



# CRP (C-Reactive Protein) Immunoturbidity Method

## INTENDED USE:

The CRP - Immunoturbidity method is a turbidimetric test for the quantitative determination of CRP in human serum or plasma.

## INTRODUCTION:

C-Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cells sedimentation rate. CRP lacks diagnostic value when the patients illness is not defined, but it is very useful for following-up inflammatory diseases as well as for the differential diagnosis in certain cases.

## PRINCIPLE:

The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-CRP, capable of aggregation in the presence of CRP. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the absorbance of the system.

## KIT CONTENTS:

**Reagent 1** : CRP Buffer.

**Reagent 2** : CRP Latex.

**Reagent 3** : CRP Calibrator.

## Product Insert

## PREPARATION OF WORKING REAGENT:

Working reagent preparation mix gently 4 part of Reagent-1 (CRP Buffer) with 1 Part of Reagent-2 (CRP Latex) and avoid foaming.

Stability of working reagent is 3 days at 2-8°C.

## STORAGE AND STABILITY:

The reagents when stored at 2-8°C are stable up to expiry date mentioned on the label. The reagent is stable for 10 days onboard the analyser at 2-10°C. Protect from light and avoid contamination.

## SPECIMEN COLLECTION AND STORAGE:

Fresh sera stored at 2-8°C for no longer than 48 hours. It is necessary to freeze the sample when the assay is to be carried out after that period of the time. Discard contaminated or haemolyzed sera.

## PRECAUTIONS:

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher

temperature as it may affect the performance of the kit.

3. Before the assay bring all the reagents to room temperature.
4. After use store the kit contents immediately at 2-8°C.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.

## PLOTTING OF MULTI-POINT CURVE:

The Immunoturbidity CRP is based on Non-Linear Reactions, hence, it is strongly recommended to run multi-standard mode to plot the multi-curve to have better accuracy and precise result.

## Serial Dilution step

Tube	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>
Calibrator	100 µl	50 µl from 1 <sup>st</sup> Tube	50 µl from 2 <sup>nd</sup> Tube	50 µl from 3 <sup>rd</sup> Tube	50 µl from 4 <sup>th</sup> Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

## PROCEDURE (Automated):

Refer to specific instrument application instructions.

## TEST PROCEDURE (Manual):

Wavelength : 546 nm

Temperature : 37°C

Cuvette : 1 cm

Pipette into clean dry test tubes labelled Calibrator (C) and Test (T) as follows:

Reagent	Calibrator (C)	Test (T)
Working Reagent	1000 µl	1000 µl
Calibrator	10 µl	—
Sample	—	10 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water. After exactly 120 secs. read the absorbance A2 of the test (T) and Calibrator (C). Calculate  $\Delta A/\text{min. (A2- A1)}$  for the test and calibrator.

## CALCULATION:

CRP concentration (mg/L) =  $\Delta A(T) / \Delta A (C) \times \text{calibrator concentration}$

## NORMAL VALUES:

Upto 6 mg/L

\*\*It is recommended for each laboratory to establish its own reference ranges for local population.

**QUALITY CONTROL:**

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

**PERFORMANCE CHARACTERISTICS:**

1. **Sensitivity / Limit of Quantitation:** 2 mg/L.
2. **Linearity:** Upto 150 mg/L.  
Samples that give higher concentration should be diluted in saline NaCl 0.9% (1-4) and the final result have to be multiplied by 5.
3. **Specificity /Interferences**  
No interference was observed by Bilirubin (170 umol/l), Haemoglobin (5 g/L), Triglycerides (2.28 mmol/L), RF (210 UI/ml), other drugs and substances may interfere in the test.

**REFERENCE:**

- 1) Manack, J.R. and Richards, CB., J. Immunol, 20, 1019(1971).
- 2) Ritchie, RF., J. Lab, Clin, Med. 70.512(1967).
- 3) Pepys MB.etal., Ann. NY Acad, Sci, 389, 459(1982).

**APPLICATIONS:**

Input parameter for semiauto/auto analyzers are given below:-

Method	Fixed Time (2-Point)
Wavelength	546 nm
Zero Setting	Distilled Water
Temperature Setting	37°C
Incubation Temperature	37°C
Incubation Time	—
Delay Time	10 secs
Read Time	120 secs
No. of Reading	2
Interval Time	—
Sample Volume	10 µl
Reagent Volume	1000 µl
Concentration	Refer Calibrator vial
Units	mg/L
Factor	—
Reaction Slope	Increasing
Linearity	150 mg/L