July 27, 2022

Phadia AB
% Jane Anthony
Senior Manager, Quality Systems and Compliance
Phadia US Inc.
4169 Commercial Avenue
Portage, Michigan 49002

Re: K210902
Trade/Device Name: EliA Ro52
EliA Ro60
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: Class II
Product Code: LKJ
Dated: April 4, 2022
Received: April 6, 2022

Dear Jane Anthony:

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.
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

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)*

K210902

Device Name

EliA Ro52

Indications for Use *(Describe)*

EliA Ro52 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro52 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and idiopathic inflammatory myopathies (IIM) in conjunction with other laboratory and clinical findings. EliA Ro52 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K210902

Device Name

EliA Ro60

Indications for Use *(Describe)*

EliA Ro60 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro60 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Ro60 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) DECISION SUMMARY

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

Premarket Notification 510(k) No: K210902

Date of Summary Preparation: July 25, 2022

Manufacturer: **Phadia AB**

Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala, Sweden

Distributor: **Phadia US Inc.**

4169 Commercial Avenue
Portage, MI 49002

Company Contact Person: **Jane Anthony**

Senior Manager, Quality Systems and Compliance
Phadia US Inc.
4169 Commercial Avenue, Portage, MI 49002
269-254-6833
jane.anthony@thermofisher.com

Proprietary and Established Device Name:

EliA Ro52
EliA Ro60

Regulatory Information:

Product Code:	LKJ
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 SS-A/Ro proteins (52 kDa and 60 kDa)

Type of Test:

Automated semi-quantitative solid phase fluoroenzymeimmunoassay.

Intended Use:

EliA Ro52 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro52 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and idiopathic inflammatory myopathies (IIM) in conjunction with other laboratory and clinical findings. EliA Ro52 uses the EliA IgG method.

EliA Ro60 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro60 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Ro60 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:

The EliA Ro52 and EliA Ro60 Immunoassays are semi-quantitative solid-phase fluoroenzyme immunoassays, for the determination of autoantibodies against SS-A/Ro 52 kDa and 60 kDa proteins. The EliA Ro52 and EliA Ro60 test System is a fully integrated and automated system composed of assay-specific reagents, EliA method-specific reagents, and general reagents.

Assay-Specific Reagents include:

- EliA Ro52 Wells: coated with human recombinant SS-A/Ro (52 kDa) protein – 2 carriers (12 wells each), ready to use.
- EliA Ro60 Wells: coated with human recombinant SS-A/Ro (60 kDa) protein – 4 carriers (12 wells each), ready to use.

- EliA ANA Positive Control 250 or 2500/5000: Human serum in PBS containing IgG antibodies to dsDNA, RNP, Sm, Ro, La, Scl-70, CENP, and Jo-1 - 6 single use vials, 0.3 mL each, ready to use.
- EliA ANA 3 Positive Control 250 or 2500/5000: Human monoclonal antibodies in PBS containing BSA, detergent and sodium azide (0.095% (w/v)) 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

The EliA Ro52 and EliA Ro60 Immunoassays are 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 Flash Ro52, Inova Diagnostics Inc. (K141655)
QUANTA Flash Ro60, Inova Diagnostics Inc. (K141328)

Comparison with Predicate Device EliA Ro52:

	EliA Ro52 (Proposed Device)	**QUANTA Flash Ro52**
Similarities		
Assay Intended Use	EliA Ro52 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro52 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and idiopathic inflammatory myopathies (IIM) in conjunction with other laboratory and clinical findings. EliA Ro52 uses the EliA IgG method.	QUANTA Flash® Ro52 is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Ro52 autoantibodies in human serum. The presence of anti-Ro52 autoantibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome, Systemic Sclerosis, Idiopathic Inflammatory Myopathies.
Classification	Class II	Class II
Regulation Number	866.5100	866.5100
Internal Controls	Positive and negative Control provided with EliA ANA 3 Positive Control 250 / 2500/5000 and EliA IgG/IgM/IgA Negative Control 250/ 2500/5000, respectively.	QUANTA Flash® Ro52 Controls (Negative and Positive Control)
Assay technique	ELISA	ELISA
Type of test	Semi-quantitative	Semi-quantitative
Reaction temperature	37°C controlled	37°C controlled
Differences		
Antigen	Human recombinant SS-A/Ro 52 (kDa) protein	Purified recombinant Ro52 antigen
Product Code	LKJ	OBE
Sample Dilution (taking a 1% pipetting imprecision into consideration, this sample dilution is regarded as a similarity)	1:100	1:23

