



May 15, 2026

Hycor Biomedical  
Hiromi Kubota  
Regulatory Affairs Specialist  
7272 Chapman Avenue  
Garden Grove, California 92841

Re: K260059

Trade/Device Name: NOVEOS Specific IgE (sIgE)  
Capture Reagent F018, Brazil Nut (*Bertholletia excelsa*);  
Capture Reagent F036, Coconut (*Cocos nucifera*);  
Capture Reagent F040, Tuna (*Thunnus* sp.);  
Capture Reagent F041, Salmon (*Salmo salar*);  
Capture Reagent F075, Egg Yolk (*Gallus gallus*);  
Capture Reagent F201, Pecan Nut (*Carya illinoensis*);  
Capture Reagent F203, Pistachio Nut (*Pistacia vera*);  
Capture Reagent F290, Oyster (*Ostrea edulis*)

Regulation Number: 21 CFR 866.5750

Regulation Name: Radioallergosorbent (RAST) immunological test system

Regulatory Class: Class II

Product Code: DHB

Dated: April 13, 2026

Received: April 13, 2026

Dear Hiromi Kubota:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical->

[devices/device-advice-comprehensive-regulatory-assistance](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao-S

Ying Mao, Ph.D.  
Branch Chief  
Division of Immunology and Hematology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K260059

### Device Name

NOVEOS Specific IgE (sIgE) Assay;  
Capture Reagent F018, Brazil Nut (*Bertholletia excelsa*);  
Capture Reagent F036, Coconut (*Cocos nucifera*);  
Capture Reagent F040, Tuna (*Thunnus* sp.);  
Capture Reagent F041, Salmon (*Salmo salar*);  
Capture Reagent F075, Egg Yolk (*Gallus gallus*);  
Capture Reagent F201, Pecan Nut (*Carya illinoensis*);  
Capture Reagent F203, Pistachio Nut (*Pistacia vera*);  
Capture Reagent F290, Oyster (*Ostrea edulis*)

### Indications for Use (Describe)

The NOVEOSTM 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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

### NOVEOS® Specific IgE

This 510(k) summary is prepared in accordance with the requirements of 21 CFR Part 807.92.

**Date of Preparation:** 7<sup>th</sup> May 2026  
**Manufacturer:** Hycor Biomedical, LLC  
7272 Chapman Avenue  
Garden Grove, CA 92841  
**Contact Person:** Hiromi Kubota  
Regulatory Affairs Specialist  
7272 Chapman Ave  
Garden Grove, CA 92841  
(714) 933-3082  
[hkubota@hycorbiomedical.com](mailto:hkubota@hycorbiomedical.com)

#### **Device Name:**

NOVEOS® Specific IgE (sIgE) Assay  
Capture Reagent F018, Brazil Nut (*Bertholletia excelsa*);  
Capture Reagent F036, Coconut (*Cocos nucifera*);  
Capture Reagent F040, Tuna (*Thunnus sp.*);  
Capture Reagent F041, Salmon (*Salmo salar*);  
Capture Reagent F075, Egg Yolk (*Gallus gallus*);  
Capture Reagent F201, Pecan Nut (*Carya illinoensis*);  
Capture Reagent F203, Pistachio Nut (*Pistacia vera*);  
Capture Reagent F290, Oyster (*Ostrea edulis*)

#### **Classification**

NOVEOS® Specific IgE (sIgE) Assay  
Product Code: DHB  
Class: II  
CFR § 866.5750

#### **Substantial Equivalence to: K051218**

ImmunoCAP Specific IgE Assay

ImmunoCAP Allergens f18, f36, f40, f41, f75, f201, f203, and f290

### **Indications for Use/ Intended 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.

### **General Description**

#### **Reagents**

The IgE common reagents include: Diluent A, Conjugate IgE, Substrate A, Substrate B, and Fluo Beads™. Other required and recommended reagents include the allergen specific Capture Reagent, IgE Calibrator Set (6 levels (kU/L) - Cal 0.07 IgE, Cal 0.35 IgE, Cal 0.70 IgE, Cal 3.5 IgE, Cal 17.5 IgE, Cal 100 IgE), Calibrator Antibody IgE, Probe Wash Pack, Wash Buffer Concentrate, Cuvette Wash Pack, IgE Negative Control Pack, and IgE Positive Control Pack.

### **Assay Principle**

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: horseradish peroxidase conjugate. If present in the sample, IgE binds to the biotinylated allergen captured to the streptavidin-coated microparticles to form a complex. After a final wash, the resulting complex is incubated with the enzyme substrate and a chemiluminescent signal is generated, the magnitude of which is proportional to the concentration of IgE in the patient sample.

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.

### **Device Comparison**

NOVEOS Specific IgE Assay on the NOVEOS Immunoassay Analyzer is comparable to ImmunoCAP Specific IgE on the Phadia 100 or 250 Analyzer. Both are automated immunoassay systems that process all assay steps and automatically generate results. See the table on the next page for a summary comparison of the two systems.

| Similarities and Differences  |                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General Device Characteristic | NOVEOS sIgE Assay                                                                                                                                                                                                                                                                                                                                                                                                                  | ImmunoCAP Specific IgE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Intended Use                  | The NOVEOS Specific IgE Assay is an <i>in vitro</i> 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 <i>in vitro</i> 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 <i>in vitro</i> 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 <i>in vitro</i> 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. |
| Specimen Type                 | Serum                                                                                                                                                                                                                                                                                                                                                                                                                              | Serum or plasma (EDTA, Na Heparin)                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Sample Volume                 | 4 µL                                                                                                                                                                                                                                                                                                                                                                                                                               | 40 µL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Assay Type                    | Quantitative                                                                                                                                                                                                                                                                                                                                                                                                                       | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Detection Antibody            | Horseradish peroxidase conjugated mouse anti-human IgE monoclonal antibody                                                                                                                                                                                                                                                                                                                                                         | β-Galactosidase-anti-human IgE (mouse monoclonal antibody)                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Detection Limit               | <p><u>F018, Brazil Nut:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.10 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F036, Coconut:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.09 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F040, Tuna:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.08 kU/L</p>                                                                                                                                                                                     | <p>LoB: 0.001 kU/L<br/>LoD: 0.02 kU/L<br/>LoQ: 0.10 kU/L</p>                                                                                                                                                                                                                                                                                                                                                                                                                                          |

|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                          |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                          | <p>LoQ: 0.10 kU/L</p> <p><u>F041, Salmon:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.08 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F075, Egg Yolk:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.08 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F201, Pecan Nut:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.09 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F203, Pistachio Nut:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.09 kU/L<br/>LoQ: 0.10 kU/L</p> <p><u>F290, Oyster:</u><br/>LoB: 0.07 kU/L<br/>LoD: 0.09 kU/L<br/>LoQ: 0.10 kU/L</p> |                          |
| Laboratory Setting       | Clinical Laboratory                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Same                     |
| Assay Principles         | Fluorescence adjusted, immunometric, chemiluminescent assay                                                                                                                                                                                                                                                                                                                                                                                                                | Fluoroenzyme-immunoassay |
| Solid Phase              | Magnetic microparticles                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Cellulose derivative     |
| Calibrator Traceability  | World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234                                                                                                                                                                                                                                                                                                                                                                                      | Same                     |
| Calibration Method       | Heterologous interpolation based on Total IgE calibration curve                                                                                                                                                                                                                                                                                                                                                                                                            | Same                     |
| Stored Calibration Curve | Yes, up to 28 days                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Same                     |
| Number of Calibrators    | Six                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Same                     |

