

General Information

Intended use:

Calprotectin Turbilatex[®] Combo is a latex turbidimetric assay only for the quantitative detection of calprotectin in human stool samples (not to be used for body fluid as blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid).

This assay is simple and widely applicable. This product is optimized for several automated analyser.

For professional in vitro diagnostic use only.

Reagents:

Materials provided by CerTest Biotec:

| Reagents | Code | | |
|------------------------------|-------------|--|--|
| Turbidimetric reagents (R1 & | TL-022CP01 | | |
| R2) | TL-022CP02 | | |
| Auxiliary Reagents | | | |
| | TL-022CP70, | | |
| | TL-022CP71 | | |
| | TL-022CP72 | | |
| Calibration kit | TL-022CP73 | | |
| | TL-022CP74 | | |
| | TL-022CP75 | | |
| Controls kit | TL-022CP08 | | |
| | TL-022CP09 | | |
| Sample dilutions vials | 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 solid 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. If not immediately tested, freeze the stored samples at -20 °C maximum 6 months. In this case, the sample will be totally thawed and brought to room temperature (15-30°C) before

testing. Homogenize stool samples as thoroughly as possible prior to preparation.

Use **Calprotectin Turbilatex**[®] **Combo** stool collection tubes for sample collections described the instructions for use.

Assay procedure

Calprotectin Turbilatex[®] **Combo** 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. Application parameter set up:

Specific analyzers settings for **Calprotectin Turbilatex**[®] **Combo** must be programmed onto the analyzer, see below. For instructions, consult the AU480/AU680 (Beckman Coulter) analyzer manual and instructions for use provided with the kit. **Loading of reagents:**

Load reagents according to the AU480/AU680 (Beckman Coulter) analyzer manual.

Calibration curve establishment:

A 6-points calibration curve can be established in AU480/AU680 (Beckman Coulter) 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[®] **Combo** 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 μ g hCp/g of stool.

Calprotectin Turbilatex Combo, AU480/AU680, Beckman Coulter (AN-CP-AU480/AU680 .EN rev 2025.02.20)

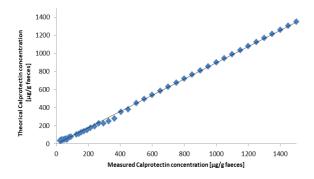


Performance characteristics (*)

The following results have been obtained during the validation of **Calprotectin Turbilatex® Combo** on the AU480/AU680 (Beckman Coulter) analyzer.

Linearity:

Calprotectin Turbilatex[®] **Combo** using calibrator kit is linear in the calibration range of 36-1500 µg hCp/g of stool.



Measuring range:

Calprotectin Turbilatex[®] **Combo** assay measuring range is 20-3125 µg hCp/g of stool. Samples more concentrated than 1500 µg hCp/g of stool must be diluted for proper quantification by the user, using additional sample buffer.

Prozone effect:

Studies have been made up to a concentration of 25000 μ g of hCp/g of stool and no false negative results have been observed. Studies using higher concentrations have not been carried out.Samples with concentrations up to 3125 μ g of hCp/g can be measured without inhibitory prozone effect.

Detection limit:

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

Limit of quantification (LOQ): $20 \ \mu g \ hCp/g$ 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%.

Precision:

Calprotectin Turbilatex was tested with three different controls levels.

| | Low (50 µg/g) | Medium (200 µg/g) | High (750 μg/g) |
|-------------|------------------|----------------------|--------------------|
| | (50 µg/g) | (200 µg/g) | (7 50 µg/g) |
| N | 20 | 20 | 20 |
| Mean (µg/g) | 51.7 | 208.1 | 765.8 |
| SD (µg/g) | 2.6 | 9.2 | 27.2 |
| CV (%) | 5 | 4 | 4 |

F-549 rev01 Page 2 of 3

Method comparison

The following tables provide information on the summary of the evaluations that have been carried out on the product **Calprotectin Turbilatex**[®] **Combo** with a cut-off of 50 µg of hCp/q of stool:

| Calprotectin Turbilatex® vs Evaluation criteria | | | |
|---|------------|-------------------------|--|
| | Mean Value | 95% confidence interval | |
| Sensitivity | 96.8% | 92.7-99.0% | |
| Specificity | 91.4% | 86.7-94.8% | |
| PPV | 89.3% | 83.7-93.6% | |
| NPV | 97.4% | 94.1-99.2% | |
| LR+ | 11.24 | 7.22-17.49 | |
| LR- | 0.035 | 0.015-0.083 | |

Shipping damage

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

Symbols key

| IVD | For in vitro diagnostic use only | Ť | Keep dry |
|-----|--|-----|------------------------|
| Ĩ | Consult instructions for use | X | Temperature limitation |
| REF | Catalogue number | LOT | Lot number |
| | Use by | AAA | Manufacturer |
| ∑ n | Contains sufficient for <n> test</n> | DIL | Sample diluent |
| 淤 | Keep out of the sunlight | | |

Manufacturer

CERTEST BIOTEC

Pol. Industrial Río Gállego II,Calle J, Nº 1, 50840, San Mateo de Gállego, Zaragoza (SPAIN) www.certest.es

NOTES

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

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

(*) Analytical performance data were obtained with the Biolis 24 i(Tokyo Boeki) analyser.



