common Ragweed	0.10 – 94.0 kU/L
G002, Bermuda Grass	0.10 – 100.0 kU/L
E005, Dog Dander	0.16 – 100.0 kU/L
T003, Common Silver Birch	0.10 – 92.2 kU/L
F001, Egg White	0.14 – 100.0 kU/L
F002, Cow's Milk	0.10 – 96.9 kU/L

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

a. Traceability:

The IgE calibrators are traceable to the World Health Organization (WHO) third International Standard 11/234 of Human Serum Immunoglobulin E.

b. Kit Stability:

Shelf-life stability: A real-time stability study was performed in accordance with CLSI EP25-A2 using three lots of the NOVEOS Specific sIgE Capture Reagent G010, T007, G002, W001, E005, T003, F001, and F002 stored at 2–8 °C. The test was planned by testing two positive samples and one negative sample with six-month intervals up to 30 months with one additional test point at 37 months. An accelerated stability study was conducted using three lots of each Capture Reagent stored at either 25°C for 99 days (for G002, G010, T007, and W001) or at 37°C for 27 days (for E005, F001, F002, T003). All other reagents required to perform specific IgE testing on the NOVEOS system are not allergen specific and the shelf-life stability of these reagents has been previously established per K182479 and K191510 (for the Fluo Beads reagent). The collected data showed the claimed shelf-life for individual assay components is listed in the table below:

NOVEOS Specific IgE		**Shelf-life Stability (2–8°C)**
Capture Reagent G010*		36 months
Capture Reagent T007*		36 months
Capture Reagent G002*		36 months
Capture Reagent W001*		9 months
Capture Reagent E005*		36 months
Capture Reagent T003*		36 months
Capture Reagent F001*		36 months
Capture Reagent F002*		28 months
IgE Common Kit	Diluent A	48 months
	Conjugate IgE	18 months
	Substrate A and B	24 months
	Fluo Beads	24 months
IgE Calibrator Set		24 months
Calibrator Antibody IgE		24 months
Controls	IgE Positive Control Pack	24 months
	IgE Negative Control Pack	48 months
Others	Wash Buffer Concentrate	48 months
	Cuvette Wash Pack	24 months
	Probe Wash Pack	24 months
*Results based on accelerated stability data		

On-board stability: A study was performed on one instrument using three samples (two positive and one negative or low-level sample) on at least one lot of each NOVEOS Specific IgE Capture Reagent E005, F001, F002, G002, G010, T003, T007 and W001 stored on the NOVEOS Immunoassay Analyzer. The test was planned by testing at Day 0 and scheduled timepoints of 15 to 29 days for E005, F001, F002, T003, T007, and W001; or with more timepoints up to 35 days for G010, or with more timepoints up to 41 days for G002. The timepoints were chosen to at minimum have a penultimate (Tn) and

ultimate (Tn+1) timepoint and range from 2-6 timepoints (excluding Day 0) depending on the allergen evaluated. The on-board stability for all the other assay components has been previously established per K182479. The results are summarized in the table below.

NOVEOS Specific IgE		On-board Stability (2–8°C)
Capture Reagent E005		15 days
Capture Reagent F001		15 days
Capture Reagent F002		15 days
Capture Reagent G002		15 days
Capture Reagent G010		15 days
Capture Reagent T003		15 days
Capture Reagent T007		15 days
Capture Reagent W001		15 days
IgE Common Kit	Diluent A	14 days
	Conjugate IgE	14 days
	Substrate A and B	14 days
	Fluo Beads	14 days
IgE Calibrator Set		48 hours
Controls	IgE Positive Control Pack	48 hours
	IgE Negative Control Pack	48 hours
Others	1x Wash Buffer	28 days
	Cuvette Wash Pack	28 days
	Probe Wash Pack	Not applicable

6. Detection Limit:

The limit of blank (LoB), limit of detection (LoD), and limit of Quantitation (LoQ) of each NOVEOS Specific IgE Assay on the NOVEOS Immunoassay Analyzer were determined according to the CLSI guideline EP17-A2 and summarized as follows:

LoB

For G010, Johnson Grass; G002, Bermuda Grass; F001, Egg White; F002, Cow's Milk, the study was done by using three lots of capture reagent on three NOVEOS Immunoassay Analyzers. Five analyte-free human serum samples were tested in replicates of two per run, over six runs, with no more than one run per instrument per day, for a total of 60 replicates per lot.

For T007, Oak; W001, Common Ragweed; E005, Dog Dander; T003, Common Silver Birch, the study was done using two lots of capture reagent and one NOVEOS Immunoassay Analyzer. Four analyte-free human serum samples were tested in replicates of five per run, over three runs, with no more than one run per day, for a total of 60 replicates per lot.

