Application Note

Calprotectin Turbilatex, Architect c1000/c4000/ c8000, Abbott

(AN-Cp-Architect.EN rev 2019.05.28)

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) 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 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.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8ºC) 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 Architect c1000 (Abbott) analyzer manual and instructions for use provided with the kit.

Loading of reagents:
Load reagents according to the Architect c1000 (Abbott) analyzer manual.

Calibration curve establishment:
A 6 point calibration curve can be established in Architect c1000 (Abbott) 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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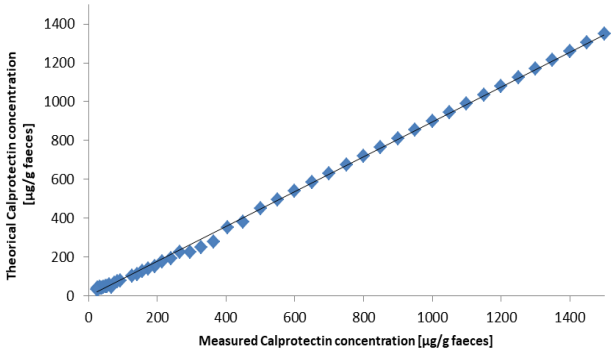
Performance characteristics

The following results have been obtained during the validation of Calprotectin Turbilatex on the Architect c1000 (Abbott) analyzer.

Linearity:
Calprotectin Turbilatex on Architect c1000 (Abbott) 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 Architect c1000 analyser. Samples higher concentrated than 1500 µg hCp/g of stool must be diluted 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 Architect c1000 (Abbott) analyzer.

Precision
Calprotectin Turbilatex was tested with three different controls levels.

	Low (20 µg/g)	Medium (80 µg/g)	High (250 µg/g)
N	20	20	20
Mean (µg/g)	21.4	81.7	255.6
SD (µg/g)	2.8	9.7	18.3
CV (%)	13	12	7

