September 13, 2021

Phadia AB
% Sheryl Skinner
Associate Director RA/QA
Phadia US Inc.
4169 Commercial Avenue
Portage, Michigan 49002

Re: K202540
Trade/Device Name: EliA Rib-P
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: Class II
Product Code: MQA
Dated: September 1, 2020
Received: September 2, 2020

Dear Sheryl Skinner:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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) 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202540

Device Name
EliA Rib-P

Indications for Use *(Describe)*
EliA Rib-P is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Rib-P in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Rib-P uses the EliA IgG method.

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.

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510(k) Summary

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

Premarket Notification 510(k) No: K202540

Date of Summary Preparation: September 3, 2021

Manufacturer:
Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala, Sweden

Distributor:
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Portage, MI 49002

Company Contact Person:
Sheryl Skinner
Associate Director, Regulatory and Quality
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Proprietary and Established Device Name:
EliA Rib-P

Regulatory Information:

Product Code:	MQA
Classification:	Class II
Regulation:	21 CFR 866.5100 – Antinuclear Antibody Immunological Test System
Panel:	Immunology

Purpose of Submission:
New Device

Measurand:
IgG autoantibodies specific to Rib-P proteins

Type of Test:
Automated semi-quantitative solid phase fluoroenzymeimmunoassay

Intended Use:
EliA Rib-P is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Rib-P in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Rib-P uses the EliA IgG method.

Indication(s) for Use:
Same as intended use

Special Conditions for Use:
Rx – For Prescription Use Only

Special Instrument Requirements:
For use on the Phadia 250 instrument and the Phadia 2500 and Phadia 5000 instrument series (E-modules).

Device Description:
EliA Rib-P is a semi-quantitative solid-phase fluoroenzymeimmunoassay, for the determination of autoantibodies against Rib-P. The EliA Rib-P test System is fully integrated and automated system which comprises of assay-specific reagents, EliA method-specific reagents, and general reagents.

Assay-Specific Reagents include:
- EliA Rib-P Wells: coated with human recombinant ribosomal P-proteins P0, P1 and P2 – 2 carriers (12 wells each), ready to use;
- EliA ANA 3 Positive Control 250 or 2500/5000: Human monoclonal antibodies in Tris buffer containing IgG antibodies to Ro52, Rib-P and RNA Pol III – 6 single use vials, 0.3 mL each, ready to use;
- EliA IgG/IgM/IgA Negative Control 250 or 2500/5000: Human blood preparation from healthy donors in PBS containing BSA, detergent and 0.095% sodium azide – 6 single-use vials, 0.3 mL each, ready to use;

EliA Method-Specific Reagents include:
- EliA Sample Diluent: PBS containing BSA, detergent and 0.095% sodium azide – 6 bottles, 48 mL each, ready to use; or 6 bottles, 400 mL each, ready to use;
- EliA IgG Conjugate 50 or 200: β-Galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and 0.06% sodium azide – 6 wedge shaped bottles, 5 mL each, ready to use; or 6 wedge shaped bottles, 19 mL each, 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% sodium azide – 5 strips, 6 single-use vials per strip, 0.3 mL each, ready to use;
- EliA IgG Curve Control Strips: Human IgG (20 µg/L) in PBS containing BSA, detergent and 0.095% sodium azide – 5 strips, 6 single-use vials per strip, 0.3 mL each, ready to use;

- EliA IgG Calibrator Well: coated with mouse monoclonal antibodies – 4 carriers (12 wells each), ready to use;

General Reagents include:

- Development Solution: 0.01% 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative – 6 bottles (11 mL, 17 mL, or 112 mL each), sufficient for 6x >110, 6x >170, or 6x >1165 determinations;
- Stop Solution: 4% Sodium Carbonate – 6 bottles (65 mL, 119 mL, or 2800 mL each), sufficient for 6x >292, 6x >560, or 6x >13100 determinations;
- Washing Solution Additive: detergent, preservative <0.13% – 6x 17.2 mL, 2x 86mL, or 4x 850 mL;
- Washing Solution Concentrate: phosphate buffer – 6x 80 mL, 2x 400 mL, or 1x 2800 mL.

