**Phadia 250**

EliA™

**Not for use in the USA**

# Calprotectin

FLUOROENZYMEIMMUNOASSAY FOR CALPROTECTIN DETERMINATION

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 Calprotectin is intended for the in vitro quantitative measurement of calprotectin in human stool as an aid in the clinical diagnosis of inflammatory bowel diseases (IBD). EliA Calprotectin uses the EliA Calprotectin method on the instrument Phadia 250.

## SUMMARY AND EXPLANATION OF THE TEST

Calprotectin is a calcium- and zinc-binding protein which is predominantly present in the cytoplasm of cells involved in pathogen defense, such as neutrophil granulocytes, monocytes and macrophages.[1,2] In neutrophil granulocytes it accounts for as much as 60% of the cytosolic protein. In intestinal inflammation neutrophil granulocytes migrate through the intestinal wall into the intestinal lumen, which leads to an elevated calprotectin level in the stool.[3] The level of fecal calprotectin correlates directly with the number of neutrophil granulocytes in the intestinal lumen and is thus specifically elevated in inflammatory bowel diseases (IBD), such as Crohn's disease and ulcerative colitis. Fecal calprotectin levels get affected by nonsteroidal anti-inflammatory drug (NSAID) intake, bleeding more than 100 ml and by malignancy.[4] Fecal calprotectin measurement is an easy, non-invasive first line test which clearly differentiates IBD from IBS (irritable bowel syndrome) and other functional bowel disorders. It has been shown to be the most sensitive and most specific test for this discrimination, clearly outperforming blood tests such as CRP or ESR.[5] Fecal calprotectin correlates with disease activity and is able to predict relapses in IBD.[6] This makes fecal calprotectin useful for both diagnosis and monitoring of IBD patients.

## PRINCIPLES OF THE PROCEDURE

The EliA Calprotectin Wells are coated with monoclonal antibodies to calprotectin. If present in the patient's specimen, calprotectin binds to the coated antibodies. After washing away non-bound components, enzyme-labeled antibodies against human calprotectin (EliA Calprotectin Conjugate) are added to form a calprotectin-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 calprotectin 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 Calprotectin Positive Control 250, the EliA Calprotectin Negative Control 250 and the EliA Stool Extraction Kit are required to carry out an EliA Calprotectin test. The EliA Calprotectin Wells are packed in carriers which are stored in sealed aluminium foil bags containing a desiccant.

### EliA Calprotectin Test-Specific Reagents

***EliA Calprotectin Well (Art. No. 14-5610-01)***

| | | | |
|---|---|---|---|
| Calprotectin Well; short name: cn | Coated with monoclonal antibodies to calprotectin | 4 carriers (12 wells each); sufficient for 48 determinations | Ready for use; store dry at 2–8°C until expiration date |

***EliA Calprotectin Positive Control 250 (Art. No. 83-1083-01)***

| | | | |
|---|---|---|---|
| Human calprotectin in PBS containing BSA, detergent and sodium azide (0.095%); symbol: pos | Control containing human calprotectin | 6 single-use vials (0.3 ml each); sufficient for 2 determinations per vial | Ready for use; store at 2–8°C until expiration date |

EliA Calprotectin Positive Control 250 is prepared from human blood.

***EliA Calprotectin Negative Control 250 (Art. No. 83-1085-01)***

| | | | |
|---|---|---|---|
| Human calprotectin in PBS containing BSA, detergent and sodium azide (0.095%); symbol: neg | Control containing human calprotectin | 6 single-use vials (0.3 ml each); sufficient for 2 determinations per vial | Ready for use; store at 2–8°C until expiration date |

EliA Calprotectin Negative Control 250 is prepared from human blood.

### EliA Method-Specific Reagents (Phadia 250)

***EliA Calprotectin Extraction Buffer (Art. No. 83-1068-01)***

| | | |
|---|---|---|
| Calprotectin Extraction Buffer (orange colored); Tris-buffer containing sodium azide (0.05%) | 6 bottles (117 ml each); sufficient for 6 x 23 extractions | Ready for use, shake before using; store at 2–8°C until expiration date |