The value at the 95th percentile of the 60 measurements for each of the lots tested was estimated.

LoD

LoD for each assay was determined by testing protocols shown in the table below:

NOVEOS sIgE Assay	No. of Sample	No. of Lot	No. of Analyzer	Testing Protocol
G010	5	3	3	5 samples x 10 replicates/run x 6 runs = 300/Lot
T007	4	2	2	4 samples x 5 replicates/run x 3 runs = 60/Lot
G002	5	3	3	5 samples x 10 replicates/run x 6 runs = 300/Lot
W010	4	2	1	4 samples x 5 replicates/run x 3 runs = 60/Lot
E005	5	2	1	5 samples x 5 replicates/run x 3 runs = 75/Lot
T003	5	2	2	5 samples x 5 replicates/run x 3 runs = 75/Lot
F001	4	3	2	4 samples x 10 replicates/run x 6 runs = 240/Lot
F002	4	3	2	4 samples x 10 replicates/run x 6 runs = 240/Lot

The LoD was calculated for each lot using a non-parametric analysis for each NOVEOS Specific IgE Assay.

LoQ

The LoQ for NOVEOS Specific IgE Assays E005, F001, F002, G002, G010, T003, T007, W001 were determined by testing four to six low IgE sample pools with replicates of three per run over three to four testing days on two assay lots using one NOVEOS Immunoassay Analyzer resulting in at least a total of 36 replicates across all samples per lot. Each run contained controls and calibrators, which were tested with two replicates for each assay. Data analysis was performed according to the precision profile method using within-lab precision results. The LoQ is defined as the mean value of the lowest sample which fulfills the specification for the total within-laboratory imprecision (<20%CV).

The claimed LoB, LoD, and LoQ are based on the highest value obtained from the lots tested for each assay and are summarized in the table below.

NOVEOS sIgE Assay	LoB (kU/L)	LoD (kU/L)	LoQ (kU/L)
G010, Johnson Grass	0.03	0.06	0.10
T007, Oak	0.04	0.05	0.10
G002, Bermuda Grass	0.03	0.05	0.10
W001, Common Ragweed	0.03	0.05	0.10
E005, Dog Dander	0.03	0.06	0.16
T003, Common Silver Birch	0.04	0.08	0.10
F001, Egg White	0.02	0.04	0.14
F002, Cow's Milk	0.03	0.05	0.10

7. Assay Cut-Off:

   See clinical cut-off.

B Comparison Studies:

1. Method Comparison with Predicate Devices:

   Refer to clinical study section below.

2. Matrix Comparison:

Not Applicable

C Clinical Studies:

1. Clinical Sensitivity/Specificity:

For each NOVEOS Specific IgE Assay, the clinical performance was evaluated by comparing the test results from a cohort of atopic and non-atopic samples to the clinical diagnosis of allergy. The atopic samples were from different U.S. and EU vendors with a clinical history of allergy-like symptoms and identified as positive by skin prick testing (SPT results with certificate of analysis) or food challenge. The non-atopic samples were from donors with no reported allergy and were deemed negative by ImmunoCAP testing (<0.35 kU/L). The sIgE test results are expressed as positive or negative using a cut-off of 0.35 kU/L. The clinical sensitivity and clinical specificity for each NOVEOS Specific IgE Assay are summarized in the following tables:

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, G010, Johnson Grass	**Positive**	62	1	63
	Negative	23	132	155
	Total	85	133	218
	Sensitivity: 72.9% (62/85) (95% CI: 62.7% to 81.2%) Specificity: 99.2% (132/133) (95% CI: 95.9% to 99.9%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, T007, Oak	**Positive**	38	2	40
	Negative	15	91	106
	Total	53	93	146
	Sensitivity: 71.7% (38/53) (95% CI: 58.4% to 82.0%) Specificity: 97.8% (91/93) (95% CI: 92.5% to 99.4%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, G002, Bermuda Grass	**Positive**	67	4	71
	Negative	21	136	157
	Total	88	140	228
	Sensitivity: 76.1% (67/88) (95% CI: 66.3% to 83.8%) Specificity: 97.1% (136/140) (95% CI: 92.9% to 98.9%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, W001, Common Ragweed	**Positive**	44	6	50
	Negative	27	88	115
	Total	71	94	165
	Sensitivity: 62.0% (44/71) (95% CI 50.3% to 72.4%) Specificity: 93.6% (88/94) (95% CI 86.8% to 97.0%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, E005, Dog Dander	**Positive**	23	0	23
	Negative	9	77	86
	Total	32	77	109
	Sensitivity: 71.9% (23/32) (95% CI: 54.6% to 84.4%) Specificity: 100.0% (109/109) (95% CI: 95.2% to 100.0%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, T003, Common Silver Birch	**Positive**	27	0	27
	Negative	22	53	75
	Total	49	53	102
	Sensitivity: 55.1% (27/49) (95% CI: 41.3% to 68.1%) Specificity: 100.0% (53/53) (95% CI: 93.2% to 100.0%)			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, F001, Egg White	**Positive**	19	0	19
	Negative	17	146	163
	Total	36	146	182
	Sensitivity: 52.8% (19/36) (95% CI: 37.0% to 68.0%) Specificity: 100.0% (182/182) (95% CI: 97.4% to			

