CRP Turbilatex

Latex Turbidimetric

IMMUNOPAK

Last update 04-2023

Ref. IM-CRT.082, 1x50 ml

INTENDED USE

Quantitative determination of C – Reactive Protein (CRP) IVD.

DIAGNOSTICS SIGNIFICANCE

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

PRINCIPLE

The 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.

PRESENTATION

All the reagents to be stored at 2-8^{0}C	No. of Bottles/ Vials
• CRP Turbilatex (R1 Diluent)	1x50 ml
• CRP Turbilatex (R2 Latex)	1x45 ml
• CRP Turbilatex Calibrator	1x5 ml
	1

* Value may vary from lot to lot.

PRECAUTION

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.

PREPARATION OF WORKING REAGENT / CALIBRATOR

Working Reagent: Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).
Working Calibrator: Ready to use.

REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8°C till the expiry date mentioned on the label.
Working Reagent: Stable for 30 days at 2-8°C.
Calibrator: Stable at 2-8°C till the expiry date mentioned on the label.
Reagent deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION

Fresh serum: Stable 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 highly hemolyzed or Lipemic samples.

REACTION PARAMETERS

- Type of Reaction : Two Point/Fix Time
- Wavelength : 540 nm (530-550)
- Flow cell temperature : 37^{0}C
- Delay Time : 5 Sec.
- Read Time : 120 Sec.
- Sample / Calibrator Volume : 5 µl
- Reagent Volume : 1 ml
- Zero setting with : Distilled water
- Light Path : 1 cm
- Calibrator Concentration : 60 mg/L

TEST PROCEDURE

PIPETTE IN TEST TUBE	Calibrator	Sample
Working Reagent (ml)	1.0	1.0
Calibrator or sample (µl)	5	-
Sample (µl)	-	5

Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition.

TEST RESULT

$$\text{CRP mg/L} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \text{ X Calibrator Concentration}$$

LIMITATIONS FOR 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.

QUALITY CONTROL

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUE

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

PERFORMANCE CHARACTERISTICS

1. Linearity: 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. Sensitivity: Δ 4.2 mA.mg/L.

NOTE

Clinical diagnosis should not be made on findings of a single test result, but should be integrated by both clinical and laboratory data.

REFERENCES

- Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997; 10; 196-201.
- Chetana Vaishanavi, Immunology and Infectious Diseases 1996;6;139-144.
- Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1; 15-27.
- Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606-607.
- Werner Muller et al. Journal of Immunological Methods 1985; 80; 77-90.
- Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121-2124.

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91-265-2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 & GMP Certified Company

RECKON DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989