Phadia 250

EliA™

Not for use in the USA

Gliadin^{DP} IgG

FLUOROENZYMEIMMUNOASSAY FOR ANTI GLIADIN 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 Gliadin^{DP} IgG is intended for the in vitro quantitative measurement of IgG antibodies directed to gliadin in human serum or plasma (heparin, citrate, EDTA) to aid in the diagnosis of celiac disease. EliA Gliadin^{DP} IgG is to be used together with the EliA IgG method on the instrument Phadia 250.

EliA products are to be used in clinical laboratories by trained professionals only.

SUMMARY AND EXPLANATION OF THE TEST

Celiac disease is a life-long condition in which ingestion of gluten, the water insoluble wheat-gliadin and the prolamins in rye and barley, leads to chronic inflammation and damage of the small intestinal mucosa. The disease is multifaceted in nature with clinical presentation ranging from gastrointestinal manifestations to asymptomatic, silent and extraintestinal forms.[1] It is widely accepted that dermatitis herpetiformis, a bullous skin disease, is induced by gluten.[2] The term gluten refers to a whole set of proteins in the so-called endosperm, the nutritive tissue of the grain seed of wheat, rye, oats and barley. The alcohol-soluble polypeptides of gluten, the gliadins, are solely responsible for the toxic effects to the intestinal mucosa.[3] More recent research revealed that gliadin peptides deamidated by tissue transglutaminase represent more specific B-cell epitopes than native peptides.[4,5] Further studies showed that increased specificity can also be observed for anti-gliadin assays based on deamidated peptides.[6,7]

PRINCIPLES OF THE PROCEDURE

The EliA Gliadin^{DP} IgG Wells are coated with synthetic deamidated gliadin peptides. If present in the patient's specimen, antibodies to gliadin peptides bind to their specific antigen.

After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG 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 higher the response value, the more specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

REAGENTS / MATERIAL

EliA reagents are available as modular packages, each purchased separately. All packages except for the EliA Celiac Positive Control 250 and the EliA IgG/IgM/IgA Negative Control 250 are required to carry out an EliA Gliadin^{DP} IgG test.

The EliA Gliadin^{DP} IgG Wells are packed in carriers which are stored in sealed aluminium foil bags containing a desiccant.

EliA Gliadin^{DP} IgG Test-Specific Reagents

EliA Gliadin^{DP} IgG Well (Art. No. 14-5539-01)

Gliadin^{DP} IgG Well; short name: Ggp	Coated with synthetic deamidated gliadin peptides	4 carriers (12 wells each); sufficient for 48 determinations	Ready for use; store dry at 2–8°C until expiration date

Positive Control

Use EliA Celiac Positive Control 250 (83-1036-01) 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%)	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%); 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%); 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%)	5 strips 6 single-use vials per strip (0.3 ml each); sufficient for one calibration curve (double determination)	Ready for use; store at 2–8°C until expiration date

Manufactured from human blood preparations.

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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%); symbol: CC-1	5 strips Each strip contains 6 x 0.3 ml CC-1 (double determination)	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.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use. For professional use only.
- 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 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.

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 IDM/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 IDM Reference Guide/ 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 IDM/Prime Software.

SPECIMEN COLLECTION, HANDLING AND PREPARATION

The procedure can be performed with serum or plasma (heparin, citrate, EDTA) specimens. Lipemic 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.[8,9]
- 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.[9,10]
- Undiluted samples are stable for at least five freeze-thaw cycles.[11]

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.[8]

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Sample Dilution
Samples must be diluted with EliA Sample Diluent. A 1:100 dilution of the samples is required for the EliA Gliadin^{DP} IgG test. Samples can be diluted manually, but instrument dilution is recommended and is a default setting in the software.

PROCEDURE

Handling of EliA Gliadin^{DP} IgG 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 9 months, 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 Gliadin^{DP} IgG 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 Gliadin^{DP} IgG Well	28 days (in Carrier Storage). 24 hours (in Carrier Loading Tray). 9 months (if not limited by the expiry date stated on the carrier and foil bag, when after first opening stored in dry condition at 2–8°C).
EliA IgG Calibrator Well	28 days (in Carrier Storage). 24 hours (in Carrier Loading Tray). 9 months (if not limited by the expiry date stated on the carrier and foil bag, when after first opening stored in dry condition at 2–8°C).
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.

