510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:
K181871

B. Purpose for Submission:
Adding previously cleared assays on a new instrument platform (Phadia 2500/5000)

C. Measurand:
IgG autoantibodies specific to tissue transglutaminase (tTG)
IgA autoantibodies specific to gliadin
IgG autoantibodies specific to gliadin

D. Type of Test:
Automated semi-quantitative solid-phase fluoroimmunoassays

E. Applicant:
Phadia AB

F. Proprietary and Established Names:
EliA Celikey IgG Immunoassay
EliA Gliadin^{DP} IgA Immunoassay
EliA Gliadin^{DP} IgG Immunoassay

G. Regulatory Information:

1. Regulation section:
   21 CFR §866.5660, Multiple autoantibodies immunological test system
   21 CFR §866.5750, Radioallergosorbent (RAST) Immunological Test System

2. Classification:
   Class II

3. Product code:
   MVM, Autoantibodies, endomysial (tissue transglutaminase)
   MST, Autoantibodies, gliadin

4. Panel:
   Immunology (82)

H. Intended Use:

1. Intended uses:

   EliA Celikey IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to tissue transglutaminase (tTG) in human serum and EDTA-plasma. EliA Celikey IgG is based on recombinant human tissue transglutaminase as antigen and is useful as an aid in the clinical diagnosis of patients with celiac disease in conjunction with other laboratory and clinical findings. EliA Celikey IgG uses the EliA IgG method on the instrument Phadia 2500/5000.

   EliA Gliadin^{DP} IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to gliadin in human serum or plasma (Li-heparin, EDTA) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin^{DP} IgA uses the EliA IgA method on the instrument Phadia 2500/5000.

   EliA Gliadin^{DP} IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to gliadin in human serum or plasma (Li-heparin, EDTA) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin^{DP} IgG uses the EliA IgG method on the instrument Phadia 2500/5000.

2. Indications for use:
   Same as intended uses

3. Special conditions for use statement:
   For prescription use only

4. Special instrument requirements:
   For use on the Phadia 2500 and Phadia5000 instruments

I. Device Description:

The method-specific reagents are identical with K062583 (EliA Celikey IgG) and K093459 (EliA Gliadin^{DP} IgA and EliA Gliadin^{DP} IgG), but are filled in containers specific for the Phadia 2500/5000 instrument. Each device consists of the folloing:

EliA Assay-specific Reagents:

- EliA Celikey IgG Wells are coated with human recombinant tissue transglutaminase (tTG), ready to use
- EliA Gliadin^{DP} IgA Wells are coated with synthetic deamidated gliadin peptides, ready to use
- EliA Gliadin^{DP} IgG Wells are coated with synthetic deamidated gliadin peptides, ready to use

EliA Method-specific Reagent:

- EliA Sample Diluent: PBS containing BSA, detergent and 0.095% (w/v) sodium azide ready to use

EliA IgG reagents (required for EliA Celikey IgG and EliA Gliadin^{DP} IgG):

- EliA IgG Conjugate 50 or 200: β-Galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and 0.06% (w/v) sodium azide, ready to use
- EliA IgG Calibrator Strips: Human IgG (0, 4, 10, 20, 100, 600 µg/L) in PBS containing BSA, detergent and 0.095% (w/v) sodium azide, ready to use
- EliA IgG Curve Control Strips: Human IgG (20 µg/L) in PBS containing BSA, detergent and 0.095% (w/v) sodium azide, ready to use
- EliA IgG Calibrator Well: Coated with mouse monoclonal antibodie), ready to use

EliA IgA reagents (required for EliA Gliadin^{DP} IgA):

- EliA IgA Conjugate 50 or 200: β-Galactosidase labeled anti-IgA (mousemonoclonal antibodies) in PBS containing BSA and 0.06% (w/v) sodium azide, ready to use
- EliA IgA Calibrator Strips: Human IgA (0, 0.3, 1.5, 5, 15, 80 µg/L) in PBS containing BSA, detergent and 0.095% (w/v) sodium azide, ready to use
- EliA IgA Curve Control Strips: Human IgA (20 µg/L) in PBS containing BSA, detergent and 0.095% (w/v) sodium azide, ready to use
- EliA IgA Calibrator Well: Coated with mouse monoclonal antibodies, ready to use

The EliA reagents are available as modular packages, each purchased separately. All packages are required to carry out EliA Celikey IgG, EliA Gliadin^{DP} IgA, and EliA Gliadin^{DP} IgG tests.

