

<b>Ref.</b>	IS-CRP.075, 25 Test
	IS-CRP.75U, 50 Test
	IS-CRP.75V, 100 Test

## INTENDED USE

Rapid latex agglutination slide test for the qualitative and semi quantitative *in-vitro* determination of inflammatory diseases.

## DIAGNOSTIC SIGNIFICANCE

C-Reactive Protein (CRP) is a normal alpha globulin which increase 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 the positive test result. If CRP is absent there will be no agglutination, indicating a negative test result.

## PRESENTATION

All the reagents to be stored at 2-8°C	No. of Bottles/Packs	
	25 Tests / 50 Tests / 100 Tests	
• Latex Reagent	1	
• Positive Control Serum	1	
• Negative Control Serum	1	
• Test slide	} Provided as per pack size	
• Mixing Sticks		
• Plastic Droppers		
• Glass Dropper		

## PRECAUTION

1. Bring all the reagents and samples to room temperature before use.
2. Do not freeze the Latex reagent.
3. Do not use hemolysed or turbid specimen. The use of plasma instead of serum could lead to erroneous results. Drying of the mixture at the periphery of the circle could lead to erroneous results.
4. The Latex reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
5. The source material used in the manufacturing of Positive control is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety the control should be handled with proper care.

While dispensing Latex reagent, hold the glass dropper vertically to ensure uniform drop size.

## REAGENT STORAGE AND STABILITY

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

## SPECIMEN COLLECTION

Fresh serum, in case of a delay in testing, store at 2-8°C. Plasma hemolysed/lipemic serum should not be used.

## TEST PROCEDURE

### A. QUALITATIVE TEST

1. Allow reagent and sample to come at room temperature before use.
2. Mix latex reagent well, before use.
3. Identify the circles on the slide.
4. Place approximately 25µl of each sample into the center of the circle marked for the sample on the slide.
5. Mix latex reagent well. Hold the dropper vertical and add equal amount of the latex suspension to each sample or controls. Spread it over the circle using separate mixing sticks for each sample.
6. Rock the slide back and forth gently for two minutes or place the slide on an automated rotator at 100 rpm.

PROCEDURE AT A GLANCE 25  
µl. of sample or control  
+  
25 µl. of CRP Latex Reagent  
Mix  
Rock the slide; observe for agglutination up to 2 minutes

### B. SEMI QUANTITATIVE TEST

1. Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline.
2. Place one drop of each diluted serum sample using plastic dropper in each circle of disposable slide & proceed further as in Qualitative Test (A).

## TEST RESULTS

The highest dilution shows positive reaction within 2 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 positive reaction

S = Sensitivity of the test is 0.6 mg/dl

## SENSITIVITY

The reagent has a sensitivity of 0.6 mg/dl serum.

## QUALITY CONTROL

The use of Positive Control is recommended along with serum sample.

## NOTES

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

## REFERENCES

1. Kidmark, C.O. 91972] Scand.J.Clin. Invest.29, 407.
2. Clyde, W.A., Jr.: Immunology, 1964.
3. Deya, R.A., Pope, R. M., Perselin, R. H. (1980).J. Rheumatol, 7, 279.