	EliA Ro52 (Proposed Device)	**QUANTA Flash Ro52**
Reporting of results	EliA U/mL (arbitrary)	Chemiluminescent units (CU)
Instrumentation	EliA Ro52 uses the EliA IgG method on the instruments Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	Quanta Flash Ro52 is run on the BIO-FLASH® instrument.
Detection antibody (conjugate)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	Isoluminol conjugated anti-human IgG
Signal	Fluorescence	Relative Light Units (RLU)
Calibration	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	Lot specific Master Curve and two Calibrators (Sold separately)
Calibration curve	Option to store curve for up to 28 days and run curve controls in each assay for calibration	These calibrators are designed for 4 calibrations. The total time the calibrator tubes can be uncapped onboard the instrument is 8 hours. If the calibrators are left uncapped, onboard, for any longer period of time, they should be discarded. Using the same calibrator tubes for more than 8 hours can result in improper calibration of the assay, which in turn could give erroneous results.
Interpretation of results	Negative < 7 EliA U/mL Equivocal 7-10 EliA U/mL Positive > 10 EliA U/mL	Negative: < 20 CU Positive: > 20 CU
Substrate	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <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)	"Trigger" reagents

Comparison with Predicate Device EliA Ro60:

	EliA Ro60 (Proposed Device)	**QUANTA Flash Ro60**
Similarities		
Assay Intended Use	EliA Ro60 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Ro60 in human serum as an aid in the diagnosis of Sjögren's syndrome (SS) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Ro60 uses the EliA IgG method.	QUANTA Flash Ro60 is a chemiluminescent immunoassay for the semi-quantitative determination of IgG anti-Ro60 autoantibodies in human serum. The presence of anti-Ro60 autoantibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Systemic Lupus Erythematosus and Sjögren's Syndrome.
Classification	Class II	Class II
Regulation Number	866.5100	866.5100
Internal Controls	Positive and negative Control provided with EliA ANA 3 Positive Control 250 / 2500/5000 and EliA IgG/IgM/IgA Negative Control 250 / 2500/5000, resp.	QUANTA Flash® Ro60 Controls (Negative and Positive Control)
Assay technique	ELISA	ELISA
Type of test	Semi-quantitative	Semi-quantitative
Reaction temperature	37°C controlled	37°C controlled
Differences		
Antigen	Human recombinant SS-A/Ro 60 (kDa) protein	Purified recombinant Ro60 antigen
Product Code	LKJ	LLL
Sample Dilution (taking a 1% pipetting imprecision into consideration, this sample dilution is regarded as a similarity)	1:100	1:23
Reporting of results	EliA U/mL (arbitrary)	Chemiluminescent units (CU)

	EliA Ro60 (Proposed Device)	**QUANTA Flash Ro60**
Instrumentation	EliA Ro60 uses the EliA IgG method on the instruments Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	Quanta Flash Ro60 is run on the BIO-FLASH® instrument.
Detection antibody (conjugate)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	Isoluminol conjugated anti-human IgG
Signal	Fluorescence	Relative Light Units (RLU)
Calibration	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	Lot specific Master Curve and two Calibrators (Sold separately)
Calibration curve	Option to store curve for up to 28 days and run curve controls in each assay for calibration	These calibrators are designed for 4 calibrations. The total time the calibrator tubes can be uncapped onboard the instrument is 8 hours. If the calibrators are left uncapped, onboard, for any longer period of time, they should be discarded. Using the same calibrator tubes for more than 8 hours can result in improper calibration of the assay, which in turn could give erroneous results.
Interpretation of results	Negative < 7 EliA U/mL Equivocal 7-10 EliA U/mL Positive > 10 EliA U/mL	Negative: < 20 CU Positive: > 20 CU
Substrate	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <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)	"Trigger" reagents

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 EP06-ED2, Evaluation of the Linearity of Quantitative Measurement Procedures, November 2020
- 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 enzyme 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 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.