***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 Calprotectin Conjugate 50 (Art. No. 83-1064-01)***

| | | |
|---|---|---|
| Calprotectin Conjugate (blue colored); β-Galactosidase-labeled mouse monoclonal antibodies to calprotectin in PBS containing BSA and sodium azide (0.06%); symbol: EI-C | 6 wedge shaped bottles (5 ml each); sufficient for 6 x 50 determinations | Ready for use; store at 2–8°C until expiration date<br>DO NOT FREEZE<br>DO NOT REUSE |



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***EliA Calprotectin Conjugate 200 (Art. No. 83-1065-01)***

| | | |
|---|---|---|
| Calprotectin Conjugate (blue colored); β-Galactosidase-labeled mouse monoclonal antibodies to calprotectin in PBS containing BSA and sodium azide (0.06%); symbol: El-C | 6 wedge shaped bottles (19 ml each); sufficient for 6 x 200 determinations | Ready for use; store at 2–8°C until expiration date<br>DO NOT FREEZE<br>DO NOT REUSE |

***EliA Calprotectin Calibrator Strips (Art. No. 83-1062-01)***

| | | |
|---|---|---|
| Human calprotectin (0, 3, 10, 20, 200, 750 ng/ml); in PBS containing BSA, detergent and sodium azide (0.095%); symbol: CAL-0, CAL-3, CAL-10, CAL-20, CAL-200, CAL-750 | 5 strips<br>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 |

EliA Calprotectin Calibrator Strip is prepared from human blood.

***EliA Calprotectin Curve Control Strips (Art. No. 83-1063-01)***

| | | |
|---|---|---|
| Human calprotectin (20 ng/ml); in PBS containing BSA, detergent and sodium azide (0.095%); symbol: CC-1 | 5 strips<br>Each strip contains 6 x 0.3 ml CC-1 (double determination) | Ready for use; store at 2–8°C until expiration date |

EliA Calprotectin Curve Control Strip is prepared from human blood.

***EliA Calprotectin Calibrator Well (Art. No. 14-5618-01)***

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

***EliA Stool Extraction Kit (Art. No. 14-5638-01)***

| | | |
|---|---|---|
| Stool extraction tubes pre-filled with 750 µl of EliA Calprotectin Extraction Buffer | 50 tubes; sufficient for 50 stool sample extractions | Ready for use; store 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<br>DO NOT FREEZE |

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

***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 |

***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<br>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.
- Do not use reagents beyond their expiration dates.
- We do not recommend to pool reagents.
- Do not use if desiccant bag is missing or 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.
Waste Bottle and ImmunoCAP/EliA Well Waste Container may be contaminated by potentially infectious material. Use appropriate safety measures and wear gloves.

**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 EXTRACT PREPARATION

The procedure can be performed with human stool specimens. Avoid repeated freezing and thawing. Samples should be stored in aliquots at -20°C (-4°F) or below for repeated measurements.

The stool samples can be extracted by two different methods:

**A) Stool extraction using the EliA Stool Extraction Kit** (order no. 14-5638-01, 50 tubes). The extraction tubes are pre-filled with 750 µl of EliA Calprotectin Extraction Buffer.

*Extraction procedure:*

1. Unscrew the tube's cap by turning the upper, light blue part of cap to the left and pull out the light blue rod.



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2. Insert the light blue rod into the stool sample. Be sure that the four notches at the lower part of the rod are completely covered with stool. If there is stool at the bottom tip of the rod, strip it off.
3. Insert the rod back into the tube carefully. Excess material will be stripped off, and a defined amount of stool sample will remain in the notches.
4. Lock the tube firmly by turning the light blue part of the cap to the right.
5. Homogenize the stool sample completely using a vortex mixer. In case of very solid stool samples it may help to soak the sample in the tube for 10 minutes before homogenizing it. Make sure that no stool sample stays in the notches. Afterwards incubate for 10 minutes.
6. Centrifuge the EliA Stool Extraction Kit tube for 5 minutes at 3000 x g.
7. Unscrew the complete cap by turning the lower, dark blue part of the cap to the left. Discard complete cap and rod.
8. Transfer the supernatant to a fresh tube.

The supernatant is the extract used for testing. If the EliA Calprotectin test cannot be performed immediately after sample extraction, the extract should be frozen at ≤ −20°C. The extract can be stored at room temperature for max. 6 h, at 4°C for max. 30 h, and at ≤ −20°C for max. 3 months.

**B) Stool extraction using conventional stool extraction devices** which are not prefilled with extraction buffer. We recommend the “Fecal sample preparation kit” by Roche Diagnostics for stool extraction. This kit is available through Thermo Fisher Scientific (order no. 14-5619-01, 50 tubes).