|                      |                                                                                                                                                                                                                                                                                                                                                                                             |                                                           |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Calibrator Levels    | Six levels at 0.07, 0.35, 0.7, 3.5, 17.5 and 100 kU/L                                                                                                                                                                                                                                                                                                                                       | Six levels at 0, 0.35, 0.7, 3.5, 17.5 and 100 kU/L        |
| Assay Range          | <u>F018, Brazil Nut:</u><br>0.10 – 93 kU/L<br><br><u>F036, Coconut:</u><br>0.10 – 100 kU/L<br><br><u>F040, Tuna:</u><br>0.10 – 99 kU/L<br><br><u>F041, Salmon:</u><br>0.10 – 90 kU/L<br><br><u>F075, Egg Yolk:</u><br>0.10 – 100 kU/L<br><br><u>F201, Pecan Nut:</u><br>0.10 – 100 kU/L<br><br><u>F203, Pistachio Nut:</u><br>0.10 – 93 kU/L<br><br><u>F290, Oyster:</u><br>0.10 – 100 kU/L | Same                                                      |
| Reaction Temperature | 37°C                                                                                                                                                                                                                                                                                                                                                                                        | Same                                                      |
| Instrument(s)        | NOVEOS Immunoassay Analyzer                                                                                                                                                                                                                                                                                                                                                                 | Phadia 100, Phadia 250/1000/2500/5000                     |
| Time to First Result | 1 hour 45 minutes                                                                                                                                                                                                                                                                                                                                                                           | 1 hour 45 minutes to 2 hour 30 minutes depending on model |

## Clinical Performance

A clinical study that compares NOVEOS sIgE allergen results to the allergic status of 157 to 171 patients was performed to support the diagnostic performance of the NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster). A total of 31 to 50 samples with allergic status (atopic) was confirmed by oral food challenge or physician diagnosis, and the other 121 to 126 samples were deemed negative (non-atopic) by ImmunoCAP testing (result <0.35 kU/L).

Results are expressed as positive when a sample has an sIgE value greater than or equal to 0.35 kU/L, and negative when a sample has an sIgE value is less than 0.35 kU/L. Clinical sensitivity and specificity for each allergen under evaluation are summarized in the following table:

| NOVEOS sIgE Allergens |                                                                                                              | Clinical Diagnosis |            |       |
|-----------------------|--------------------------------------------------------------------------------------------------------------|--------------------|------------|-------|
|                       |                                                                                                              | Atopic             | Non-Atopic | Total |
| F018,<br>Brazil Nut   | Positive                                                                                                     | 31                 | 0          | 31    |
|                       | Negative                                                                                                     | 3                  | 126        | 129   |
|                       | Total                                                                                                        | 34                 | 126        | 160   |
|                       | Clinical sensitivity: 91.2% (95% CI 77.0% to 97.0%)<br>Clinical specificity: 100.0% (95% CI 97.0% to 100.0%) |                    |            |       |
| F036,<br>Coconut      | Positive                                                                                                     | 33                 | 0          | 33    |
|                       | Negative                                                                                                     | 7                  | 125        | 132   |
|                       | Total                                                                                                        | 40                 | 125        | 165   |
|                       | Clinical sensitivity: 82.5% (95% CI 68.1% to 91.3%)<br>Clinical specificity: 100.0% (95% CI 97.0% to 100.0%) |                    |            |       |
| F040,<br>Tuna         | Positive                                                                                                     | 35                 | 0          | 35    |
|                       | Negative                                                                                                     | 15                 | 121        | 136   |
|                       | Total                                                                                                        | 50                 | 121        | 171   |
|                       | Clinical sensitivity: 70.0% (95% CI 56.2% to 80.9%)<br>Clinical specificity: 100.0% (95% CI 96.9% to 100.0%) |                    |            |       |
| F041,<br>Salmon       | Positive                                                                                                     | 35                 | 0          | 35    |
|                       | Negative                                                                                                     | 7                  | 125        | 132   |
|                       | Total                                                                                                        | 42                 | 125        | 167   |
|                       | Clinical sensitivity: 83.3% (95% CI 69.4% to 91.7%)<br>Clinical specificity: 100.0% (95% CI 97.0% to 100.0%) |                    |            |       |
| F075,<br>Egg Yolk     | Positive                                                                                                     | 28                 | 0          | 28    |
|                       | Negative                                                                                                     | 3                  | 126        | 129   |
|                       | Total                                                                                                        | 31                 | 126        | 157   |
|                       | Clinical sensitivity: 90.3% (95% CI 75.1% to 96.7%)<br>Clinical specificity: 100.0% (95% CI 97.0% to 100.0%) |                    |            |       |

| NOVEOS sIgE Allergens  |                                                                                                              | Clinical Diagnosis |            |       |
|------------------------|--------------------------------------------------------------------------------------------------------------|--------------------|------------|-------|
|                        |                                                                                                              | Atopic             | Non-Atopic | Total |
| F201,<br>Pecan Nut     | Positive                                                                                                     | 30                 | 0          | 30    |
|                        | Negative                                                                                                     | 5                  | 126        | 131   |
|                        | Total                                                                                                        | 35                 | 126        | 161   |
|                        | Clinical sensitivity: 85.7% (95% CI 70.6% to 93.7%)<br>Clinical specificity: 100.0% (95% CI 97.0% to 100.0%) |                    |            |       |
| F203,<br>Pistachio Nut | Positive                                                                                                     | 34                 | 0          | 34    |
|                        | Negative                                                                                                     | 2                  | 121        | 123   |
|                        | Total                                                                                                        | 36                 | 121        | 157   |
|                        | Clinical sensitivity: 94.4% (95% CI 81.9% to 98.5%)<br>Clinical specificity: 100.0% (95% CI 96.9% to 100.0%) |                    |            |       |
| F290,<br>Oyster        | Positive                                                                                                     | 29                 | 1          | 30    |
|                        | Negative                                                                                                     | 9                  | 124        | 133   |
|                        | Total                                                                                                        | 38                 | 125        | 163   |
|                        | Clinical sensitivity: 76.3% (95% CI 60.8% to 87.0%)<br>Clinical specificity: 99.2% (95% CI 95.6% to 99.9%)   |                    |            |       |

The following literature was published that supports the observed sensitivity of the NOVEOS sIgE assay F040 allergen.

| NOVEOS sIgE Assay                         | Literature Citation(s)                                         | Prevalence                         | Reported Performance                 |
|-------------------------------------------|----------------------------------------------------------------|------------------------------------|--------------------------------------|
| F040, Tuna                                | Kalic T et al. Front Allergy. 2021;2:732178                    | 0.1% – 0.9% fish allergy in the US | not reported                         |
| Sensitivity: 70.0%<br>Specificity: 100.0% | Schulkes et al. Clinical and Translational Allergy. 2014;4:27. | n/a                                | Sensitivity: 67%<br>Specificity: 43% |

### Precision/Reproducibility

Repeatability and within-laboratory precision of NOVEOS sIgE allergens were determined in accordance with CLSI guideline EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures – 3<sup>rd</sup> Edition* and CLSI guideline EP15-A3: *User Verification of Precision and Estimation of Bias – 3<sup>rd</sup> Edition*. A panel of four to six samples (two negative and two to four positive patient samples) was assayed in replicates of two to five for two runs per day, over 20 to 21 days, on one to two NOVEOS Immunoassay Analyzers for a total of 80 to 97 replicates per sample. One lot of NOVEOS sIgE allergens was used for the testing of each sample.

