

C - Reactive Protein (CRP- Turbidimetric Method)

In-vitro Diagnostic reagent/kit for quantitative determination of C-Reactive Protein (CRP) in serum/plasma sample on Photometric System.

Reagent

Reagent 1: Diluent Solution

Reagent 2: Latex Solution

Calibrator: 0.5ml (Value on Label)

Principle

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

Summary

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.

Storage instruction and Reagent stability

The reagent and Calibrator are stable until the expiration date on the label when stored tightly closed at 2°-8°C.

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

Components and Concentrations

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with goat IgG anti-human CRP and Preservative.

Calibrator: CRP Value on Label

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 and Calibrator are ready to use.

Materials required but not provided

NaCl solution 9 g/L

General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days at 2°-8°C

60 days at -20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength: 546 nm

Temperature: 37°C

Cuvette light path: 10 mm

	Sample/ Calibrator
Reagent 1	800 µl
Reagent 2	200 µl
Sample /Calibrator	5 µl
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

Calculations

$$\text{CRP mg/L} = \frac{(\text{A2-A1}) \text{ sample}}{(\text{A2-A1}) \text{ calibrator}} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Performance Characteristics

Measuring Range

The test has been developed determine CRP activities within a measuring range from 2 - 150 mg/L. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

Linearity

The higher limit of detection is 150 mg/L.

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/L.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Precision

Intra-assay n = 20	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	6.67	0.10	1.48
Sample 2	20.18	0.26	1.29
Sample 3	87.58	0.65	0.74

Precision

Inter-assay n = 20	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	6.68	0.11	1.68
Sample 2	22.03	0.36	1.63
Sample 3	87.43	0.80	0.91

Method Comparison

A comparison of Precision Biomed C-reactive protein (CRP) (y) with a commercially available test (x) using 15 samples gave following results:
y = 0.990x + 0.071; r² = 0.998.

Reference Range

Adults < 6 mg/L, Newborn up to 3 weeks < 4.1 mg/L, Infants and children < 2.8 mg/L

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	CRP
Mode	Fixed time
Reaction slope	Increasing
Wavelength	546 nm
Path length	10 mm
Temperature	37°C
Reagent 1 volume	800 µL
Reagent 2 volume	200 µL
Sample volume	5 µL
Delay	5 Sec
Rate	120 sec
No. of readings	2 Nos.
Normal range	Adults - < 6 mg/L
	Children < 2.8 mg/L
Linearity	150 mg/L
Sensitivity	2 mg/L

Pack Size

Cat No.	Configuration	Pack
CRPT0050	Reagent R1 - 1 x 40mL Reagent R2 - 1 x 10mL Calibrator – 1 x 0.5mL	50mL

Literature

1. Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997; 10: 196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1: 15 – 27.
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606 –607.
5. Werner Müller et al. Journal of Immunological Methods 1985; 80: 77 – 90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121 –2124.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Version : CRPT/00



 In Vitro Diagnostic Use
  See Pack Insert For Procedure
  Single Use only
  CE

 Temperature Limit
  Manufacturer's Address
  Manufacturing Date
  Expiry Date
  LOT Lot Number



Manufactured in India by:
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