Instrument System

EliA Rib-P is run on the Phadia 250 instrument and the Phadia 2500 and 5000 instrument series. The instruments are automated platforms for EliA test procedures from sample and reagent handling to the processing of results.

Substantial Equivalence

Quanta Lite Ribosome P ELISA, INOVA Diagnostics, Inc., (K981237)

Comparison with Predicate Device:

	Similarities	
Feature	**Proposed Device** EliA Rib-P	**Predicate Device** Quanta Lite Ribosome P ELISA
Intended Use	EliA Rib-P is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Rib-P in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Rib-P uses the EliA IgG method.	QUANTA Lite Ribosome P is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative detection of Ribosome P antibodies in human serum. The presence of Ribosome P antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and other related connective tissue diseases.
Internal Controls	Positive and negative Control provided with EliA ANA 3 Positive Control 250 and 2500/5000 and EliA IgG/IgM/IgA Negative Control 250 and 2500/5000, resp.	Low Positive, High Positive and Negative Control included in the kit

Assay technique	ELISA	Same
Type of test	Semi-quantitative	Same
Sample Dilution (taking a 1% pipetting imprecision into consideration, this sample dilution is regarded as a similarity)	1:100	1:101
Reported Unit	EliA U/mL (arbitrary)	Units (arbitrary)

	Differences	
Feature	**Proposed Device** EliA Rib-P	**Predicate Device** Quanta Lite Ribosome P ELISA
Antigen	Human recombinant P-proteins P0, P1 and P2	Synthetic Ribosome P antigen
Instrumentation	EliA Rib-P uses the EliA IgG method on the instruments Phadia 250 and the E-modules of the Phadia 2500 and Phadia 5000 series.	ELISA-Reader needed
Reaction temperature	37°C controlled	Room temperature, 20-26°C
Detection antibody (conjugate)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	IgG conjugate: HRP IgG Conjugate, (goat), anti-human IgG
Signal	Fluorescence	Optical density
Calibration	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	One-point calibration
Calibration curve	Option to store curve for up to 28 days and run curve controls in each assay for calibration	N/A
Interpretation of results	Negative < 7 EliA U/mL Equivocal 7-10 EliA U/mL Positive > 10 EliA U/mL	Negative < 20 Units Weak positive 20-39 Units Moderate positive 40-80 Units Strong positive > 80 Units
Substrate	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside,	TMB Chromogen

	<0.0010% preservative* *Preservative: mixture of 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	

Standard/Guidance Document Referenced

- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents, September 2009
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures, September 2014
- CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, April 2003
- CLSI EP07-ED3, Interference Testing in Clinical Chemistry, September 2018
- CLSI EP37-ED1, Supplemental Tables for Interference Testing, September 2018
- CLSI EP09c-ED3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples, June 2018
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, June 2012
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, October 2010

Test Principle

The EliA tests are fluorescence immunoassays for the detection and measurement of human antibodies based on EliA solid-phase components, which contain specific antigens for the antibodies to be measured.

The specific antigen for the antibodies to be detected is bound to the EliA solid phase component (EliA Well). 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 wells are at the same time a holder of the coupled antigen for convenient automation and a reaction chamber with reaction/washing solution handling based on pipetting to add and aspiration to remove liquids.
If present in the patient's specimen, antibodies to these proteins bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (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 assay directly measures the amount of antibody of interest bound to the antigen coating the EliA well, therefore the higher the value of fluorescent signal detected by the instrument, the higher the amount of antibody bound and detected in the sample tested. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Performance Characteristics

1. Analytical performance:
   a) Precision/Reproducibility:

To determine the precision of the assay on the Phadia 250 instrument and the Phadia 2500 and Phadia 5000 instrument series, the variability was assessed on 5 samples.