The SD and % CV of the within- run, between-run, between-day, and total imprecision were calculated for each sample and results are summarized in the following table:

| Sample                                                                                                             | N   | Mean<br>(kU/L) | Within-Run<br>(Repeatability) |       | Between-Run |      | Between-Day |       | Total |       |
|--------------------------------------------------------------------------------------------------------------------|-----|----------------|-------------------------------|-------|-------------|------|-------------|-------|-------|-------|
|                                                                                                                    |     |                | SD                            | CV    | SD          | CV   | SD          | CV    | SD    | CV    |
| NOVEOS F018, Brazil Nut                                                                                            |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.10           | 0.01                          | 14.4% | 0.00        | 0.0% | 0.01        | 12.3% | 0.02  | 19.1% |
| 2                                                                                                                  | 80  | 0.33           | 0.01                          | 3.9%  | 0.01        | 2.3% | 0.01        | 3.1%  | 0.02  | 5.5%  |
| 3                                                                                                                  | 80  | 0.85           | 0.03                          | 3.7%  | 0.01        | 1.1% | 0.03        | 3.5%  | 0.04  | 5.2%  |
| 4                                                                                                                  | 95* | 89.39          | 6.56                          | 7.3%  | 8.44        | 9.4% | 4.25        | 4.8%  | 11.50 | 12.9% |
| *Sample 4 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days |     |                |                               |       |             |      |             |       |       |       |
| NOVEOS F036, Coconut                                                                                               |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.14           | 0.01                          | 5.9%  | 0.01        | 4.5% | 0.01        | 8.3%  | 0.02  | 11.2% |
| 2                                                                                                                  | 80  | 0.27           | 0.02                          | 8.4%  | 0.00        | 0.0% | 0.01        | 5.0%  | 0.03  | 9.8%  |
| 3                                                                                                                  | 80  | 1.40           | 0.04                          | 2.5%  | 0.07        | 5.1% | 0.00        | 0.0%  | 0.08  | 5.7%  |
| 4                                                                                                                  | 95* | 78.78          | 4.67                          | 5.9%  | 5.61        | 7.1% | 4.31        | 5.5%  | 8.47  | 10.8% |
| *Sample 4 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days |     |                |                               |       |             |      |             |       |       |       |
| NOVEOS F040, Tuna                                                                                                  |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.14           | 0.02                          | 11.0% | 0.00        | 0.0% | 0.02        | 11.7% | 0.02  | 16.0% |
| 2                                                                                                                  | 80  | 0.30           | 0.02                          | 5.8%  | 0.01        | 4.4% | 0.02        | 7.0%  | 0.03  | 10.1% |
| 3                                                                                                                  | 80  | 2.41           | 0.09                          | 3.6%  | 0.10        | 4.1% | 0.05        | 2.1%  | 0.14  | 5.9%  |
| 4                                                                                                                  | 80  | 9.97           | 0.46                          | 4.6%  | 0.24        | 2.4% | 0.24        | 2.4%  | 0.57  | 5.7%  |
| 5                                                                                                                  | 95* | 47.32          | 2.84                          | 6.0%  | 0.91        | 1.9% | 0.51        | 1.1%  | 3.03  | 6.4%  |
| 6                                                                                                                  | 80  | 73.33          | 4.92                          | 6.7%  | 3.70        | 5.0% | 1.55        | 2.1%  | 6.35  | 8.7%  |
| *Sample 5 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days |     |                |                               |       |             |      |             |       |       |       |
| NOVEOS F041, Salmon                                                                                                |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.17           | 0.01                          | 6.5%  | 0.01        | 7.8% | 0.02        | 9.5%  | 0.02  | 13.9% |
| 2                                                                                                                  | 80  | 0.24           | 0.01                          | 5.2%  | 0.01        | 4.5% | 0.01        | 5.0%  | 0.02  | 8.5%  |
| 3                                                                                                                  | 80  | 1.25           | 0.04                          | 3.3%  | 0.05        | 3.7% | 0.05        | 4.0%  | 0.08  | 6.4%  |
| 4                                                                                                                  | 80  | 9.68           | 0.38                          | 3.9%  | 0.23        | 2.3% | 0.27        | 2.8%  | 0.51  | 5.3%  |
| 5                                                                                                                  | 95* | 86.34          | 3.55                          | 4.1%  | 3.55        | 4.1% | 0.75        | 0.9%  | 5.07  | 5.9%  |
| *Sample 5 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days |     |                |                               |       |             |      |             |       |       |       |
| NOVEOS F075, Egg Yolk                                                                                              |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.17           | 0.02                          | 8.7%  | 0.00        | 2.5% | 0.02        | 9.7%  | 0.02  | 13.3% |
| 2                                                                                                                  | 80  | 0.27           | 0.01                          | 5.0%  | 0.01        | 3.7% | 0.01        | 4.3%  | 0.02  | 7.6%  |
| 3                                                                                                                  | 80  | 1.44           | 0.08                          | 5.5%  | 0.00        | 0.0% | 0.05        | 3.5%  | 0.09  | 6.5%  |
| 4                                                                                                                  | 95* | 82.22          | 4.56                          | 5.5%  | 3.59        | 4.4% | 1.85        | 2.3%  | 6.09  | 7.4%  |
| *Sample 4 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days |     |                |                               |       |             |      |             |       |       |       |
| NOVEOS F201, Pecan Nut                                                                                             |     |                |                               |       |             |      |             |       |       |       |
| 1                                                                                                                  | 80  | 0.17           | 0.01                          | 7.84% | 0.01        | 4.8% | 0.01        | 6.1%  | 0.02  | 10.9% |
| 2                                                                                                                  | 80  | 0.32           | 0.02                          | 5.01% | 0.01        | 3.0% | 0.01        | 3.9%  | 0.02  | 6.7%  |