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 (1:100)	20 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
- From one sample diluted by the instrument (1:100), up to 11 determinations can be made.
- 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 10 samples can be loaded continuously and are processed by random access.
- Incubations are automatically performed at 37°C (98.6°F).
- If you want to perform more than one test per patient, you can use the predefined test panels in Phadia IDM/Prime. For further information regarding the test panels, see Phadia IDM Reference Guide/Phadia Prime Reference Guide.

CALIBRATION AND REFERENCE MATERIAL
The calibration curve is obtained with EliA IgG Calibrators which are run in duplicate. The curve is stored and subsequent tests are evaluated against the stored curve using only the EliA IgG Curve Control (run in duplicate).
The EliA IgG Calibrators are traceable via an unbroken chain of calibrations to its primary reference, the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A, G and M from World Health Organization (WHO). The highest deviation for an EliA IgG Calibrator towards its primary reference, with a 95% probability, is ± 4.7%.

A new calibration curve must be run when:
- the last calibration was made more than one month ago or
- a new lot of EliA IgG Conjugate is introduced or
- when the EliA IgG Curve Control is outside the specified limits (defined in Phadia IDM/Prime Software).

There are no international standards for gliadin antibodies. Results are given in arbitrary EliA Units/ml.

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QUALITY CONTROL

Control Specimens

Good laboratory practice requires that quality control specimens should be included in every run. 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 Gliadin^{DP} IgG Well, the results are automatically converted to EliA U/ml.

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 Gliadin^{DP} IgG	EliA U/ml	< 7	7 – 10	> 10

Good laboratory practice requires that each laboratory establishes its own range of expected values.

LIMITATIONS

A definitive clinical diagnosis should not be based on the results of a single diagnostic method, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Antibody prevalence in autoimmune patients varies widely depending on disease area. The proportion of sera from a normal population found positive for the antibodies covered by the EliA Gliadin^{DP} IgG test is below 1%. Expected values may vary depending on the population tested.

Results Obtained for Healthy Subjects

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

Test	Unit	No. of samples	Mean value	95%-percentile	99%-percentile
EliA Gliadin^{DP} IgG	EliA U/ml	400	1.3	4.1	13

PERFORMANCE CHARACTERISTICS

Measuring Range

The measuring range (detection limit, upper limit) for EliA Gliadin^{DP} IgG is from 0.6 to ≥ 302 EliA U/ml.

No hook effect is expected for the used assay format.

Only values above the Detection Limit can be regarded as valid results. The upper limit of the reported results can vary due to a lot-specific conversion from µg/l to EliA U/ml. Results above the upper limit are reported as “above”.

Please note that due to differing binding characteristics of the antibodies in patient samples, not all samples can be diluted linearly within the measuring range.

Specificity

The EliA Gliadin^{DP} IgG test permits the determination of IgG antibodies directed against the gliadin antigen as described in section “Reagents/Material”.

Precision

To determine the precision of the assay, the variability was assessed in a study with 18 runs by examining the samples in 108 replicates on 3 instruments with a calibration curve included in each run. The statistical evaluation was performed by Analysis of Variance. The results are given in the table below.

Test	Sample	Unit	Mean value	Coefficients of variation (%)	
				Intra-run	Inter-run
EliA Gliadin^{DP} IgG	1	EliA U/ml	11	4.1	3.9
	2	EliA U/ml	16	6.0	4.0
	3	EliA U/ml	45	4.9	4.1

The lot-to-lot variation of EliA Gliadin^{DP} IgG Well was determined to be 3.1% with 3 samples in 108 replicates per sample over 3 lots.

Interference

Interference by chromophoric substances (bilirubin, hemoglobin) and rheumatoid factor is not expected for the used assay format. Treatment with intravenous immunoglobulin (IVIG) therapy may in rare cases lead to false positive results of the EliA Gliadin^{DP} IgG test.

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.

Phadia AB and its authorized distributors, in such event, shall not be liable for damages, indirect or consequential.