J. Substantial Equivalence Information:

1. Predicate device names and Predicates:
   EliA Celikey IgG on Phadia 250 instrument, K062583
   EliA Gliadin^{DP} IgA on Phadia 250 instrument, K093459
   EliA Gliadin^{DP} IgG on Phadia 250 instrument,K093459

2. Comparison with predicate:

Similarities		
Item	Device *Phadia 2500/5000 EliA Celikey IgG and EliA Gliadin^{DP} IgA/IgG (K181871)	Predicate Phadia 250 EliA Celikey IgG (K062583) EliA Gliadin^{DP} IgA/IgG (K093459)
Intended Use: EliA Celikey IgG	EliA Celikey IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to tissue transglutaminase (tTG) in human serum and EDTA-plasma. EliA Celikey IgG is based on recombinant human tissue transglutaminase as antigen and is useful as an aid in the clinical	EliA Celikey IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to tissue transglutaminase (tTG) in human serum and plasma. EliA Celikey IgG is based on recombinant human tissue transglutaminase as antigen and is useful as an aid in the

Similarities		
Item	Device *Phadia 2500/5000 EliA Celikey IgG and EliA Gliadin^{DP} IgA/IgG (K181871)	Predicate Phadia 250 EliA Celikey IgG (K062583) EliA Gliadin^{DP} IgA/IgG (K093459)
	diagnosis of patients with celiac disease in conjunction with other laboratory and clinical findings. EliA Celikey IgG uses the EliA IgG method on the instrument Phadia 2500/5000.	clinical diagnosis of patients with Celiac disease. EliA Celikey IgG uses the EliA IgG method on the instrument ImmunoCAP 250*. (* Former name of Phadia 250)
Intended Use: EliA Gliadin^{DP} IgA/IgG	EliA Gliadin^{DP} IgA/IgG is intended for the in vitro semi-quantitative measurement of IgA/IgG antibodies directed to gliadin in human serum or plasma (Li-heparin, EDTA) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin^{DP} IgA/IgG uses the EliA IgA/IgG method on the instrument Phadia 2500/5000.	EliA Gliadin^{DP} IgA/IgG is intended for the in vitro semi-quantitative measurement of IgA/IgG antibodies directed to gliadin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin^{DP} IgA/IgG uses the EliA IgA/IgG method on the instrument Phadia 250.
Signal	Immuno-fluorescence measurement	Same
Assay type	ELISA	Same
Type of test	Semi-quantitative	Same
Antigen: Celikey IgG Gliadin ^{DP} IgA/IgG	Human recombinant transglutaminase (tTG) Synthetic deaminated gliadin peptides	 Same Same
Common, dedicated Phadia reagents	Same. Introduction of new article numbers for Development Solution, Stop Solution and Washing Solution is only due to larger filling volumes which are required for the bigger instruments Phadia 2500/5000	Same
Time to 1st result	About two hours	Same
Detection antibody		

Similarities		
Item	Device *Phadia 2500/5000 EliA Celikey IgG and EliA Gliadin^{DP} IgA/IgG (K181871)	Predicate Phadia 250 EliA Celikey IgG (K062583) EliA Gliadin^{DP} IgA/IgG (K093459)
<u>(conjugate)</u>: Celikey IgG and Gliadin^{DP} IgG Gliadin^{DP} IgA	 ß-Galactosidase anti-IgG, mouse monoclonal antibodies ß-Galactosidase anti-IgA, mouse monoclonal antibodies	 Same Same
Incubation temperature	37°C	Same
<u>Sample matrix</u>: Celikey IgG	 Serum and plasma (EDTA)	 Same
<u>Calibrator strips</u>: Celikey IgG and Gliadin^{DP} IgG Gliadin^{DP} IgA	 Human IgG 0, 4, 10, 20, 100, 600 µg/L Human IgA 1, 0.3, 1.5, 5, 15, 80 µg/L	 Same Same
<u>Control</u>: Celikey IgG and Gliadin^{DP} IgG Gliadin^{DP} IgA	 EliA IgG curve control strips, 20 µg/L EliA IgA curve control strips, 5µg/L	 Same Same
Cutt-off	Negative <7 Equivocal 7-10 Positive >10	Same
Assay set-up	Random access	Same
Result calculation software	Phadia Information Data Manager (IDM)	Same
Sample volume Conjugate volume Development solution Stop solution	90 µL (20 µL of non-diluted sample) 90 µL 90 µL 200 µL	Same Same Same Same

