



C-REACTIVE PROTEIN (CRP)

PRODUCT CODE: LXCRP025/LXCRP050/LXCRP100/LXCRP150



LXCRP025	LXCRP050	LXCRP100	LXCRP150
25 TESTS	50 TESTS	100 TESTS	150 TESTS
STORE AT 2-8°C			
INSTRUCTIONS FOR USE			
FOR IN-VITRO DIAGNOSTIC USE ONLY			

- For In Vitro Diagnostics Use Only
- Lot Number
- Catalogue Number
- Storage Temperature
- Expiry Date (Year / Month)
- Warning, Read Enclosed Documents
- Instructions For Use
- Manufactured By

C-REACTIVE PROTEIN (CRP)

LATEX

Principle:

The CRP Latex test is a rapid slide agglutination test for the qualitative and semi-quantitative detection of C-Reactive Protein in serum. The reagent containing particles coated with specific anti-human C-Reactive protein antibodies, agglutinates in the presence of CRP in the patient's serum.

Presentation:

Contents	25 Tests	50 Tests	100 Tests	150 Tests
CRP Latex	1 x 1.0ml	1 x 2.0ml	1 x 4.0ml	2 x 3.0 ml
Positive Control	1 x 0.5ml	1 x 0.5ml	1 x 1.0ml	1 x 1.5ml
Negative Control	1 x 0.5ml	1 x 0.5ml	1 x 1.0ml	1 x 1.5ml
Test Cards Reusable	1	1	2	3
Pipette / Stirrers	25	50	100	150

Composition:

CRP Latex	Suspension of white latex particles coated with specific anti-human C-Reactive protein antibodies. The sensitivity has been adjusted to detect between 6mg/L and 250mg/L of C-Reactive Protein.
Positive Control	Sodium azide 0.95g/L. Human Serum Sodium Azide 0.95g/L.
Negative Control	Animal Serum Sodium Azide 0.95g/L.

Although all our components which have been derived from human origin have been tested and found to be negative for the presence of anti-HIV, anti-HCV as well as HbsAg, it is recommended that they be handled cautiously and treated potentially infectious.

Storage:

Store components at 2-8°C. Cards and Pipettes may be kept at Room Temperature.

Samples:

- Serum stable for 48 hours at 2-8°C,
- Samples should be free from contamination, haemolysis and Lipaemia.

Additional Equipment:

Mechanical Rotator set at 100 r.p.m.

Test Procedure:

1. Bring the reagents and samples to room temperature.
2. Place 50µl of the sample and 1 drop of the control into separate circles on the card.
3. Resuspend the latex gently.
4. Add one drop of the latex reagent to each circle next to the sample which is to be tested.
5. Mix with the disposable pipette / stirrer and spread over the entire area enclosed by the ring. Use a new stirrer for each sample.
6. Rotate the cards at 100 r.p.m. for 2 minutes.

Quantitative Test

1. Using a semi-automatic pipette, add 50µl of 9g/L saline to circles 2, 3, 4 and 5. Do not spread the saline.
2. Add 50µl of patient sample to circles 1 & 2.
3. Mix the saline and sample in circle 2 by drawing the mixture up and down being careful to avoid the formation of any bubbles.
4. Transfer 50µl from circle 2 to the saline in circle 3.
5. Perform serial dilutions in the same manner until the last circle, discarding 50µl at the end.
6. Using the pipette / stirrer, spread the diluted samples over the entire area of each circle starting at circle 5 and working backwards to the neat sample in circle 1.
7. Proceed as a qualitative test from step 3.

Quality Control:

Each run of tests should be validated with a positive and negative control.

Reading And Interpretation:

- Examine macroscopically for the presence or absence of clumps or agglutination within 1 minute of removing the card from the rotator.

- Positive Results – the presence of agglutination indicates a level of ≥6mg/L.
- Negative Results – no agglutination would indicate a level of CRP <6mg/L.
- Normal Levels in Adults - >6mg/L.
- Positive sera may be titred. To titrate make serial two-fold dilutions in 9g/L saline as indicated in the Quantitative Test procedure. For example:-
- The serum titre is defined as the highest dilution showing macroscopic agglutination. The approximate CRP concentration in the sample may be obtained by multiplying the titre by the limit of sensitivity – 6mg/L.

Dilution	CRP mg/L
Neat	6
1:2	12
1:4	24
1:8	48
1:16	96

Note: CRP has been detected in serum obtained from apparently healthy adults and children. The reported mean value ranged from 0.1mg/L in newborns to 0.5mg/L in male adults. The CRP level can increase significantly above the normal levels with the onset of substantial inflammatory stimulus.

Limitations Of The Procedure:

- CRP Levels in the range of 15mg/L or above may cause false negative results due to prozone effects.
- A final diagnosis should not be made on the result of a single test but should be based on a correlation of test results with other clinical findings.

Notes:

1. The sensitivity of the test may be reduced at low temperatures. The best results are obtained over 10°C.
2. Delay in reading the results may result in over-estimation of the CRP level.

Reference:

1. Tillet WS and Francis T.J. Exp. Med. 52: 561 (1930)
2. Singer JM et al. Am. Journal Med. 1956; 888 – 892
3. Amos RS et al. Br Med Journal 1:195 – 197 (1977)
4. Pepys MB et al. Lancet 1:653 – 660 (1981)
5. Pepys MB et al. Adv. Immuno 34: 141 – 149 (1983)
6. Kidmark CO Scand. J. Clin. Lab Invest. 29: 407 – 411 (1972)