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 S.L.:

Reagents	Quantity	Cat. reference
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x27 mL. R2: 1 vial, 1x8 mL.	TL-022CP01 TL-022CP02
Auxiliary Reagents	**Quantity**	**Cat. reference**
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, 2x1mL/vial.	TL-022CP08 TL-022CP09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022CP03E
Sample dilutions vials	1x2 mL/vial 1x2 mL/vial	MST-0006MC MST-0008C

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 (2-8ºC) for 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20ºC. In this case, the sample will be totally thawed, and brought to room temperature (15-30ºC) before testing. Freezing and thawing cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

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 Cobas c501 (Roche) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Cobas c501 (Roche) analyzer manual.

Calibration curve establishment:

A 6-points calibration curve can be established in Cobas c501 (Roche) 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.
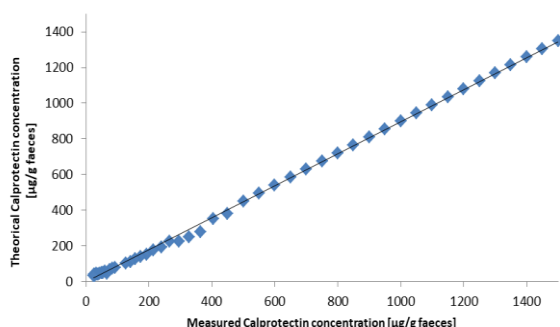
Performance characteristics

The following results have been obtained during the validation of Calprotectin Turbilatex on the Cobas c501 (Roche) analyzer.

Linearity:
Calprotectin Turbilatex on Cobas c501 (Roche) 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 Cobas c501 (Roche) analyzer. Samples higher concentrated than 1500 µg hCp/g of stool must be diluted for proper quantification.

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/g.

Detection limit
Limit of detection (LOD): 15 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 Cobas c501 (Roche) analyzer.

Precision
Calprotectin Turbilatex was tested with three different controls levels.

	Low (50 µg/g)	Medium (100 µg/g)	High (750 µg/g)
N	20	20	20
Mean (µg/g)	49.5	101.1	749.8
SD (µg/g)	2.4	3.9	18.9
CV (%)	4.8	3.8	2.5

Method comparison

Results obtained with Calprotectin Turbilatex on the Cobas c501 (Roche) analyzer were compared with a commercial immunoassay (Calprest®, Eurospital).

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

Shipping damage
Please notify your distributor, it this product was received damaged.

Symbols key

IVD	For *in vitro* diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
REF	Catalogue number	LOT	Lot number
	Use by		Manufacturer
Σ n	Contains sufficient for <n> test	DIL	Sample diluent
	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.

Final lecture

Cobas c501, Roche /Application parameters

Test information:

Std. No	6
R1	180 µl
Sample	5 µl
R2	20 µl

Reaction parameters:

Reaction type	Endpoint
Primary Wavelenght	480 nm
Secondary Wavelenght	800 nm
Direction	Increase
Reagent Blank Lecture	12 cycle
Final Lecture	47 cycle
Reaction Time	10 min
Linear range	0-1500 µg/g

Calibration	Linear
Calibrator 0	0 µg/g
Calibrator 1	50 µg/g
Calibrator 2	100 µg/g
Calibrator 3	250 µg/g
Calibrator 4	750 µg/g
Calibrator 5	1500 µg/g

Steps:

Addition R1
Addition Sample
Incubation 5 min
Addition R2
Blank Lecture
Incubation 5 min

Application Note
Calprotectin Turbilatex, Cobas c501, Roche
(AN-Cp-Cobas c501.EN rev 2019.01.11)

For *in vitro* diagnostic device
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Cobas Module c501
July 2018

Instrument Settings

Analyse	Calibration	Range	Others

Assay/Time/Point	2 Point End	10		12	47	0	0

Wave (2nd/Primary) | 800 nm | 480 nm

Sample volume

S.vol (Normal)	5.0	0.0	0
S.vol (Decrease)	5.0	0.0	0
S.vol (Increase)	5.0	0,0	0

Cassette Configuration

Code	xxxx
Expiration days	30

√	Water		
	Diluent	0	1

Reagent (R1) A	180	0	inactive
Reagent (R2)	20	0	
Reagent (R3)	0	0	

Linearity Limit	0	%	0	%	0	0

Prozone Limit	0	0	0	0	0	0	Inside	▼	0	0

Abs Limit	0	Decrease	▼

Cell Detergent	Detergent 1	▼	Stirring Level	1

Stirring setting

		M1	M2	M3	
UP	stirring ▼	LOW	stirring ▼	stirring ▼	stirring ▼

Analyse	Calibration	Range	Others

Calibration type	Spline	▼

AutoCalibration

▼ Time Calibration

Cassette		▼
	30	days

	Point	6
	Span	6
	Weight	0

Update	None	▼	0	0

SD Limit	999	999
Duplicate Limit	99 %	3200 %
Sensitivity Limit	-99999	99999
S1Abs Limit	-32000	32000

Application Note
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Cobas Module c501
July 2018

Analyze	Calibration	Range	Others

Application Code		
Report Name	Calprotectin Turbilatex	
Data Mode	Active	
Control Interval	0	

Automatic Rerun	√	
Technical Limit	-99999	999999
Repeat Limit	-99999	999999

Expected Values

(Male)	99	Year	-99999	999999
	100	Year	-99999	999999
			-99999	999999
(Female)	99	Year	-99999	999999
	100	Year	-99999	999999
(Default)			-99999	999999
	Male		Range1	

Analyze	Calibration	Range	Others

Calib Code	902*	903*	904*	905*	906*	907*
Concentration	0.0	50	100	250	750	1500
Position	0*	0*	0*	0*	0*	0*

* Calibration Code and Position chosen by user

Sample Volume	5.0	5.0	5.0	5.0	5.0	5.0
Diluted S.Vol	0.0	0.0	0.0	0.0	0.0	0.0
Diluent Volume	0.0	0.0	0.0	0.0	0.0	0.0

Bottle Setting

Cassette Type   A
Bottle

A	R1 ▼	80	15.6
B	R2 ▼	80	1.7
C	Cancel ▼	0	0.0