NEOLATEX
C-REACTIVE PROTEIN(CRP)

(LATEX AGGLUTINATION TEST)

KIT NAME	KIT SIZE	KIT SIZE
NEO LATEX - CRP	25 Test	100 Test

NEOGENIX
DIAGNOSTICS PVT LTD

INTRODUCTION

C- Reactive Protein (CRP) is a normal alpha globulin, which increases inflammatory process. The name CRP is derived form 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 septicemia and meningitis. CRP levels are always elevated after myocardial infection and surgery. The CRP test can also help in determining post -surgical complications.

METHOD PRINCIPLE

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

KIT CONTENTS

Reagent Name	25 Test	100 Test
R1 CRP Latex	1 ml	4 ml
R2 Positive Control	0.5 ml	0.9 ml
R3 Negative Control	0.5 ml	0.9 ml

WORKING REAGENT PREPARATION AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

SPECIMEN

Only serum should be used to testing. If any delay in testing store the samples at 2-8°C. Samples can be stored for upto a week. Do not use hemolysed serum.

MATERIAL PROVIDED WITH THE KIT

Accessories : Glass Slide, Plastic Droppers, Mixing sticks.

ADDITIONAL MATERIAL REQUIRED

Stop watch.

NOTES:

1. In vitro diagnostic regent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibodies and found to be non-reactive
3. Reagent contains 0.1% sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
5. Shake the CRP latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

1. Pipette one drop of the test specimen (serum) on the glass slide using disposable pipette provided with the kit.
2. Add one drop of CRP latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen and CRP latex reagent uniformly over the entire circle.
4. Immediately starts a stop watch, Rock the slide gently back and forth, observing for agglutination macroscopically at two minutes.

SEMI QUANTITTIVE METHOD

1. Using isotonic saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2,1:4,1:8,1:16, and so on.
2. Pipette each dilution of the test specimen onto separate reaction circles.
3. Add one drop of CRP latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
5. Immediately start a stop watch. Rock the slide gently, back and forth, observing for agglutination macroscopically at two minutes.

INTERPRETATION OF RESULTS

Quantitative Method

Agglutination is a positive test result and indicates the presence of detectable levels of CRP in the test specimen.

No agglutination is a negative test result and indicates absence of detectable levels of CRP in the test specimen

Semi Quantitative Method

Agglutination in the highest serum dilution for responds to the amount of CRP in mg/l present in the specimen.

Calculation

CRP (mg/L)= S x D

Where S = Sensitivity of the reagent ie., 6.0 mg/l
D = Highest dilution of serum showing agglutination.

REMARKS:

1. Marked lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. CRP is found to be present after the first trimester of pregnancy and persists until delivery.
4. CRP levels increase in women who are on oral contraceptives.
5. CRP response is not affected by the commonly used anti-inflammatory or immuno suppressive drugs, including steroids, unless the disease activity is affected and it covers an exceptionally board incremental range up to 3000 times.
6. Do not read results beyond indicated testing time limits.
7. Since CRP production is a non-specific response to tissue injury, it is recommended the result of the test should be correlated with clinical findings to arrive at the final diagnosis.
8. In case where an increase in CRP levels is suspected, but the screening test shows a negative result, semi-quantitation should be done to rule out prozone effect.

LITERATURE

1. Kidmark, C.O. (1972) Scand J. Clin. Invest . 29, 407.
2. Deya, R.A., pope, R.M. , Perselin, R.H. (1980). J. Rhematol, 7, 279.