Differences		
Item	Device	Predicate
Instrument	Phadia 2500/5000	Phadia 250
Sample matrix: Gliadin^{DP} IgA/ IgG	Serum and plasma (Li-heparin, EDTA)	Serum and plasma (Li-heparin, EDTA, citrate)
Measuring range: Celikey IgG Gliadin^{DP} IgA Gliadin^{DP} IgG	LoQ to upper limit 1.7 to 227 EliA U/mL0.4 to 142 EliA U/mL 1.4 to 302 EliA U/mL	LoD to upper limit 0.6 to ≥ 600 EliA U/mL 0.1 to ≥ 142 EliA U/mL 0.4 to ≥ 132 EliA U/mL
Sample dilution, pipets	Disposable Pipette Tips in Racks for pipetting samples in Dilution Well	Steel pipette to dilute the samples in Dilution Plates
Risk for carry-over	When running EliA tests on the Phadia 2500/5000 instruments, there is no need for this warning statement because these instruments use disposable tips for pipetting samples and a separate pipette for the conjugate, and carry-over from samples to conjugate is impossible.	The warning "DO NOT REUSE" in the Phadia 250 DFU for EliA Conjugates is due to the fact that a low risk of conjugate contamination by carry-over from samples was identified. In order to reduce the risk, the single use statement for the conjugate was included in the Phadia 250 DFU.
Loading of EliA Carriers	The Phadia 2500/5000 instruments do not have Loading Tray. The EliA carriers are loaded into racks which are directly transferred to the cooled storage compartment	EliA carriers are loaded manually on the Loading Tray from where they can be processed directly or transferred to the cooled storage compartment.
Barcode reader	On the Phadia 2500/5000 the reagents are on a moving belt which conveys them past the barcode reader. The lot-specific information will be read automatically by the instrument during loading.	The Phadia 250 instrument has a built-in barcode reader at the front of the instrument, but the operator needs to scan the barcodes manually by showing the reagents to the barcode reader. Alternatively, the operator can also enter the characters below the barcode manually.
Process time / Time to patient result	Phadia 2500/5000 instruments process two Wells in parallel in 48 seconds. Phadia 2500/5000 provides the results at a 24 seconds interval.	Phadia 250 needs one minute to process one Well. Phadia 250 provides the results at a one minute interval.
Daily throughput	About 2500/5000 tests	About 250 tests

*Phadia 2500/5000 – Phadia 2500 and Phadia 5000 are identical instruments except for sample throughput. The difference is that Phadia 2500 consists of one process module (two process lines) and Phadia 5000 consists of 2 process modules (2x2 process lines). For that reason Phadia uses the Phadia 2500 and Phadia 5000 instrument names interchangeably.

K. Standard/Guidance Document Referenced:

CLSI EP05-A3; Evaluation of Precision Performance of Quantitative Measurement Methods
CLSI EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures
CLSI EP17-A2, Protocols for Determination of Limits of Detection and Limits of Quantification

L. Test Principle:

The EliA wells are molded cups comparable to excised wells from a microtiter plate. They are made of polystyrene and are coated with the respective antigen.

The EliA wells are coated with human recombinant tissue transglutaminase for Celikey IgG, or with synthetic deamidated gliadin peptides for Gliadin^{DP} IgA and Gliadin^{DP} IgG. If present in the patient's specimen, antibodies to these proteins bind to the specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgA or IgG antibodies (EliA IgA Conjugate or EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgA or IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

M. Performance Characteristics:

1. <u>Analytical performance:</u>

   All results presented below met the manufacturer's predetermined acceptance criteria.

   a. Precision:

   The imprecision of the assay was assessed in a study with a total of 21 runs (3 instruments × 7 runs, 28 replicates/instrument/per sample) using serum native patient samples.

   The studies were performed with 1 run/day over a period of 7 days. Each sample was tested in four replicates/run giving in total 84 replicates per sample. The data was calculated against the calibration curve from Day 1. The results are summarized in the table below:

EliA Celikey IgG on Phadia 2500/5000

Mean (EliA U/mL)	Within-run		Between-run		Between-Instruments		Total Total Imprecision	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1.6	0.2	10.0	0.1	7.2	0.4	25.0	0.4	27.9
7.6	0.2	2.8	0.2	3.1	0.3	4.2	0.4	5.9
9.6	0.3	2.7	0.3	2.6	0.5	5.4	0.6	6.6
100.4	2.7	2.6	3.1	3.0	3.4	3.3	5.3	5.1
274.6	8.4	3.1	6.9	2.5	9.5	3.5	14.5	5.3