*Extraction procedure:*
1. Weigh the empty extraction device.
2. Transfer approximately 100 mg of homogeneous stool sample to the extraction device.
3. Weigh the transferred amount of stool.
4. Add 50 times the stool weight of EliA Calprotectin Extraction Buffer (e.g. 100 mg stool sample + 5 ml buffer).
5. Lock the tube firmly.
6. Homogenize the sample completely using a vortex mixer. Afterwards incubate for 10 minutes.
7. Transfer 1-2 ml of the homogenate to an Eppendorf tube and centrifuge for 5 minutes at 3000 x g.
8. Transfer the supernatant to a fresh tube.

The supernatant is the extract used for testing. If the EliA Calprotectin test cannot be performed immediately after sample extraction, the extract should be frozen at ≤ −20°C. The extract can be stored at room temperature for max. 6 h, at 4°C for max. 30 h, and at ≤ −20°C for max. 3 months.

### Extract Dilution
Extracts must be diluted with EliA Sample Diluent. A 1:100 dilution of the extracts is required for the EliA Calprotectin test. Extracts can be diluted manually, but instrument dilution is recommended and is a default setting in the software.

## PROCEDURE
### Handling of EliA Calprotectin 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 Calprotectin Well, EliA Calprotectin Calibrator Well and EliA Calprotectin Conjugate. In case of manual handling make sure to enter the characters below the barcode.

### On-board stability of reagents

| | |
|---|---|
| **EliA Calprotectin Well** | 28 days (in Carrier Storage).<br>24 hours (in Carrier Loading Tray). |
| **EliA Calprotectin Calibrator/Curve Control** | 28 days |
| **EliA Calprotectin Conjugate** | Single use.<br>Open vials must not be stored. |
| **EliA Sample Diluent** | 7 days<br>Recap bottles every night. |
| **Development Solution** | 5 days<br>Recap bottles every night. |
| **Stop Solution** | 14 days<br>Recap bottles every night. |
| **Washing Solution** *(prepared solution)* | 7 days<br>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 Calprotectin Conjugate | 90 µl |
| Development Solution | 90 µl |
| Stop Solution | 200 µl |

***Extract volumes per determination***

| | |
|---|---|
| Manual dilution | 90 µl of diluted extract |
| Instrument dilution (1:100) | 20 µl of non diluted extract |

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


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***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 extract diluted by the instrument (1:100), up to 11 determinations can be made.
- When using software default, extracts 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/extracts can be loaded continuously and are processed by random access.
- Incubations are automatically performed at 37°C (98.6°F).

## CALIBRATION AND REFERENCE MATERIAL

The calibration curve is obtained with EliA Calprotectin Calibrators which are run in duplicate. The curve is stored and subsequent tests are evaluated against the stored curve using only the EliA Calprotectin Curve Control (run in duplicate).

**A new calibration curve must be run when:**

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

**There are no international standards for calprotectin. Results are given in mg/kg.**

## 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 calprotectin concentrations in ng/ml. By using a conversion factor given by the lot-specific code of the EliA Calprotectin Well, the results are automatically converted to mg/kg.

**Interpretation of Test Results**

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

| Test | Unit | Negative | Positive |
|---|---|---|---|
| EliA Calprotectin | mg/kg | ≤ 50 | > 50 |

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

Calprotectin is positive in a certain percentage of the normal population, for instance in 25% of subjects between 50 and 70 years of age.[7] This is strongly dependent on age. Calprotectin levels in small children, especially in infants less than one year of age, are higher than in healthy adults.[8] Calprotectin levels show large variations between individual children up to 4 years of age.[8] Expected values may vary depending on the population tested.

**Results Obtained for Healthy Subjects**

The frequency distribution for calprotectin was investigated in a group of apparently healthy subjects equally distributed by age and gender, using stool samples from a Caucasian population. The results are given in the table below.

| Test | Unit | No. of samples | Mean value | 95%-percentile | 99%-percentile |
|---|---|---|---|---|---|
| EliA Calprotectin | mg/kg | 85 | < 15.0 | 27.3 | 43.6 |

## PERFORMANCE CHARACTERISTICS

**Measuring Range**

The measuring range (detection limit, upper limit) for EliA Calprotectin is from 15.0 to ≥ 3000 mg/kg. No hook effects could be observed for concentrations up to 6-fold above the measuring range.

