

**Intended Use:** For the Qualitative and Semi-Quantitative determination of C-Reactive Protein in Human Serum.

**Summary and Clinical Significance:**

C-Reactive Protein (CRP) is a Normal Alpha Globulin, which increases in Inflammatory Processes. The name CRP is derived from the fact that this protein has the capacity to precipitate the somatic C-carbohydrate of Pneumococcus. Elevated CRP levels are usually observed in a variety of infections and inflammatory conditions where there is tissue destruction.

The CRP level measurement is useful in differential diagnosis of Neonatal Septicaemia and Meningitis. CRP levels are always elevated after Myocardial Infarction and Surgery. The CRP test can also help in determining Post-Surgical complications.

**Principle:**

Uniform Latex particles are coated with Anti-Human CRP. The specimen containing CRP on mixing with Latex Reagent agglutinates, showing a positive test results. If CRP is absent, there will be no agglutination, indicating a negative test result

**Storage and Stability:**

All the reagents are stable at 2-8°C till the expiry date mentioned on the labels.

**Precautions:**

1. Do not read results after 2 Minutes.
2. Bring all the reagents to RT before use.
3. Do not freeze the Latex Reagent.
4. Do not use Hemolysed or Turbid Specimen.
5. The Latex Reagent (1 ) should be shaken well before use to ensure a homogeneous suspension of latex particles.
6. The source material used in the manufacture of Positive and Negative Controls is tested for HBsAg and HIV antibodies and are found to be negative. However, for better safety these controls should be handled with proper care as If they are potentially dangerous.
7. While dispensing Latex Reagent, hold the Latex dropper vertically to ensure uniform drop size.

**Procedure**

**A. Qualitative Test:**

- 1) Bring the Latex Reagent, Controls and Specimens to room temperature before use. Shake the Latex Reagent gently to ensure Homogenous Suspension.
- 2) Place one drop (Approximately 40-50µl) each of Specimen, Positive Control & Negative Control into the separate circle of glass slide using a separate disposable sample dropper provided in the kit.

- 3) Add one drop Latex Reagent in each of these circles.
- 4) Mix the contents of each circle separately by the disposable mixing sticks provided and spread it in the entire circle.
- 5) Rock the slide gently for 2 minutes and look for agglutination.
- 6) Results should be read at a normal reading distance in good light.
- 7) **Do not read results after 2 minutes**

**Interpretation of Results:**

Agglutination with Positive Control and no agglutination with Negative Control validates test results. Distinct agglutination within two minutes is a positive test and indicates presence of CRP in the test specimen. No agglutination up to two minutes is a negative test, and indicates absence of CRP in the test specimen.

**B. Semi Quantitative Test**

- 1) Dilute the specimen serially 1 : 2, 1 : 4, 1 : 8, 1 : 32, 1 : 64 using Normal Saline.
- 2) Place one drop each of diluted serum sample using sample droppers in each circle of glass slide & proceed further as in Qualitative Test (A).

**Interpretation of results:**

The highest dilution which shows clear cut agglutination within two minutes indicates the CRP titre. The approximate CRP concentration can be obtained by multiplying titre by sensitivity of the test.

CRP in mg/dL = D x S

D = Highest dilution showing clear cut agglutination.

S = Sensitivity of the test - 0.6 mg/dL

**NOTES :**

1. Do not read results after 2 Minutes.
2. Positive and Negative Controls are ready to use and should not be diluted while using in test procedure.
3. Improper mixing and drying of reagents may lead to erroneous results.
4. Contaminated sera and longer reaction time may lead to false positive results.
5. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms and findings.
6. Elevated CRP levels may also be found during pregnancy as well as in woman who are on oral contraceptives.

**Ordering information:**

	Ref. No. P-CRP-25	Ref. No. P-CRP-50	Ref. No. P-CRP-100
Latex Reagent	1.0 ml	2 ml	2 x 2 ml
Positive Control	0.2 ml	0.2 ml	0.2 ml
Negative Control	0.2ml	0.2 ml	0.2 ml



**Pariksha  
Biotech**  
A game changer in IVD

**Product Features**

Latex Reagent, Positive and Negative Controls

Qualitative and Semi Quantitative Test Procedures

Homogenous Latex Particles

Detects CRP at 0.6 mg/dl (Cut off Sensitivity 0.6 mg/dl)

Reagent sensitivity calibrated against WHO calibrators

Sample Dilution not required for Qualitative Test Procedure

Avid agglutination,

No Prozone Effect.

Results correlate with quantitative turbidimetry

Symbols used with IVD devices



Date of manufacture



Manufactured by



In vitro diagnostic device



Keep away from sunlight



Do not freeze



This way up



Use by (yyyy-mm-dd or mm/yyyy)



Reagent



Calibrator Material



Batch code



Temperature limitation (store at)



Control



Consult instructions for use



Keep dry  
Keep away from rain



Catalog Number

eIFU Indicator



Pariksha's world inside  
SCAN TO EXPLORE MORE

Manufactured in India by :  
Pariksha Biotech Pvt Ltd,  
Plot no.1/B-14, SVICE,  
Balanagar,  
Hyderabad-500037  
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