AU480/AU680, Beckman Coulter/ Application parameters

| Sample Cartering Constraints of the second s | ASSAY PARAMETERS | |
|--|-------------------------------|--------------------------|
| Sample2.5 µLR2(15 µL)Others(N/A)Reaction modeEnd pointPrimary wavelength(16 m)Secondary wavelength(16 m)Secondary wavelength(16 m)Direction(16 m)Direction(16 m)Reagent blank lecture (cycle)(16 m)Final lecture (cycle)(16 m)Reaction time(16 m)Linear range(16 m)Calibration Method(16 m)Calibration set5 calibrators + BlankBlank(Calibrator 0 (0 µg/g))Calibrator 1(16 m)Calibrator 2(20 m)/gg)Calibrator 3(Calibrator 1 (50 µg/g))Calibrator 4(750 µg/g)Calibrator 5(Calibrator 3 (250 µg/g))Calibrator 5(Calibrator 5 (1500 µg/g))Calibrator 4(750 µg/g)Calibrator 5(20 m)STEPS(20 m)Addition R1(12 m)Addition R2(12 m)Blank Lecture(Cycle 11Incubation reactionclose to 300 sec | Std. No | 6 |
| R215 µLOthers15 µLOthersN/AReaction modeEnd pointPrimary wavelength600 nmSecondary wavelength800 nmDirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µd/gCalibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µd/g)Calibrator 1Calibrator 1 (50 µd/g)Calibrator 2Calibrator 1 (50 µd/g)Calibrator 3Calibrator 3 (250 µd/g)Calibrator 4Calibrator 5 (1500 µd/g)Calibrator 5Calibrator 4 (750 µd/g)Calibrator 5Calibrator 5 (1500 µd/g)STEPSIncreaseAddition R1120-180 sAddition R2120-180 sBank LectureCalibrator 6 (1500 µd/g) | R1 | 125 µL |
| OthersN/AReaction modeEnd pointPrimary wavelengthEnd pointSecondary wavelength800 nmDirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONClibrator 3Calibration MethodLinearCalibration set5 calibrators + BlankBankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 1 (50 µg/g)Calibrator 4Calibrator 1 (50 µg/g)Calibrator 5Calibrator 3 (250 µg/g)Calibrator 5Calibrator 3 (250 µg/g)Calibrator 5StepsAddition R1Addition Sample120-180 sAddition R2Blank LectureCycle 11Incubation reactionClose to 300 sec | Sample | 2.5 μL |
| Reaction modeEnd pointPrimary wavelength450 nmSecondary wavelength800 nmDirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONCalibratorCalibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 1 (50 µg/g)Calibrator 4Calibrator 1 (50 µg/g)Calibrator 5StepsSTEPSCalibrator 5 (1500 µg/g)Addition R1100Addition R1+S120-180 sAddition R2120-180 sBlank LectureCycle 11Incubation reactionclose to 300 sec | R2 | 15 µL |
| Primary wavelength450 nmSecondary wavelength800 nmDirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONCalibrator 1Calibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 1 (50 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)Calibrator 6Calibrator 5 (1500 µg/g)Calibrator 7Calibrator 3 (250 µg/g)Calibrator 8Madition 81Addition 81120-180 sAddition R1+S120-180 sAddition R2Incubation R2Biank LectureCycle 11Incubation reactionclose to 300 sec | Others | N/A |
| Secondary wavelength800 nmDirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONCalibrators + BlankCalibration MethodLinearCalibrator 1Calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 1 (50 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 4 (750 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)Calibrator 6120-180 sAddition R1120-180 sAddition R2120-180 sBank LectureCycle 11Incubation reactionclose to 300 sec | Reaction mode | End point |
| DirectionIncreaseReagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATION1000000000000000000000000000000000000 | Primary wavelength | 450 nm |
| Reagent blank lecture (cycle)11 cycleFinal lecture (cycle)27 cycleReaction timeclose to 10 minLinear rangeclose to 10 minCalibrator nage36-1500 µg/gCALIBRATIONCalibrators + BlankCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 2 (100 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)STEPSAddition SampleIncubation R1+SAddition R2Bank LectureCalibrator 100 µg/g)Calibrator 2Culor 100 µg/g)Calibrator 1Culor 100 µg/g)Calibrator 3Culor 100 µg/g)Calibrator 4Culor 100 µg/g)Calibrator 5Culor 100 µg/g)Calibrator 6Culor 100 µg/g)Culor 7Culor 100 µg/g)Culor 8Culor 100 µg/g)Culor 8Culor 100 µg/g)Culor 9Culor 100 µg/g)Culor 9 <t< td=""><td>Secondary wavelength</td><td>800 nm</td></t<> | Secondary wavelength | 800 nm |