Three lots were used to determine the precision of the assay on Phadia 250 (totaling 252 replicate determinations per sample).

One lot was used to determine the precision of the assay on Phadia 2500E, which is a representative of the Phadia 2500 and Phadia 5000 instrument series.

EliA Rib-P on Phadia 250:

To determine the precision of the assay on the Phadia 250 instrument, the variability was assessed in a study with 21 runs by examining the samples in 252 replicates across 3 lots and 3 Phadia 250 instruments over 7 days. The data was calculated against the calibration curve from Day 1. The statistical evaluation was performed by Analysis of Variance. The results are given in the table below.

Mean EliA U/mL	Within-Run		Between-Run		Between-Instrument		Lot-to-Lot		Total Imprecision	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
2.8	0.2	5.9	0.2	6.6	0.2	8.5	0.1	5.0	0.4	13.3
7.8	0.3	3.2	0.3	4.1	0.3	4.2	0.0	0.0	0.5	6.7
9.5	0.4	3.8	0.3	2.9	0.5	5.3	0.4	3.9	0.8	8.1
56.8	1.8	3.2	2.9	5.1	1.0	1.8	0.6	1.0	3.6	6.4
316.4	9.3	2.9	7.5	2.4	2.6	0.8	3.0	1.0	12.5	4.0

Within-lab Imprecision

To determine the within-lab precision of the assay, the variability was assessed in a study with 40 runs by examining the samples in 80 replicates on 1 instrument over 20 days. The data was calculated against the calibration curve from Day 1. The statistical evaluation was performed by Analysis of Variance. The results are given in the table below.

Mean (EliA U/mL)	Within-Run		Between-Run		Between-Day		Within-Lab Imprecision	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV
3.0	0.2	7.2	0.4	11.8	0.1	3.6	0.4	13.8
7.6	0.3	3.9	0.4	5.9	0.0	0.0	0.5	7.0
11.0	0.2	2.2	0.5	4.2	0.3	2.3	0.5	4.7
87.6	2.0	2.2	2.3	2.7	1.6	1.8	3.0	3.5

EliA Rib-P on the Phadia 2500 and Phadia 5000 instrument series:
To determine the precision of the assay on the of the Phadia 2500 and Phadia 5000 instrument series (E-module), the variability was assessed in a study with 21 runs by examining the samples in 84 replicates on 3 Phadia 2500E instruments over 7 days. The data was calculated against the calibration curve from Day 1. The statistical evaluation was performed by Analysis of Variance.

The results are given in the table below.

Mean EliA U/mL	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
2.1	83*	0.2	8.1	0.4	16.5	0.0	1.0	0.4	18.4
7.1	84	0.4	5.4	0.5	6.6	0.1	1.9	0.6	8.7
8.8	84	0.5	5.5	0.8	8.7	0.4	4.3	1.0	11.2
48.7	84	1.5	3.1	1.7	3.4	1.7	3.4	2.8	5.7
362.1	84	31.6	8.7	20.9	5.8	0.0	0.0	37.9	10.5

* One sample result is missing due to an instrument error.

b) Linearity/Assay Reportable Range:
3 serum samples were diluted in EliA Sample Diluent and tested on Phadia 250 and Phadia 2500E. The ratios of observed/expected values were calculated. The results are summarized below.

Phadia 250

Dilution Range (EliA U/mL)	Slope	Intercept	R^2
45.1 – 452.6	0.95	9.01	1.00
2.7 - 122.9	1.00	1.28	1.00
0.5 - 32.2	1.00	0.24	1.00

Phadia 2500E

Dilution Range (EliA U/mL)	Slope	Intercept	R^2
8.5 - 427.6	1.03	2.96	0.99
0.5 - 34.3	1.00	0.44	1.00
0.7 - 22.6	1.02	0.30	0.99

Linearity was shown for the entire measuring range.