| Sample                                                                                                                                                                       | N   | Mean (kU/L) | Within-Run (Repeatability) |       | Between-Run |      | Between-Day |       | Total |       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|-------------|----------------------------|-------|-------------|------|-------------|-------|-------|-------|
|                                                                                                                                                                              |     |             | SD                         | CV    | SD          | CV   | SD          | CV    | SD    | CV    |
| 3                                                                                                                                                                            | 80  | 1.38        | 0.07                       | 5.05% | 0.04        | 3.1% | 0.06        | 4.2%  | 0.08  | 6.1%  |
| 4                                                                                                                                                                            | 80  | 1.47        | 0.07                       | 4.47% | 0.05        | 3.5% | 0.04        | 2.8%  | 0.08  | 5.4%  |
| 5                                                                                                                                                                            | 97* | 97.84       | 4.72                       | 4.8%  | 7.51        | 7.7% | 2.47        | 2.5%  | 9.20  | 9.4%  |
| *Sample 5 was tested with 2 replicates/1st run and 5 replicates/2nd run x 5 days, 2 replicates/1st run and 4 replicates/2nd run x 1 day, and 2 replicates x 2 runs x 14 days |     |             |                            |       |             |      |             |       |       |       |
| <b>NOVEOS F203, Pistachio Nut</b>                                                                                                                                            |     |             |                            |       |             |      |             |       |       |       |
| 1                                                                                                                                                                            | 83* | 0.16        | 0.02                       | 10.7% | 0.00        | 1.0% | 0.02        | 10.3% | 0.02  | 14.8% |
| 2                                                                                                                                                                            | 80  | 0.32        | 0.02                       | 4.9%  | 0.00        | 0.7% | 0.02        | 6.8%  | 0.03  | 8.5%  |
| 3                                                                                                                                                                            | 80  | 2.21        | 0.12                       | 5.6%  | 0.00        | 0.0% | 0.08        | 3.7%  | 0.15  | 6.7%  |
| 4                                                                                                                                                                            | 80  | 89.75       | 3.11                       | 3.5%  | 2.49        | 2.8% | 3.54        | 3.9%  | 5.33  | 5.9%  |
| *Sample 1 was tested with 2 replicates/run x 2 runs/day x 21 days with exclusion of 1 outlier for Day 12                                                                     |     |             |                            |       |             |      |             |       |       |       |
| <b>NOVEOS F290, Oyster</b>                                                                                                                                                   |     |             |                            |       |             |      |             |       |       |       |
| 1                                                                                                                                                                            | 80  | 0.16        | 0.01                       | 6.6%  | 0.01        | 5.0% | 0.02        | 9.7%  | 0.02  | 12.8% |
| 2                                                                                                                                                                            | 80  | 0.31        | 0.03                       | 8.6%  | 0.01        | 3.7% | 0.02        | 5.6%  | 0.03  | 10.9% |
| 3                                                                                                                                                                            | 80  | 1.44        | 0.04                       | 2.9%  | 0.04        | 2.9% | 0.02        | 1.4%  | 0.06  | 4.3%  |
| 4                                                                                                                                                                            | 80  | 75.65       | 2.99                       | 4.0%  | 2.41        | 3.2% | 1.96        | 2.6%  | 4.31  | 5.7%  |

### Lot-to-lot imprecision

Lot-to-lot imprecision was evaluated using a panel of four to six serum samples tested with three different lots of each NOVEOS sIgE allergen. For NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040, (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) the samples were tested in replicates of five for one run per day, over five to six days, for a total of 75 to 79 replicates per sample. The results are summarized in the following table:

| Sample                                                                                                             | N   | Mean (kU/L) | Within-Run (Repeatability) |      | Between-Day |      | Between-Lot |      | Total |      |
|--------------------------------------------------------------------------------------------------------------------|-----|-------------|----------------------------|------|-------------|------|-------------|------|-------|------|
|                                                                                                                    |     |             | SD                         | CV   | SD          | CV   | SD          | CV   | SD    | CV   |
| NOVEOS F018, Brazil Nut                                                                                            |     |             |                            |      |             |      |             |      |       |      |
| 1                                                                                                                  | 75  | 0.22        | 0.01                       | 4.4% | 0.01        | 5.2% | 0.00        | 2.3% | 0.02  | 7.2% |
| 2                                                                                                                  | 79* | 0.55        | 0.03                       | 5.3% | 0.02        | 3.9% | 0.01        | 1.2% | 0.04  | 6.6% |
| 3                                                                                                                  | 75  | 0.90        | 0.04                       | 4.0% | 0.01        | 1.6% | 0.01        | 1.0% | 0.04  | 4.4% |
| 4                                                                                                                  | 75  | 86.39       | 6.29                       | 7.3% | 5.18        | 6.0% | 0.00        | 0.0% | 8.15  | 9.4% |
| *Sample 2 was tested with 5 replicates/run x 1 run/day x 6 days with exclusion of 1 outlier for Day 5 (Lot 169064) |     |             |                            |      |             |      |             |      |       |      |