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 on 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 tables below.

EliA Ro52 on Phadia 250:

Mean EliA U/mL	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
4.4	252	0.2	3.7	0.3	5.8	0.1	1.3	0.3	6.9
8.3	252	0.3	3.0	0.3	3.2	0.0	0.0	0.4	5.0
10.6	252	0.3	2.5	0.3	2.9	0.1	0.7	0.5	4.1
32.8	252	0.8	2.4	1.2	3.6	0.6	1.7	2.0	5.9
215.4	252	8.3	3.9	7.9	3.7	8.2	3.8	14.7	5.7

EliA Ro60 on Phadia 250:

Mean EliA U/mL	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
3.5	252	0.1	3.6	0.3	7.2	0.1	1.5	0.3	8.2
6.1	252	0.2	3.0	0.3	4.5	0.0	0.0	0.3	5.4
10.2	252	0.2	2.3	0.3	3.2	0.1	0.7	0.5	4.4
32.2	252	1.1	3.3	1.3	3.9	0.0	0.0	1.9	5.8
201.0	252	9.6	4.8	11.6	5.7	2.9	1.4	18.6	9.1

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.

EliA Ro52:

Mean (EliA U/mL)	Within-Run		Within-Lab Imprecision	
	SD	%CV	SD	%CV
3.0	0.1	2.9	0.1	4.6
7.9	0.2	2.9	0.3	3.9
10.5	0.3	2.5	0.6	5.3
69.1	1.9	2.7	4.9	7.1

EliA Ro60:

Mean (EliA U/mL)	Within-Run		Within-Lab Imprecision	
	SD	%CV	SD	%CV
2.6	0.1	5.4	0.2	8.9
6.3	0.2	2.6	0.6	9.7
10.0	0.2	2.0	0.7	6.9
33.3	1.3	3.8	2.6	7.7

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.

EliA Ro52 on Phadia 2500 and Phadia 5000 instrument series:

Mean EliA U/mL	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
4.7	84	0.2	4.0	0.1	3.0	0.1	2.2	0.3	5.0
8.6	84	0.3	3.5	0.2	2.3	0.1	0.7	0.4	4.2
11.0	84	0.3	2.5	0.5	4.7	0.2	1.9	0.6	5.4
36.3	84	1.5	4.0	1.0	2.8	0.0	0.0	1.8	4.9
212.9	84	10.3	4.8	9.1	4.3	0.0	0.0	13.7	6.4

EliA Ro60 on Phadia 2500 and Phadia 5000 instrument series:

Mean EliA U/mL	n	Within-Run		Between-Run		Between-Instrument		Total Imprecision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
3.6	84	0.2	5.3	0.3	6.9	0.1	1.4	0.3	8.7
6.6	84	0.2	2.9	0.3	4.3	0.2	2.9	0.4	5.2
10.5	84	0.3	2.9	0.4	3.4	0.1	0.8	0.5	4.5
35.8	84	1.2	3.3	1.3	3.7	0.0	0.0	1.8	4.9
219.9	84	11.7	5.3	10.3	4.7	10.7	4.9	18.9	7.1

b) Linearity/Assay Reportable Range**:**

The linearity of EliA Ro52 and EliA Ro60 was evaluated by a study performed according to CLSI EP06-ED2. Three patient serum samples were serially diluted in at least 9 dilution steps using a blood donor serum sample and tested in quadruplicates on one batch EliA Ro52 Well and one batch EliA Ro60 Well with one set of system reagents on the Phadia 250 instrument and the Phadia 2500E instrument, respectively. Results were analyzed according to the guideline performing a weighted linear regression with intercept. All sample sets showed dilution linearity for the entire measuring range.