Hook Effect/Over the Range Results:
Not applicable. Results above the upper limit of the measuring range are reported as “>403”. No recommendations are made for dilution of samples outside measuring range in the Directions For Use.

c) Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
Traceability:
The IgG calibrators are traceable (via unbroken chain of calibrations) to the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A, G and M from WHO. New batches of IgG calibrators are compared to a secondary standard (standardized with the IRP) or the IRP directly and adjusted accordingly to meet the correct concentration.

The instrument measures specific IgG concentrations in µg/L. By using a conversion factor given by the lot-specific code of the EliA test well, the results are automatically converted to EliA U/mL.

Stability:
Data for open and closed real-time stability and on-board stability of EliA IgG reagents and general EliA reagents on Phadia 250 as well as on the E-module of the Phadia 2500 and Phadia 5000 series were already cleared with several other EliA tests, e.g. under K141375 (EliA M2 on Phadia 250). For the Phadia 2500 and Phadia 5000 instrument series, they were already cleared under K061165/A003 (EliA CCP).

Shelf-life:
The stability of EliA Rib-P Wells was evaluated with a real-time study. The results support stability of the test under the recommended storage of 2 – 8°C for up to 36 months.

On-board stability:
The on-board stability EliA Rib-P carriers (containing the antigen coated wells) was tested over 8 weeks using 3 positive and 2 negative samples only on the Phadia 250 instrument. As the storage conditions in the E-module of the Phadia 2500 and Phadia 5000 series are similar to the Phadia 250, the results can also be used for stability claims for these instruments. The on-board stability for the Phadia 250 was determined to be 28 days at 2-8°C.

Open Stability:
Stability after first opening of the foil bag containing the EliA Rib-P wells was tested with a real-time study. According to this study, a shelf-life of 9 months at 2-8°C after first opening can be assigned to EliA Rib-P wells.

d) Detection Limit:
Four blank and four low level samples were measured with two different reagent sets (two lots of antigen wells). The four blank samples were created from depleted IgG sera, each diluted with EliA Sample Diluent. The blank samples and the low-level samples were assayed in three runs using two different sets of EliA Rib-P Well lots over three different days on a Phadia 250 and Phadia 2500E each in 5-fold determination.

For each instrument type, the total number of combined observations for blank and low-level samples is 120 (60 per reagent set, 15 per sample and reagent set).

The results are summarized in the table below:

Instrument	LoB EliA U/mL	LoD EliA U/mL	LoQ EliA U/mL
Phadia 250	0.0	0.5	1.9
E-module of the Phadia 2500 and Phadia 5000 series	0.1	0.4	1.1

A harmonized LoB of 0.1 EliA U/mL, LoD of 0.5 EliA U/mL, and LoQ of 1.9 EliA U/mL for the immunoassay was used.

The LoD for EliA Rib-P is 0.5 EliA U/mL, determined consistent with the guidelines in CLSI document EP17-A2 and with proportions of false positives (α) less than 5% and false negatives (β) less than 5%; based on 240 determinations with 120 blank and 120 low-level replicates per instrument type; and LoB of 0.1 EliA U/mL.

e) Analytical specificity:
Endogenous and Exogenous Interference:
A study was run to investigate whether high concentrations of potentially interfering substances in serum, like bilirubin, hemoglobin, lipemic factor, rheumatoid factor, Ibuprofen, Losartan, Hydroxychloroquine, Azathioprine, Prednisone, Rituximab and Infliximab adversely affect the results of the new device.

Three serum samples (one negative sample, one sample with a concentration within the equivocal range, and one high positive sample) were prediluted in EliA Sample Diluent and spiked with the different interfering substances or blank solution. The samples were tested in triplicates. A calibration curve was run in duplicate. The runs were repeated twice. One batch of EliA antigen wells and one batch of system reagents were used throughout the studies.

