CRP

1 x 24/1 x 8/2 mL **51808001**

2 x 24/2 x 8/2 mL **51808002**

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of C-reactive protein in human serum or plasma by immunoturbidimetry.

-Latex enhanced immunoturbidimetry

-Linear up to 200 mg/L

-Ready to use reagents

-No sample dilution needed

CLINICAL SIGNIFICANCE

CRP (C – Reactive Protein) is a cytokine - induced, acute phase protein that increases in concentration as a result of inflammation. CRP levels in the body has been used as a marker or indicator of infections and inflammation. The assay of CRP is more sensitive than the erythrocyte sedimentation rate (ESR) and leukocyte count. The CRP levels rise and return to reference ranges more rapidly after the disease has subsided.

PRINCIPLE

This is a latex enhanced turbidimetric immuno assay. CRP in the samples binds to specific anti-CRP antibodies, which have been adsorbed to latex particles and agglutinates. The agglutination is proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

REAGENT COMPOSITION

CRP R1 **1 x 24 mL, 2 x 24 mL**

Glycine buffer

CRP R2 **1 x 8 mL, 2 x 8 mL**

Latex suspension coated with anti-CRP antibodies. (rabbit polyclonal antibody)

CALIBRATOR **1 x 2 mL, 1 x 2 mL**

CRP calibrator concentration as on vial label

STORAGE AND STABILITY

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2-8°C.

NORMAL RANGE

It is recommended that each laboratory should establish its own reference values. The following value may be used as a guide line.

Serum up to 6 mg/L

PRECAUTION

To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

The reagent should be used according to this pack insert. If used otherwise, appropriate performance is not guaranteed.

SAMPLE

Fresh serum (Do not use hemolized or lipemic serum)

GENERAL SYSTEM PARAMETER	SEMI AUTO	FULLY AUTO
Mode of Reaction	Fixed Time	End point
Slope of reaction	Increasing	Increasing
Wavelength	578 nm	570/ 800nm
Temperature	37°C	37°C
No.of calib.	6	6
Calibrator concentration	As on vial label x Dilution factor	
Linearity	200 mg/L	200 mg/L
Blank	DI Water	Reagent blank
Delay	5 sec	--
Interval	120 sec	--
Sample volume	5 µL	3 µL
Reagent 1 volume	450 µL	210 µL
Reagent 2 volume	150 µL	70 µL
Cuvette	1cm light path	1cm light path

CALIBRATION

Preparation of calibration curve:

Prepare the following calibrator dilutions using normal saline as diluent. Multiply the concentration of the CRP calibrator by the corresponding factor stated in the table below to obtain the CRP concentration of each dilution.

Dilution	1	2	3	4	5	6
Cali. (µL)	-	10	10	20	50	100
Saline (µL)	100	150	70	60	50	-
Dil. factor	0	0.0625	0.125	0.25	0.5	1.0

LABORATORY PROCEDURE FOR FULLY AUTO ANALYZER

	Blank	calibrator	Sample/Control
CRP R 1	210 µL	210 µL	210 µL
Dil. Calibrator	-	3 µL	-
Sample/control	-	-	3 µL
Mix and incubate for 5 minutes at 37°C.			
CRP R 2	70 µL	70 µL	70 µL

Mix and measure the absorbance immediately (A1) and after 2 minutes (A2) at 570/ 800nm.

ALTERNATIVE PROCEDURE FOR SEMI AUTO ANALYZER:

	calibrator	Sample/Control
CRP R 1	450 µL	450 µL
Dil. Calibrator	5 µL	-
Sample/control	-	5 µL
CRP R 2	150 µL	150 µL

Mix and measure the absorbance immediately (A1) and after 2 minutes (A2) at 578nm.

CALCULATION

Multi point calibration

Calculate the ΔAbs, plot a standard curve & read the concentration of controls & samples.

PERFORMANCE CHARACTERISTICS:

Measuring Range:- 1 –200 mg/L.

If the concentration is greater than 200mg/L, dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

Prozone Effect:- >1000mg/L

Precision in CV%:-

	Low	Medium	High
Intra - Run	7.0	5.0	3.0
Inter - Run	10	8	5

Accuracy in mg/L

control	Assigned value	Measured value
level 1	5.85(4.68-7.02)	5.05
level 2	27.3(21.9-32.8)	26.8
level 3	51.9(41.5-62.2)	49.6

INTERFERENCE

No interference for

Hemoglobin	500mg/dL
Intrafat	500 mg/dL
Bilirubin	30mg /dL
RF up to	500 IU/mL

BIBLIOGRAPHY

1. Tillett.W.S.,*et al*: Serological reactions in pneumonia with a non protein somatic fraction of pneumococcus.J.Exp.Med..52,561(1930).
2. Zeigenhagen G,Drahovshy D.Klinishe Bedeutung des C-reaktiven protein.Med klin 1983;78:45-50.
3. Rifal.N.Tracy.R.P.Ridker,P.M.Clinical efficacy of an Automated High sensitivity C-Reactive protein Assay: Clin chem. 45-12.

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS : IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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