| Sample                     | N  | Mean<br>(kU/L) | Within-Run<br>(Repeatability) |       | Between-Day |       | Between-Lot |      | Total |       |
|----------------------------|----|----------------|-------------------------------|-------|-------------|-------|-------------|------|-------|-------|
|                            |    |                | SD                            | CV    | SD          | CV    | SD          | CV   | SD    | CV    |
| NOVEOS F036, Coconut       |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.18           | 0.01                          | 4.3%  | 0.01        | 5.6%  | 0.01        | 6.5% | 0.01  | 6.5%  |
| 2                          | 75 | 0.66           | 0.03                          | 4.0%  | 0.04        | 5.8%  | 0.04        | 6.1% | 0.04  | 6.1%  |
| 3                          | 75 | 1.75           | 0.07                          | 4.2%  | 0.08        | 4.4%  | 0.13        | 7.2% | 0.13  | 7.2%  |
| 4                          | 75 | 74.80          | 4.23                          | 5.7%  | 1.59        | 2.1%  | 2.59        | 3.5% | 5.21  | 7.0%  |
| NOVEOS F040, Tuna          |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.13           | 0.02                          | 15.7% | 0.01        | 9.1%  | 0.00        | 0.0% | 0.02  | 18.2% |
| 2                          | 75 | 0.52           | 0.02                          | 4.7%  | 0.02        | 3.8%  | 0.00        | 0.0% | 0.03  | 6.0%  |
| 3                          | 75 | 2.52           | 0.09                          | 3.4%  | 0.07        | 2.9%  | 0.03        | 1.3% | 0.12  | 4.7%  |
| 4                          | 75 | 10.48          | 0.33                          | 3.1%  | 0.29        | 2.7%  | 0.00        | 0.0% | 0.44  | 4.2%  |
| 5                          | 75 | 47.75          | 3.09                          | 6.5%  | 0.94        | 2.0%  | 0.43        | 0.9% | 3.26  | 6.8%  |
| 6                          | 75 | 87.62          | 5.77                          | 6.6%  | 1.36        | 1.6%  | 1.00        | 1.1% | 6.01  | 6.9%  |
| NOVEOS F041, Salmon        |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.16           | 0.02                          | 15.5% | 0.01        | 5.4%  | 0.01        | 5.7% | 0.03  | 17.4% |
| 2                          | 75 | 0.46           | 0.02                          | 5.0%  | 0.02        | 4.6%  | 0.00        | 0.0% | 0.03  | 6.8%  |
| 3                          | 75 | 1.22           | 0.07                          | 6.1%  | 0.06        | 5.3%  | 0.00        | 0.0% | 0.10  | 8.0%  |
| 4                          | 75 | 9.08           | 0.35                          | 3.8%  | 0.33        | 3.7%  | 0.02        | 0.2% | 0.48  | 5.3%  |
| 5                          | 75 | 87.89          | 5.01                          | 5.7%  | 1.21        | 1.3%  | 1.95        | 2.2% | 5.49  | 6.2%  |
| NOVEOS F075, Egg Yolk      |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.23           | 0.02                          | 9.3%  | 0.02        | 6.5%  | 0.00        | 0.0% | 0.03  | 11.4% |
| 2                          | 75 | 0.50           | 0.02                          | 4.4%  | 0.02        | 3.2%  | 0.01        | 2.4% | 0.03  | 6.0%  |
| 3                          | 75 | 1.51           | 0.03                          | 2.1%  | 0.06        | 3.9%  | 0.05        | 3.5% | 0.09  | 5.7%  |
| 4                          | 75 | 85.74          | 4.02                          | 4.7%  | 2.79        | 3.2%  | 2.55        | 3.0% | 5.52  | 6.4%  |
| NOVEOS F201, Pecan Nut     |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.12           | 0.01                          | 10.6% | 0.01        | 7.5%  | 0.01        | 7.7% | 0.02  | 15.1% |
| 2                          | 75 | 0.41           | 0.02                          | 4.2%  | 0.03        | 7.2%  | 0.00        | 0.0% | 0.03  | 8.3%  |
| 3                          | 75 | 1.19           | 0.05                          | 4.4%  | 0.03        | 2.3%  | 0.00        | 0.0% | 0.06  | 5.0%  |
| 4                          | 75 | 93.39          | 5.04                          | 5.4%  | 6.13        | 6.6%  | 0.00        | 0.0% | 7.94  | 8.5%  |
| NOVEOS F203, Pistachio Nut |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.20           | 0.02                          | 11.5% | 0.02        | 12.2% | 0.00        | 0.0% | 0.03  | 16.8% |
| 2                          | 75 | 0.52           | 0.02                          | 4.7%  | 0.03        | 5.1%  | 0.00        | 0.0% | 0.04  | 7.0%  |
| 3                          | 75 | 2.25           | 0.07                          | 3.1%  | 0.07        | 3.2%  | 0.04        | 1.6% | 0.11  | 4.8%  |
| 4                          | 75 | 87.38          | 3.73                          | 4.3%  | 2.65        | 3.0%  | 1.08        | 1.2% | 4.70  | 5.4%  |
| NOVEOS F290, Oyster        |    |                |                               |       |             |       |             |      |       |       |
| 1                          | 75 | 0.17           | 0.01                          | 5.9%  | 0.02        | 11.6% | 0.00        | 0.0% | 0.02  | 13.0% |
| 2                          | 75 | 0.55           | 0.02                          | 3.5%  | 0.03        | 6.2%  | 0.00        | 0.0% | 0.04  | 7.1%  |

| Sample | N  | Mean (kU/L) | Within-Run (Repeatability) |      | Between-Day |      | Between-Lot |      | Total |      |
|--------|----|-------------|----------------------------|------|-------------|------|-------------|------|-------|------|
|        |    |             | SD                         | CV   | SD          | CV   | SD          | CV   | SD    | CV   |
| 3      | 75 | 1.50        | 0.05                       | 3.1% | 0.05        | 3.6% | 0.00        | 0.0% | 0.07  | 4.7% |
| 4      | 75 | 79.36       | 2.73                       | 3.4% | 3.03        | 3.8% | 0.00        | 0.0% | 4.08  | 5.1% |

### Linearity

Linearity of NOVEOS sIgE allergens was evaluated in accordance with CLSI guideline I/LA20-3<sup>rd</sup> Edition, *Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities*. Three sets of linearity dilution panels consisting of three neat positive human serum samples (low, mid, and high) were used for testing. One negative sample below the assay detection limit was used as the diluent. Each sample was serially diluted in a two-fold scheme (1/2, 1/4, 1/8, 1/16, 1/32, and 1/64) to create the full dilution panel. Testing was performed using one to two lots of each NOVEOS sIgE allergen. The linear regression statistics calculated using the weighted least squares with intercept analysis per CLSI guideline EP06-2<sup>nd</sup> Edition, *Evaluation of Linearity of Quantitative Measurement Procedures*, are shown in the following tables.

| NOVEOS Specific IgE Assay, F018, Brazil Nut |                       |                     |                        |                |
|---------------------------------------------|-----------------------|---------------------|------------------------|----------------|
| Dilution Series                             | Dilution Range (kU/L) | Slope (95% CI)      | Intercept (95% CI)     | R <sup>2</sup> |
| 1                                           | 0.08 to 2.51          | 1.06 (0.99 to 1.13) | 0.01 (0.00 to 0.03)    | 0.996          |
| 2                                           | 1.16 to 69.32         | 0.98 (0.97 to 1.00) | 0.09 (0.04 to 0.13)    | 1.000          |
| 3                                           | 1.20 to 93.96         | 0.93 (0.89 to 0.98) | -0.19 (-0.34 to -0.04) | 0.998          |
| All                                         | 0.08 to 93.96         | 0.95 (0.91 to 0.99) | 0.03 (0.01 to 0.04)    | 0.993          |

| NOVEOS Specific IgE Assay, F036, Coconut |                       |                     |                        |                |
|------------------------------------------|-----------------------|---------------------|------------------------|----------------|
| Dilution Series                          | Dilution Range (kU/L) | Slope (95% CI)      | Intercept (95% CI)     | R <sup>2</sup> |
| 1                                        | 0.06 to 2.30          | 1.06 (1.01 to 1.10) | -0.02 (-0.03 to -0.01) | 0.998          |
| 2                                        | 1.13 to 74.30         | 0.98 (0.92 to 1.05) | -0.06 (-0.18 to 0.05)  | 0.997          |
| 3                                        | 16.67 to 108.26       | 0.94 (0.82 to 1.06) | -2.46 (-6.62 to 1.70)  | 0.988          |
| All                                      | 0.06 to 108.26        | 0.95 (0.91 to 0.99) | -0.01 (-0.02 to 0.01)  | 0.992          |

| NOVEOS Specific IgE Assay, F040, Tuna |                       |                     |                       |                |
|---------------------------------------|-----------------------|---------------------|-----------------------|----------------|
| Dilution Series                       | Dilution Range (kU/L) | Slope (95% CI)      | Intercept (95% CI)    | R <sup>2</sup> |
| 1                                     | 0.08 to 4.50          | 1.02 (0.95 to 1.08) | -0.01 (-0.02 to 0.01) | 0.997          |
| 2                                     | 0.85 to 64.02         | 0.91 (0.85 to 0.97) | -0.07 (-0.23 to 0.10) | 0.997          |
| 3                                     | 1.45 to 99.32         | 0.99 (0.94 to 1.04) | -0.25 (-0.51 to 0.00) | 0.998          |
| All                                   | 0.08 to 99.32         | 0.93 (0.90 to 0.96) | 0.00 (-0.02 to 0.03)  | 0.995          |