| Final lecture (cycle)27 cycleReaction time27 cycleReaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONCalibratonCalibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 2 (100 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)STEPSStepsAddition R1120-180 sAddition R2120-180 sBank LectureCycle 11Incubation reactionClose to 300 sec | Direction | Increase |
| Reaction timeclose to 10 minLinear range36-1500 µg/gCALIBRATIONCalibratonCalibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 3Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)STEPSStepsAddition R1120-180 sAddition R2120-180 sBlank LectureCycle 11Incubation reactionclose to 300 sec | Reagent blank lecture (cycle) | 11 cycle |
| Linear range 36-1500 µg/g CALIBRATION Calibration Method Linear Calibration set 5 calibrators + Blank Blank Blank Calibrator 1 (50 µg/g) Calibrator 1 (50 µg/g) Calibrator 2 (100 µg/g) Calibrator 2 (100 µg/g) Calibrator 3 (250 µg/g) Calibrator 3 (250 µg/g) Calibrator 4 (750 µg/g) Calibrator 5 (1500 µg/g) Calibrator 5 (1500 µg/g) STEPS Addition R1 Addition R1 Addition R1+S Addition R2 Blank Lecture (1) (1) (1) (1) (1) (1) (1) (1) (1) (1) | Final lecture (cycle) | 27 cycle |
| CALIBRATIONCalibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSAddition R1Addition R1120-180 sAddition R2SBlank LectureCycle 11Incubation reactionclose to 300 sec | Reaction time | close to 10 min |
| Calibration MethodLinearCalibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)STEPSCalibrator 5 (1500 µg/g)Addition R1120-180 sAddition R1+S120-180 sAddition R2Calibrator 2 (200 µg/g)Blank LectureCycle 11Incubation reactionClose to 300 sec | Linear range | 36-1500 µg/g |
| Calibration set5 calibrators + BlankBlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 2Calibrator 1 (50 µg/g)Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 4 (750 µg/g)STEPSStepsAddition R1Calibrator 5 (1500 µg/g)Addition R1+S120-180 sAddition R2StepsBlank LectureCycle 11Incubation reactionclose to 300 sec | CALIBRATION | |
| BlankCalibrator 0 (0 µg/g)Calibrator 1Calibrator 0 (0 µg/g)Calibrator 1Calibrator 1 (50 µg/g)Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSAddition R1Addition R1+S120-180 sAddition R2Blank LectureCycle 11Incubation reactionClose to 300 sec | Calibration Method | Linear |
| Calibrator 1Calibrator 1 (50 µg/g)Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSAddition R1Addition Sample120-180 sIncubation R1+S120-180 sAddition R2Cycle 11Blank LectureCycle 300 sec | Calibration set | 5 calibrators + Blank |
| Calibrator 2Calibrator 2 (100 µg/g)Calibrator 3Calibrator 2 (100 µg/g)Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSCalibrator 5 (1500 µg/g)Addition R1Calibrator 5 (1500 µg/g)Addition R1+S120-180 sAddition R2Calibrator 5 (1500 µg/g)Blank LectureCycle 11Incubation reactionclose to 300 sec | Blank | Calibrator 0 (0 µg/g) |
| Calibrator 3Calibrator 3 (250 µg/g)Calibrator 4Calibrator 3 (250 µg/g)Calibrator 5Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSAddition R1Addition Sample120-180 sIncubation R1+S120-180 sAddition R2Cycle 11Incubation reactionclose to 300 sec | Calibrator 1 | Calibrator 1 (50 µg/g) |
| Calibrator 4Calibrator 4 (750 µg/g)Calibrator 5Calibrator 5 (1500 µg/g)STEPSCalibrator 5 (1500 µg/g)Addition R1Addition SampleIncubation R1+S120-180 sAddition R2Calibrator 8 (120-180 s)Blank LectureCycle 11Incubation reactionclose to 300 sec | Calibrator 2 | Calibrator 2 (100 µg/g) |
| Calibrator 5Calibrator 5 (1500 μg/g)STEPSAddition R1Addition SampleIncubation R1+SAddition R2Blank LectureIncubation reaction | Calibrator 3 | Calibrator 3 (250 µg/g) |
| STEPSAddition R1Addition SampleIncubation R1+SAddition R2Blank LectureIncubation reactionClose to 300 sec | Calibrator 4 | Calibrator 4 (750 µg/g) |
| Addition R1Addition R1Addition Sample1000000000000000000000000000000000000 | Calibrator 5 | Calibrator 5 (1500 µg/g) |
| Addition SampleIncubation R1+SAddition R2Blank LectureIncubation reaction | STEPS | |
| Incubation R1+S120-180 sAddition R2Cycle 11Blank LectureCycle 11Incubation reactionclose to 300 sec | Addition R1 | |
| Addition R2Blank LectureIncubation reactionClose to 300 sec | Addition Sample | |
| Blank Lecture Cycle 11 Incubation reaction close to 300 sec | Incubation R1+S | 120-180 s |
| Incubation reaction close to 300 sec | Addition R2 | |
| | Blank Lecture | Cycle 11 |
| Final lecture Cycle 27 | Incubation reaction | close to 300 sec |
| | Final lecture | Cycle 27 |