# CRP TURBILATEX


**INTENDED USE :**

The reagent kit is intended for the "in vitro" quantitative determination of C-Reactive Protein in serum.

**CLINICAL 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 infection the CRP concentration can rise up to 300 mg/L in 12-24 hrs.

**PRINCIPLE:**

The 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 CRR 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.

**CONTENTS:**

Reagent 1: Diluent 40 m

Reagent 2 : Latex Antigen 10 ml

Reagent 3 : CRP Calibrator

**PREPARATION OF WORKING REAGENT**

Working Reagent: Swirl the latex vial gently before use Prepare the necessary amount as follow:

1 ml latex Reagent + 4 ml Diluent

CRP Calibrator : Reconstitute with 1.0 ml of Distilled water. Mix gently and keep at room temperature for 10 minutes before use.

**STORAGE & STABILITY :**

Working Reagent: Stable for 30 days at 2-8°C

CRP Calibrator : Stable for I month at 2-8°C or 3 months at -20 C. Do not freeze; frozen latex or diluent could change the functionality of the test.

**MATERIALS REQUIRED BUT NOT PROVIDED:**

- Clean & Dry Glassware.
- Laboratory Glass Pipettes or Micropipettes 8rTrps.
- Bio-Chemistry Analyzer.

**SAMPLES:**

Fresh serum stable for? days at 2 -8° C or 3 months at -20° C. The samples with presence of fibrin should be centrifuged before testing. 00 not use highly hemolyzed or lipemic samples.

**GENERAL SYSTEM PARAMETERS**

| | |
|---|---|
| Reaction Type | Fix Time |
| Wave Length | 546 nm (530-550 nm) |
| Cuvette Temperature | $37^0$c |
| Delay Time | 10 Sec. |
| Read Time | 120sec |
| Sample Volume | 5 |
| Reagent Volume | 1ml |
| Calibrator Concentration | AsMentioned on Calibrator vial |
| Zero Setting | Deionised Water |
| Linearity | 150mg/L |
| Units | mg/L |

**PROCEDURE :**

| Reagent | Calibrator | Sample |
|---|---|---|
| Working Reagent | 1ml | 1ml |
| Calibrator | 5 µl | ----- |
| Sample | --- | 5 µl |

**CALCULATION OF RESULTS :**

CRP mg/L = ( (A2-A1)Sample/(A2-A1)Calibrator) X Calibrator Concentration

**NORMAL VALUE:**

Up to 6 mg/L

Each laboratory should establish its own reference range.

**LINEARITY:**

The reaction is linear up to 150 mg/L

**PERFORMANCE CHARACTERISTS:**

1. Linearity Limit: Up to 150 mg/L, under the described assay conditions.
2. Detection Limit: Values less than 2 mg/L give non-reproducible results
3. Prozone Effect: No prozone effect was detected up to 800 mg/L

**QUALITY CONTROL:**

It is recommended that each laboratory should prepare their own quality control scheme

**LIMITATIONS AND PRECAUTIONS:**

Storage conditions mentioned on the kit to be adhered.

Bilirugin (20 mg/dl) lipemia (10 g/L) and Rheumatoid factors (300 lU/ml) not interfere. Haemoglobin (>5 g/L) may interferes. Other substances ay interfere

**REFERENCES:**


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