ACCUCARE
C - REACTIVE PROTEIN (CRP) REAGENT
Latex test without predilution

Qualitative determination of C-REACTIVE PROTEIN (CRP) in Serum
(*For In vitro Diagnostic Use Only*)

ORDER INFORMATION

Kit Size	Cat. No.
25 TESTS	CRP 25
50 TESTS	CRP 50
100 TESTS	CRP 100

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 infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase by as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assay have been devised to measure CRP such as capillary precipitation, double immunediffusion and radial immunodiffusion. The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is rapid two (2) minute reaction time.

PRINCIPLE

The CRP-latex is a slide agglutination test for the qualitative and semi-quantitative detection of C - reactive protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP.

TEST SENSITIVITY

The sensitivity is of 0.6 mg/dl of C-reactive protein according to the World Health Organization (WHO) International Reference preparation.

REAGENT COMPOSITION

Reagent 1 :	CRP Latex Reagent
Reagent 2 :	Positive Control Sera
Reagent 3 :	Negative Control Sera

ACCESSORIES

Slides, Stirrer rods, Droppers

SAFETY PRECAUTIONS AND WARNINGS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

REAGENT PREPARATION, STORAGE AND STABILITY.

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration: Presence of particles and turbidity.

ASSAY PROCEDURE

QUALITATIVE DETERMINATION	
Add in different circles of the slide :	
Serum to be tested	1 drop
Positive Control	1 drop
Negative Control	1 drop
In all circles add :	
CRP latex Reagent	1 drop

Mix and spread with the stirring rod to fill the test circle. Rotate the slide and observe for any agglutination which should occur within two minutes.

INTERPRETATION OF THE RESULTS

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
The presence of agglutination indicates a CRP concentration equal or greater than 6 mg/L (Note 2 and 3).
The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

SEMI-QUANTITATIVE DETERMINATION

Prepare sample dilutions with saline 1:2, 1:4 ... 1:64. Test each dilution according to the qualitative procedure until no further agglutination is observed. The CRP concentration can then be estimated from the last dilution with the visible agglutination.

CALCULATION

The approximate CRP concentration in the patient sample is calculated as follow: 6 x CRP Titer = mg/L

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

REFERENCE INTERVAL

< 0.6 mg/dl

BIBLIOGRAPHY

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