

C-REACTIVE PROTEIN (CRP)

Turbidimetric Latex Immunoassay (Fixed Time)



Product Code: 10021	Reaction Type: Fixed Time (Two Point Kinetic)
Pack Size: 1 x 50 ml	Matrix Target: Human Serum
Storage Temp: 2-8°C (Do Not Freeze)	Wavelength: 546 nm (Flow Cell: 37°C)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This advanced liquid diagnostic reagent system is configured for the quantitative in vitro turbidimetric immunoassay determination of C-Reactive Protein (CRP) in human serum specimens.

Clinical Significance: CRP is an acute-phase protein synthesized in the liver. Present only in trace quantities in healthy individuals, its expression can accelerate up to 1000-fold in direct response to tissue necrosis, injury, or microbial infections, rising up to 300 mg/L within 12–24 hours. Serum CRP measurement acts as an essential screening index for tracking organic inflammatory, infective, and ischemic disease activity.

METHOD PRINCIPLE

This assay utilizes a uniform suspension of latex particles chemically sensitized with specific anti-human CRP antibodies. When exposed to patient serum containing CRP, specific immune aggregation occurs:

Latex-Anti-CRP Particles + Serum CRP → Immuno-Aggregated Lattice (Increased Turbidity)

This macro-aggregation alters the structural light path, creating a distinct increase in optical density measured at 546 nm. The absolute rate of change is proportional to the concentration of CRP.

MULTIPOINT CALIBRATION CURVE SEQUENCE (HIGHLY RECOMMENDED)

Because latex immunoassays exhibit distinct non-linear kinetics, running a multi-standard sequence using normal saline to build a multi-point calibration curve is essential for precision:

Tube / Dilution Stage	1st (Neat)	2nd (1/2)	3rd (1/4)	4th (1/8)	5th (1/16)
CRP Calibrator Vol.	100 µl	50 µl (from 1st)	50 µl (from 2nd)	50 µl (from 3rd)	50 µl (from 4th)
Normal Saline Vol.	0 µl	50 µl	50 µl	50 µl	50 µl

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Working Reagent Option: Reagents are ready to use. Alternatively, mix gently 4 parts of R1-CRP Buffer with 1 part of R2-CRP Latex (avoid foaming). Stable for 4 days at 2-8°C.

Assay Component	Calibrator (C) Track	Patient Test (T) Track
R1 - CRP Buffer Reagent	400 µl	400 µl
R2 - CRP Latex Suspension	100 µl	100 µl
CRP Calibrator Vector	05 µl	—
Patient Serum Sample (Fresh / Unhemolysed)	—	05 µl

Operational Directive: Mix cleanly. After exactly 10 seconds of incubation at 37°C, capture initial absorbance A_1 at 546 nm against distilled water. Read secondary absorbance A_2 exactly 120 seconds later.

STEP 2: CALCULATIONS & DATA TRACKING

$$\Delta A_{Test} = A_2(Test) - A_1(Test) \quad | \quad \Delta A_{Cal} = A_2(Cal) - A_1(Cal)$$

$$CRP \text{ Concentration (mg/L)} = (\Delta A_{Test} / \Delta A_{Cal}) \times \text{Calibrator Concentration}$$

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional <i>in vitro</i> use. Discard contaminated or hemolysed serum. Biological matrices must be processed fresh or frozen if stored beyond 48 hours. Avoid reagent inhalation or skin contact. Separate pipette tips are mandatory.
Expected Range	Normal Baseline: Up to 5.0 mg/L. Each individual laboratory should independently establish its own reference boundaries.
Analytical Linearity	Linear up to 150.0 mg/L. High samples should be diluted with standard saline and re-assayed.

Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.

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