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS Specific IgE Assay, F002, Cow's Milk	**Positive**	17	0	17
	Negative	17	132	149
	Total	34	132	166
	Sensitivity: 50.0% (17/34) 95% CI: 34.1% to 65.9% Specificity: 100.0% (166/166) 95% CI: 97.2% to 100.0%			

The following literature was published to support the observed low performance, especially sensitivity, from the NOVEOS sIgE Assay, T003, F001, and F002:

NOVEOS sIgE Assay	Literature Citation(s)	Prevalence	Reported Performance
T003, Oak Sensitivity: 55.1% Specificity: 100%	Knight, V., et al., (2018). Journal of Immunological Methods, 462, 9–12.	Not reported	53% (95 CI: 29% to 76%) - concordance of SPT vs. sIgE
	Salo, P. M., et al., (2014). The Journal of Allergy and Clinical Immunology, 134(2), 350–359.	~12% in subjects ≥6 years old in US	Not reported
F001, Egg White Sensitivity: 52.8% Specificity: 100%	Nacaroglu HT, et al. (2017) Allergol Immunopathol (Madr).	Not reported	Sensitivity: 41.3% Specificity: 86.67%
	Salo, P. M., et al. (2014). The Journal of Allergy and Clinical Immunology, 134(2), 350–359.	3.5% in subjects ≥ 6 years old in US	Not reported
	Min, T. K., et al. (2013). Allergy, Asthma & Immunology Research, 5(3), 138–142.	Not reported (study done in subjects < 2 years old in Korea)	Sensitivity: 60.0% Specificity: 62.5% (with 2 kU_A/L as cut-off)
F002, Cow's Milk Sensitivity: 50% Specificity: 100%	Sampson H. A. (2001). The Journal of Allergy and Clinical Immunology, 107(5), 891–896.	Not reported	Sensitivity: 51% PPV: 95%
	Salo, P. M., et al. (2014). The Journal of Allergy and Clinical Immunology, 134(2), 350–359.	5.7% (In 8203 subjects between 1 to >60 years old in US)	Not reported
	Mehl, A., et al. (2012). Journal of the British Society for Allergy and Clinical Immunology, 42(8), 1266–1272.	Not reported	"low" between sIgE vs SPT on an individual basis.

2. Other Clinical Supportive Data:

Not applicable

D Clinical Cut-Off:

The clinical cut-off of the assay is 0.35 kU/L. The interpretation of results of the assay uses the following classification system:

Class	Concentration (kU/L)	Interpretation
0	<0.35	Negative
I	0.35 to <0.70	Positive with increasing sIgE concentration
II	0.70 to <3.50	
III	0.35 to <17.50	
IV	17.50 to <50.00	
V	50.00 to <100.00	
VI	≥100	

E Expected Values/Reference Range:

The expected value is < 0.35 kU/L(negative) for a specific allergen in an apparently healthy (non-atopic) person. Each laboratory should establish its own expected value/reference range.

The reference range of NOVEOS Specific IgE Assay for G010 (Johnson Grass), T007 (Oak), G002 (Bermuda Grass), W001 (Common Ragweed), E005 (Dog Dander), T003 (Common Silver Birch), F001 (Egg White), and F002 (Cow's Milk), in the normal population was evaluated based on the data collected in the clinical study in which was used to test samples from apparently healthy subjects including: 121 non-atopic samples for G010; 129 non-atopic samples for T007; 129 non-atopic samples for G002; 123 non-atopic samples for W001; 132 non-atopic samples for E005; 128 non-atopic samples for T003; 137 non-atopic samples for F001; and 131 non-atopic samples for F002, was tested by corresponding NOVEOS Specific IgE Assay. All samples were below <0.35 kU/L.

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.