EliA Gliadin^{DP} IgA on Phadia 2500/5000

Mean (EliA U/mL)	Within-run		Between run		Between Instruments		Total Imprecision	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV
0.8	0.1	8.9	0.0	5.7	0.1	14.5	0.1	18.2
7.4	0.2	3.0	0.1	1.5	0.1	1.3	0.3	3.6
8.7	0.2	2.8	0.2	2.6	0.2	2.3	0.4	4.5
42.8	1.5	3.6	0.9	2.1	0.2	2.8	2.1	5.0
135.3	5.8	4.3	3.8	2.8	10.4	7.7	12.5	9.3

EliA Gliadin^{DP} IgG on Phadia 2500/5000

Mean (EliA U/mL)	Within-run		Between run		Between Instruments		Total Imprecision	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV
3.6	0.3	8.2	0.2	5.2	0.3	8.6	0.5	13.0
7.2	0.2	3.3	0.4	5.4	0.2	3.1	0.5	7.0
9.3	0.3	2.8	0.5	5.2	0.0	0.0	0.5	5.9
73.7	2.6	3.5	4.9	6.7	2.2	3.0	6.0	8.1
219.6	8.2	3.7	13.2	6.0	6.8	3.1	17.0	7.7

b. Linearity/assay reportable range:

Four patient serum samples were tested with one batch of EliA Celikey IgG, EliA Gliadin^{DP} IgA and EliA Gliadin^{DP} IgG Immunoassays and one set of system reagents on Phadia 2500/5000. The samples were serially diluted using the EliA Sample Diluent and tested in triplicates. The ratio of observed/expected (O/E) values were calculated. Observed values were graphed against the calculated values and a linear regression was performed. The results of the regression analysis are summarized below:

EliA Celikey IgG on Phadia 2500/5000

Dilution range (EliA U/mL)	Slope	95% CI	Intercept	95% CI	R^2
1.3–35.5	1.03	0.95–1.10	0.49	−0.71–1.69	0.99
1.8–2.9	1.02	0.93–1.11	0.69	−0.69–2.07	0.99
2.2–96.6	1.02	0.98–1.06	1.68	−1.18–4.54	1.00
7.1–174.0	1.01	0.97–1.05	2.26	−1.11–5.63	1.00
2.8–227.8	1.04	0.98–1.10	2.48	−2.75–7.72	0.99

The reportable range (Limit of Detection, upper limit) for EliA Celikey IgG is from 0.6–227 EliA U/mL. The measuring range (Limit of Quantitation, upper limit) is from 1.7–227 EliA U/mL.

EliA Gliadin^{DP} IgA on Phadia 2500/5000

Dilution range (EliA U/mL)	Slope	95% CI	Intercept	95% CI	R^2
0.4–28.5	1.00	0.99–1.01	−0.04	−0.16–0.09	1.00
1.3–137.8	0.99	0.95–1.02	−1.69	−3.39–0.00	1.00
0.6–26.9	1.00	0.98–1.02	−0.30	−0.54–−0.05	1.00
2.1–162.0	0.99	0.98–1.00	0.79	0.02–1.57	1.00

The reportable range (Limit of Detection, upper limit) and the measuring range (Limit of Quantitation, upper limit) for EliA Gliadin^{DP} IgA is from 0.4–142 EliA U/mL. The measuring range (Limit of Quantitation, upper limit) is from 0.4 to 142 EliA U/mL.

EliA Gliadin^{DP} IgG on Phadia 2500/5000

Dilution range (EliA U/mL)	Slope	95% CI	Intercept	95% CI	R^2
0.6– 26.3	0.99	0.96–1.02	−0.32	−0.65– 0.02	1.00
0.8– 54.4	1.00	0.98–1.01	−0.50	−0.86–−0.13	1.00
7.0– 334.9	0.98	0.92–1.03	−5.65	−13.85–2.56	0.99
7.3– 288.3	1.00	0.99–1.01	1.02	−0.31–2.35	1.00

The reportable range (Limit of Detection, upper limit) for EliA Gliadin^{DP} IgG is from 0.6 to 302 EliA U/mL. The measuring range (Limit of Quantitation, upper limit) is from 1.4 to 302 EliA U/mL.

The following statements are included in the package inserts: "*Please note that concentration values between LoD and LoQ may show a higher uncertainty.*" "*Please note that due to differing binding characteristics of the antibodies in patient samples, not all sera can be diluted linearly within the measuring range*."