EliA Ro52 on Phadia 250:

Sample	Parameter	Estimate	Lower 95% CI	Upper 95% CI	R^2
1	Intercept	1.226	0.865	1.587	0.9989
	slope	0.987	0.961	1.012	
2	Intercept	0.435	0.320	0.551	0.9994
	slope	0.994	0.977	1.011	
3	Intercept	0.091	-0.053	0.235	0.9899
	slope	0.948	0.884	1.013	
Sample 1-3 combined	Intercept	0.025	-0.080	0.130	0.9928
	slope	1.014	0.983	1.045	

EliA Ro52 on Phadia 2500E:

Sample	Parameter	Estimate	Lower 95% CI	Upper 95% CI	R^2
1	Intercept	0.776	-0.291	1.842	0.9941
	slope	0.862	0.811	0.913	
2	Intercept	0.490	0.265	0.715	0.9980
	slope	0.911	0.884	0.938	

3	Intercept	-0.045	-0.163	0.073	0.9875
	slope	0.904	0.831	0.976	
Sample 1-3 combined	Intercept	-0.010	-0.114	0.094	0.9942
	slope	0.928	0.902	0.953	

For EliA Ro52, linearity was shown for the entire measuring range.

EliA Ro60 on Phadia 250:

Sample	Parameter	Estimate	Lower 95% CI	Upper 95% CI	R^2
1	Intercept	0.674	0.397	0.951	0.9961
	slope	1.016	0.967	1.064	
2	Intercept	1.282	0.515	2.048	0.9996
	slope	1.047	1.030	1.064	
3	Intercept	0.053	0.020	0.086	0.9994
	slope	0.988	0.971	1.005	
Sample 1-3 combined	Intercept	-0.004	-0.076	0.069	0.9979
	slope	1.063	1.044	1.081	

EliA Ro60 on Phadia 2500E:

Sample	Parameter	Estimate	Lower 95% CI	Upper 95% CI	R^2
1	Intercept	0.136	-0.125	0.396	0.9967
	slope	1.013	0.968	1.058	
2	Intercept	0.910	0.171	1.649	0.9949
	slope	1.033	0.980	1.086	
3	Intercept	0.040	0.009	0.071	0.9992
	slope	0.963	0.942	0.984	
Sample 1-3 combined	Intercept	-0.039	-0.131	0.053	0.9964
	slope	1.069	1.045	1.093	

For EliA Ro60, 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 ">240" for both assays. 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 Ro52 and EliA Ro60 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 24 months for EliA Ro52 and 18 months for EliA Ro60.

On-board stability:
The on-board stability EliA Ro52 and EliA Ro60 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 Ro52 and EliA Ro60 wells was tested with a real-time study. According to the accelerated stability study, a shelf-life of 9 months at 2-8°C after first opening can be assigned to EliA Ro52 and EliA Ro60 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 Ro52 and EliA Ro60 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 tables below.

EliA Ro52:

Instrument	LoB EliA U/mL	LoD EliA U/mL	LoQ EliA U/mL
Phadia 250	0.0	0.2	0.6
E-module of the Phadia 2500 and Phadia 5000 series	0.1	0.3	0.7

The LoD for EliA Ro52 is 0.3 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.

A harmonized LoB of 0.1 EliA U/mL, LoD of 0.3 EliA U/mL, and LoQ of 0.7 EliA U/mL for the immunoassay was used.

EliA Ro60:

Instrument	LoB EliA U/mL	LoD EliA U/mL	LoQ EliA U/mL
Phadia 250	0.1	0.2	0.4
E-module of the Phadia 2500 and Phadia 5000 series	0.1	0.2	0.5

The LoD for EliA Ro60 is 0.4 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.

As the LoB, LoD and LoQ were harmonized over both instrument types, the LoB was set to 0.1 EliA U/mL, the LoD to 0.2 EliA U/mL, and the LoQ to 0.5 EliA U/mL. The DfU states our current worldwide harmonized LoD of 0.4 EliA U/mL for both instrument types as the lower limit of the measuring range.

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, human IgG, Ibuprofen, Losartan, Hydroxychloroquine, Azathioprine, Prednisone, Rituximab, Infliximab, Diltiazem and Omeprazole 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 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 Ro52 and EliA Ro60. 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	500 IU/mL
Human IgG	3500 mg/dL
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
Omeprazole	0.84 mg/dL
Diltiazem	0.09 mg/dL

Reference Sera:
The panel of CDC ANA human reference sera #1 - #12 was tested with EliA Ro52 and EliA Ro60.

In the EliA Ro52 test, CDC ANA #2 (speckled pattern in FANA), CDC ANA #7 (SS-A/Ro) and CDC ANA #10 (Jo-1) showed positive results with 13.9 EliA U/mL, 19.5 EliA U/mL and 247.4 EliA U/mL, respectively. CDC ANA #3 (RNP-Sm, SS-A/Ro, SS-B/La) showed an equivocal result with 7.4 EliA U/mL. All other CDC ANA samples remained negative.

In the EliA Ro60 test, CDC ANA #2 (speckled pattern in FANA), CDC ANA #3 (RNP-Sm, SS-A/Ro, SS-B/La), and CDC ANA #7 (SS-A/Ro) showed positive results with 143.0 EliA U/mL, 146.2 EliA U/mL and 207.2 EliA U/mL, respectively. All other CDC ANA samples remained negative.

f) Assay Cut-Off:

EliA Ro52:
To define the cut-off, a study was performed using a cohort consisting of 69 apparently healthy blood donors, 19 samples from SLE patients and 9 samples from Sjögren's syndrome (SS) patients. The samples were measured on a Phadia 250 instrument.
The cut-off value of EliA Ro52 that was initially set with the intended use target diseases SLE and SS could be verified for the additional intended use groups using 10 IIM and 14 SSc patient sera.

EliA Ro60:
To define the cut-off, a study was performed using a cohort consisting of 70 apparently healthy blood donors, 22 samples from SLE patients and 6 samples from Sjögren's syndrome patients. The samples were measured on a Phadia 250 instrument

The cut-off was set as follows for EliA Ro52 and EliA Ro60:

<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 208 patient serum samples with concentrations covering the measuring range were tested with EliA Ro52, EliA Ro60 and QUANTA Flash Ro52 and QUANTA Flash Ro60 assays. Observed concentrations of samples outside the measuring intervals of the EliA and/or QUANTA Flash tests were disregarded in the agreement calculations.

The tests were run in single determination and evaluated according to their Directions for Use. The results are summarized in the tables below:

EliA Ro52: equivocal results considered negative

n = 181	QUANTA Flash Ro52 positive: ≥ 20 CU	QUANTA Flash Ro52 negative: < 20 CU	Total
EliA Ro52 positive:> 10 EliA U/mL	42	2	44
EliA Ro52 negative:< 10 EliA U/mL	10	127	137
Total	52	129	181

	Calculation	Agreement (%)	95% CI
PPA	100% x 42 / 52	80.8	67.5 – 90.4
NPA	100% 127 / 129	98.4	94.5 – 99.8
TPA	100% x (42+127) / 181	93.4	88.8 – 96.5

EliA Ro52: equivocal results considered positive

n = 181	QUANTA Flash Ro52 positive: ≥ 20 CU	QUANTA Flash Ro52 negative: < 20 CU	Total
EliA Ro52 positive: > 7 EliA U/mL	48	12	60
EliA Ro52 negative: < 7 EliA U/mL	4	117	121
Total	52	129	181

	Calculation	Agreement (%)	95% CI
PPA	100% x 48 / 52	92.3	81.5 – 97.9
NPA	100% 117 / 129	90.7	84.3 – 95.1
TPA	100% x (48+117) / 181	91.2	86.1 – 94.9

EliA Ro60: equivocal results considered negative

n = 104	QUANTA Flash Ro60 positive: ≥ 20 CU	QUANTA Flash Ro60 negative: < 20 CU	Total
EliA Ro60 positive: > 10 EliA U/mL	62	3	65
EliA Ro60 negative: < 10 EliA U/mL	4	35	39
Total	66	38	104

	Calculation	Agreement (%)	95% CI
PPA	100% x 62 / 66	93.9	85.2 - 98.3
NPA	100% 35 / 38	92.1	78.6 - 98.3
TPA	100% x (62+35) / 104	93.3	86.6 - 97.3

EliA Ro60: equivocal results considered positive

n = 104	QUANTA Flash Ro60 positive: ≥ 20 CU	QUANTA Flash Ro60 negative: < 20 CU	Total
EliA Ro60 positive: > 7 EliA U/mL	64	7	71
EliA Ro60 negative: < 7 EliA U/mL	2	31	33
Total	66	38	104

	Calculation	Agreement (%)	95% CI
PPA	100% x 64 / 66	97.0	89.5 - 99.6
NPA	100% 31 / 38	81.6	65.7 - 92.3
TPA	100% x (64+31) / 104	91.3	84.2 – 96.0

b) Instrument Comparison:

EliA Ro52:

Performance of EliA Ro52 was evaluated on the Phadia 250 and Phadia 2500E instrument using 57 positive, 6 equivocal and 30 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	0.91	0.94
95% CI	0.46 - 1.14	0.93 - 0.97

EliA Ro60:

Performance of EliA Ro60 was evaluated on the Phadia 250 and Phadia 2500E instrument using 42 positive, 9 equivocal and 39 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	0.24	1.01
95% CI	0.15 - 0.48	0.97 – 1.04

3. Clinical Studies

c) Clinical Sensitivity and Specificity:

EliA Ro52:

In total, 755 clinically and ethnically defined serum samples, including those of US origin, were used to determine sensitivity and specificity of the assay. Samples with a diagnosis of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), idiopathic inflammatory myopathies (IIM) and systemic sclerosis represent the diagnostic group (target diseases: SLE n=120, Sjögren's syndrome n=60, IIM n=94, SSc n=91).

Samples with various autoimmune and infectious disease diagnoses represent the disease control group (n=390). The results are summarized in the tables below.

Results of clinically defined samples. SLE samples represented the "target disease", SS, IIM and SSc samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease". Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	SLE	Controls	Total
Positive	57	12	69
Negative	63	378	441
Total	120	390	510

	Value	95% CI
Sensitivity	47.5%	38.3 - 56.8
Specificity	96.9%	94.7 - 98.4

Equivocal = positive

Result	SLE	Controls	Total
Positive	61	17	78
Negative	59	373	432
Total	120	390	510

	Value	95% CI
Sensitivity	50.8%	41.6 - 60.1
Specificity	95.6%	93.1 - 97.4

Results of clinically defined samples. Sjögren's syndrome samples represented the "target disease", SLE, IIM and SSc samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease". Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	SS	Controls	Total
Positive	30	12	42
Negative	30	378	408
Total	60	390	450

	Value	95% CI
Sensitivity	50.0%	36.8 - 63.2
Specificity	96.9%	94.7 - 98.4

Equivocal = positive

Result	SS	Controls	Total
Positive	33	17	50
Negative	27	373	400
Total	60	390	450

	Value	95% CI
Sensitivity	55.0%	41.6 - 67.9
Specificity	95.6%	93.1 - 97.4

Results of clinically defined samples. IIM samples represented the "target disease", SLE, SS, and SSc samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease". Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	IIM	Controls	Total
Positive	34	12	46
Negative	60	378	438
Total	94	390	484

	Value	95% CI
Sensitivity	36.2%	26.5 - 46.7
Specificity	96.9%	94.7 - 98.4

Equivocal = positive

Result	IIM	Controls	Total
Positive	35	17	52
Negative	59	373	432
Total	94	390	484

	Value	95% CI
Sensitivity	37.2%	27.5 - 47.8
Specificity	95.6%	93.1 - 97.4

Results of clinically defined samples. SSc samples represented the "target disease", SLE, SS and IIM samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease". Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	SSc	Controls	Total
Positive	19	12	31
Negative	72	378	450
Total	91	390	481

	Value	95% CI
Sensitivity	20.9%	13.1 - 30.7
Specificity	96.9%	94.7 - 98.4

Equivocal = positive

Result	SSc	Controls	Total
Positive	24	17	41
Negative	67	373	440
Total	91	390	481

	Value	95% CI
Sensitivity	26.4%	17.7 - 36.7
Specificity	95.6%	93.1 - 97.4

The table below shows the results for each clinical subgroup:

Diagnosis	total n	Positive n	Equivocal n	Negative n
Systemic lupus erythematosus	**120**	**57**	**4**	**59**
Primary Sjögren's syndrome	**60**	**30**	**3**	**27**
Idiopathic inflammatory myopathies (IIM) [total]	**94**	**34**	**1**	**59**
IIM PM	40	7	0	33
IIM DM	13	3	1	9
IIM Myositis/CTD-overlap	18	3	0	15
IIM Overlap / MCTD	9	9	0	0
IIM Jo-1 Positive	10	9	0	1
IIM Sporadic inclusion body myositis (sIBM)	4	3	0	1
Systemic sclerosis (SSc) [total]	**91**	**19**	**5**	**67**
SSc, diffuse	56	11	3	42
SSc, limited	27	8	2	17
SSc, various*	8	0	0	8
Celiac disease	13	0	0	13
Crohn's disease	12	0	0	12
CTD overlap Non-MCTD	10	0	1	9
Graves' disease	12	0	0	12
Primary antiphospholipid syndrome	12	1	0	11
Primary Biliary Cholangitis	25	1	2	22
Primary Sclerosing Cholangitis	24	0	0	24
Type 1 Diabetes	12	0	0	12

Diagnosis	total n	Positive n	Equivocal n	Negative n
Ulcerative colitis	35	0	1	34
Lymphoma	21	0	0	21
Leukemia	20	0	0	20
Varied Cancer	9	0	0	9
Mixed connective tissue disease	10	2	0	8
Rheumatoid arthritis	35	2	0	33
Bacterial infections **[total]**	**17**	**1**	**0**	**16**
Bacterial infections (Mycoplasma)	3	0	0	3
Bacterial infections (Borrelia)	7	0	0	7
Bacterial infections (var. Staphylococcus)	3	1	0	2
Bacterial infections (various)	4	0	0	4
Viral infections **[total]**	**80**	**4**	**1**	**75**
Viral infections (Dengue)	4	0	0	4
Viral infections (EBV)	3	0	0	3
Viral infections (HBV)	11	1	0	10
Viral infections (HCV)	31	2	1	28
Viral infections (HIV)	24	1	0	23
Viral infections (various)	7	0	0	7
Hashimoto's disease	10	1	0	9
Vasculitis **[total]**	**33**	**0**	**0**	**33**
Granulomatosis with Polyangiitis	10	0	0	10
Eosinophilic granulomatosis with polyangiitis	4	0	0	4
Microscopic polyangiitis	13	0	0	13
Polyarteritis nodosa	3	0	0	3
Giant cell arteritis	3	0	0	3
Target diseases	365	140	13	212
Control disease	390	12	5	373
Total	**755**	**152**	**18**	**585**

*"SSc various" group is composed of the patients having SSc, classified according to the ACR/EULAR van den Hoogen 2013 criterion. The patients were not further sub-grouped.

EliA Ro60:

In total, 713 clinically and ethnically defined serum samples, including those of US origin, were used to determine sensitivity and specificity of the assay. Samples with a diagnosis of systemic lupus erythematosus (SLE) and Sjögren's syndrome (SS) represent the diagnostic group (target diseases: SLE n=120 + Sjögren's syndrome n=60). Samples with various autoimmune and infectious disease diagnoses represent the disease control group (n=533). The results are summarized in the tables below.

Results of clinically defined samples. SLE samples represented the "target disease", Sjögren's syndrome samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease", but without control group SSc since these patients may have Ro antibodies. Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	SLE	Controls	Total
Positive	58	6	64
Negative	62	436	498
Total	120	442	562

	Value	95% CI
Sensitivity	48.3%	39.1 - 57.6
Specificity	98.6%	97.1 - 99.5

Equivocal = positive

Result	SLE	Controls	Total
Positive	61	7	68
Negative	59	435	494
Total	120	442	562

	Value	95% CI
Sensitivity	50.8%	41.6 - 60.1
Specificity	98.4%	96.8 - 99.4

Results of clinically defined samples. Sjögren's syndrome samples represented the "target disease", SLE samples were excluded, other autoimmune diseases and infectious diseases were used as "control disease", but without control group SSc since these patients may have Ro antibodies. Equivocal results were either judged as negative or positive.

Equivocal = negative

Result	SS	Controls	Total
Positive	41	6	47
Negative	19	436	455
Total	60	442	502

	Value	95% CI
Sensitivity	68.3%	55 - 79.7
Specificity	98.6%	97.1 - 99.5

Equivocal = positive

Result	SS	Controls	Total
Positive	43	7	50
Negative	17	435	452
Total	60	442	502

	Value	95% CI
Sensitivity	71.7%	58.6 - 82.5
Specificity	98.4%	96.8 - 99.4

The table below shows the results for each clinical subgroup:

Diagnosis	**total n**	**positive n**	**equivocal n**	**negative n**
Systemic lupus erythematosus (SLE)	**120**	**58**	**3**	**59**
Sjögren's syndrome (SS)	**60**	**41**	**2**	**17**
Idiopathic inflammatory myopathies (IIM)	10	0	0	10
Systemic sclerosis (SSc) **[total]**	91	21	0	70
SSc, diffuse	56	11	0	45
SSc, limited	27	10	0	17
SSc, various*	8	0	0	8
Celiac disease	13	0	0	13
Crohn's disease	12	0	0	12
CTD overlap Non-MCTD	10	1	0	9
Graves' disease	12	0	0	12
Primary antiphospholipid syndrome	12	1	0	11
Primary Biliary Cholangitis	25	0	0	25
Primary Sclerosing Cholangitis	24	0	0	24
Type 1 Diabetes	12	0	0	12
Ulcerative colitis	35	1	0	34
Lymphoma	21	0	0	21
Leukemia	20	0	0	20
Varied Cancer	9	0	0	9
Mixed connective tissue disease	10	0	0	10
Rheumatoid arthritis	77	1	1	75
Bacterial infections **[total]**	**17**	**0**	**0**	**17**
Bacterial infections (Mycoplasma)	3	0	0	3
Bacterial infections (Borrelia)	7	0	0	7
Bacterial infections (var. Staphylococcus)	3	0	0	3
Bacterial infections (various)	**4**	**0**	**0**	**4**
Viral infections **[total]**	**80**	**1**	**0**	**79**
Viral infections (Dengue)	4	0	0	4
Viral infections (EBV)	3	0	0	3
Viral infections (HBV)	11	0	0	11
Viral infections (HCV)	31	1	0	30
Viral infections (HIV)	24	0	0	24
Viral infections (various)	7	0	0	7

Diagnosis	total n	positive n	equivocal n	negative n
Hashimoto's disease	10	1	0	9
Vasculitis **[total]**	**33**	**0**	**0**	**33**
Granulomatosis with Polyangiitis	10	0	0	10
Eosinophilic granulomatosis with polyangiitis	4	0	0	4
Microscopic polyangiitis	13	0	0	13
Polyarteritis nodosa	3	0	0	3
Giant cell arteritis	3	0	0	3
Target diseases	180	99	5	76
Control disease	533	27	1	505
Total	**713**	**126**	**6**	**581**

*"SSc various" group is composed of the patients having SSc, classified according to the ACR/EULAR van den Hoogen 2013 criterion. The patients were not further sub-grouped.

d) Other Clinical Supportive Data:

Not applicable.

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

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 Ro52 and EliA Ro60 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 Ro52	638	1.0	1.8	2.6
EliA Ro60	638	0.5	0.9	7.4

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 devices EliA Ro52 and EliA Ro60 and their proposed predicate devices QUANTA Flash Ro52 and QUANTA Flash Ro60 perform substantially equivalent.

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