

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k093459

B. Purpose for Submission:

New device

C. Measurand:

Anti-gliadin IgA and anti-gliadin IgG autoantibodies

D. Type of Test:

Semi-quantitative measurement immunoassay

E. Applicant:

Phadia US Inc.

F. Proprietary and Established Names:

EliA™ Gliadin^{DP} IgA and EliA™ Gliadin^{DP} IgG

G. Regulatory Information:

1. Regulation section:

21 CFR §866.5750 – Radioallergosorbent (RAST) Immunological Test System

21 CFR §862.1660 – Quality Control Material (Assayed and Unassayed)

2. Classification:

Class II (assay)

Class I (control)

3. Product code:

MST – autoantibodies, gliadin

JJY – multi-analyte controls (assayed)

4. Panel:

Immunology (82)

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

EliA™ Gliadin^{DP} IgA is intended for the in vitro semi-quantitative measurement of IgA 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 uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.

EliA™ Gliadin^{DP} IgG is intended for the in vitro semi-quantitative measurement of 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} IgG uses the EliA IgG method on the instruments Phadia® 100 and Phadia® 250.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

For use on the Phadia 100 and Phadia 250 (formerly known as the ImmunoCAP® 100 and ImmunoCAP® 250)

I. Device Description:

EliA uses a modular reagent system. The test specific, method specific and general reagents are packaged and purchased as separate units. The reagents on Phadia 100 and Phadia 250 are identical; they are only filled in different containers.

EliA Gliadin Test-Specific Reagents consist of:

- 1) EliA Gliadin IgG/IgA Well coated with synthetic deamidated gliadin peptides-sufficient for 48 determinations;
- 2) EliA Celiac Positive Control, a multiparameter control containing IgG and IgA antibodies to tTg and gliadin;
- 3) EliA IgG/IgM/IgA Negative Control containing normal human serum from healthy donors;

Also required for the test are:

EliA Method-Specific Reagents:

EliA method-specific sample diluent (PBS with 0.095% sodium azide), EliA IgA or IgG conjugate (β -galactosidase labeled mouse monoclonal anti-IgA or -IgG antibodies), EliA IgA or IgG calibrators [human IgA or IgG in PBS at measured concentrations (0, 0.3, 1.5, 5, 15, 80 $\mu\text{g/L}$ for IgA and 0, 4, 10, 20, 100, and 600 $\mu\text{g/L}$ for the IgG)], EliA IgG or IgA Curve Control, EliA IgG or IgA Calibrator Well

General Reagents include:

Development Solution, Stop Solution, Washing Solution, and Dilution Plates.

J. Substantial Equivalence Information:

1. Predicate device name(s) and Predicate K number(s):
Quanta Lite™ Gliadin IgG II, k052142
Quanta Lite™ Gliadin IgA II, k052143
2. Comparison with predicate:

Similarities		
Feature	Predicate Device	New Device
	QUANTA Lite™ Gliadin IgA/IgG II	EliA™ Gliadin ^{DP} IgA/IgG
Intended Use: IgA assay	QUANTA Lite™ Gliadin IgA II is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of gliadin IgA antibodies in human serum. The presence of gliadin antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease.	EliA™ Gliadin ^{DP} IgA is intended for the in vitro semi-quantitative measurement of IgA 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 uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.
Intended Use: IgG assay	QUANTA Lite™ Gliadin IgG II is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of gliadin IgG antibodies in human serum. The presence of gliadin antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease.	EliA™ Gliadin ^{DP} IgG is intended for the in vitro semi-quantitative measurement of 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} IgG uses the EliA IgG method on the instruments Phadia 100 and Phadia 250.
Internal Controls	ELISA Negative Control ELISA Low positive Control ELISA High positive Control included in the kit	Positive and negative Control Sera provided with the EliA Celiac Positive Control 100 / 250 and EliA IgG/IgM/IgA Negative Control 100 / 250, respectively
Type of test	Semi-quantitative	Same