High dose hook effect: The hook effect was previously reviewed in the predicate devices (K062583 and K093459).

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The EliA IgG stability and calibration method was previously reviewed in K061165.

The EliA IgA stability and calibration method was previously reviewed in K062787.

Controls:
Controls are sold separately from the assay. Calibrators are traceable to the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A,G and M from World Health Organization (WHO).

d. Detection limit:

The limit of blank (LoB), limit of detection (LoD), and limit of quantitation studies were performed on the Phadia 2500/5000 instrument. One blank sample was run in 33 replicates in two runs for a total of 66 observations. The LoD was measured by assaying three low level samples (11 replicates for each sample in each run) using two assay runs, for a total of 66 observations. Three additional low level samples were used for the LoD determination of the EliA Celikiey IgG for a total of 132 determinations.

The LoB and LoD were calculated according to CLSI guideline EP17-A2. To estimate the LoQ, a target level for the CV% of 20% has been defined. The mean value of the sample with the CV% closest to and below the precision target of 20% CV is selected as LoQ.

The results are summarized in the table below:

Phadia 2500/5000	Units	LoB	LoD	LoQ
EliA Celikey IgG	EliA U/mL	0.0	0.6	1.7
EliA Gliadin^{DP} IgA	EliA U/mL	0.0	0.2	0.4
EliA Gliadin^{DP} IgG	EliA U/mL	0.3	0.6	1.4

e. Analytical specificity:

Interference: Previously reviewed in K062583 for Celikey^{R} IgG and in K093459 for Gliadin^{DP} IgA and IgG.

Carry-over: Phadia 2500/5000 instruments use disposable tips for pipetting samples and a separate pipette for the conjugate, therefore carry-over from samples to conjugate was not evaluated.

f. Assay cut-off:
The three assays' cut-offs are the same as in the predicate devices, K062583 Celikey^{R} IgG and in K093459 for Gliadin^{DP} IgA and IgG and are summarized in the table below:

EliA Celikey IgG, EliA Gliadin^{DP} IgA , EliA Gliadin^{DP} IgG	
Negative	< 7 EliA U/mL
Equivocal	7 – 10 EliA U/mL
Positive	> 10 EliA U/mL

2. Comparison studies:

a. Method comparison with predicate device:
Instrument comparison was performed with the predicate device, see 2c below.

b. Matrix comparison:
Matrix comparison between serum and plasma was previously reviewed in K062583 for Celikey IgG and in K093459 for Gliadin^{DP} IgA and IgG.

c. Instrument comparison
The purpose of this study is to evaluate conformance and show comparability of the EliA assays on the instruments Phadia 250 (PH250) versus Phadia 2500/5000 (PH2500/5000). The samples were run in single replicates on one PH250 instrument and three PH2500/5000 (A, B, C) instruments for a total of four measurments per sample. Only samples inside the measuring range were included in the calculations. Results were analyzed by Passing-Bablock regression.

EliA Celikey IgG:
100 samples were used in the study, 77 positive, 23 negative and 10 equivocal samples. The results are summarised below:

Instrument	Intercept	95% CI	Slope	95% CI	R
PH2500/5000 A	0.49	0.26–0.73	0.93	0.91–0.94	0.998
PH2500/5000 B	0.14	−0.19–0.46	0.96	0.93–1.00	0.992
PH2500/5000 C	−0.28	−0.55–−0.00	0.98	0.97–1.00	0.998

Positive percent agreement (PPA), negative percent agreement (NPA), and total percent agreement (TPA) were evaluated with equivocal results considered positive in the table below:

Criteria	PH2500/5000 A	PH2500/5000 B	PH2500/5000 C
PPA	97.4%	97.4%	96.1%
95% CI	90.9% – 99.7%	90.9% – 99.7%	89.0% – 99.2%
NPA	82.6%	87.0%	91.3%
95% CI	61.2% – 95.0%	66.4% – 97.2%	72.0% – 98.9%
TPA	94.0%	95.0%	95.0%
95% CI	87.4% – 97.8%	88.7% – 98.4%	88.7% – 98.4%

Results when equivocal results are considered negative are presented in the table below:

Criteria	PH2500/5000 A	PH2500/5000 B	PH2500/5000 C
PPA	95.5%	97.0%	94.0%
95% CI	87.5% – 99.1%	89.6% – 99.6%	85.4% – 98.3%
NPA	100%	100%	100%
95% CI	89.4% – 100%	89.4% – 100%	89.4% – 100%
TPA	97.0%	98.0%	96.0%
95% CI	91.5% – 99.4%	93.0% – 99.8%	90.1% – 98.9%

