CRP-Turbilatex

INTENDED USE

Vitro CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C-Reactive Protein in human serum or plasma on both manual and automated systems.

METHOD

Highly sensitive immunoturbidimetric assay.

CLINICAL SIGNIFICANCE

C-reactive protein (CRP) is a serum protein which is synthesized in the liver. Its rate of synthesis and secretion increases within hours of an acute injury or the onset of inflammation and may reach as high as 20 times the normal levels.

Elevated serum concentration of CRP is an unequivocal evidence of an active tissue damage process and CRP measurement thus provides a simple screening test for organic disorders. Apart from indicating inflammatory disorders, CRP measurement helps in differential diagnosis, in the management of neonatal septicemia and meningitis where standard microbiological investigations are difficult.

Its use in post-operative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7-10 days. Absence of this fall is indicative of possible septic or inflammatory post-operative complications.

Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and creatine phosphokinase (CPK).

ASSAY PRINCIPLE

Vitro CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C-reactive protein (CRP) in human serum or plasma. Latex particles coated with specific anti- human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

EXPECTED VALUES

Normal values up to 6 mg/L

Each laboratory should establish its own reference range.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative.
Latex (R2)	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Preservative.
CRP-CAL	Calibrator. Human serum. CRP concentration is stated on the vial label.

- **Reagent Preparation & Stability**

CRP Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.

Precautions

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

Storage and Stability

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: Presence of particles and turbidity.

CRP Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.

Do not freeze; frozen Latex or Diluent could change the functionality of the test.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolyzed or lipemic samples.

PROCEDURE

Wavelength	530 - 550 nm (540 nm)
Cuvette	1 cm light path
Temperature	37 ^{0}C
Zero adjustment	against distilled water
Specimen	Serum

	Calibrator	Specimen
Diluent (R1)	400 µl	400 µl
Latex R2	100 µl	100 µl
Calibrator	3 µl	……
Specimen	……	3 µl

Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

CALCULATION

$$\text{mg/L CRP} = \frac{(A_2\text{-}A_1)\ \text{specimen}}{(A_2\text{-}A_1)\ \text{calibrator}} \times \text{Calibrator concentration}$$

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established CRP values may be routinely used for quality control.

Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

PERFORMANCE CHARACTERISTICS

1. Linearity limit: Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

2. Detection limit: Values less than 2 mg/L give non-reproducible results.

3. Prozone effect: No prozone effect was detected upon 800 mg/L.

4. Sensitivity: 4.2 mA.mg/L.

5. Precision: The reagent has been tested for 20 days, using three different CRP concentrations in a EP5-based study.

EP5	CV (%)		
mg/L	9.2 mg/L	16.8 mg/L	57.97 mg/L
Total	7.3%	6.9%	5.9%
Within Run	2.8%	3.1%	2.9%
Between Run	6.1%	4.7%	3.9%
Between Day	3.0%	4.0%	3.4%

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 50 samples of different concentrations of CRP were assayed. The correlation coefficient (r) was 0.99 and the regression equation y = 1.101x + 2.518.

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INTERFERING SUBSTANCES

Bilirrubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere.
Hemoglobin (≥ 5 g/L), interferes.
Other substances may interfere[7].

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
	Batch code (Lot #)
	Catalog number
	Temperature limitation
	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
70201	100 TEST

Article # :702 -EN
Date of Revision : 03/2021

ISO 13485:2016 CE

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