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IMPORTANT NOTICE

For healthcare professionals in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

	Do not re-use		Contains sufficient for <*n*> tests
	Use-by date	IVD	*In vitro* diagnostic medical device
LOT	Batch code		Temperature limit
	Date of manufacture		Consult instructions for use
REF	Catalogue number		Biological risks
	Manufacturer	**Rx only**	For prescription use only – only applicable under US legislation
Made in Germany	Made in Germany		

Full symbol glossary is available at: https://symbols_glossary.phadia.com

Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala
Sweden
Tel: +46-18-16 50 00
Fax: +46-18-14 03 58
Autoimmunity@phadia.com
www.phadia.com

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Revision History

Version	Countries	Change
21	all, except US	All instruments, chapter "Specimen collection, handling and preparation": additional information regarding sample stability
22	all, except US	Harmonization of texts and translations between DfUs/instruments.
		Chapter “Reagents/Material”: rephrasing of the origin of EliA Positive Control, EliA Negative Control, EliA Calibrators, EliA Calibrator Strips, EliA Curve Control and EliA Curve Control Strips.
		Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Reagents/Material”, EliA Sample Diluent: the information on the number of determinations has been removed.
		Phadia 200, chapter “Reagents/Material”, Dilution Plates: correction of package size from 50 to 100.
		Phadia 200 and Phadia 250, chapter “Reagents/Material”, Dilution Plates: the information on plastic material has been removed.
		Phadia 100, chapter “Reagents/Material”, “Detailed reagents”, Washing Solution: the information on expiry date and additional material provided has been removed. Translation corrected in other instrument versions, where applicable.
		Chapter “Warnings and Precautions”: insertion of “Do not use if desiccant bag is missing or foilbag is damaged.”
		Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Warnings and Precautions”: insertion of “Wear gloves while handling samples and reagents provided.”
		Phadia 200, Phadia 250 and Phadia 2500/5000, chapter "Instrument": clarification that the Phadia instrument processes all steps of the test.
		Phadia 250 and Phadia 2500/5000, chapter “Procedure”: update and new presentation of “On-board stability” section.
		Phadia 200, chapter "Procedure", "On-board stability", Development Solution and Stop Solution: addition of "Recap bottles every night".
		Chapter “Procedure”: software panels have been removed.
		Phadia 250 and Phadia 2500/5000, chapter “Performance Characteristics”, “Measuring Range”: updated Limit of Detection.
		Phadia 200, chapter “Performance Characteristics”, “Measuring Range”: correction of the concentration range that was checked for absence of the hook effect.
		Phadia 200, chapter “Performance Characteristics”, “Precision”: corrected explanation of study design.
		Updated symbol table. Link to full symbol glossary inserted.
22	all, except UK, US	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Procedure”, “Procedural Comments”: correction of translations.
22	DE, DK, EE, ES, FR, IT, PT, SE	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Performance Characteristics”, “Measuring Range”: correction of translations.
22	DE, IT, PL, PT, SE	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Reagents/Material”: correction of translations.
22	GR, HR, NL, SP	Phadia 250, chapter “Procedure”, “Handling of EliA Well”: correction of text “...the carriers should be unloaded and...” to “...the carriers should be loaded via the Phadia 250 Loading Tray... ”.
22	DE, DK, NO	Chapter "Reagents/Material": addition of "single-use" to vial description.
22	DE/AT/CH	Merge German language versions (DE, AT, CH) into one German version.
22	ES, FR, PT	Phadia 2500/5000, chapter “Expected Values”, “Results Obtained for Healthy Subjects”: correction of translations.
22	IT, PL, SE	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "Expected Values": correction of translations.
22	CZ, NO	Chapter “Reagents/Material”, Stop Solution (Art. No. 10-9442-01 and Art. No. 10-9479-01): correction of number of determinations.
22	FR, IT	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Intended Use”: correction of translations.
22	FR, SE	Chapter "Specimen Collection, Handling and Preparation": correction of translations.
22	CZ	Correction of Czech translations.
		Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Reagents/Material”: updated storage conditions for EliA Well.
		Chapter “Reagents/Material”, Stop Solution (Art. No. 10-9479-01): correction of number of bottles.
		Chapter "Warnings and Precautions": insertion of "Some of the reagents are manufactured from human blood components."
22	DE	Chapter "Specimen Collection, Handling and Preparation": updated translations of chapter title, sample storage conditions and duration.
22	ES	Phadia 2500/5000, chapter “Procedure”, table “Reagent volumes per 200 determinations”: correction of translation of tablenote.
		Chapter “Performance Characteristics”, “Precision”: correction of translations.
22	IT	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter “Warnings and Precautions”: correction of translations.
22	NL	Phadia 2500/5000, chapter “Procedure”, “Handling of EliA Well”: correction of text “...the carriers should be loaded via the Phadia 2500/5000 Loading Tray... ” to “...the carriers should be unloaded and...”.
		Phadia 100, chapter “Procedure”: correction of translations.
		Phadia 100 and Phadia 250, chapter “Performance Characteristics”, “Precision”: correction of translations.
22	NO	Chapter “Contents”: correction of translations.
		Chapter “Intended Use”: correction of translations.

