todylaboratories®

Latex Reagents

REF C23LX1002

C-Reactive Protein (CRP)
Instructions for use

For *in-vitro* diagnostic use only.
Store at 2-8°C.

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	100 Tests
CRP Latex	1 x 4,0 ml
Positive Control	1 x 1,0 ml
Negative Control	1 x 1,0 ml
Test Cards Reusable	2
Pipette/Stirrers	100

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.
• Sodium azide 0.95g/L
Positive Control:
• Human Serum
• Sodium Azide 0.95g/L
Control Negativ:
• 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 or Vortex mixer

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. Re-suspend 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. Mix the CRP-latex reagent vigorously or on a vortex mixer before using.
2. Using a semi-automatic pipette, add 50µl of 9g/L saline to circles 2, 3, 4 and 5. Do not spread the saline.
3. Add 50µl of patient sample to circles 1 & 2.
4. Mix the saline and sample in circle 2 by drawing the mixture up and down being careful to avoid the formation of any bubbles.
5. Transfer 50µl from circle 2 to the saline in circle 3.
6. Perform serial dilutions in the same manner until the last circle, discarding 50µl at the end.
7. 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.
8. 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. This would indicate a level of CRP below 3mg/L.
• Normal Levels in Adults is up to 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.*

ANALYTICAL SENSITIVITY

5-10 mg/L

DIAGNOSTIC SENSITIVITY & SPECIFICITY

over 96%

LIMITATIONS OF THE PROCEDURE

• High CRP Levels over 1500mg/L may cause false negative results due to prozone effects. In such cases, repeat the test with 20ul of the sample.
• 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 TJ. 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)

SYMBOL INDEX

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

Rev: 1.2020

todylaboratories®

Tody Laboratories Int. SRL
22 Vadul Moldovei, s1, OP 18, Bucharest, CP 014033, ROMANIA
+4021 269 00 00 +4021 269 06 41
ISO 15189, 17043, 9001, 13485
www.todylaboratories.com

CE IVD 2°C 8°C