Method comparison

Results obtained with Calprotectin Turbilatex on the Architect c1000 (Abbott) 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 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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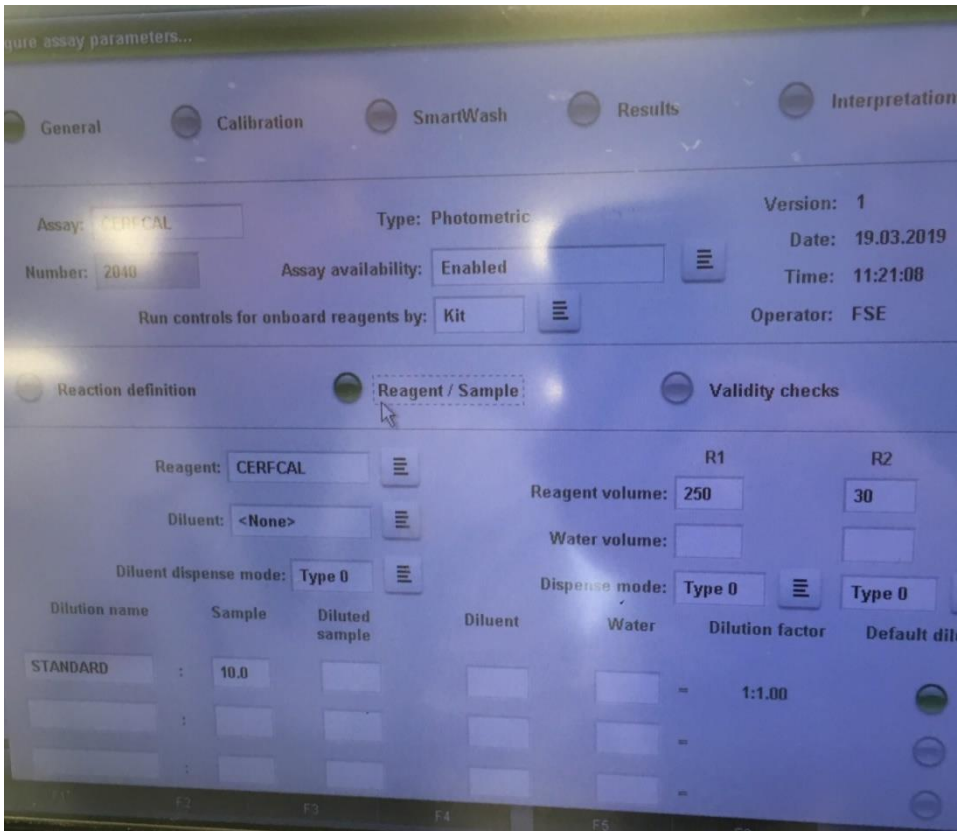
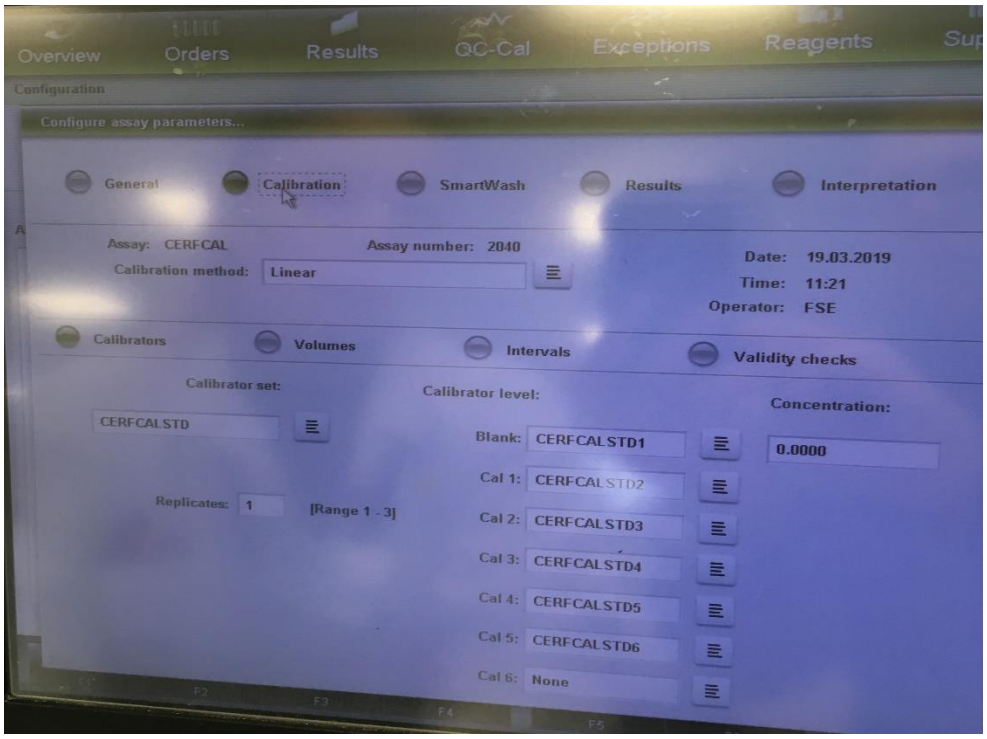
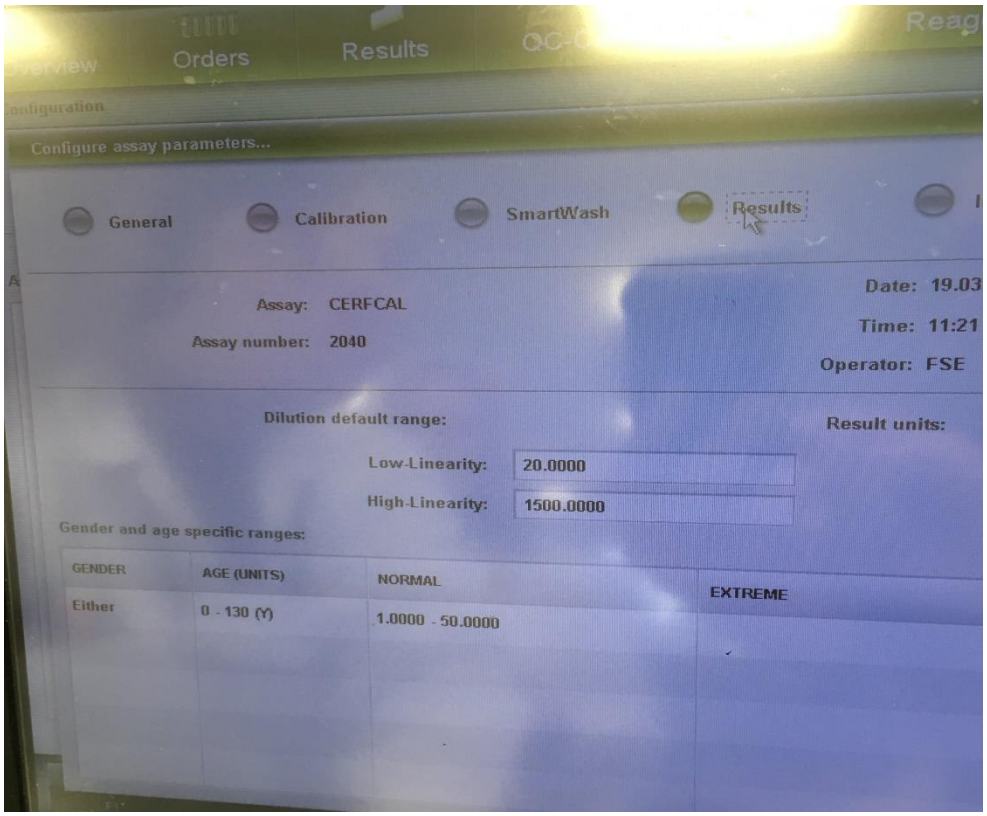
The parameters optimized for Architect c1000 might be applied for Architect c4000 and Architect c8000