The ratio of blank/spiked sample ranged from 0.90 – 1.10 for EliA Rib-P. No interference was observed up to the concentrations listed in the table below:

Potential Interfering Compound	Concentration in undiluted sample
Bilirubin F	40 mg/dL
Bilirubin C	40 mg/dL
Hemoglobin	1000 mg/dL
Lipemic factor	2000 mg/dL
Rheumatoid factor	550 IU/mL

Ibuprofen	21.9 mg/dL
Losartan	1.14 mg/dL
Hydroxychloroquine	0.23 mg/dL
Azathioprine	0.26 mg/dL
Prednisone	0.01 mg/dL
Rituximab	109 mg/dL
Infliximab	26.4 mg/dL

Reference Sera:
Externally defined sera should be measured according to their target values as mentioned by the institution CDC. Using EliA Rib-P, all 12 CDC samples were found according to their target.

f) Assay Cut-Off:
To define the cut-off, a study was performed using a cohort consisting of 70 apparently healthy blood donors and 30 samples from SLE patients. The samples were measured on a Phadia 250 instrument.

The cut-off was set as follows for EliA Rib-P:

<7 EliA U/mL	Negative
7-10 EliA U/mL	Equivocal
>10 EliA U/mL	Positive

In case of equivocal results, it is recommended to retest the patient after 8-12 weeks.

2. Comparison Studies:
   a) Method Comparison with Predicate Device:

A total of 323 patient samples with concentrations covering the measuring range were tested.

The samples were analyzed with the EliA Rib-P and Quanta Lite Ribosome P ELISA assay. The test was run in single determination and evaluated according to the Directions for Use. The results are summarized in the tables below:

EliA Rib-P: equivocal results considered negative

N = 323	Quanta Lite Ribosome P positive: ≥ 20 Units	Quanta Lite Ribosome P negative: < 20 Units	Total
EliA Rib-P positive: > 10 EliA U/mL	36	4	40
EliA Rib-P negative: < 10 EliA U/mL	2	281	283
Total	38	285	323
	Calculation	Agreement (%)	95% CI
Positive Percent Agreement	100% x 36 / 38	94.7	82.3 - 99.4
Negative Percent Agreement	100% x 281 / 285	98.6	96.4 - 99.6
Total Agreement	100% x (36 + 281) / 323	98.1	96.0 - 99.3

EliA Rib-P: equivocal results considered positive

N = 323	Quanta Lite Ribosome P positive: ≥ 20 Units	Quanta Lite Ribosome P negative: < 20 Units	Total
EliA Rib-P positive: >7 EliA U/mL	38	34	72
EliA Rib-P negative: < 7 EliA U/mL	0	251	251
Total	38	285	323
	Calculation	Agreement (%)	95% CI
Positive Percent Agreement	100% x 38 / 38	100	90.7 - 100
Negative Percent Agreement	100% x 251 / 285	88.1	83.7 - 91.6
Total Agreement	100% x (38 + 251) / 323	89.5	85.6 - 92.6

b) Instrument Comparison:
Performance of EliA Rib-P was evaluated on the Phadia 250 and Phadia 2500E instrument using 47 positive, 10 equivocal and 28 negative samples. The samples were analyzed in single determination on one Phadia 250 and one Phadia 2500E instrument each. The regression analysis results are summarized as follows:

