Phadia 250

EliA™

Rx only
CLIA Complexity: Moderate

CTD 13 Screen

FLUOROENZYMEIMMUNOASSAY FOR ANTINUCLEAR ANTIBODIES

FOR IN VITRO DIAGNOSTIC USE

DIRECTIONS FOR USE

CONTENTS

EliA uses a modular reagent system. All information needed to understand the use of the EliA tests can be found in this analyte-specific DfU and the corresponding EliA Control DfU.

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.

SUMMARY AND EXPLANATION OF THE TEST

The determination of antinuclear antibodies (ANA) is of central importance for the clinical diagnosis of connective tissue diseases (CTDs). CTDs are comprised of systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM) and mixed connective tissue disease (MCTD). These chronic diseases exhibit overlapping symptomatic features that render an accurate diagnosis difficult.[1]

For the diagnosis of SLE, antibodies against dsDNA and Sm are considered to be highly specific markers represented within the 2019 EULAR/ACR classification criteria for SLE.[2]

While dsDNA antibodies occur in up to 98% of patients with active disease, anti-Sm antibodies are detectable in approximately 20–40% of SLE patients.[3]

Though anti-ribosomal-P frequency is varied, it is considered to be a highly specific marker for the diagnosis of SLE.[4]

Detection of SS-A/Ro antibodies is of significance for the clinical diagnosis of SLE (prevalence 30–40%) and SS (prevalence 33–74%), and is included in the classification criteria for SS. They have been reported to occur in association with certain disease subsets, such as subacute cutaneous lupus erythematosus, neonatal lupus erythematosus or vasculitis in SS.[5,6,7]

SS-B/La antibodies occur in SS and SLE patients at a frequency of up to 52% and 25%. They occur infrequently in the absence of SS-A/Ro antibodies.[6,7,8]

Antibodies against Scl-70 (also known as anti-topoisomerase I) are characteristic and specific for SSc (particularly the diffuse form) in about 40% of patients and are known to increase the risk of pulmonary fibrosis.[9]

Anti-centromere antibodies (anti-CENP) are typically found in 20–30% of SSc patients, particularly those presenting with the limited form of SSc.[9]

RNA polymerase III (RNA Pol III) antibodies are highly specific for diffuse cutaneous systemic sclerosis (dcSSc). In the EUSTAR registry, 58% of anti-RNA pol III positive SSc patients had dcSSc. They are also known to be associated with renal crisis in approximately 50% of patients.[10]

Scl-70 antibodies, CENP antibodies and RNA Pol III antibodies are all included in the 2013 ACR/EULAR classification criteria for SSc.[11]

Jo-1 antibodies are the most frequent and most widely known autoantibody in idiopathic inflammatory myopathies (IIM) with a frequency of 25–40% in adult cases of PM/DM.[12] They are the only myositis-specific autoantibody included in the 2017 EULAR/ACR classification criteria for IIM.[13]

Anti-U1RNP antibodies are a hallmark biomarker for MCTD, and the only biomarker listed within any of the MCTD classification criteria.[14]

PRINCIPLES OF THE PROCEDURE

The EliA CTD 13 Screen Wells are 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, RNP70, U1RNP-A and U1RNP-C proteins. If present in the patient's specimen, antibodies to the antigens 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.

REAGENTS / MATERIAL

The EliA reagents are available as modular packages, each purchased separately. Apart from the EliA ANA Positive Control 250 and the EliA IgG/IgM/IgA Negative Control 250, all packages are required to carry out an EliA CTD 13 Screen test.

The EliA CTD 13 Screen Wells are packed in carriers which are stored in sealed aluminum foil bags containing a desiccant.

EliA CTD 13 Screen Test-Specific Reagents

EliA CTD 13 Screen Well (Art. No. 14-6661-01)

CTD 13 Screen Well; short name: ctd13	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, RNP70, U1RNP-A and U1RNP-C proteins.	4 carriers (16 wells each); sufficient for 64 determinations	Ready for use; store dry at 2–8°C until expiration date

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Positive Control
Use EliA ANA Positive Control 250 (83-1033-01) in conjunction with this product. For details see the DfU for the control.

Negative Control
Use EliA IgG/IgM/IgA Negative Control 250 (83-1037-01) in conjunction with this product. For details see the DfU for the control.

