

General Information

Intended use:

Calprotectin Turbilatex is a latex turbidimetric assay for the quantitative detection of calprotectin (hCp) in human stool samples.

This assay is simple and widely applicable. Test results aid in a presumptive diagnosis of IBD patient with inflammation and from irritable bowel syndrome (IBS).

For professional *in vitro* diagnostic use only.

Calprotectin Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions in order to assure performance characteristics as describes in the instructions for use. This instruction has been validated by CerTest BIOTEC S.L. Laboratories.

Additionally, please read the "Instructions for use" for instructions on operating and programming user defined test.

Reagents:

Materials provided by CerTest BIOTEC:

| Reagents | Quantity | Code |
|---|---|---|
| Turbidimetric reagents (R1 & R2) 200 Det/kit | R1: 2 vials, 2x27 mL R2: 1 vial, 1x8 mL | TL-022CP01 TL-022CP02 |
| Auxiliary Reagents | | |
| Calibration kit | Calibrator: 6 vials, 6x1 mL. | TL-022CP70, TL-022CP71 TL-022CP72 TL-022CP73 TL-022CP74 TL-022CP75 |
| Controls kit | Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x 1 mL/vial. | TL-022CP08 TL-022CP09 |
| Sample dilutions vials | 1x2 mL/vial 1x2.4 mL/vial | MST-0018MU MST-0019U |

Preparation of reagents:

R1 and R2 are ready to use.

Calibrators are ready to use.

Controls are ready to use

Storage and stability

Kit components must be stored at temperature indicated on the label. Do not freeze.

Reagents are stable up to the expiration date printed on the label, always considering that reagent containers must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at temperature indicated on the label of each reagent.

Specimen:

Collect enough quantity of human stool samples. These samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20°C. In this case, the sample will be totally thawed, and brought to room temperature (15-30°C) before testing. Freezing and thawing cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8°C) prior to testing.

Use Calprotectin Turbilatex stool collection tubes for sample collections described the instructions for use.

Assay procedure

Application parameter set up:

Specific analyzers settings for Calprotectin Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the ATELLICA (Siemens) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the ATELLICA (Siemens) analyzer manual.

Calibration curve establishment:

A 6 point calibration curve can be established in ATELLICA (Siemens) analyzer. For instructions consult analyzer manual.

Calibration stability:

Calibrate the system at least once a month is extremely recommended. Recalibrate the system when reagent lot is change or when the controls are out of the assigned range given in the control label and CoA.

QC controls:

Calprotectin Turbilatex controls C1 and C2 must be assayed each day before running patient fecal sample extract to validate the calibration curve. The controls have assigned value ranges indicated on the label and certificate of analysis supplied. The control measurements must be within the indicated value range to obtain valid results for patient fecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:

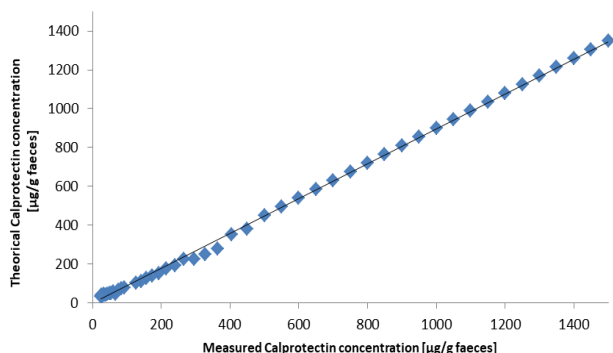
The results are evaluated automatically by the analyzer and presented in µg hCp/g of stool.

Performance characteristics

The following results have been obtained during the validation of Calprotectin Turbilatex on the ATELLICA (Siemens) analyzer.

Linearity:

Calprotectin Turbilatex on ATELLICA (Siemens) analyzer using calibrator kit is linear in the calibration range of 0-1500 µg hCp/g of stool.



Measuring range:

Calprotectin Turbilatex assay measuring range is 20-8000 µg hCp/g of stool on the ATELLICA (Siemens) analyser. Samples higher concentrated than 1500 µg hCp/g of stool must be diluted 1:10 for proper quantification by the user, using additional sample buffer.

Prozone effect

Using the reported parameters, no hook effect was observed up to 8000 µg hCp/g of stool. Samples with calprotectin concentration of 8000 µg hCp/g of stool give a typical positive result >1500 µg hCp/mL.

Detection limit

Limit of detection (LOD): 7 µg hCp/g of stool (*). The lower limit of detection of Calprotectin Turbilatex was determined on 20 samples and 2 sample replicates as the mean value + 2 · SD.

Limit of quantification (LOQ): 20 µg hCp/g of stool (*). The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV% on the ATELLICA (Siemens) analyzer.

(* Data obtained by the analyser Biolis 24i (Tokyo Boeki)

Precision

Calprotectin Turbilatex was tested with three different controls levels.

| | Low (100 µg/g) | Medium (750 µg/g) | High (1500 µg/g) |
|-------------|-------------------|----------------------|---------------------|
| N | 6 | 6 | 6 |
| Mean (µg/g) | 90.7 | 791.5 | 1512.7 |
| SD (µg/g) | 2.4 | 10.6 | 12 |
| CV (%) | 3 | 1 | 1 |

Method comparison











Results obtained with Calprotectin Turbilatex on the analyser Biolis 24i (Tokyo Boeki) were compared with a commercial immunoassay (Calprest®, Eurospital).

| | Sensitivity | Specificity |
|--------------------------------------|-------------|-------------|
| Calprotectin Turbilatex vs Calprest® | 94% | >99% |

Shipping damage

Please notify your distributor, if this product was received damaged.

Symbols key

| | | | |
|---|----------------------------------|---|------------------------|
|  | For in vitro diagnostic use only |  | Keep dry |
|  | Consult instructions for use |  | Temperature limitation |
|  | Catalogue number |  | Lot number |
|  | Use by |  | Manufacturer |
|  | Contains sufficient for <n> test | DIL | Sample diluent |
|  | Keep out of the sunlight | | |

Manufacturer

CERTEST BIOTEC

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San Mateo de Gállego, Zaragoza (SPAIN)
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NOTES

Please refer to the instruction for use for the detailed information about the test on the following:

Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.

ATELLICA (Siemens) / Application parameters

| ASSAY PARAMETERS | |
|-------------------------|--------------------------|
| Std. No | 6 |
| R1 | 100 µL |
| Sample | 6 µL |
| R2 | 15 µL |
| Others | Dilution 1:2 |
| Reaction mode | Endpoint (EPA) |
| Primary wavelength | 451 nm |
| Secondary wavelength | None |
| Direction | Increase |
| Main Start Time | 312 |
| Main End Time | 552 |
| Linear range | 0-1500 µg/g |
| CALIBRATION | |
| Calibration Method | Multi Linear |
| Calibration set | 6 calibrators |
| Blank | Calibrator 1 (0 µg/g) |
| Calibrator 1 | Calibrator 2 (50 µg/g) |
| Calibrator 2 | Calibrator 3 (100 µg/g) |
| Calibrator 3 | Calibrator 4 (250 µg/g) |
| Calibrator 4 | Calibrator 5 (750 µg/g) |
| Calibrator 5 | Calibrator 6 (1500 µg/g) |
| STEPS | |
| Addition R1 | 0 s |
| Addition Sample | 12 s |
| Incubation | 273 s |
| Addition R2 | |
| Blank Lecture | 312 s |
| Incubation | |
| Final lecture | 552 s |