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 ng/ml to mg/kg. Results above the upper limit are reported as “above”.

**Specificity**

The EliA Calprotectin test permits the determination of human calprotectin in stool samples as described in section “Reagents/Material”.

**Precision**

To determine the precision of the assay, the variability was assessed in a study with 21 runs by examining the samples in 252 replicates on 3 instruments over 7 days 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 Calprotectin | 1 | mg/kg | 66.4 | 4.5 | 5.3 |
| | 2 | mg/kg | 184.6 | 2.8 | 5.8 |
| | 3 | mg/kg | 509.4 | 3.3 | 5.8 |



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## 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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| | | | |
|---|---|---|---|
| | 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 | | |

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


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# Revision History

| Version | Countries | Change |
|---|---|---|
| **21** | all, except US | Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "Summary and Explanation of the Test": Insertion of the sentence " Fecal calprotectin levels get affected by nonsteroidal anti-inflammatory drug (NSAID) intake, bleeding more than 100 ml and by malignancy" |
| **21** | UK | Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "Limitations": Deletion of the sentence "Blood in the stool may affect EliA Calprotectin results" |
| **21** | all, except US | Phadia 100, Phadia 250 and Phadia 2500/5000, chapter "References": Insertion of a new literature article (reference number 4) and renumbering of the following references. |
| **22** | all, except US | Harmonization of texts and translations between DfUs/instruments. |
| | | General text improvements throughout the DfU, e.g. changing "sample(s)" to "extract(s)". |
| | | Chapter "Reagents/Material": rephrasing the composition of EliA Calprotectin Conjugates. |
| | | Chapter "Reagents/Material": for Stop Solution (Art. No. 34-2337-11 and Art. No. 10-9479-01), changed storage temperatures to 2–32°C. |
| | | Phadia 100, chapter "Reagents/Material", Detailed reagents, Washing Solution: Delete information on expiry date and additional material provided. |
| | | Phadia 100 and Phadia 250, chapter "Reagents/Material", Dilution Plates: Remove information on plastic material. |
| | | Chapter "Warnings and Precautions": insertion of "Do not use if desiccant bag is missing or foilbag is damaged." |
| | | Chapter "Warnings and Precautions": insertion of "Wear gloves while handling samples and reagents provided." |
| | | Phadia 250 and Phadia 2500/5000, chapter "Instrument": Clarification that the Phadia instrument processes all steps of the test. |
| | | Chapter "Specimen Collection, Handling and Extract Preparation", update of extraction method A. |
| | | Phadia 250 and Phadia 2500/5000, chapter "Procedure": Update and new presentation of On-board stability section. |
| | | Chapter "Expected Values": Updated text. |
| | | Chapter “Performance Characteristics”, Specificity: Updated text. |
| | | Deletion of reference number 7, renumbering of references after that. New literature article reference 8 added. |
| | | Updated symbol table. Link to full symbol glossary inserted. |
| **22** | DE/AT/CH | Merge German language versions (DE, AT, CH) into one German version. |
| **22** | CZ | Correction of Czech translations. |
| | | Chapter "Specimen Collection, Handling and Extract Preparation": Deletion of recommended Faecal sample kit from Roche Diagnostics. |
| | | Chapter “Performance Characteristics”: Insertion of "≥" symbol before the upper limit. |
| | CZ, NL, PL | Chapters "Reagents/Material", "Calculation and Interpretation of Results" and “Performance Characteristics”: Updated unit from ng/l to ng/ml. |
| **22** | BG, FR, IT, NO, PL, PT, SE | Chapter "Reagents/Material": Correction of translations. |
| **22** | GR | Chapter "Specimen Collection, Handling and Extract Preparation", Extract Dilution: Correction of translations. |
| **22** | ES | Chapter "Procedure": Correction of translations. |
| | | Chapter "Reagents/Material", EliA Stool Extraction Kit: Removal of "store dry" from the storage conditions. |
| **22** | DK | Phadia 100, chapter "Quality Control": Added section on Record Keeping. |
| **22** | NO | Phadia 2500/5000, chapter “Performance Characteristics”: Updated precision table. |
| **22** | DK, ES, NL | Chapter “Performance Characteristics”: Correction of translations. |



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