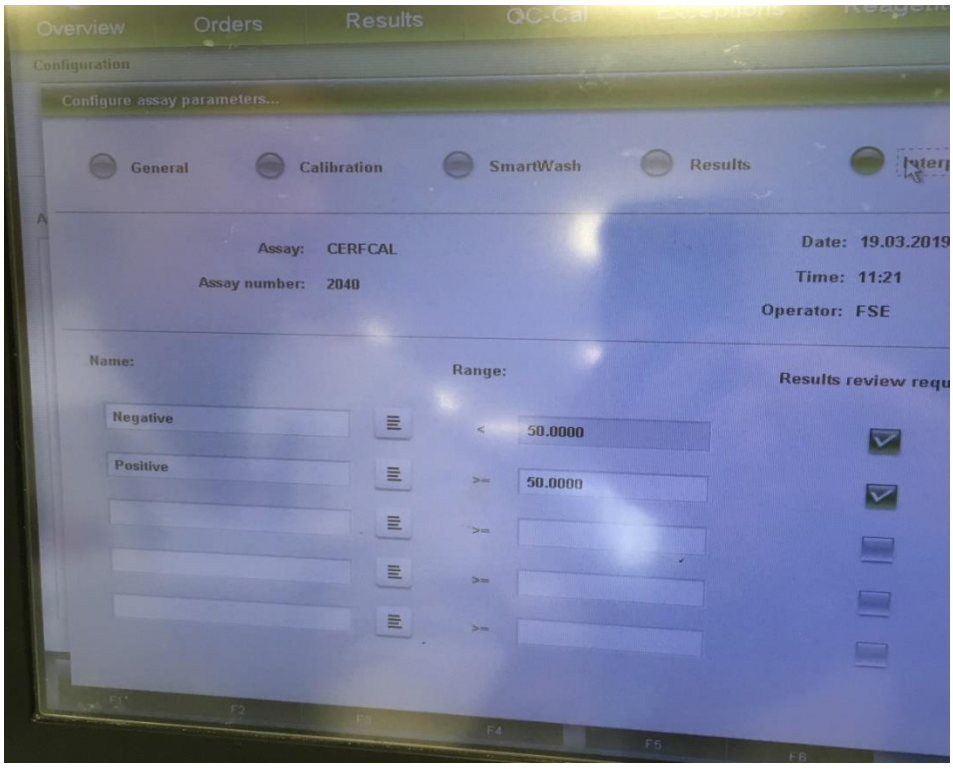
Architect c1000 (Abbot) / Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	250 µL
Sample	10 µL
R2	30 µL
Others	NA
Reaction mode	End up
Primary wavelength	476 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture	19 cycle
Final lecture	24-25 cycle
Linear range	0-1500 µg/g
CALIBRATION	
Calibration Method	Linear
Calibration set	5 calibrators + Blank
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)


General
Calibration
SmartWash
Results
Interpretation
Assay: CERFCAL
Type: Photometric
Version: 1
Number: 2040
Assay availability: Enabled
Date: 19.03.2019
Time: 11:21:08
Run controls for onboard reagents by: Kit
Operator: FSE
Reaction definition
Reagent / Sample
Validity checks
Reagent: CERFCAL
Diluent: <None>
Diluent dispense mode: Type 0
R1
R2
Reagent volume: 250
30
Water volume:
Dispense mode: Type 0
Type 0
Dilution name
Sample
Diluted sample
Diluent
Water
Dilution factor
STANDARD
10.0
1:1.00


Overview
Orders
Results
QC-Cal
Exceptions
Reagents
Configuration
Configure assay parameters...
General
Calibration
SmartWash
Results
Interpretation
Assay: CERFCAL
Assay number: 2040
Calibration method: Linear
Date: 19.03.2019
Time: 11:21
Operator: FSE
Calibrators
Volumes
Intervals
Validity checks
Calibrator set:
Calibrator level:
Concentration:
CERFCALSTD
Blank: CERFCALSTD1
0.0000
Cal 1: CERFCALSTD2
Replicates: 1
[Range 1 - 3]
Cal 2: CERFCALSTD3
Cal 3: CERFCALSTD4
Cal 4: CERFCALSTD5
Cal 5: CERFCALSTD6
Cal 6: None


Orders
Results
Configure assay parameters...
General
Calibration
SmartWash
Results
Assay: CERFCAL
Assay number: 2040
Date: 19.03
Time: 11:21
Operator: FSE
Dilution default range:
Result units:
Low-Linearity: 20.0000
High-Linearity: 1500.0000
Gender and age specific ranges:
GENDER
AGE (UNITS)
NORMAL
EXTREME
Either
0 - 130 (Y)
1.0000 - 50.0000


Overview
Orders
Results
Configuration
Configure assay parameters...
General
Calibration
SmartWash
Results
Assay: CERFCAL
Assay number: 2040
Date: 19.03.2019
Time: 11:21
Operator: FSE
Name:
Range:
Results review requ
Negative
< 50.0000
Positive
>= 50.0000