CRP TURBILATEX

(Latex-turbidimetry)

Quantitative Determination of C-Reactive Protein (CRP)

PRINCIPLE OF THE METHOD

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.

CLINICALSIGNIFICANCE

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/dl in 12 – 24 hours.

REAGENT PROVIDED

Diluent (R1) **:-** 2x 20 ml
Latex (R2) **:-** 2 x 5 ml
CRP Calibrator **:-** 1 x 0.5 ml (Ready to use)

WORKING REAGENT PREPARATION

Swirl the latex vial gently before use. Prepare the necessary amount as follows:

1 ml Latex Reagent + 4 ml Diluent

STORAGE AND STABILITY

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

REAGENT DETERIORATION:

Presence of particles and turbidity.

SAMPLES

Fresh serum or plasma. Stable for 7 days at 2-8°C or 3 months at -20°C. The samples with presence of fibrin should be centrifuged before testing. Do not use hemolized or lipemic samples.

CALIBRATION

Use CRP Liquid Stable Calibrator provided in the kit.

PRECAUTIONS

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

ASSAY GUIDELINE FOR ANALYZERS

Reaction type	Fixed Time
Reaction Slope	Increasing
Wavelength	540 nm (530-550)
Flow cell Temperature	37°C
Delay time	5 seconds
Readings Time	120 Seconds
Zero Setting	Distilled water
Sample volume	10 µl
Working Reagent volume	1000 µl
Linearity	Up to 150mg/L

ASSAY GUIDELINES FOR MANUAL PROCEDURE

Pre warm the required amount of working reagent at Room Temperature before use. Perform the assay as given below:

Reagents	Calibrator	Test
Working Reagent	1000 µl (1.0 ml)	1000 µl (1.0 ml)
Calibrator	10 µl	-
Serum/Plasma	-	10µl

Mix and read the absorbance at 5 sec. (A_1) and after 120 sec. (A_2) of the sample addition.

CALCULATIONS

$$\frac{(A_2 - A_1)\ \text{sample}}{(A_2 - A_1)\ \text{calibrator}} \times \text{calibrator concentration} = \text{mg/lCRP}$$

REFERENCE VALUES

Normal values up to 6mg/L.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Linearity Limit:** Up to 150mg/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 2mg/L give non-reproducible results.
3. **Prozone Effect:** No prozone effect was detected up to 800 mg/L.
4. **Sensitivity:** Δ4.2 mA.mg/L.

QULATITY CONTROL

Control Sera (Level L and Level H) are recommended to monitor the performance of manual and automated assay procedures.

INTERFERENCES

Bilirubin (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.

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