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22	SE	Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "Specimen Collection, Handling and Preparation", “Sample Dilution”: correction of translations.
		Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "Quality Control": removed section on "Record Keeping".
23	EE	Phadia 200, chapter “Warnings and Precautions”, “Indication of Instability”: Reference to IDM Reference Guide removed.
23	US	Phadia 250: Update due to US FDA regulatory requirements.
24	all	Chapters “Intended Use” and “Specimen Collection, Handling and Preparation”: Clarification of plasma types used.
		Chapter “Intended use”: addition of text indicating use in clinical laboratories by trained professionals only.
		Chapter “Reagents / Material”: Removal of redundant information on composition.
		Phadia 200, chapter “Reagents / Material”: Inclusion of EliA Dummy Wells.
		Phadia 2500/5000, chapter “Reagents / Material”: Correction in number of Stop Solution bottles.
		Chapters “Reagents / Material” and “Warnings and Precautions”: Additional information on preservative contained in reagents.
		Phadia 100, chapter “Reagents/Material”: inclusion of materials required but not provided.
		Chapter “Warnings and Precautions”: addition of professional use and advice on storage conditions for the use of reagents. Rephrasing of the warning for pooling of reagents.
		Chapter “Warnings and Precautions”, “Warning”: addition of precautions to CMR substances and instrument relevant subjects.
		Chapter “Specimen Collection, Handling and Preparation”: exclusion of hemolyzed sample in the current sentence.
		Chapter “Specimen Collection, Handling and Preparation”: Updated reference numbers, additional reference 9 added.
		Chapter “Specimen Collection, Handling and Preparation”: Additional information on freeze-thaw cycles.
		Phadia 200, Phadia 250 and Phadia 2500/5000, chapter “Procedure”, on-board stability of reagents: updated title and more details for the stability information of test and calibrator wells.
		Phadia 200, chapter “Procedure”: Removal of Washing Solution consumption.
		Chapter “Calibration and Reference Material”: additional information on metrological traceability.
		Chapter “Expected Values”, “Results Obtained for Healthy Subjects”: Updated table and/or rephrasing of section.
		Phadia 100, chapter “Expected Values”: Harmonization of values with other instruments.
		Chapters “Expected Values” and “Performance Characteristics”: Concentration values are now presented using the same rounding rules as applied in the user software.
		Chapter “Performance Characteristics”, “Measuring Range”: updated sentence for hook effects.
		Chapter “Performance Characteristics”: updated data in sub-chapter “Precision”.
		Chapter “Performance Characteristics”, “Precision”: inclusion of EliA Well lot-to-lot variation.
		Introduction of new sub-chapter “Interference”.
		Chapter “References”: Reference list updated with additional reference 11, other references renumbered.
		Introduction of new chapter “Important Notice”.
		Symbol table: addition of Rx only (For prescription use only – only applicable under US legislation).
		Symbol table: Addition of "Made in Germany".
24	CZ, DK, EE, FI, GR, HR, LT, NO, SK, TR	Chapter “Performance Characteristics”: More precise use of the terms "precision" and "accuracy".
24	EE	Chapter “Performance Characteristics”, “Measuring Range”: Correction of unit from “µg/ml” to "µg/l”.

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