| NOVEOS Specific IgE Assay, F041, Salmon |                       |                            |                               |                |
|-----------------------------------------|-----------------------|----------------------------|-------------------------------|----------------|
| Dilution Series                         | Dilution Range (kU/L) | Slope (95% CI)             | Intercept (95% CI)            | R <sup>2</sup> |
| 1                                       | 0.07 to 2.87          | 0.99 (0.95 to 1.03)        | -0.03 (-0.04 to -0.02)        | 0.999          |
| 2                                       | 0.80 to 59.89         | 0.96 (0.94 to 0.98)        | -0.15 (-0.22 to -0.09)        | 1.000          |
| 3                                       | 1.23 to 90.06         | 0.99 (0.98 to 1.01)        | -0.22 (-0.27 to -0.17)        | 1.000          |
| All                                     | <b>0.07 to 90.06</b>  | <b>0.95 (0.93 to 0.96)</b> | <b>-0.03 (-0.05 to -0.01)</b> | <b>0.998</b>   |

| NOVEOS Specific IgE Assay, F075, Egg Yolk |                       |                            |                             |                |
|-------------------------------------------|-----------------------|----------------------------|-----------------------------|----------------|
| Dilution Series                           | Dilution Range (kU/L) | Slope (95% CI)             | Intercept (95% CI)          | R <sup>2</sup> |
| 1                                         | 0.06 to 2.72          | 1.06 (1.01 to 1.10)        | -0.01 (-0.01 to 0.00)       | 0.998          |
| 2                                         | 0.79 to 59.69         | 0.93 (0.89 to 0.98)        | -0.16 (-0.28 to -0.03)      | 0.998          |
| 3                                         | 1.53 to 110.79        | 0.94 (0.87 to 1.01)        | -0.20 (-0.40 to 0.01)       | 0.996          |
| All                                       | <b>0.06 to 110.79</b> | <b>0.93 (0.89 to 0.97)</b> | <b>0.00 (-0.01 to 0.01)</b> | <b>0.992</b>   |

| NOVEOS Specific IgE Assay, F201, Pecan Nut |                       |                            |                              |                |
|--------------------------------------------|-----------------------|----------------------------|------------------------------|----------------|
| Dilution Series                            | Dilution Range (kU/L) | Slope (95% CI)             | Intercept (95% CI)           | R <sup>2</sup> |
| 1                                          | 0.08 to 4.11          | 1.06 (0.98 to 1.14)        | -0.02 (-0.04 to 0.00)        | 0.996          |
| 2                                          | 0.89 to 59.34         | 1.05 (1.00 to 1.11)        | -0.10 (-0.24 to 0.04)        | 0.998          |
| 3                                          | 22.83 to 121.37       | 1.01 (0.99 to 1.02)        | 1.11 (0.64 to 1.57)          | 1.000          |
| All                                        | <b>0.08 to 121.37</b> | <b>1.04 (1.02 to 1.07)</b> | <b>-0.02 (-0.03 to 0.00)</b> | <b>0.998</b>   |

| NOVEOS Specific IgE Assay, F203, Pistachio Nut |                       |                            |                               |                |
|------------------------------------------------|-----------------------|----------------------------|-------------------------------|----------------|
| Dilution Series                                | Dilution Range (kU/L) | Slope (95% CI)             | Intercept (95% CI)            | R <sup>2</sup> |
| 1                                              | 0.09 to 5.25          | 1.02 (0.99 to 1.05)        | -0.04 (-0.05 to -0.03)        | 0.999          |
| 2                                              | 0.59 to 40.44         | 1.07 (1.04 to 1.11)        | -0.11 (-0.15 to -0.06)        | 0.999          |
| 3                                              | 1.23 to 93.41         | 0.88 (0.82 to 0.94)        | -0.18 (-0.42 to 0.06)         | 0.997          |
| All                                            | <b>0.09 to 93.41</b>  | <b>0.98 (0.93 to 1.02)</b> | <b>-0.03 (-0.06 to -0.01)</b> | <b>0.991</b>   |

| NOVEOS Specific IgE Assay, F290, Oyster |                       |                            |                              |                |
|-----------------------------------------|-----------------------|----------------------------|------------------------------|----------------|
| Dilution Series                         | Dilution Range (kU/L) | Slope (95% CI)             | Intercept (95% CI)           | R <sup>2</sup> |
| 1                                       | 0.07 to 2.54          | 0.98 (0.95 to 1.01)        | -0.02 (-0.03 to -0.01)       | 0.999          |
| 2                                       | 0.47 to 27.65         | 0.94 (0.90 to 0.98)        | 0.00 (-0.06 to 0.06)         | 0.999          |
| 3                                       | 1.49 to 109.86        | 0.95 (0.91 to 1.00)        | -0.24 (-0.48 to -0.01)       | 0.998          |
| All                                     | <b>0.07 to 109.86</b> | <b>0.94 (0.92 to 0.96)</b> | <b>-0.01 (-0.02 to 0.00)</b> | <b>0.998</b>   |

### Endogenous Substance Interference

Interference testing by endogenous substances of NOVEOS sIgE allergens was carried out in accordance with CLSI guideline EP07, *Interference Testing in Clinical Chemistry – Third Edition*. The effect of the presence of elevated levels of human serum albumin, hemoglobin, triglyceride, conjugated bilirubin, and unconjugated bilirubin in serum samples was evaluated by testing three serum sample pools (one negative, one near the cut-off, and one positive) spiked with varying levels of each interferent. To mimic the dilution effect caused by the spiked interferent, the same amount of respective solvent was spiked into each of the sample pools and tested as control samples.

For NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) the samples were tested in replicates of seven in one assay run with one lot of Capture Reagent.

The % recovery for each sample spiked with the potential interfering substance was calculated by comparing its result to that of the corresponding control sample. The substances listed in the table below show no significant interference at the indicated test concentrations for all allergens under evaluation.

| Substance              | Concentration |
|------------------------|---------------|
| Hemoglobin             | 200 mg/dL     |
| Conjugated Bilirubin   | 30 mg/dL      |
| Unconjugated Bilirubin | 20 mg/dL      |
| Intralipid             | 3000 mg/dL    |
| Human Serum Albumin    | 121 g/L       |

Interference testing with rheumatoid factor (RF) was previously performed for NOVEOS sIgE allergens and found no significant interference at 513 IU/mL. For RF interference testing, refer to cleared 510(k) submission K200825.