EliA Method-Specific Reagents (Phadia 250)

EliA Sample Diluent (Art. No. 83-1023-01)

Sample Diluent (yellow colored); PBS containing BSA, detergent and sodium azide (0.095% (w/v))	6 bottles (48 mL each)	Ready for use; store at 2–8°C until expiration date

EliA IgG Conjugate 50 (Art. No. 83-1017-01)

IgG Conjugate (blue colored); β-Galactosidase anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and sodium azide (0.06% (w/v)); symbol: EI-G	6 wedge shaped bottles (5 mL each); sufficient for 6 x 50 determinations	Ready for use; store at 2–8°C until expiration date DO NOT FREEZE DO NOT REUSE

EliA IgG Conjugate 200 (Art. No. 83-1018-01)

IgG Conjugate (blue colored); β-Galactosidase anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and sodium azide (0.06% (w/v)); symbol: EI-G	6 wedge shaped bottles (19 mL each); sufficient for 6 x 200 determinations	Ready for use; store at 2–8°C until expiration date DO NOT FREEZE DO NOT REUSE

EliA IgG Calibrator Strips (Art. No. 83-1015-01)

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); sufficient for one calibration curve (measured in duplicates)	Ready for use; store at 2–8°C until expiration date

Manufactured from human blood preparations.

EliA IgG Curve Control Strips (Art. No. 83-1016-01)

Human IgG (20 µg/L); in PBS containing BSA, detergent and sodium azide (0.095% (w/v)); symbol: CC-1	5 strips Each strip contains 6 x 0.3 mL CC-1 (measured in duplicates)	Ready for use; store at 2–8°C until expiration date

Manufactured from human blood preparations.

EliA IgG Calibrator Well (Art. No. 14-5509-01)

IgG Calibrator Well coated with mouse monoclonal antibodies; short name: Gcal	4 carriers (12 wells each); sufficient for 48 determinations	Ready for use; store dry at 2–8°C until expiration date

Phadia 250 General Reagents

Development Solution (Art. No. 10-9440-01)

Development Solution 0.01% 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative*	6 bottles (17 mL each); sufficient for 6 x >170 determinations	Ready for use; store at 2–8°C until expiration date DO NOT FREEZE

Development Solution (Art. No. 10-9441-01)

Development Solution 0.01% 4-Methylumbelliferyl-β-D-galactoside, <0.0010% preservative*	6 bottles (11 mL each); sufficient for 6 x >110 determinations	Ready for use; store at 2–8°C until expiration date DO NOT FREEZE

* Preservative: Reaction mass of CMIT/MIT (3:1), (CAS No: 55965-84-9)

Stop Solution (Art. No. 10-9442-01)

Stop Solution 4% Sodium Carbonate	6 bottles (119 mL each); sufficient for 6 x >560 determinations	Ready for use; store at 2–32°C until expiration date

Stop Solution (Art. No. 10-9479-01)

Stop Solution 4% Sodium Carbonate	6 bottles (65 mL each); sufficient for 6 x >292 determinations	Ready for use; store at 2–32°C until expiration date

Dilution Plates (Art. No. 12-3907-08)

MicroWell™ plates with 96 wells, 0.5 mL each	100 plates per package; sufficient for 100 x 96 samples	Ready for use DO NOT REUSE

Washing Solution (Art. No. 10-9422-01/10-9202-01)
For information see separate Washing Solution package insert.
The expiration date for each of the complete packages is stated on the outer label. However, each component is stable until the date stated on the respective vial label.

Material required but not provided by Phadia AB:
- Measuring cylinder 1000 mL
- Clinical laboratory reagent water (CLRW, may be used in place of Type I and Type II water) as defined by CLSI Standards Document, GP40-A4-AMD: Preparation and Testing of reagent Water in the Clinical Laboratory; Approved Guideline - Fourth Edition.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use reagents beyond their expiration dates, or if damaged or incorrectly stored.
- We recommend not to pool reagents.
- Do not use if desiccant bag is missing or damaged.
- Do not use if foilbag is damaged.
- Wear gloves while handling samples and reagents provided.
- Some of the reagents are manufactured from human blood components. The source materials have been tested by FDA approved immunoassay for hepatitis B surface antigen, for antibodies to HIV1, HIV2 and hepatitis C virus and found negative. Nevertheless, all recommended precautions for the handling of blood derivatives should be observed. Please refer to Human Health Service (HHS) Publication No. (CDC) 93-8395 or local and national guidelines on laboratory safety procedures.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

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WARNING! Reagents contain sodium azide (NaN_3) as a preservative. NaN_3 may be toxic if ingested or absorbed by skin or eyes. NaN_3 may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Please refer to decontamination procedures as outlined by CDC or other local and national guidelines.
Reagents containing ≥ 0.00015% reaction mass of CMIT/MIT (3:1) (CAS No: 55965-84-9) may produce an allergic reaction (EUH 208).
Besides the substances stated above, no other carcinogenic, mutagenic, reprotoxic (CMR) or endocrine disrupting substances, or materials that could result in the sensitization or an allergic reaction of the user are incorporated into the reagents and materials. For the most recent information on ingredients classified as hazardous substances, please refer to the respective safety data sheet.
Waste Bottle and ImmunoCAP/EliA Well Waste Container may be contaminated by potentially infectious material. Use appropriate safety measures and wear gloves.
For warnings and precautions related to Phadia instruments, please refer to the respective user manuals.