Differences		
Feature	Predicate device	New device
Antigen used	Purified gliadin peptides	Synthetic deamidated gliadin peptides
Sample matrix	Serum	serum and plasma (heparin, EDTA, citrate)
Assay Type	Manual ELISA	Automated immunoassay
Instrumentation	ELISA-Reader needed	Phadia 100 and 250 are fully automated immunoassay analyzers
Reaction temperature	Room temperature, 20-26°C	37°C controlled
Detection antibody (conjugate)	anti-human IgA or IgG horseradish peroxidase (goat)	anti-human IgA or IgG β -Galactosidase (mouse monoclonal antibodies)
Substrate	TMB	4-Methylumbelliferyl- β D-Galactoside
Signal	Optical density	Fluorescence
Calibration	1-point Calibration	Total IgA or IgG Calibration
Calibration curve	Not applicable.	Option to store curve for up to 28 days and run curve controls in each assay for calibration
Concept	All reagents in a single kit	Modular reagents concept (test-method specific and general reagents)

K. Standard/Guidance Document Referenced (if applicable):

None referenced by the sponsor.

L. Test Principle:

The EliA Gliadin IgG and IgA Wells are coated with synthetic deamidated gliadin peptides. If present in the patient's specimen, antibodies to gliadin peptides bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG or IgA antibodies, respectively (EliA IgG Conjugate / EliA IgA 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 IgG or IgA is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

The total IgG and IgA calibration is based on a set of six WHO-standardized IgG and IgA Calibrators, respectively, derived from human serum. They are used to establish

an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method specific and general reagents that are packaged as separate units.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision of both assays on both instruments was examined by performing 108 replicate determinations each of six samples across the claimed measuring range of the assay (3 instruments x 6 runs each, 6 replicates per run). The statistical evaluation was performed by Analysis of Variance. Results of the studies are shown in the tables below:

EliA Gliadin IgG Phadia 100:

Test	Sample	Mean value (U/mL)	Intra Run CV%	SD	Inter Run (between days) CV%	SD	Total Imprecision CV%	SD
EliA Gliadin ^{DP} IgG	1	3.1	3.5	0.11	3.6	0.11	5.0	0.15
	2	10.5	4.6	0.49	3.0	0.31	5.5	0.58
	3	14.7	4.9	0.72	1.9	0.29	5.3	0.78
	4	44.2	4.2	1.87	2.8	1.23	5.1	2.24
	5	206.9	5.1	10.49	4.7	9.72	6.9	14.30
	6	324.4	4.5	14.55	4.1	13.26	6.1	19.69

EliA Gliadin IgG Phadia 250:

Test	Sample	Mean value (U/mL)	Intra Run CV%	SD	Inter Run (between days) CV%	SD	Total Imprecision CV%	SD
EliA Gliadin ^{DP} IgG	1	3.4	3.0	0.10	1.8	0.06	3.5	0.12
	2	10.7	4.1	0.44	3.9	0.42	5.7	0.61
	3	15.6	6.0	0.93	4.0	0.63	7.2	1.12
	4	45.2	4.9	2.23	4.1	1.86	6.4	2.91
	5	213.9	2.9	6.26	2.1	4.54	3.6	7.73
	6	297.0	4.3	12.78	2.7	8.10	5.1	15.13

EliA Gliadin IgA Phadia 100:

Test	Sample	Mean value (U/mL)	Intra Run CV%	SD	Inter Run (between days) CV%	SD	Total Imprecision CV%	SD
EliA Gliadin ^{DP} IgA	1	3.6	3.6	0.13	2.9	0.10	4.6	0.17
	2	7.4	3.8	0.28	1.8	0.13	4.2	0.31
	3	11.3	4.2	0.47	2.4	0.27	4.8	0.54
	4	22.7	4.4	0.99	1.2	0.27	4.5	1.03
	5	69.9	4.9	3.42	4.0	2.78	6.3	4.41
	6	124.0	5.1	6.36	5.0	6.15	7.1	8.85

EliA Gliadin IgA Phadia 250:

