PATHOZYME DIAGNOSTICS

CRP TURBILATEX

(TURBIDIMETRY METHOD)

CAT NO.: CRT

Reagent kit for quantitative estimation of C-Reactive Protein (CRP) in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

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/L in 12-24 hours.

PRINCIPLE:

The latex particles coated with anti-CRP are agglutinated when they react with samples that contain C-reactive protein (CRP). The latex particles agglutination is proportional to the concentration of the CRP in the sample and can be measured by turbidimetry.

SPECIMEN COLLECTION:

Fresh serum or plasma. Stable for 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

KIT PRESENTATION:

Pack Size	1 X 50 ml
R1 - CRP (Buffer Reagent)	1 X 45 ml
R2 - CRP (Latex Reagent)	1 X 05 ml
CRP Calibrator	1 Vial

WORKING REAGENT PREPARATION:

R1 – CRP (Buffer Reagent) & R2 – CRP (Latex Reagent) are Ready To Use.

REAGENT STORAGE AND STABILITY:

All reagents are stable at 2-8ºC until the expiry date stated on the label.

NOTES:

1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
2. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
3. 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.

INTERFERENCES:

Bilirubin (20 mg/dL), Hemoglobin (40 g/L) and Lipemia (10 g/L) and Rheumatoid Factor (800 IU/ml) do not interfere. Other substances may interfere.

ASSAY PARAMETERS:

Reaction	**: Fix Time**	**Sample Volume**	**: 10 µl**
Wavelength	**: 578 nm**	**R1 + R2 Volume**	**: 900 µl + 100 µl**
Flow Cell Temp.	**: 37ºC**	**Calibrator Conc.**	**: As On Vial**
Initial Delay	**: 5 Sec**	**Reaction Slope**	**: Increasing**
Interval Time	**: 120 Sec**	**Zero Setting**	**: Dist. Water**
Read Time	**: 120 Sec**	**Linearity**	**: 160**
No. of Reading	**: 01**	**Unit**	**: mg/L**

PROCEDURE:

Pipette into TT	Calibrator	Test
R1 - CRP (Buffer Reagent)	900 µl	900 µl
CRP Calibrator	10 µl	--
Sample (Test)	--	10 µl
R2 - CRP (Latex Reagent)	100 µl	100 µl

Mix & aspirate immediately and read difference in absorbance between 5 seconds (AT_1) and 120 seconds (AT_2) for Calibrator and Test at 578 nm.

CALCULATION:

$$\text{CRP (mg/L)} = \frac{\Delta\text{Abs of Test} \times \text{Calibrator Conc.}}{\Delta\text{Abs of Calibrator}}$$

Where $\Delta Abs = (AT_1) - (AT_2)$

NORMAL VALUES:

Adults : Up to 6 mg/L
New Born up to 3 weeks: < 4.1 mg/L
Infants and Children : < 2.8 mg/L
Each laboratory should establish its own reference range.

LINEARITY:

This method is linear up to **160 mg/L**. For values above 160 mg/L, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

Detection limit: Values less than 1 mg/L give non reproducible results.
Analytical sensitivity: 2.9 mA /mg CRP/L.
Prozone effect: Up to 800 mg/L.

REFERENCES:

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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