Indication of Instability

Phadia Prime has built-in acceptance limits for the calibration curve and the curve control. EliA Wells are moisture sensitive. Any activity loss that might occur due to inappropriate handling can be detected using the appropriate EliA Control. For more information see the respective Phadia Instrument User Manual and Phadia Prime Reference Guide.

INSTRUMENT

EliA reagents are to be used with the latest software versions. The Phadia instrument processes all steps of the test. For further information regarding test set-up, instrumentation and software etc. see the user documentation for the instrument and the Phadia Prime Software.

SPECIMEN COLLECTION, HANDLING AND PREPARATION

The procedure can be performed with serum specimens. Lipemic, hemolyzed or microbially contaminated samples may give poor results and should not be used.

- Undiluted samples should remain at room temperature for no longer than eight hours.[15]
- Undiluted samples can be stored at 2–8°C for two weeks without degradation provided they do not become contaminated by bacteria or fungi and they should be frozen at below -20°C for any long-term storage.[16]

Note: It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. In general, laboratories should perform validation studies before implementing a change in specimen acceptance criteria.[15]

Sample Dilution

Samples must be diluted with EliA Sample Diluent. A 1:10 dilution of the samples is required for the EliA CTD 13 Screen test. Samples can be diluted manually, but instrument dilution is recommended and is a default setting in the software.

PROCEDURE

Handling of EliA CTD 13 Screen Well

In the Phadia 250 storage chamber, carriers are stable for up to 28 days. If you are not expecting to use them up within this time, the carriers should be loaded via the Phadia 250 Loading Tray and, for stability reasons, must be put back into the desiccant-containing foil bag directly after the run. Because it is important to store the wells in dry conditions at 2–8°C, the bag must be properly resealed. If stored under these conditions, the shelf-life from the date of first opening is 12 weeks, if not limited by the expiry date stated on the carrier and foil bag.

Lot-specific barcode

Use the built-in barcode reader to enter the lot-specific information of EliA CTD 13 Screen Well, EliA IgG Calibrator Well and EliA IgG Conjugate. In case of manual handling make sure to enter the characters below the barcode.

In-use and on-board stability of reagents

EliA CTD 13 Screen Well	28 days (in Carrier Storage). 24 hours (when left on-board in Carrier Loading Tray). After first opening, when stored in dry conditions at 2–8°C, carriers are stable for 12 weeks, if not limited by the expiry date stated on the carrier and foil bag.
EliA IgG Calibrator Well	28 days (in Carrier Storage). 24 hours (when left on-board in Carrier Loading Tray). After first opening, when stored in dry conditions at 2–8°C, carriers are stable for 9 months, if not limited by the expiry date stated on the carrier and foil bag.
EliA Calibrator/Curve Control	28 days
EliA Conjugate	Single use. Open vials must not be stored.
EliA Sample Diluent	7 days Recap bottles every night.
Development Solution	5 days Recap bottles every night.
Stop Solution	14 days Recap bottles every night.
Washing Solution *(prepared solution)*	7 days Discard every seventh day and perform weekly maintenance according to the instrument user manual.

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Volumes per determination

Reagent volumes per determination

Calibrator	90 µL
EliA IgG Conjugate	90 µL
Development Solution	90 µL
Stop Solution	200 µL

Sample volumes per determination

Manual dilution	90 µL of diluted sample
Instrument dilution (1:10)	9 µL of non-diluted sample

For tube-specific dead volumes see respective Phadia Instrument User Manual.

Reagent volumes per 200 determinations

Washing Solution	5 – 7 L*
Rinse Solution	5 – 6 L*

* The residual volume depends on the number of samples and dilution method used.

Procedural comments

- When using software default, samples are run in single determination.
- Washing Solution must be at room temperature when used.
- The first result is available after approx. 2 hours and further results at one minute intervals afterwards. Up to 5 x 16 samples can be loaded continuously and are processed by random access.
- Incubations are automatically performed at 37°C (98.6°F).