Test	Sample	Mean value (U/mL)	Intra Run CV%	SD	Inter Run (between days) CV%	SD	Total Imprecision CV%	SD
EliA Gliadin ^{DP} IgA	1	3.7	6.5	0.24	10.5	0.39	12.3	0.46
	2	7.7	5.2	0.40	2.8	0.21	5.9	0.45
	3	11.1	4.6	0.51	2.7	0.30	5.3	0.59
	4	22.7	5.6	1.27	4.0	0.91	6.9	1.56
	5	67.4	3.7	2.52	3.9	2.60	5.4	3.62
	6	125.7	4.1	5.18	1.8	2.27	4.5	5.65

b. Linearity/assay reportable range:

Six patient samples were diluted between 8 and 11 times. Each dilution was tested in triplicate, each replicate representing the mean of two sample wells as per the assay instructions. A regression analysis and a calculation of the percent recovery were performed on the results. Of note, the samples with $> \pm 10\%$ recovery from the expected value were typically highly diluted samples; absolute differences in concentration were small.

EliA Gliadin IgG linearity results:

The measuring range (detection limit, upper limit) for EliA Gliadin IgG is from 0.4 to ≥ 302 EliA U/mL.

Instrument: Phadia 100 - Gliadin IgG				
Sample:	Range (U/mL)	Regression analysis	R2	Recovery Range
9	4.5 – 193.8	1.06x – 2.8	0.999	85 – 107%
10	2.5 – 115.8	1.05x – 1.2	0.999	81 – 106%
11	6.7 – 307.1	0.96x – 1.6	0.999	84 – 98%
15	0.5 – 59.0	1.01x – 0.85	0.999	85 – 100%
16	0.5 – 45.9	0.99x – 0.15	0.999	90 – 100%
17	0.6 – 8.3	0.99x - 0.29	0.999	88 – 99%

Instrument: Phadia 250 - Gliadin IgG				
Sample:	Range (U/mL)	Regression analysis	R2	Recovery Range
9	4.6 – 189.7	0.99x – 0.3	0.999	88 – 103%
10	2.4 – 115.6	0.96x + 0.4	0.999	80 – 105%
11	7.0 – 344.8	0.94x – 1.8	0.999	78 – 94%
15	0.9 – 63.5	0.95x – 0.7	0.999	81 – 96%
16	0.9 – 46.5	0.98x + 0.14	0.999	99 – 109%
17	1.2 – 59.6	1.01x - 0.2	0.999	96 – 114%

EliA Gliadin IgA linearity results:

The measuring range (detection limit, upper limit) for EliA GliadinDP IgA is from 0.1 to ≥ 142 EliA U/ml.

Instrument: Phadia 100 - Gliadin IgA				
Sample:	Range (U/mL)	Regression analysis	R2	Recovery Range
6	1.1 – 46.8	0.95x + 0.01	0.999	90 – 100%
7	1.6 – 68.1	0.95x + 0.02	0.999	87 – 97%
8	1.3 – 57.5	0.97x – 0.2	0.999	85 – 100%
12	1.4 – 139.1	0.99x – 0.5	0.999	86 – 99%
13	0.6 – 28.2	1.01x – 0.22	0.999	86 – 103%
14	0.4 – 31.2	1.02x - 0.29	0.999	76 – 102%

Instrument: Phadia 250 - Gliadin IgA				
Sample:	Range (U/mL)	Regression analysis	R2	Recovery Range
6	1.1 – 43.8	1.00x + 0.03	0.999	97 – 105%
7	1.6 – 64.6	0.98x – 0.1	0.999	92 – 99%
8	1.4 – 58.9	0.99x – 0.24	0.999	90 – 101%
12	1.6 – 134.2	1.02x – 0.4	0.999	95 – 103%
13	0.7 – 33.2	1.04x – 0.3	0.999	79 – 103%
14	0.6 – 32.6	1.08x - 0.3	0.999	83 – 107%

Hook Effect EliA IgG: Hook effect was analyzed by using dilutions from high positive serum samples with an estimated concentration well above the highest calibrator. A hook effect was not observed when analyzing a high positive sample that had a concentration up to 1.7 times above the upper limit of the measuring range.

