General Information

Intended use:

HS-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.

HS-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 R2: 1 vial, 1x12 mL	TL-022CR01 TL-022CR02
Auxiliary Reagents		
Calibration kit	Calibrator: 3 vials, 3 x 0,3 mL.	TL-022CR70 TL-022CR71 TL-022CR72
Controls kit	Control C1, 1 vials, 1x0,5 mL/vial.	TL-022CR08

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.

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 (2-8ºC) for 7 days prior to testing.

Specimen:

Assay procedure

Application parameter set up:

Specific analyzers settings for HS-CRP Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the Biolis 24i/50i (Tokyo Boeki) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the Biolis 24i/50i (Tokyo Boeki) analyzer manual.

Calibration curve establishment:

A 3-point calibration curve can be established in Biolis 24i/50i (Tokyo Boeki) 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:

HS-CRP Turbilatex control C1 must be assayed each day before running patient serum 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:

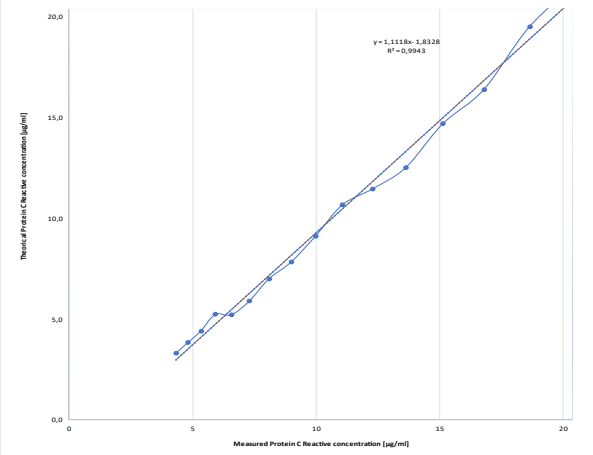
The results are evaluated automatically by the analyzer and presented in µg C-Protein/mL of serum.

Performance characteristics

The following results have been obtained during the validation of HS-CRP Turbilatex on the Biolis 24i/50i (Tokyo Boeki) analyzer.

Linearity:

HS-CRP Turbilatex on Biolis 24i/50i (Tokyo Boeki) analyzer using calibrator kit is linear in the calibration range of 0.0-20 µg /mL of serum.



Measuring range:

HS-CRP Turbilatex assay measuring range is 0-20 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).

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:

LoD=LoB+1.645*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%.

Precision

HS-CRP Turbilatex was tested with three different controls levels.

	Low (5.0 µg/mL)	High (20 µg/mL)
N	20	20
Mean (µg/mL)	3.6	17.5
SD (µg/mL)	0.4	1.3
CV (%)	11.0%	8.0%

Method comparison

Results obtained with HS-CRP Turbilatex on the Biolis 24i/50i (Tokyo Boeki) analyzer were compared with CRP Ultra Spinreact.

	Sensitivity	Specificity
HS-CRP Turbilatex vs CRP Ultra Spinreact ®	**100.0%**	**90.6%**

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.

Biolis 24i/50i (Tokyo Boeki) / Application parameters

ASSAY PARAMETERS	
Std. No	3
R1	200µL
Sample	2 µL
R2	50 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	570 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture	33-34 cycle
Final lecture	49-50 cycle
Reaction time	10 min
Linear range	0-20 µg/mL
CALIBRATION	
Calibration Method	Spline
Calibration set	2 calibrators + Blank
Blank	Calibrator 0 (0 µg/mL)
Calibrator 1	Calibrator 1 (5 µg/ mL)
Calibrator 2	Calibrator 2 (20 µg/ mL)
STEPS	
Addition R1	
Addition sample	
Incubation	
Addition R2	
Blank lecture	Cycle 33-34
Incubation	
Final lecture	Cycle 49-50