	Intercept	Slope
Estimate	-0.76	0.94
95% CI	-1.20 - -0.48	0.93 - 0.98

3. Clinical Studies:
   a) Clinical Sensitivity and Specificity:

560 clinically defined serum samples with a diagnosis from patients with systemic lupus erythematosus (n = 146), Celiac disease (n = 13), Crohn's disease (n = 12), CTD overlap Non-MCTD (n = 10), Dermatomyositis (n = 4), Polymyositis (n = 6), Graves' disease (n = 12), Primary antiphospholipid syndrome (n = 12), Primary biliary cirrhosis (n = 21), Sjögren's syndrome (n = 23), Type 1 Diabetes (n = 12), Ulcerative colitis (n = 11) cancer (n = 10), Mixed connective tissue disease (n = 10), Rheumatoid arthritis (n = 30), bacterial infections (n = 36), viral infections (n = 56), Hashimoto's disease (n = 10), Granulomatosis with Polyangiitis (n = 4), Autoimmune Hepatitis (n = 16), Polymyalgia Rheumatica (n = 25), Systemic sclerosis, diffuse (n = 48) and Systemic sclerosis, limited (n = 33) were used to determine sensitivity and specificity of the assay.

The results are summarized in the tables below.

EliA Rib-P – equivocal results evaluated as positive:

n=560	Diagnostic Group	Disease Controls	Total
Positive test ≥ 7 EliA U/mL	51	3	54
Negative test < 7 EliA U/mL	95	411	506
Total	146	414	560

Sensitivity (95% CI): 34.9% (27.2% – 43.3%)
Specificity (95% CI): 99.3% (97.9% – 99.9%)

EliA Rib-P – equivocal results evaluated as negative:

n=560	Diagnostic Group	Disease Controls	Total
Positive test > 10 EliA U/mL	41	1	42
Negative test ≤ 10 EliA U/mL	105	413	518
Total	146	414	560

Sensitivity (95% CI): 28.1% (21.0 % - 36.1%)

Specificity (95% CI): 99.8% (98.7% - 100%)

The table below shows the results for each clinical subgroup:

Diagnostic Groups	total n	positive n	positive %
Systemic lupus erythematosus	136	38	28%
Systemic lupus erythematosus with secondary antiphospholipid syndrome	10	3	30%
Target disease (Total)	**146**	**41**	
Celiac disease	13	0	0%
Crohn's disease	12	0	0%
CTD overlap Non-MCTD	10	0	0%
Dermatomyositis	4	0	0%
Polymyositis	6	0	0%
Graves' disease	12	0	0%
Primary antiphospholipid syndrome	12	0	0%
Primary Biliary Cholangitis	21	0	0%
Sjögren's syndrome	23	0	0%
Type 1 Diabetes	12	0	0%
Ulcerative colitis	11	0	0%
Varied Cancer	10	0	0%
Mixed connective tissue disease	10	0	0%
Rheumatoid arthritis	30	0	0%
Bacterial infections	36	0	0%
Viral infections	56	0	0%
Hashimoto's disease	10	0	0%
Granulomatosis with Polyangiitis	4	0	0%
Systemic sclerosis, diffuse	48	1	2%
Autoimmune Hepatitis	16	0	0%
Polymyalgia Rheumatica	25	0	0%
Systemic sclerosis, limited	33	0	0%
Disease Controls (Total)	**414**	**1**	
Total	560		

b) Other Clinical Supportive Data:
Not applicable.

4. Clinical Cut-Off:
   Same as assay cut-off.

5. Expected Values/Reference Range:
   Antibody prevalence in autoimmune patients varies widely depending on disease area. The proportion of sera from a normal population found positive for the antinuclear antibodies covered by the EliA Rib-P test is below 1%. Expected values may vary depending on the population tested.

   The frequency distribution for antinuclear antibodies was investigated in a group of apparently healthy subjects equally distributed by age and gender, using sera from Caucasian, African American, Hispanic and Asian population obtained from a blood bank.

   The results are given in the table below:

Test	n	Median EliA U/mL	95th percentile EliA U/mL	99th percentile EliA U/mL
EliA Rib-P	638	1.6	3.4	5.0

Proposed Labeling
The labeling is drafted in accordance with the requirements of 21 CFR Part 809.10.

Conclusion
All available data support that both immunoassays, the new device EliA Rib-P and its predicate device Quanta Lite Ribosome P ELISA perform substantially equivalent.