Hook Effect EliA IgA: Hook effect was analyzed by using dilutions from high positive serum samples with an estimated concentration well above the highest calibrator. A hook effect was not observed when analyzing a high positive sample that had a concentration up to 60 times above the upper limit of the measuring range.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods)*:
The IgG and IgA Calibrators are traceable via an unbroken chain of calibrations to the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A, G and M from the World Health Organization (WHO). There are no international standards for Gliadin antibodies. Results are given in arbitrary EliA Units/mL.

EliA Celiac Positive Control is prepared from selected pooled human sera and contains IgG and IgA antibodies to tissue transglutaminase (tTG) and gliadin. The controls are pre-diluted and ready for use. This material was previously reviewed in k062583.

EliA IgG/IgM/IgA Negative Control is prepared from normal human serum and is ready-to-use. This material was previously reviewed in k072393. The acceptance criterion for the Gliadin IgG and the Gliadin IgA assays is that the mean of the negative value is below the lower limit of the assays' equivocal values (7 U/mL).

Stability: An accelerated stability study set the shelf-life of the EliA Gliadin IgG and IgA Wells at 24 months. Other required components (previously reviewed) of the assay method have a shelf life of 18 to 24 months. It is important to store the wells in dry conditions at 2-8°C. A real-time stability study was presented that supported the sponsor's claim that opened EliA Gliadin IgG and IgA Wells are stable for up to 9 months if not limited by expiry date stated on the carrier and foil bag and if stored according to the instructions for use.

The sponsor recommends following the guidelines in CLSI H18-A3 for sample storage.

- d. *Detection limit*:
The lower limit of the measuring range of both assays was established by showing that the each assay could differentiate between the background (sample buffer) and a 1/8 dilution of the lowest calibrator point. The results in Response Units (RU) were compared with the result of the sample diluent on EliA Gliadin Wells. The discrimination ability (D) of the assay is the ability of

the assay to discriminate a reading from background at a given concentration; the value should be >2.0. EliA Gliadin **IgG** was able to discriminate samples containing 0.5 µg/L IgG (Cal 4.0, 1:8) from the background. The corresponding detection limit was **0.4 EliA U/mL** when using 0.63 as conversion factor (to convert µg/L to U/mL). EliA Gliadin **IgA** was able to discriminate samples containing 0.038 µg/L IgA (Cal 0.3, 1:8) from the background. The corresponding detection limit was **0.1 EliA U/mL**: when using 2.23 as conversion factor (to convert µg/L to U/mL).

e. Analytical specificity:

The analytical specificity of the EliA Gliadin IgG and IgA assays were partly addressed by testing samples from patients with Crohn’s Disease, ulcerative colitis (UC), and *H. pylori* infection. The expected result for these samples is typically negative (< 1% of the population is positive, see Section M.3.5 below for additional discussion). The results are shown in the table below:

Assay	Disease	n =	negative	equivocal	positive
Gliadin IgG	Crohn’s	50	48	1	1
	UC	42	41	1	0
	<i>H. pylori</i>	14	14	0	0
		n =	negative	equivocal	positive
Gliadin IgA	Crohn’s	50	47	3	0
	UC	42	41	0	1
	<i>H. pylori</i>	14	14	0	0

The sponsor examined the specificity of the EliA Gliadin IgG and IgA assays further by comparing test results to the consensus results from a panel of five samples from the College of American Pathologists (CAP) and one sample from the National External Quality Assessment Service (NEQAS). The test samples were diluted according to the assay instructions and the assays were performed as per the instructions. Results are shown in the table below:

Sample ID	IgG Consensus Result	EliA Gliadin IgG Result (IU/mL)	IgA Consensus Result	EliA Gliadin IgA Result (IU/mL)
Celiac 0911	borderline	positive (18.6)	equivocal	equivocal (8.4)
CES-B 2008 CES-03	positive	positive (77.0)	positive	positive (>142)
CES-B 2008 CES-04	negative	negative (0.0)	negative	negative (0.0)
CES-B 2008 CES-05	positive	positive (>302)	positive	positive (>142)
CES-A 2008 CES-01	borderline /positive	positive (17.8)	positive	positive (>142)
CES-A 2008 CES-02	negative	positive (147.2)	equivocal/ positive	positive (20.5)