CALIBRATION AND METROLOGICAL TRACEABILITY INCLUDING REFERENCE MATERIAL

This EliA test uses the 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).
The calibration curve is created by measuring EliA IgG Calibrators in duplicate. The curve is stored by the software, and subsequent results will be evaluated against the stored calibration curve when an EliA IgG Curve Control (measured in duplicate) is included in the subsequent testing.

A new calibration curve must be created when

- the last calibration was generated >28 days ago or
- a new lot of EliA IgG Conjugate is introduced or
- the EliA IgG Curve Control is outside the specified limits (defined in Phadia Prime Software).

Results are provided in Ratio.

QUALITY CONTROL

Control Specimens

Good laboratory practice and CLIA guidelines recommend that quality control specimens of at least two levels should be performed every day. Any material used should be assayed repeatedly to establish mean values and acceptance ranges. EliA Controls are available for the quality control of the measurements.

CALCULATION AND INTERPRETATION OF RESULTS

Presentation of Results

Phadia 250 measures specific IgG concentrations in µg/L. By using a conversion factor given by the lot-specific code of the EliA CTD 13 Screen Well, the results are automatically converted to Ratio.

Interpretation of Test Results

The ranges (negative, equivocal, positive) recommended for the evaluation of the results are given in the table below.

Test	Unit	Negative	Equivocal	Positive
EliA CTD 13 Screen	Ratio	< 0.7	0.7 – 1.0	> 1.0

Good laboratory practice requires that each laboratory establishes its own range of expected values.
In case of equivocal results, we recommend retesting the patient within 8–12 weeks.
In the case of a positive result, it is recommended to perform further tests (with the patient sample) for reactivity against individual antigens.

EXPECTED VALUES

Antibody prevalence in autoimmune patients varies widely depending on disease area. A normal study (found below) was conducted to support the cut-off determination for EliA CTD 13 Screen, in order to ensure positivity in less than 3% of a normal population. Expected values may vary depending on the population tested.

Results Obtained for Healthy Subjects

The frequency distribution for antinuclear antibodies was investigated in a group of apparently healthy subjects equally distributed by age and gender, using sera from a Caucasian, African American, Hispanic and Asian population obtained from a blood bank. The results given in the table show the concentration below which 95% and 97% of the blood donor samples are found.

Test	Unit	No. of samples	Median value	95th percentile	97th percentile
EliA CTD 13 Screen	Ratio	330	0.1	0.5	0.8

PERFORMANCE CHARACTERISTICS

Specificity

The EliA CTD 13 Screen test permits the determination of IgG antibodies directed against the antigens as described in section "Reagents/Material".

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Interference

Interference of the following substances was evaluated at two or three different analyte concentrations. The acceptance criterion was interference of ≤ 10%. The indicated substance concentrations are the highest tested concentrations that fulfilled this criterion. Substance names are based on CLSI EP37-Ed. 1[18], CLSI EP37-Ed. 2[19] and INN[20] in English.

Substance	Interference ≤ 10% up to a concentration
Albumin	6,000 mg/dL
Bilirubin, unconjugated	40 mg/dL
Bilirubin, conjugated	40 mg/dL
Hemoglobin	1,000 mg/dL
Rheumatoid factor IgM	500 IU/mL
Triglycerides	2,000 mg/dL
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

Precision

Within-laboratory precision

Within-laboratory precision of EliA CTD 13 Screen was evaluated by assaying 10 samples on 1 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)	
			No.	%
1	0.3 (neg)	0.2–0.3	0/0/84	0/0/100
2	0.3 (neg)	0.3–0.4	0/0/84	0/0/100
3	0.5 (neg)	0.4–0.6	0/0/80	0/0/100
4	0.8 (equ)	0.7–0.9	0/78/5	0/94/6
5	1.0 (pos)	0.8–1.2	48/36/0	57/43/0
6	1.2 (pos)	1.0–1.4	84/0/0	100/0/0
7	4.5 (pos)	3.8–5.8	84/0/0	100/0/0
8	5.3 (pos)	4.4–6.0	84/0/0	100/0/0
9	23 (pos)	19–28.1	81/0/0	100/0/0
10	26 (pos)	22–>31	84/0/0	100/0/0

Reproducibility

The reproducibility of EliA CTD 13 Screen was evaluated by assaying 10 samples on 3 instruments, 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 across the 3 instruments.

