

Application Note**Calprotectin Turbilatex, ATELLICA, Siemens**
(AN-Cp-ATELLICA.EN rev 2020.04.07)For *in vitro* diagnostic device
ENGLISH**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)	R1: 2 vials, 2x27 mL	TL-022CP01
200 Det/kit	R2: 1 vial, 1x8 mL	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, 2x1mL/vial. Control C2, 2 vials, 2x 1 mL/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 (2-8°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.

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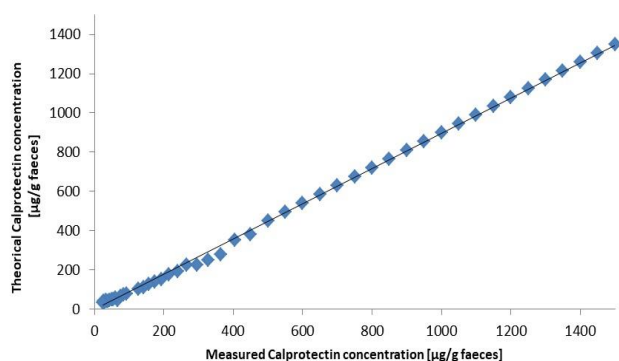


Performance characteristics

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) analyzer. 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): 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 ATELLICA (Siemens) analyzer.

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 ATELLICA (Siemens) analyzer 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 <i>in vitro</i> 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

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

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.

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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 (1500µg/g)
STEPS	
Addition R1	0 s
Addition Sample	12 s
Addition R2	273 s

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SIEMENS Healthineers Atellica® Solution Version 1.18.0.3241002SP2

System Samples Inventory Calibration QC Patient Orders Worklist Maintenance Setup

Test Definition Settings Accounts Result Monitor

Assay List

CH Test Definition

IM Test Definition

Ratios, Panels, and Off-System

Test Display Order

Open Channel

Sort Test Definition

Assay

XADA

XCH1

XCHE

XcheS

XCKMB

XFERN

XFERR

XG6PD

XG6RD

XHCS

XLAC

XMYO

XnG6rDz

XIHb

XZINC

XcalpNd

XCALP

It is the operator's responsibility to validate any modifications made to the instructions, systems, reagents, or software provided by Siemens Healthineers. Available Channels 5

Definition	Sample/Reagent	Calculation	Calibration	Mitigation	
R1 Reagent Time: 0 seconds	Component 1 Volume [Well 1] R1 100 µL	Component 2 Volume [Well 2] 0 µL	Diluent Volume 0 µL	Total Volume 100 µL	Mix Moderate
Sample Time: 12 seconds	6 µL			6 µL	
R2 Reagent Time: 273 seconds	R2 15 µL	0 µL	0 µL	15 µL	Moderate
				Total Volume 121 µL	

Select Reagent: XcalpNd

Test Count: 110

Life (hours): 1440

Onboard Life: 1440 (hours)

Use Well 2

Well 1

Well 2

Pack 1 Volume

Pack 2 Volume

Well 1 : 14.63 mL

Well 2 : 0 mL

Well 1 : 4.48 mL

Well 2 : 0 mL

R1

Empty

R2

Empty

Create New Copy Modify Existing Delete Assay Discard Changes Save Changes

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Calibration Results Details for XcalpNd on CH

Information

Activity: Reagent Lot Calibration
 Assay: XcalpNd
 Units: ng/mL
 Calculation Type: Logit3
 Ordered Date: 5/8/2019 11:59:27 AM
 Completed Date: 5/8/2019 12:18:48 PM
 Accepted By: CSE: G2
 Analyzer Name: CH
 Analyzer Serial Number: CM00434
 Reagent Lot: 123456
 Pack/Well: 00270:Well 1
 Ancillary 1:
 Ancillary 1 Lot/Pack:
 Ancillary 2:
 Ancillary 2 Lot/Pack:
 Calibrator Name: CALP-CAL
 Calibrator Lot: 022CP01
 Cal Status: Valid
 Acceptance Criteria: OK
 Acceptance Mode: Manual
 Trigger Mode: Operator Initiated
 Cal Expiration: 7/19/2019 12:03:49 PM

Coefficients

C0: C5
 C1: C6
 C2:
 C3:
 C4:

Data

1 (L)					2 (H)					3				
Replicate	Include	Analyte	Signal	Flag	Include	Analyte	Signal	Flag	Include	Replicate	Include	Analyte	Signal	Flag
Replicate 1	<input checked="" type="checkbox"/>		-0.44		<input checked="" type="checkbox"/>		4.85		<input checked="" type="checkbox"/>					
Replicate 2	<input checked="" type="checkbox"/>		-0.57		<input checked="" type="checkbox"/>		3.08		<input checked="" type="checkbox"/>					
Replicate 3	<input checked="" type="checkbox"/>		-3.69		<input checked="" type="checkbox"/>		4.06		<input checked="" type="checkbox"/>					
Mean														
Median														
SD														
Observed %CV														

QC Performed with Calibration

QC	QC Limits	New Observed	Old Observed

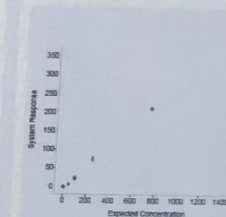
Acceptance Criteria

Criteria	Result	Value	Expected	Observed
No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5
No flags or comments	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5

Comments

Edit

Graph



Curve Shape

ΔA.1 358.08
 ΔA.5 140.63
 ΔA.5/ΔA.1 0.41

Statistics

Slope NaN
 Intercept NaN
 Corr. Coefficient NaN

Enlarge

Print

Accept

Reject

Close



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