Interference:

The purpose of this study was to investigate whether high concentrations of potentially interfering substances in serum, like Bilirubin, Hemoglobin, chyle and Rheumatoid Factor (RF) adversely affect the results of the EliA Gliadin IgG and IgA assays. Two positive serum samples with concentration levels around the cut-off and one high positive serum sample were spiked with bilirubin C, bilirubin F, hemoglobin, chyle or RF. The same samples were also spiked with substance specific blanks. The samples were tested in 3 replicates and the runs were repeated twice (n = 6). The %CV for each sample and interferent combination was less than 12%. The samples containing the interferents at the concentrations in the table below interfered with the non-spiked samples $\leq \pm 12\%$; the majority of the interferents interfered with the assay results $\leq \pm 10\%$:

Substance	Concentration in Test Sample ($\mu\text{g/mL}$)	
	Gliadin IgG Assay	Gliadin IgA Assay
Bilirubin C	20.6	412
Bilirubin F	19.1	382
Hemoglobin	49.9	98.8
Chyle	15.9 FTU	31.8 FTU
Rheumatoid Factor	550 IU/mL	1100 IU/mL

f. Assay cut-off:

Based on the results of the expected values/reference range study described below in Section M.5 and the results with defined reference sera and the correlation study, the assay cutoffs were set as follows (all units EliA U/mL) :

	Negative	Equivocal	Positive
EliA Gliadin IgG	< 7	7 – 10	> 10
EliA Gliadin IgA	< 7	7 – 10	> 10

In case of equivocal results, it is recommended to retest the patient after 4-6 weeks. Good laboratory practice requires that each laboratory establishes its own range of expected values.

2. Comparison studies:

a. Method comparison with predicate device:

EliA Gliadin IgA:

309 serum samples that tested within the measuring range of both assays were collected from the serum bank at Phadia GmbH; these samples included 64 samples from patients who had been clinically defined as suffering from celiac disease (CD). 21 samples from IgA deficient patients were tested with both methods; as expected, all were negative and are not included in this analysis:

		Predicate Assay		
		Positive	Negative	Total
EliA Gliadin IgA	Positive	50	3	53
	Equivocal	3	4	7
	Negative	6	243	249
	<i>Total</i>	59	250	309

Regarding Equivocal as Negative:

Positive Agreement: 84.7% 95% CI: 73.0 – 92.8%
 Negative Agreement: 98.8% 95% CI: 96.5 – 99.8.0%
 Overall Agreement: 96.1% 95% CI: 93.3 – 98.0%

Regarding Equivocal as Positive:

Positive Agreement: 89.8% 95% CI: 79.2 – 96.2%
 Negative Agreement: 97.2% 95% CI: 94.3 – 98.9%
 Overall Agreement: 95.8% 95% CI: 92.9 – 97.7%

EliA Gliadin IgG:

337 serum samples that tested within the measuring range of both assays were collected from the serum bank at Phadia GmbH; these samples included 102 samples from patients who had been clinically defined as suffering from celiac disease (CD) including 17 samples from IgA deficient patients:

		Predicate Assay		
		Positive	Negative	Total
EliA Gliadin IgG	Positive	87	4	91
	Equivocal	0	6	6
	Negative	2	238	240
	<i>Total</i>	89	248	337

Regarding Equivocal as Negative:

Positive Agreement: 97.8% 95% CI¹: 92.1 – 99.7%
 Negative Agreement: 98.4% 95% CI: 95.9 – 99.6%
 Overall Agreement: 98.2% 95% CI: 96.2 – 99.3%

Regarding Equivocal as Positive:

Positive Agreement: 97.8% 95% CI*: 92.1 – 99.7%
 Negative Agreement: 96.0% 95% CI: 92.7 – 98.0%
 Overall Agreement: 96.4% 95% CI: 93.9 – 98.1%

b. Matrix comparison:

The purpose of this study was to demonstrate that recovery of analyte from lithium heparin plasma, citrate plasma and EDTA plasma collection tubes was

