

General Information

Intended use:

CRP Turbilatex® is a latex turbidimetric assay **only for the quantitative detection of C-reactive protein in human serum samples** (not to be used for body fluid as whole blood or plasma).

This assay is indicated to evaluate the amount of C-reactive protein in serum samples.

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

For professional *in vitro* diagnostic use only.

CRP Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions to assure performance characteristics as describes in the Application Note. This instruction has been validated by CerTest Biotec S.L.

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, 2x22 mL	TL-022CR01
	R2: 1 vial, 1x12 mL	TL-022CR02
Auxiliary Reagents		
Calibration kit	Calibrator: 3 vials, 3 x 0,3 mL	TL-022CR70 TL-022CR72 TL-022CR73
Controls kit	Control C2, 1 vials, 1x0,5 mL/vial.	TL-022CR09

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 blood samples. These samples should be collected in clean and dry normal

extraction tubes (no preservatives or additives). The samples must be centrifugated to remove blood cells and plasma and get the serum. Serum samples can be directly analyzed or stored in the refrigerator (2-8°C) for 7 days prior to testing.

Extraction tube can be directly introduced in the analyzer after centrifugation.

Assay procedure

Application parameter set up:

Specific analyzers settings for CRP Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the BS-200/200E/240 (Mindray) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the BS-200/200E/240 (Mindray) analyzer manual.

Calibration curve establishment:

A 3 point calibration curve can be established in BS-200/200E/240 (Mindray) 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 changed or when the controls are out of the assigned range given in the control label and CoA.

QC controls:

CRP Turbilatex control 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:

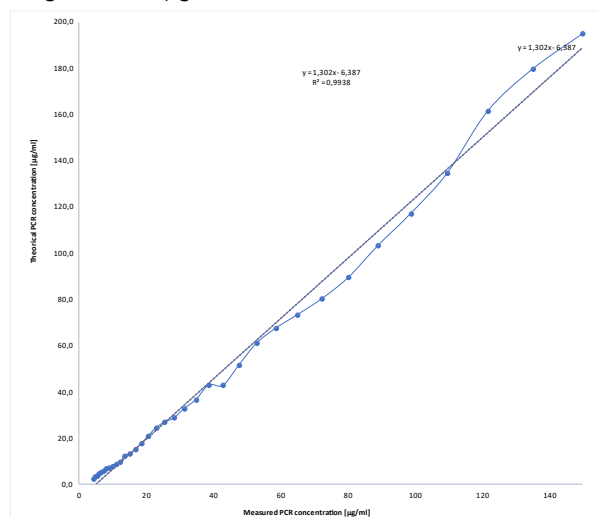
The results are evaluated automatically by the analyzer and presented in µg C-Protein reactive/mL of serum.

Performance characteristics

The following results have been obtained during the validation of CRP Turbilatex.

Linearity:

CRP Turbilatex using calibrator kit is linear in the calibration range of 4-150 µg /mL of serum.



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

Measuring range:

CRP Turbilatex assay measuring range is 4-150 µg /mL of serum.

Prozone effect:

Using the reported parameters, no hook effect was observed in values lower than 640 µg /mL of serum because we have not found in any of the dilutions made an antigen concentration that give us a false negative (below our cut-off).

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

Detection limit:

Limit of detection (LOD): 0.1 µg /mL of serum. A dilution with four times LoB concentration antigen is made. This concentration is measured for twenty times and mean, and standard deviation is calculated. LoD is calculated as follows:

$$\text{LoD} = \text{LoB} + 1.645 * \text{SD}$$

Limit of quantification (LOQ): 1.0 µg /mL of serum. The limit of quantification is defined as the lowest concentration whose CV is less than 20%.

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

Precision:

CRP Turbilatex was tested with three different controls levels.

	Low (20 µg/mL)	High (150 µg/mL)
N	20	20
Mean (µg/mL)	16.6	151.7
SD (µg/mL)	1.8	9.0
CV (%)	11.0%	6.0%

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

Method comparison

Results obtained with CRP Turbilatex were compared with with CRP Ultra Spinreact.

	Sensitivity	Specificity
CRP Turbilatex vs CRP Ultra Spinreact ®	92.9%	97.7%

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

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		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.

BS-200/200E/240, Mindray / Application parameters

ASSAY PARAMETERS	
Std. No	3
R1	200 µL
Sample	2 µL
R2	60 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	578 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture	0 cycle
Final lecture	9 cycles
Reaction time	4 min
Linear range	0-150 µg/mL
CALIBRATION	
Calibration Method	Spline
Calibration set	2 calibrators + Blank
Blank	Calibrator 0 (0 µg/mL)
Calibrator 2	Calibrator 2 (20 µg/ mL)
Calibrator 3	Calibrator 3 (150 µg/ mL)
STEPS	
Addition R1	
Addition Sample	
Incubation	
Addition R2	
Blank Lecture	Cycle 0
Incubation	
Final lecture	Cycle 9