### Exogenous Substance Interference

Interference testing with potentially interfering exogenous substances biotin, diphenhydramine, methylprednisolone, ranitidine, and omalizumab was previously performed for NOVEOS sIgE allergens and found no significant interference at the concentrations listed in the table below. Refer to previously cleared 510(k) submission K200825.

| Substance          | Concentration |
|--------------------|---------------|
| Biotin             | 3500 ng/mL    |
| Diphenhydramine    | 19.5 µmol/L   |
| Methylprednisolone | 1000 ng/mL    |
| Ranitidine         | 19.1 µmol/L   |

| Substance  | Concentration |
|------------|---------------|
| Omalizumab | 0.12 mg/mL    |

### Cross-Reactivity

Cross-reactivity testing with other human immunoglobulins (IgA, IgD, IgG, and IgM) was previously performed for NOVEOS sIgE allergens that utilize the same universal anti-IgE conjugate reagent as those currently under evaluation and found no significant interference at physiological concentrations of IgA, IgG, IgM (14.86 mg/mL), and IgG (0.173 mg/mL). Refer to previously cleared 510(k) submission K200825.

### Competitive Inhibition (Analytical Specificity)

Immunological specificity of NOVEOS sIgE allergens was demonstrated through competitive inhibition in accordance with CLSI I/LA20-3<sup>rd</sup> Edition, *Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities*.

For each NOVEOS sIgE allergen, a positive sample was tested with specific IgE concentrations shown in the table below:

| NOVEOS sIgE Allergen | Concentration (kU/L)                                              |
|----------------------|-------------------------------------------------------------------|
| F018, Brazil Nut     | 6.13                                                              |
| F036, Coconut        | 0.84                                                              |
| F040, Tuna           | 2.12, 2.22*<br>*the control sample was tested two different times |
| F041, Salmon         | 4.05                                                              |
| F075, Egg Yolk       | 4.68                                                              |
| F201, Pecan Nut      | 15.27                                                             |
| F203, Pistachio Nut  | 5.14                                                              |
| F290, Oyster         | 2.31                                                              |

The allergen solution (inhibitor) was diluted 1:1 into the positive sample and subsequently serially diluted five times in two-fold increments. Each diluted sample was evaluated for dose-dependent inhibition in replicates of five using one lot of NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster).

Related and unrelated allergen inhibitors were tested for each NOVEOS sIgE allergen in a single-dose competitive inhibition study. The related and unrelated allergen inhibitors were tested at a concentration at least 10 times the final concentration that achieved >50% inhibition for the

allergen under evaluation. The related and unrelated allergens used for each NOVEOS sIgE allergen are shown in the table below:

| NOVEOS sIgE Allergen | Related Inhibitor     | Unrelated Inhibitors                                                                                                                                       |
|----------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| F018, Brazil Nut     | F040, Yellowfin Tuna  | <ul style="list-style-type: none"> <li>E003, Horse Epithelia</li> <li>I006, German Cockroach</li> <li>M006, <i>Alternaria alternata</i></li> </ul>         |
| F036, Coconut        | F041, Atlantic Salmon | <ul style="list-style-type: none"> <li>E003, Horse Epithelia</li> <li>I006, German Cockroach</li> <li>M006, <i>Alternaria alternata</i></li> </ul>         |
| F040, Tuna           | F020, Almond          | <ul style="list-style-type: none"> <li>E070, Goose Feathers/Skin</li> <li>I006, German Cockroach</li> <li>W013, Cocklebur Pollen</li> </ul>                |
| F041, Salmon         | F014, Soybean         | <ul style="list-style-type: none"> <li>D201, <i>Blomia tropicalis</i></li> <li>I006, German Cockroach</li> <li>M005, <i>Candida albicans</i></li> </ul>    |
| F075, Egg Yolk       | F083, Chicken Meat    | <ul style="list-style-type: none"> <li>K082, Latex</li> <li>M006, <i>Alternaria alternata</i></li> <li>T218, Virginia Live Oak</li> </ul>                  |
| F201, Pecan Nut      | F003, Atlantic Cod    | <ul style="list-style-type: none"> <li>E003, Horse Epithelia</li> <li>I006, German Cockroach</li> <li>M006, <i>Alternaria alternata</i></li> </ul>         |
| F203, Pistachio Nut  | F020, Almond          | <ul style="list-style-type: none"> <li>D201, <i>Blomia tropicalis</i></li> <li>E070, Goose Feathers/Skin</li> <li>M005, <i>Candida albicans</i></li> </ul> |
| F290, Oyster         | F003, Atlantic Cod    | <ul style="list-style-type: none"> <li>E003, Horse Epithelia</li> <li>K082, Latex</li> <li>M005, <i>Candida albicans</i></li> </ul>                        |

Inhibitor concentrations used for testing of the NOVEOS sIgE allergens are shown in the table below:

| NOVEOS sIgE Allergen | Dose-Dependent Inhibition              |                                        | Single-Dose Inhibition                   |                                             |
|----------------------|----------------------------------------|----------------------------------------|------------------------------------------|---------------------------------------------|
|                      | Highest Tested Inhibitor Conc. (µg/mL) | Final Conc. at >50% Inhibition (µg/mL) | Final Conc. of Related Inhibitor (µg/mL) | Final Conc. of Unrelated Inhibitors (µg/mL) |
| F018, Brazil Nut     | 50                                     | 1.5625                                 | 15.625                                   | 15.625                                      |
| F036, Coconut        | 100                                    | 50                                     | 500                                      | 500                                         |

| NOVEOS sIgE Allergen | Dose-Dependent Inhibition              |                                        | Single-Dose Inhibition                   |                                             |
|----------------------|----------------------------------------|----------------------------------------|------------------------------------------|---------------------------------------------|
|                      | Highest Tested Inhibitor Conc. (µg/mL) | Final Conc. at >50% Inhibition (µg/mL) | Final Conc. of Related Inhibitor (µg/mL) | Final Conc. of Unrelated Inhibitors (µg/mL) |
| F040, Tuna           | 100                                    | 50                                     | 2565                                     | 570 - 1080                                  |
| F041, Salmon         | 50                                     | 3.125                                  | 31.25                                    | 31.25                                       |
| F075, Egg Yolk       | 50                                     | 0.390                                  | 15.626                                   | 15.626                                      |
| F201, Pecan Nut      | 50                                     | 3.125                                  | 555                                      | 510 - 830                                   |
| F203, Pistachio Nut  | 50                                     | 12.5                                   | 125                                      | 125                                         |
| F290, Oyster         | 50                                     | 1.5625                                 | 15.625                                   | 15.625                                      |

Greater than 50% inhibition was achieved in the dose-dependent inhibition studies and no inhibition was observed for the related and unrelated inhibitors for all NOVEOS sIgE allergens. The inhibition studies indicate that the NOVEOS sIgE allergens contain their respective immunologically relevant allergens.

#### Detection Limit

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) of NOVEOS sIgE allergens were estimated in accordance with CLSI guideline EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition*.

