CRP - LATEX

METHOD - IMMUNO AGGLUTINATION
PACK SIZE -25 Test, 50 Test, 100 Test
PRODUCT CODE –LX02

INSTRUCTIONS FOR USE

INTENDED USE: Test for determination of C-Reactive Protein (CRP) by Immuno Agglutination method.

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.

PRINCIPLE

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

REAGENTS

Latex Reagent	- Latex particles coated with goat IgG anti-human CRP, pH 8.2. Sodium azide 0.95 g/L.
Positive Control	- Human serum with an CRP conc. >20 mg/L. Sodium azide 0.95 g/L.
Negative Control	- Protein based with Sodium Azide 1 gm/L.

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 at 2-8 ^{0}C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionally of the test.

Reagents deterioration: Presence of particles and turbidity.

SAMPLES

Fresh serum. Stable for 7 days at 2-8^0 C or 3 months at -20 ^{0}C. Samples with presence of fibrin should be centrifuged. Do not use highly haemolysed or lipemic samples.

PROCEDURE

QUALITATIVE METHOD

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 40 µl of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the CRP-latex reagent gently before using and add one drop (40 µl) next to the sample to be tested.
4. Mix the drop with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

SEMI-QUANTITATIVE METHOD

1. Make serial two fold dilution of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates on CRP concentration equal or greater than 8 IU/mL. The titre, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

6 x CRP Titre = mg/L.

REFERENCE VALUES

Up to 6 mg/L.
Each laboratory should establish its own reference range.

PERFROMANCE CHARACTERISTICS

1. Analytical sensitivity: 6 (5-10) mg/L, under the described assay conditions.
2. Prozone effect: Not detected up to 1600 IU/mL.
3. Diagnostic sensitivity: 95.6%.
4. Diagnostic specificity: 96.2%.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L) do not interfere. Rheumatoid Factors (100 IU/mL) interfere. Other substances may interfere.

NOTES

High CRP concentration samples may give negative results (prozone effect). Retest the sample again using a drop of 20 µl volume. The strength of agglutination is not indicative of CRP concentration in the sample tested.

CALIBRATION

The CRP-latex sensitivity is calibrated to the Reference Material CRM 470/RPPHS.

BIBLIOGRAPHY

1. Lars-Olof Hanson *et. al.* Current opinion in infectious diseases1997; 10: 196-201
2. M.M. Pepys. The Lancet 1981; March 21: 653-656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139-144.
4. Yoshitsugy Hokama *et. al.* journal of Clinical Laboratory Status 1987; 1: 15-27.
5. Yamamoto S *et. al.* Veterinary Immunology and Immunopathy 1993; 36: 257-264.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE