June 25, 2026

Phadia AB
% Carla Krause
Director, Regulatory Affairs and Quality Assurance US
Phadia US, Inc.
4169 Commercial Ave.
Portage, Michigan 49002

Re: K253367
Trade/Device Name: EliA CTD 13 Screen
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL
Dated: May 18, 2026
Received: May 18, 2026

Dear Carla Krause:

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

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

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

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

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

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

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

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

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253367

Device Name
EliA CTD 13 Screen

Indications for Use *(Describe)*
EliA CTD 13 Screen is intended for the in vitro qualitative detection of antinuclear IgG antibodies in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM) and mixed connective tissue disease (MCTD), in conjunction with other laboratory and clinical findings. EliA CTD 13 Screen detects antibodies against RNP70, U1RNP-A, U1RNP-C, SS-A/Ro60, SS-A/Ro52, SS-B/La, Centromere B, Scl-70, Jo-1, RNA Pol III, Rib-P, Sm and dsDNA. EliA CTD 13 Screen 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.

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This 510(k) Summary is prepared as per the requirements of 21 CFR Part 807.92.

Premarket Notification 510(k) No: K253367

Date of Summary Preparation: June 25th, 2026

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: Carla Krause
Director, Regulatory Affairs and Quality Assurance US
Phadia US Inc.
4169 Commercial Avenue, Portage, MI 49002
616-286-4138
carla.krause@thermofisher.com

Proprietary and Established Device Name:
EliA CTD 13 Screen

Regulatory Information:

Device Trade Name:	EliA CTD 13 Screen (14-6661-01)
FDA Classification:	Class II device
Classification Regulation:	21 CFR 866.5100 – Antinuclear Antibody Immunological Test System
Product Code(s):	LLL
Device common Name:	Extractable Antinuclear Antibody, Antigen and Control

Purpose of Submission:
New Device

Measurand:
IgG autoantibodies specific to native purified dsDNA, synthetic SmD_3 peptide and human recombinant Rib-P, SS-A/Ro60, SS-A/Ro52, SS-B/La, Scl-70, Centromere B, RNA Polymerase III, Jo-1, RNP70, U1RNP-A and U1RNP-C proteins.

Type of Test:
Automated qualitative solid phase fluoroenzymeimmunoassay

Intended Use:
EliA CTD 13 Screen is intended for the in vitro qualitative detection of antinuclear IgG antibodies in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM) and mixed connective tissue disease (MCTD), in conjunction with other laboratory and clinical findings. EliA CTD 13 Screen detects antibodies against RNP70, U1RNP-A, U1RNP-C, SS-A/Ro60, SS-A/Ro52, SS-B/La, Centromere B, Scl-70, Jo-1, RNA Pol III, Rib-P, Sm and dsDNA. EliA CTD 13 Screen 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.

Device Description:
EliA CTD 13 Screen is a qualitative solid-phase fluoroenzymeimmunoassay, for the determination of autoantibodies against native purified dsDNA, synthetic SmD_3 peptide and human recombinant Rib-P, SS-A/Ro60, SS-A/Ro52, SS-B/La, Scl-70, Centromere B, RNA Pol III, Jo-1, RNP70, U1RNP-A and U1RNP-C proteins. The EliA CTD 13 Screen test system is a fully integrated and automated system which comprises of assay-specific reagents, EliA method-specific reagents, and general reagents.

Assay-Specific Reagents include:

- EliA CTD 13 Screen Well: coated with native purified dsDNA, synthetic SmD_3 peptide and human recombinant Rib-P, SS-A/Ro60, SS-A/Ro52, SS-B/La, Scl-70, Centromere B, RNA Pol III, Jo-1 and RNP70, U1RNP-A and U1RNP-C proteins – 4 carriers (16 wells each), ready to use.
- EliA ANA Positive Control 250: Human blood preparations and monoclonal antibodies in PBS containing IgG antibodies to dsDNA, RNP, Sm, Ro, La, Scl-70, CENP and Jo-1, detergent and sodium azide (0.095% (w/v)) - 6 single use vials, 0.3 mL each, ready to use.
- EliA IgG/IgM/IgA Negative Control 250: Human Serum from healthy donors in PBS containing BSA, detergent and sodium azide (0.095% (w/v)) – 6 single-use vials, 0.3 mL each, ready to use.

EliA Method-Specific Reagents include:

- EliA Sample Diluent: PBS containing BSA, detergent and sodium azide (0.095% (w/v)) – 6 bottles, 48 mL each, ready to use.
- EliA IgG Conjugate 50 or 200: β-Galactosidase anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and sodium azide (0.06% (w/v)) – 6 wedge shaped bottles, 5 mL each (Conjugate 50), or 6 wedge shaped bottles, 19 mL each (Conjugate 200), ready to use.
- EliA IgG Calibrator Strips: Human IgG (0, 4, 10, 20, 100, 600 µg/L) in PBS containing BSA, detergent and sodium azide (0.095% (w/v)) – 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 sodium azide (0.095% (w/v)) – 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, or 17 mL, each), ready to use.
- Stop Solution: 4% Sodium Carbonate – 6 bottles (65 mL, or 119 mL each), ready to use.
- Washing Solution Additive: detergent, preservative <0.13% – 6x 17.2 mL or 2x 86 mL;
- Washing Solution Concentrate: phosphate buffer, preservative <0.0015% – 6x 80 mL or 2x 400 mL.

Instrument System

EliA CTD 13 Screen is run on the Phadia 250 instrument. The Phadia 250 instruments are automated platforms for EliA test procedures from sample and reagent handling to the processing of results.

Substantial Equivalence

Predicate devices:

EliA Symphony^{S} Immunoassay, Phadia AB, Sweden (K190710)
EliA dsDNA Immunoassay, Phadia AB, Sweden (K072393)
EliA Rib-P, Phadia AB, Sweden (K202540)
EliA RNA Pol III, Phadia AB, Sweden (K202541)

Comparison with Predicate Device:

	EliA CTD 13 Screen (Candidate device)	**EliA Symphony^S (Predicate device) K190710**	**EliA dsDNA (Predicate device) K072939**	**EliA Rib-P (Predicate device) K202540**	**EliA RNA Pol III (Predicate device) K202541**
Assay Intended Use	EliA CTD 13 Screen is intended for the in vitro qualitative detection of antinuclear IgG antibodies in human serum as an aid in the diagnosis of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM) and mixed connective tissue disease (MCTD), in conjunction with other laboratory and clinical findings. EliA CTD 13 Screen detects antibodies against RNP70, U1RNP-A, U1RNP-C, SS-A/Ro60, SS-A/Ro52, SS-B/La, Centromere B, Scl-70, Jo-1, RNA Pol III, Rib-P, Sm and dsDNA. EliA CTD 13 Screen uses the EliA IgG method.	EliA Symphony^S is intended for the in vitro, qualitative measurement of antinuclear IgG antibodies in human serum and plasma (Li-heparin, EDTA). EliA Symphony^S is based on human recombinant U1RNP (RNP 70, A, C), SS-A/Ro (60 kDa, 52 kDa), SS-B/La, Centromere B, Scl-70, Jo-1 proteins and a synthetic SmD_3 peptide as antigen and is useful as an aid in the clinical diagnosis of patients with systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), Sjögren's syndrome, scleroderma and polymyositis/dermatomyositis, in conjunction with other laboratory and clinical findings. EliA Symphony^S uses the EliA IgG method.	EliA dsDNA is intended for the in vitro quantitative measurement of IgG antibodies directed to dsDNA in human serum and plasma (Li-heparin, EDTA) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA dsDNA uses the EliA IgG method.	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.	EliA RNA Pol III is intended for the in vitro semi-quantitative measurement of antinuclear IgG antibodies directed to RNA polymerase III (RNA Pol III) in human serum as an aid in the diagnosis of systemic sclerosis (diffuse form) in conjunction with other laboratory and clinical findings. EliA RNA Pol III uses the EliA IgG method.

	EliA CTD 13 Screen (Candidate device)	**EliA Symphony^S (Predicate device) K190710**	**EliA dsDNA (Predicate device) K072939**	**EliA Rib-P (Predicate device) K202540**	**EliA RNA Pol III (Predicate device) K202541**
Similarities					
Classification	Class II	Class II	Class II	Class II	Class II
Regulation Number	866.5100	866.5100	866.5100	866.5100	866.5100
Internal Controls	Positive and negative Control provided with EliA ANA Positive Control 250 and EliA IgG/IgM/IgA Negative Control 250, resp.	Positive and negative Control provided with EliA ANA Positive Control 250, 2500/5000 and EliA IgG/IgM/IgA Negative Control 250, 2500/5000, resp.	Positive and negative Control provided with EliA ANA Positive Control 250, 2500/5000 and EliA IgG/IgM/IgA Negative Control 250, 2500/5000, resp.	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.	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.
Assay technique	ELISA	ELISA	ELISA	ELISA	ELISA
Instrumentation	EliA CTD 13 Screen uses the EliA IgG method on the instruments Phadia 250.	EliA Symphony^S uses the EliA IgG method on the instruments Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	EliA dsDNA uses the EliA IgG method on the instruments Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	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.	EliA RNA Pol III uses the EliA IgG method on the instruments Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.
Reaction temperature	37°C controlled	37°C controlled	37°C controlled	37°C controlled	37°C controlled
Detection antibody (conjugate)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)	IgG conjugate: anti-human IgG ß-Galactosidase (mouse monoclonal antibodies)

	EliA CTD 13 Screen (Candidate device)	EliA Symphony^{S} (Predicate device) K190710	EliA dsDNA (Predicate device) K072939	EliA Rib-P (Predicate device) K202540	EliA RNA Pol III (Predicate device) K202541
Signal	Fluorescence	Fluorescence	Fluorescence	Fluorescence	Fluorescence
Calibration	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	6-point total IgG Calibration 6 vials of human IgG at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L
Calibration curve	Option to store curve for up to 28 days and run curve controls in each assay for calibration	Option to store curve for up to 28 days and run curve controls in each assay for calibration	Option to store curve for up to 28 days and run curve controls in each assay for calibration	Option to store curve for up to 28 days and run curve controls in each assay for calibration	Option to store curve for up to 28 days and run curve controls in each assay for calibration
Substrate	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)	Development Solution 0.01 % 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)

	EliA CTD 13 Screen (Candidate device)	**EliA Symphony^S (Predicate device) K190710**	**EliA dsDNA (Predicate device) K072939**	**EliA Rib-P (Predicate device) K202540**	**EliA RNA Pol III (Predicate device) K202541**
Differences					
Product Code	LLL	LLL	LSW	MQA	NYO
Antigen	native purified dsDNA, synthetic SmD_3 peptide and human recombinant Rib-P, SS-A/Ro60, SS-A/Ro52, SS-B/La, Scl-70, Centromere B, RNA Polymerase III, Jo-1, RNP70, U1RNP-A and U1RNP-C proteins	human recombinant U1RNP (RNP70, A, C), SS-A/Ro (60 kDa, 52 kDa), SS-B/La, Centromere B, Scl-70 and Jo-1 proteins, synthetic SmD_3 peptide	double-stranded plasmid DNA	human recombinant ribosomal P proteins P0, P1 and P2	human recombinant RNA polymerase III protein
Type of test	Qualitative	Qualitative	Quantitative	Semi-quantitative	Semi-quantitative
Sample Type	Serum	Serum and plasma	Serum and plasma	Serum	Serum
Instrument platform	Phadia 250	Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.	Phadia 250 and the E-Modules of the Phadia 2500 and Phadia 5000 series.
Sample Dilution	1:10	1:100	1:10	1:100	1:200
Reporting of results	Ratio	Ratio	IU/mL	EliA U/mL (arbitrary)	EliA U/mL (arbitrary)
Interpretation of results	Negative < 0.7 Ratio Equivocal 0.7-1.0 Ratio Positive > 1.0 Ratio	Negative < 0.7 Ratio Equivocal 0.7-1.0 Ratio Positive > 1.0 Ratio	Negative < 10 IU/mL Equivocal 10-15 IU/mL Positive > 15 IU/mL	Negative < 7 EliA U/mL Equivocal 7-10 EliA U/mL Positive > 10 EliA U/mL	Negative < 7 EliA U/mL Equivocal 7-10 EliA U/mL Positive > 10 EliA U/mL

Standard/Guidance Document Referenced

- CLSI EP07, Interference Testing in Clinical Chemistry, 3rd edition, April 2018
- CLSI EP12, Evaluation of Qualitative, Binary Output Examination Performance, 3rd edition, March 2023
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd edition, June 2012
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, 3rd edition, October 2010
- CLSI EP34, Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st edition, August 2018
- CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry, 1st edition, July 2018
- CLSI EP37, Supplemental Tables for Interference Testing in Clinical Chemistry, 2nd edition, CLSI EP37 Database
- CLSI GP44-A4, Procedures for the handling and processing of blood specimens for common laboratory tests, 4th edition, May 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

A. Analytical performance:

1) Precision (Repeatability/Reproducibility):
Precision and reproducibility of EliA CTD 13 Screen were evaluated in accordance with the CLSI guideline EP05-A3.

Single-site precision
Within-Laboratory precision (Repeatability) of EliA CTD 13 Screen was evaluated by assaying ten serum samples on one Phadia 250 instrument, twice a day for 20 or 21 days in duplicates. Resulting data are summarized in the table below by the proportion of positive, equivocal and negative results.

Sample	Mean Ratio (interpretation)	Range of Ratio	Results (positive/equivocal/negative)	
			Number	%
1	0.3 (negative)	0.2 - 0.3	0/0/84	0/0/100
2	0.3 (negative)	0.3 - 0.4	0/0/84	0/0/100
3	0.5 (negative)	0.4 - 0.6	0/0/80	0/0/100
4	0.8 (equivocal)	0.7 - 0.9	0/78/5	0/94/6
5	1.0 (positive)	0.8 - 1.2	48/36/0	57/43/0
6	1.2 (positive)	1.0 - 1.4	84/0/0	100/0/0
7	4.5 (positive)	3.8 - 5.8	84/0/0	100/0/0
8	5.3 (positive)	4.4 - 6.0	84/0/0	100/0/0
9	23 (positive)	19 - 28.1	81/0/0	100/0/0
10	26 (positive)	22 - >31	84/0/0	100/0/0

Reproducibility
The reproducibility of EliA CTD 13 Screen was evaluated by assaying ten serum samples on three Phadia 250 instruments, once a day, for 5 days in replicates of 5. Data obtained is summarized in the table below by the proportion of positive, equivocal, and negative results.

Sample	Mean Ratio (interpretation)	Range of Ratio	Results (positive/equivocal/negative)							
			Total		Instrument 1		Instrument 2		Instrument 3	
			Number	%	Number	%	Number	%	Number	%
1	0.6 (negative)	0.5 - 0.6	0/0/75	0/0/100	0/0/25	0/0/100	0/0/25	0/0/100	0/0/25	0/0/100
2	0.6 (negative)	0.6 - 0.7	0/1/74	0/1/99	0/0/25	0/0/100	0/0/25	0/0/100	0/1/24	0/4/96
3	0.7 (equivocal)	0.6 - 0.8	0/34/41	0/45/55	0/18/7	0/72/28	0/7/18	0/28/72	0/9/16	0/36/64

Sample	Mean Ratio (interpretation)	Range of Ratio	Results (positive/equivocal/negative)							
			Total		Instrument 1		Instrument 2		Instrument 3	
			Number	%	Number	%	Number	%	Number	%
4	0.8 (equivocal)	0.7 - 0.9	0/74/1	0/99/1	0/25/0	0/100/0	0/24/1	0/96/4	0/25/0	0/100/0
5	0.9 (equivocal)	0.8 - 1.0	0/75/0	0/100/0	0/25/0	0/100/0	0/25/0	0/100/0	0/25/0	0/100/0
6	1.1 (positive)	0.9 - 1.4	70/5/0	93/7/0	22/3/0	88/12/0	25/0/0	100/0/0	23/2/0	92/8/0
7	3.6 (positive)	3.3 - 3.9	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
8	4.8 (positive)	4.2 - 5.3	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
9	23 (positive)	20 - 25	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
10	30 (positive)	25 - >31	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0

Between-lot imprecision

Between-lot imprecision of EliA CTD 13 Screen was evaluated by assaying ten serum samples with 3 reagent sets, once a day for 5 days in replicates of 5. Data obtained are summarized in the table below by the proportion of positive, equivocal, and negative results.

Sample	Mean Ratio (interpretation)	Range of Ratio	Results (positive/equivocal/negative)							
			Total		Lot 1		Lot 2		Lot 3	
			Number	%	Number	%	Number	%	Number	%
1	0.6 (negative)	0.6 - 0.7	0/4/71	0/5/95	0/1/24	0/4/96	0/3/22	0/12/88	0/0/25	0/0/100
2	0.6 (negative)	0.5 - 0.6	0/0/75	0/0/100	0/0/25	0/0/100	0/0/25	0/0/100	0/0/25	0/0/100
3	0.7 (equivocal)	0.6 - 0.8	0/30/45	0/40/60	0/9/16	0/36/64	0/9/16	0/36/64	0/12/13	0/48/52
4	0.8 (equivocal)	0.6 - 0.9	0/65/10	0/87/13	0/25/0	0/100/0	0/25/0	0/100/0	0/15/10	0/60/40
5	0.9 (equivocal)	0.8 - 1.0	0/75/0	0/100/0	0/25/0	0/100/0	0/25/0	0/100/0	0/25/0	0/100/0
6	1.2 (positive)	0.9 - 1.4	68/7/0	91/9/0	25/0/0	100/0/0	25/0/0	100/0/0	18/7/0	72/28/0
7	3.7 (positive)	3.3 - 4.1	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
8	4.8 (positive)	4.0 - 5.6	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
9	23 (positive)	20 - 28	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0
10	30 (positive)	25 - >31	75/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0	25/0/0	100/0/0

2) Linearity:

Not applicable for a qualitative screening assay

3) Detection Limit:
Not applicable.

4) Reportable Range:
Not applicable.

5) Hook Effect:
No hook effect is expected for the used assay format.

6) Interference:

Endogenous and exogenous interference
A study was conducted to investigate whether high concentrations of potentially interfering substances in serum, such as Albumin, Bilirubin (unconjugated and conjugated), Hemoglobin, Rheumatoid factor IgM, Triglycerides, Alendronate, Amlodipine, Amoxicillin, Atorvastatin, Azathioprine, Belimumab, Cyclophosphamide, Diltiazem, Enalapril, Erythromycin, Hydroxychloroquine, Ibuprofen, Infliximab, Losartan, Methotrexate, Mycophenolic acid, Omeprazole, Prednisone, Ranitidine, Rituximab, Simvastatin adversely affect the results of the new device.

Serum samples (including negative, equivocal and positive) were prediluted in EliA Sample Diluent and spiked with different interfering substances or blank solution. Six replicates were measured for all test samples and control samples. The aliquots (test and control) of each sample were assayed in the same run. A calibration and curve controls were included in each run.

The acceptance criteria for the interference study were Interference of ≤ 10%. The substance concentrations indicated below, are the highest concentrations tested that fulfilled this criterion:

Potential interfering substance	Concentration in undiluted sample
Albumin	6000 mg/dL
Bilirubin, unconjugated	40 mg/dL
Bilirubin, conjugated	40 mg/dL
Hemoglobin	1000 mg/dL
Rheumatoid factor IgM	500 IU/mL
Triglycerides	2000 mg/dL

Potential interfering substance	Concentration in undiluted sample
Alendronate	0.0034 mg/dL
Amlodipine	0.0075 mg/dL
Amoxicillin	12.9 mg/dL
Atorvastatin	0.075 mg/dL
Azathioprine	0.26 mg/dL
Belimumab	94.0 mg/dL
Cyclophosphamide	54.9 mg/dL
Diltiazem	0.09 mg/dL
Enalapril	0.0819 mg/dL
Erythromycin	13.8 mg/dL
Hydroxychloroquine	0.36 mg/dL
Ibuprofen	21.9 mg/dL
Infliximab	90 mg/dL
Losartan	0.09 mg/dL
Methotrexate	205.0 mg/dL
Mycophenolic acid	33.0 mg/dL
Omeprazole	0.84 mg/dL
Prednisone	0.01 mg/dL
Ranitidine	1.05 mg/dL
Rituximab	114.3 mg/dL
Simvastatin	0.168 mg/dL

7) Analytical specificity (Reference Sera):

The analytical specificity was evaluated using the Center for Disease Controls and Prevention (CDC) ANA Reference Panel sera with EliA CTD 13 Screen. The assay results were compared to the known assigned specificity ("target values") of the CDC panel.

Evaluation of CDC sera on EliA CTD 13 Screen

Sample	Description/Assigned Specificity	Target	EliA CTD 13 Screen [Ratio] (judgment)
CDC ANA #1	Homogeneous Rim Pattern in FANA test due to antibodies to dsDNA	Positive	20.0 (positive)
CDC ANA #2	Speckled pattern in FANA test due to antibodies to SS-B/La	Positive	13.7 (positive)

Sample	Description/Assigned Specificity	Target	EliA CTD 13 Screen [Ratio] (judgment)
CDC ANA #3	Speckled pattern in FANA due to antibodies to U1-RNP, SS-B/La and SS-A/Ro	Positive	17.9 (positive)
CDC ANA #4	High levels of antibodies to U1-RNP	Positive	3.6 (positive)
CDC ANA #5	High levels of antibodies to Sm	Positive	14.0 (positive)
CDC ANA #6	Nucleolar pattern in FANA test (due antibodies to U3-RNP)	Negative	0.3 (negative)
CDC ANA #7	High levels of antibodies to SS-A/Ro	Positive	9.8 (positive)
CDC ANA #8	Centromere pattern in FANA test	Positive	3.3 (positive)
CDC ANA #9	High levels of antibodies to Scl-70	Positive	6.7 (positive)
CDC ANA #10	High levels of antibodies to Jo-1	Positive	24.0 (positive)
CDC ANA #11	High levels of antibodies to PM/Scl	Negative	0.1 (negative)
CDC ANA #12	High levels of antibodies to Ribosomal P	Positive	6.8 (positive)

FANA= Fluorescent Antinuclear Antibody

8) Assay Cut-Off:

To define the cut-off, a study was performed using a cohort consisting of 70 apparently healthy blood donors, 4 serum samples from MCTD patients, 8 serum samples from IIM patients, 7 serum samples from systemic sclerosis patients, 6 serum samples from SLE patients and 5 serum samples from Sjögren's syndrome patients. The samples were measured on a Phadia 250 instrument.

The cut-off was set as follows for EliA CTD 13 Screen:

	Negative	Equivocal	Positive
Result [Ratio]	<0.7	0.7 – 1.0	>1.0

9) Traceability:

This EliA test uses EliA IgG Calibrators. EliA IgG Calibrators are traceable to an internal reference material which is based on the WHO International Standard Immunoglobulins A, G and M, Human Serum (NIBSC code: 67/086).

10) Stability:

Data for open and closed real-time stability and on-board stability of EliA IgG reagents and general EliA reagents on Phadia 250 were already cleared with several other EliA tests, e.g., under K141375 (EliA M2 on Phadia 250).

Shelf-life/transport stability

Shelf-life

The stability of the EliA CTD 13 Screen wells was evaluated with a real-time study on the Phadia 250 instrument. Three lots of EliA CTD 13 Screen wells were stored under recommended conditions at 2 - 8°C and tested at different timepoints.

The results support an initial shelf-life of 9 months at 2 - 8°C for EliA CTD 13 Screen.

Transport stability

Transport stability was evaluated on the Phadia 250 instrument with real-time stability study. EliA CTD 13 Screen wells were incubated under two different transport stress conditions (24 hours at -20°C and 5 days at 35°C) and tested after stress.

The results supported that transport conditions like freezing and thawing or storage for up to 5 days at up to 35°C are possible without any impact on the shelf-life up to 12 weeks.

On-board stability (storage chamber of the Phadia 250 instrument)

The on-board stability of EliA CTD 13 Screen Well carriers was evaluated at 80% humidity and at 11°C for 15, 29 and 43 days in the Phadia 250 carrier storage tray using eight positive serum samples, two equivocal serum samples, two negative serum samples and a positive control.

The on-board stability in the storage chamber of the Phadia 250 instrument was determined to be 28 days under operating conditions at 2 - 8°C.

On-board stability (Loading Tray of the Phadia 250 instrument)

The on-board stability of EliA CTD 13 Screen Well carriers was evaluated on the loading tray of the Phadia 250 instrument at 32°C and 80% RH. The wells were stored on a loading tray in a climate chamber for 12 hours, 24 hours, 25 hours and 72 hours and tested with eight positive serum samples, two equivocal serum samples, nine negative serum samples and positive control.

The on-board stability of EliA CTD 13 Screen Well on the loading tray of the Phadia 250 instrument was determined to be 24 hours.

Stability after 1st opening (in-use stability)

For evaluation of Stability after first opening, foil bags containing the EliA CTD 13 Screen wells in carriers (stored under standard conditions, at 2 - 8 °C) were opened. The process of opening and sealing of the foil bags was repeated multiple times over the study duration exposing the wells to 11°C and 80% RH. Ten positive serum samples (including

one high- and one low-positive), two equivocal serum samples and three negative serum samples were tested.

The in-use stability after first opening of EliA CTD 13 Screen Well was determined to be 12 weeks at 2 - 8°C.

Sample Stability

The sample stability was evaluated to support the stability of samples, when stored frozen for 27 months from blood draw using ten serum samples (across the reportable range of EliA CTD 13 Screen) were included in this study. Four positive serum samples, four equivocal serum samples and two negative serum samples were tested at 7 weeks, 5 months, 8 months, 14 months, 16 months, 24 months, 24.5 months and 27 months timepoints.

All tested serum samples fulfilled the study specifications, when stored frozen up to 27 months and supported the sample stability claim of 24.5 months.

B. Comparison Studies:

1) Method Comparison with Predicate Device:

A total of 1082 serum samples were tested with EliA CTD 13 Screen and compared to the combination of the predicate devices EliA Symphony^{S}, EliA dsDNA, EliA Rib-P and EliA RNA Pol III assays.

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

Equivocal results considered negative:

n=1082	**Combination of Predicate Devices**			
		Positive	Negative	Total
EliA CTD 13 Screen	Positive	572	59	631
	Negative	10	441	451
	Total	582	500	1082

Agreement calculation with equivocal results = negative	**Agreement (%)**	**95% Confidence Interval**
Positive Percent Agreement	98.3	96.9 - 99.2
Negative Percent Agreement	88.2	85.0 - 90.9
Total Percent Agreement	93.6	92.0 - 95.0

Equivocal results considered positive:

n=1082		Combination of Predicate Devices		
		Positive	Negative	Total
EliA CTD 13 Screen	Positive	614	79	693
	Negative	21	368	389
	Total	635	447	1082

Agreement calculation with equivocal results = positive	Agreement (%)	95% Confidence Interval
Positive Percent Agreement	96.7	95.0 - 97.9
Negative Percent Agreement	82.3	78.5 - 85.8
Total Percent Agreement	90.8	88.9 - 92.4

2) Matrix Comparison:

The EliA CTD 13 Screen is to be used with serum samples only. All analytical and clinical performance studies and method comparison study were performed using serum samples only. Therefore, a matrix comparison study is not required.

C. Clinical Studies:

1) Clinical Sensitivity and Specificity:

In total, 1027 clinically and ethnically defined serum samples were used to determine sensitivity and specificity of the assay.

Samples with a diagnosis of polymyositis (PM), dermatomyositis (DM), mixed connective tissue disease (MCTD), Raynaud's phenomenon, Sjögren's syndrome (SS), systemic lupus erythematous (SLE) (including lupus nephritis) and systemic sclerosis (SSc) (including limited systemic sclerosis (lSSc) represented the diagnostic group (target disease group, n=575).

Samples with various autoimmune and infectious disease diagnosis represent the disease control group (n=452).

The distribution of the cohort and the EliA CTD 13 Screen positivity rate for each clinical subgroup is summarized in the following table.

Disease	Number of samples	Number of positive samples [a]	% of positive samples [a]	95% Confidence Interval
Target Disease				
Systemic Lupus Erythematous (SLE)	200	200	100	98.2 - 100.0
Lupus Nephritis	11	11	100	71.5 - 100.0
Polymyositis (PM)	45	31	68.9	53.4 - 81.8
Dermatomyositis (DM)	51	24	47.1	32.9 - 61.5
Mixed Connective Tissue Disease (MCTD)	53	29	54.7	40.4 - 68.4
Sjogren's Syndrome (SS)	97	97	100	96.3 - 100.0
Systemic Sclerosis (SSc)	57	50	87.7	76.3 - 94.9
Limited Systemic Sclerosis (lSSc)	22	21	95.5	77.2 - 99.9
Raynaud's Phenomenon	39	36	92.3	79.1 - 98.4
Disease Controls				
Antiphospholipid Syndrome (pAPS+sAPS)[b]	47	27	57.4	42.2 - 71.7
Autoimmune Hepatitis (AIH)	20	18	90	68.3 - 98.8
Bacterial Infection	35	5	14.3	4.8 - 30.3
Celiac Disease	28	4	14.3	4.0 - 32.7
Crohn's Disease	21	0	0	0.0 - 16.1
Graves' Disease	27	0	0	0.0 - 12.8
HIV	24	0	0	0.0 - 14.2
Hashimoto's Thyroiditis	10	0	0	0.0 - 30.8
Hepatitis C	19	0	0	0.0 - 17.6
Leukemia	20	0	0	0.0 - 16.8
Lymphoma	20	0	0	0.0 - 16.8
Polymyalgia Rheumatica	25	0	0	0.0 - 13.7
Primary Biliary Cholangitis (PBC)	20	2	10	1.2 - 31.7
Primary Sclerosing Cholangitis (PSC)	24	0	0	0.0 - 14.2
Rheumatoid Arthritis (RA)	40	25	62.5	45.8 - 77.3
Ulcerative Colitis	22	1	4.5	0.1 - 22.8
Vasculitis	32	3	9.4	2.0 - 25.0
Other Viral Infections (EBV, HBV etc.)	18	0	0	0.0 - 18.5

[a] Equivocal results were considered as negative in this evaluation.

[b] Primary Antiphospholipid Syndrome (pAPS) = 27; Antiphospholipid Syndrome associated with SLE (sAPS) = 20.

Clinical sensitivity and specificity of EliA CTD 13 Screen are summarized in the tables below:

When equivocal results are considered negative:

n= 1027	Target Disease	Disease Controls	Total
Positive test > 1.0	499	85	584
Negative test ≤1.0	76	367	443
Total	575	452	1027

	Value	95% CI
Sensitivity (%)	86.8	83.7 - 89.4
Specificity (%)	81.2	77.3 – 84.7

When equivocal results are considered positive:

n=1027	Target Disease	Disease Controls	Total
Positive test ≥ 0.7	520	124	644
Negative test < 0.7	55	328	383
total	575	452	1027

	Value	95% CI
Sensitivity (%)	90.4	87.7 - 92.7
Specificity (%)	72.6	68.2 - 76.6

2) Other Clinical Supportive Data:
Not applicable.

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

4) Reference Range (Blood Donor/Normal Study):
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 (reflecting the ethnical distribution of the United States) obtained from a blood bank.

The table below shows the composition of the blood donor panel:

Ethnicity	Male		Female		Total	
	n	%	n	%	n	%
Caucasian	98	29.7	99	30.0	197	59.7
African American	24	7.3	26	7.9	50	15.2
Asian	9	2.7	8	2.4	17	5.1
Hispanic	34	10.3	32	9.7	66	20.0

The reference range results are given in the table below:

Test	n	Median [Ratio]	95th percentile [Ratio]	97th percentile [Ratio]
EliA CTD 13 Screen	330	0.1	0.5	0.8

The proportion of sera from an apparently healthy population found positive for the antinuclear antibodies covered by the EliA CTD 13 Screen test is below 3%. Reference range values may vary depending on the population tested.

Proposed Labeling

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

Conclusion

All available data support that the new device EliA CTD 13 Screen performs substantially equivalent to the combination of its predicate devices EliA Symphony^{S}, EliA dsDNA, EliA Rib-P and EliA RNA Pol III.

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