¹ Confidence Intervals in the ‘Regarding Equivocal as Negative’ analysis were calculated by the sponsor; Confidence Intervals in the ‘Regarding Equivocal as Positive’ analysis were calculated by the reviewer

equivalent to the analyte recovered from serum collection tubes. Samples from the same patient were collected in all four collection tubes and tested according to the directions for use. Samples spanned the measuring range of both assays; 39 samples were tested using the EliA Gliadin IgG assay and 50 samples were tested using the EliA Gliadin IgA assay. Regression analysis was performed using serum as the comparator; results are shown in the table below:

Matrix	EliA Gliadin IgG	EliA Gliadin IgA
heparin plasma	$y = 0.98x + 0.80$ R2 = 0.992	$y = 1.02x - 0.14$ R2 = 0.9979
citrate plasma	$y = 0.99x - 0.40$ R2 = 0.995	$y = 1.00x - 0.03$ R2 = 0.9976
EDTA plasma	$y = 1.01x + 0.52$ R2 = 0.989	$y = 1.00x + 0.17$ R2 = 0.997

In the EliA Gliadin IgG study no negative samples changed to equivocal or positive and all equivocal and all but two positive samples were $\leq \pm 10\%$ of the serum value. In the EliA Gliadin IgA study no negative samples changed to equivocal or positive and all equivocal and positive samples were $\leq \pm 10\%$ of the serum value.

3. Clinical studies:

a. *Clinical Sensitivity and Clinical Specificity:*

EliA Gliadin IgG

367 serum samples were collected from the serum bank at Phadia GmbH. In this study 119 samples from patients who had been clinically defined as suffering from celiac disease (CD) were included; 21 samples were from IgA deficient patients. 50 samples were from Crohn's Disease patients, 42 were from ulcerative colitis patients, 54 were from patients with various infectious diseases including hepatitis B and C and *H. pylori*, Results of both assays were compared to the clinical diagnosis:

		Celiac Disease		
		Positive	Negative	Total
EliA Gliadin IgG	Positive	108	5	113
	Equivocal	2	4	6
	Negative	9	239	248
	Total	119	248	367

Regarding Equivocal as Negative:

Sensitivity: 90.8% 95% CI: 84.2 – 94.8%

Specificity: 98.0% 95% CI: 95.4 – 99.1%

Regarding Equivocal as Positive:

Sensitivity: 92.4% 95% CI: 86.2 – 96.0%

Specificity: 96.4% 95% CI: 93.2 – 98.1%

EliA Gliadin IgA:

The same 367 samples described above were also tested with the EliA Gliadin IgA test; as expected, the 21 IgA-deficient samples were all negative and are not included in this analysis:

		Celiac Disease		
		Positive	Negative	Total
EliA Gliadin IgA	Positive	81	4	85
	Equivocal	1	6	7
	Negative	16	238	254
	Total	98	248	346

Regarding Equivocal as Negative:

Sensitivity: 82.6% 95% CI: 73.7 – 89.6%

Specificity: 98.4% 95% CI: 95.9 – 99.6%

Regarding Equivocal as Positive:

Sensitivity: 83.7% 95% CI: 75.1 – 89.7%

Specificity: 96.0% 95% CI: 92.7 – 97.8%

b. Other clinical supportive data (when a. is not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The frequency distribution for Gliadin antibodies was investigated in a group of apparently healthy subjects equally distributed by age and gender, using sera from a Caucasian population obtained from a blood bank. The results are given in the table below:

Test	n =	Mean (EliA U/mL)	95 th percentile	99 th percentile
EliA Gliadin IgG Phadia 100	400	1.4	3.7	14.2
EliA Gliadin IgG Phadia 250	400	1.3	4.1	12.7
EliA Gliadin IgA Phadia 100	400	1.7	3.5	10.4
EliA Gliadin IgA Phadia 250	400	1.7	3.9	11.4

Antibody prevalence in autoimmune patients varies widely depending on disease area. The proportion of sera from a normal population found positive for gliadin antibodies covered by the EliA GliadinDP IgG and IgA tests is below 1 %.

Expected values may vary depending on the population tested.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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