Sample	Mean Ratio (Interpretation)	Range of Ratio	Results (positive / equivocal / negative)							
			Total		Instrument 1		Instrument 2		Instrument 3	
			No.	%	No.	%	No.	%	No.	%
1	0.6 (neg)	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 (neg)	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 (equ)	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
4	0.8 (equ)	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 (equ)	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 (pos)	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 (pos)	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

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Sample	Mean Ratio (Interpretation)	Range of Ratio	Results (positive / equivocal / negative)							
			Total		Instrument 1		Instrument 2		Instrument 3	
			No.	%	No.	%	No.	%	No.	%
8	4.8 (pos)	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 (pos)	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 (pos)	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 10 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 across the 3 reagent sets.

Sample	Mean Ratio (Interpretation)	Range of Ratio	Results (positive / equivocal / negative)							
			Total		Lot 1		Lot 2		Lot 3	
			No.	%	No.	%	No.	%	No.	%
1	0.6 (neg)	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 (neg)	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 (equ)	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 (equ)	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 (equ)	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 (pos)	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 (pos)	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 (pos)	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 (pos)	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 (pos)	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

METHOD COMPARISON

For analysis of agreement, 1082 sera were measured with EliA CTD 13 Screen on the Phadia 250 and with the predicate devices EliA Symphony*S*, EliA dsDNA, EliA Rib-P and EliA RNA Pol III.

n = 1082	Method Comparison	Combination of Predicate Devices			
		Positive	Equivocal	Negative	Total
EliA CTD 13 Screen	Positive > 1.0 Ratio	572	35	24	631
	Equivocal 0.7 – 1.0 Ratio	3	4	55	62
	Negative < 0.7 Ratio	7	14	368	389
	Total	582	53	447	1082

Agreement calculation with equivocal results = negative	Agreement (%)	95% CI
Positive Percent Agreement	98.3	96.9 – 99.2
Negative Percent Agreement	88.2	85.0 – 90.9
Overall Percent Agreement	93.6	92.0 – 95.0

Agreement calculation with equivocal results = positive	Agreement (%)	95% CI
Positive Percent Agreement	96.7	95.0 – 97.9
Negative Percent Agreement	82.3	78.5 – 85.8
Overall Percent Agreement	90.8	88.9 – 92.4

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Clinical Evaluation

Disease groups	Number of samples	Number of pos.[a] results	% of pos.[a] results	95% CI
Target diseases				
Systemic lupus erythematosus (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
Sjögren'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				
Rheumatoid arthritis (RA)	40	25	62.5	45.8 – 77.3
Polymyalgia rheumatica (PMR)	25	0	0	0.0 – 13.7
Celiac disease	28	4	14.3	4.0 – 32.7
Crohn's disease	21	0	0	0.0 – 16.1
Ulcerative colitis	22	1	4.5	0.1 – 22.8
Graves' disease	27	0	0	0.0 – 12.8
Hashimoto’s thyroiditis	10	0	0	0.0 – 30.8
Antiphospholipid syndrome (pAPS + sAPS)[b]	47	27	57.4	42.2 – 71.7
Primary biliary cholangitis (PBC)	20	2	10	1.2 – 31.7
Primary sclerosing cholangitis (PSC)	24	0	0	0.0 – 14.2
Autoimmune hepatitis (AIH)	20	18	90	68.3 – 98.8
Vasculitis	32	3	9.4	2.0 – 25.0
Leukemia	20	0	0	0.0 – 16.8
Lymphoma	20	0	0	0.0 – 16.8
Bacterial infections	35	5	14.3	4.8 – 30.3
HIV	24	0	0	0.0 – 14.2
Hepatitis C	19	0	0	0.0 – 17.6
Other viral infections (EBV, HBV, etc.)	18	0	0	0.0 – 18.5
Total	**1027**			

[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, equivocal results considered negative.

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

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

Clinical Sensitivity and Specificity of EliA CTD 13 Screen, equivocal results considered positive.

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

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

LIMITATIONS

In rare cases, interference due to antibodies to streptavidin can occur and may lead to elevated results.

Samples from patients undergoing immunoglobulin replacement therapy (e.g., treatment with intravenous immunoglobulin, IVIG) may show falsely elevated results as a consequence of specific antibodies contained in IVIG preparations.

Samples from patients with hypergammaglobulinemia may show elevated results. This effect is patient-specific and cannot be predicted.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

WARRANTY

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Phadia AB may affect the results, in which event Phadia AB disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and fitness for use.

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Do not re-use		*In vitro* diagnostic medical device	
Use-by date		Temperature limit	
Batch code		Consult instructions for use	
Date of manufacture		Biological risks	
Catalogue number		**Rx only**	For prescription use only
Manufacturer		European conformity mark (with notified body identification number, if applicable)	
Made in Germany		Unique device identifier	
Contains sufficient for <*n*> tests			

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