

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.

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 HS-CRP Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the ChemWell®-T (Awareness Technology Inc.) analyzer manual and instructions for use provided with the kit.

Loading of reagents:

Load reagents according to the ChemWell®-T (Awareness Technology Inc.) analyzer manual.

Calibration curve establishment:

A 3-points calibration curve can be established in ChemWell®-T (Awareness Technology Inc.) 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 serum extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:

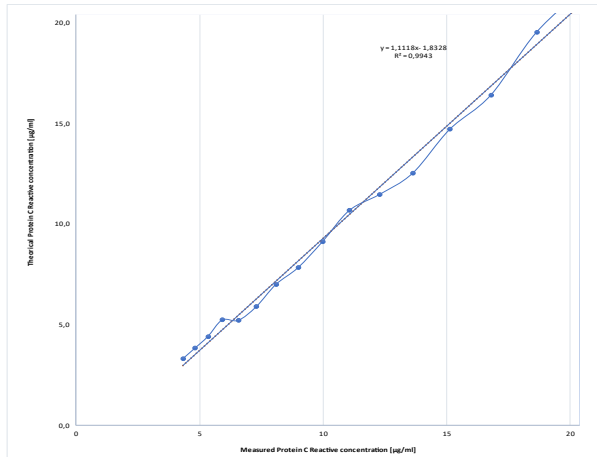
The results are evaluated automatically by the analyzer and presented in µg C-Protein reactive /ml of serum.

Performance characteristics

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

Linearity:

HS-CRP Turbilatex using calibrator kit is linear in the calibration range of 0.0-20 µg /ml of serum.



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

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).

*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:

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

| | Low (1.0 µg/mL) | Medium (5.0 µg/mL) | High (20 µg/mL) |
|---------------------|--------------------|-----------------------|--------------------|
| N | 20 | 20 | 20 |
| Mean (µg/mL) | 1.0 | 4.8 | 19.6 |
| SD (µg/mL) | 0.1 | 0.2 | 0.9 |
| CV (%) | 11.2% | 5.2% | 4.4% |

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

Method comparison

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












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

*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 instructions for use for the detailed information about the test on the following:

Synthesis, Principle, Precautions, Reagents, Specimen collection, Interpretation of results.

ChemWell-T (Awareness) / Application parameters

| ASSAY PARAMETERS | |
|-------------------------|----------------------------|
| Std. No | 3 |
| R1 | 200 µL |
| Sample | 3 µL |
| R2 | 50 µL |
| Others | NA |
| Reaction mode | Endpoint |
| Primary wavelength | 545 nm |
| Secondary wavelength | None |
| Direction | Increase |
| Reagent blank lecture | 5 s after R2 addition |
| Final lecture | 5 min after 1st lecture |
| Reaction time | 10 min |
| Linear range | 0-20 µg/ml |
| CALIBRATION | |
| Calibration Method | Cubic Spline (Constrained) |
| Calibration set | 3 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 | 5 s after R2 addition |
| Incubation | |
| Final lecture | 5 min after 1st lecture |