EliA Gliadin^{DP} IgA:
105 samples were used in the study, 79 positive, 21 negative and 5 equivocal samples.The results are summarised below:

Instrument	Intercept	95% CI	Slope	95% CI	R
PH2500/5000 A	0.60	0.40–0.93	0.95	0.92–0.98	0.993
PH2500/5000 B	0.55	0.28–0.83	0.97	0.95–1.00	0.994
PH2500/5000 C	−0.24	-0.71–−0.06	1.09	1.06–1.11	0.994

Positive percent agreement (PPA), negative percent agreement (NPA), and total percent agreement (TPA) were evaluated with equivocal results considered positive in the table below:

Criteria	PH2500/5000 A	PH2500/5000 B	PH2500/5000 C
PPA	100%	100%	100%
95% CI	95.7% – 100%	95.7% – 100%	95.7% – 100%
NPA	90.5%	85.7%	90.5%
95% CI	69.6% – 98.8%	63.7% – 97.0%	69.6% – 98.8%
TPA	98.1%	97.1%	98.1%
95% CI	93.3% – 99.8%	91.9% – 99.4%	93.3% – 99.8%

Results when equivocal results are considered negative are presented in the table below:

Criteria	PH2500/5000 A	PH2500/5000 A	PH2500/5000 A
PPA	98.7%	100.0%	98.7%
95% CI	93.2% – 100%	95.4% – 100%	93.2% – 100%
NPA	96.2%	96.2%	96.2%
95% CI	80.4% – 99.9%	80.4% – 99.9%	80.4% – 99.9%
TPA	98.1%	99.0%	98.1%
95% CI	93.3% – 99.8%	94.8% – 100%	93.3% – 99.8%

EliA Gliadin^{DP} IgG:
104 samples were used in the study, 80 positive, 19 negative and 5 equivocal samples.The results are summarised below:

Instrument	Intercept	95% CI	Slope	95% CI	R
PH2500/5000 A	−0.14	−0.41–0.13	1.06	1.04–1.09	0.997
PH2500/5000 B	0.43	0.13–1.16	0.99	0.94–1.02	0.994
PH2500/5000 C	−0.06	−0.20–0.20	1.08	1.07–1.10	0.998

Positive percent agreement (PPA), negative percent agreement (NPA), and total percent agreement (TPA) were evaluated with equivocal results considered positive in the table below:

Criteria	PH2500/5000 A	PH2500/5000 B	PH2500/5000 C
PPA	100.0%	100.0%	100%
95% CI	95.8% – 100%	95.8% – 100%	95.8% – 100%
NPA	89.5%	100.0%	94.7%
95% CI	66.9% – 98.7%	82.4% – 100.0%	74.0% – 99.9%
TPA	98.1%	100.0%	99.0%
95% CI	93.2% – 99.8%	96.5% – 100%	94.8% – 100%

Results when equivocal results are considered negative are presented in the table below:

Criteria	PH2500/5000 A	PH2500/5000 B	PH2500/5000 C
PPA	98.8%	100%	100%
95% CI	93.2% – 100%	95.5% – 100%	95.5% – 100%
NPA	100%	95.8%	91.7%
95% CI	85.8% – 100%	78.9% – 99.9%	73.0% – 99.0%
TPA	99.0%	99.0%	98.1%
95% CI	94.8% – 100%	94.8% – 100%	93.2% – 99.8%

3. Clinical studies:
   Clinical performance was previously reviewed in Previously reviewed in K062583 for Celikey^{R} IgG and in K093459 for Gliadin^{DP} IgA and IgG.

4. Clinical cut-off**:**
   See assay cut-off

5. Expected values/Reference range:
   A total of 400 apparantly healthy Caucasian blood donors matched by age and sex were tested on the Phadia 2500/5000 instrument to evaluate expected values in the normal population. The results are summarized below:

Test (n=400)	Mean (EliA U/mL)	Median (EliA U/mL)	Range	95th percentile	99th percentile
EliA Celikey IgG	2.3	2.3	0.1–6.1	3.3	3.9
EliA Gliadin^{DP} IgA	1.8	1.4	0.0–16.1	3.8	7.1
EliA Gliadin^{DP} IgG	1.6	0.9	0.1–51.5	2.7	13.3

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable

O. Conclusion:

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