#### Limit of Blank

For F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) 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 one run per day, for a total of 60 replicates per lot of F018, F036, F040, F041, F075, F201, and F203. However, for F290, four analyte-free human serum samples were tested in replicates of 5 per run for two runs, and 10 per run for one run, with one run per day, for 80 replicates per lot. The value at the 95<sup>th</sup> percentile of the total measurements for each of the lots tested was estimated.

#### Limit of Detection

LoD for each assay was determined by testing multiple human serum samples with low IgE concentrations using two lots of capture reagents and one NOVEOS Immunoassay Analyzer. The LoD was calculated for each lot of F018 using a precision profile method. The LoD was calculated for each lot of F036, F040, F041, F075, F201, F203, and F290 using a parametric analysis.

The study protocol is summarized in the table below:

| NOVEOS sIgE Assay | No. of Samples | No. of Lots | No. of Analyzers | Testing Protocol                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------|----------------|-------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| F018              | 5              | 2           | 1                | 5 samples x 5 replicates/run x 3 runs = 75/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |
| F036              | 4              | 2           | 1                | 4 samples x 5 replicates/run x 3 runs = 60/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |
| F040              | 5              | 2           | 1                | Lot 1: 5 samples x 5 replicates/run x 3 runs = 80/Lot*<br>Lot 2: 5 samples x 5 replicates/run x 3 runs = 95/Lot**<br><br><i>*One sample had 1 additional replicate, and one sample had 4 additional replicates, for a total of 5 additional replicates.</i><br><i>**Three samples had 5 additional replicates, one sample had 4 additional replicates, and one sample had 1 additional replicate, for a total of 20 additional replicates.</i> |
| F041              | 5              | 2           | 1                | 5 samples x 5 replicates/run x 3 runs = 75/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |
| F075              | 4              | 2           | 1                | Lot 1: 4 samples x 5 replicates/run x 3 runs = 62/Lot*<br>Lot 2: 4 samples x 5 replicates/run x 3 runs = 60/Lot<br><br><i>*Two samples had one additional replicate.</i>                                                                                                                                                                                                                                                                       |
| F201              | 5              | 2           | 1                | 5 samples x 5 replicates/run x 3 runs = 75/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |
| F203              | 5              | 2           | 1                | 5 samples x 5 replicates/run x 3 runs = 75/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |
| F290              | 6              | 2           | 1                | 6 samples x 5 replicates/run x 3 runs = 90/Lot                                                                                                                                                                                                                                                                                                                                                                                                 |

#### Limit of Quantitation

LoQ was evaluated as a functional sensitivity-based approach with no bias component to LoQ. Functional sensitivity for NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) was determined using a set of four to six samples with low IgE concentrations and two lots of NOVEOS sIgE allergen. The samples were tested with one to ten replicates, over three to four testing days, with one run per day, resulting in a total of 60 to 95 replicates. 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 or by calculating the mean dose at 20%CV 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 and are summarized in the table below:

| NOVEOS sIgE Allergen | LoB (kU/L) | LoD (kU/L) | LoQ (kU/L) |
|----------------------|------------|------------|------------|
| F018, Brazil Nut     | 0.07       | 0.10       | 0.10       |
| F036, Coconut        | 0.07       | 0.09       | 0.10       |
| F040, Tuna           | 0.07       | 0.08       | 0.10       |
| F041, Salmon         | 0.07       | 0.08       | 0.10       |
| F075, Egg Yolk       | 0.07       | 0.08       | 0.10       |
| F201, Pecan Nut      | 0.07       | 0.09       | 0.10       |
| F203, Pistachio Nut  | 0.07       | 0.09       | 0.10       |
| F290, Oyster         | 0.07       | 0.09       | 0.10       |

## Reference Range

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

The expected value/reference range of NOVEOS sIgE assays for F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) in a normal population was verified in accordance with CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory – 3rd Edition.

The 95% reference range was calculated by ordering the dose recoveries from 120 to 126 non-atopic samples in ascending order of concentration and identifying the dose recovery that fell at the 95th percentile rank. The 95% reference range for each allergen under evaluation was below the established NOVEOS sIgE cutoff of 0.35 kU/L.

## Stability

### Shelf-Life Stability

Both an ongoing real-time stability study and an accelerated stability study were performed for NOVEOS sIgE assays for F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) in accordance with CLSI EP25-Ed2 *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – Second Edition*. The accelerated stability study and ongoing real-time stability study were performed with two positive and one negative sample using three lots of NOVEOS sIgE allergen (Capture Reagent).

The accelerated stability data supports the manufacturer's claim of unopened shelf-life stability for the capture reagents as listed in the table below. Stability of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479.

|                                    | <b>Shelf-life Stability (2-8°C)</b> |
|------------------------------------|-------------------------------------|
| Specific IgE Capture Reagent F018* | 36 months                           |
| Specific IgE Capture Reagent F036* | 36 months                           |
| Specific IgE Capture Reagent F040* | 36 months                           |
| Specific IgE Capture Reagent F041* | 36 months                           |
| Specific IgE Capture Reagent F075* | 36 months                           |
| Specific IgE Capture Reagent F201* | 36 months                           |
| Specific IgE Capture Reagent F203* | 36 months                           |
| Specific IgE Capture Reagent F290* | 36 months                           |

\*Based on accelerated stability data

Real-time stability studies of the NOVEOS sIgE allergens are on-going to further support the manufacturer's claim of unopened shelf-life stability when stored at 2-8°C per the manufacturer's instructions for use.

#### On-Board Stability (OBS)

Real-time OBS stability studies using one lot of NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) support the on-board stability claims for capture reagents as summarized in the table below. The real-time on-board stability study was performed with three samples, including two positive samples and one negative or low-level sample using one lot of NOVEOS allergen (Capture Reagent) stored on-board the instrument. OBS of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479.

|                                   | <b>On-board Stability (2-8°C)</b> |
|-----------------------------------|-----------------------------------|
| Specific IgE Capture Reagent F018 | 28 days                           |
| Specific IgE Capture Reagent F036 | 28 days                           |
| Specific IgE Capture Reagent F040 | 28 days                           |
| Specific IgE Capture Reagent F041 | 28 days                           |
| Specific IgE Capture Reagent F075 | 28 days                           |
| Specific IgE Capture Reagent F201 | 28 days                           |
| Specific IgE Capture Reagent F203 | 28 days                           |
| Specific IgE Capture Reagent F290 | 28 days                           |

#### Open-Vial Stability (OVS)

Both an ongoing real-time stability study and an accelerated stability study were performed for the NOVEOS sIgE allergens F018 (Brazil Nut), F036 (Coconut), F040 (Tuna), F041 (Salmon), F075 (Egg Yolk), F201 (Pecan Nut), F203 (Pistachio Nut), and F290 (Oyster) in accordance with CLSI EP25-Ed2 *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – Second Edition*. OVS of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479. The result supports that the allergen specific capture reagent is stable for 15 days once opened and stored at 2-8°C

Real-time stability studies of the NOVEOS sIgE allergens are on-going to further support the manufacturer's claim of open-vial shelf-life stability when stored per the manufacturer's instructions for use.

#### Proposed Labeling:

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

#### Conclusion:

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