C-REACTIVE PROTEIN (CRP)

Slide agglutination

Qualitative determination of C-Reactive Protein (CRP)

CE

IVD

PACKAGING

Ref.: 101-0246; 50 tests	2.5 ml CRP latex; 1 ml Control +; 1 ml Control - 8x6 disposable slides
Ref.: 101-0217; 100 tests	5 ml CRP latex; 1 ml Control +; 1 ml Control - 16x6 disposable slides
Ref.: 101-0189; 100 tests	5 ml CRP latex

Store at 2 - 8ºC.

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 Protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP.

REAGENTS

1. Latex
Latex particles coated with goat IgG anti-human CRP, pH 8.2. Sodium azide, 0.95 g/L.
2. Control + (Red cap)
Human serum with a CRP concentration >20 IU/mL.
Sodium azide, 0.95 g/L.
3. Control – (Blue cap)
Animal serum. Sodium azide, 0.95 g/L.

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION

The CRP-latex sensitivity is calibrated to the Reference Material ERM-DA 472/IFCC.

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 tightly closed at +2 to +8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Mechanical rotator with adjustable speed at 80-100 r.p.m.

SAMPLE

Fresh serum. Stable 7 days at +2 to +8º C or 3 months at –20º C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

NOTES

-High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
-The strength of agglutination is not indicative of the CRP concentration in the samples tested.
-Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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 50 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 (50 µL) next to the samples to be tested.
4. Mix the drops 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 dilutions 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 a CRP concentration equal or greater than 6 mg/L. The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATION

The approximate CRP concentration in the patient sample is calculated as follows:
6 x CRP Titer = mg/L

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

REFERENCE VALUES

Up to 6 IU/mL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity: 6 (5 – 10) mg/L, under the described assay conditions.
2. Prozone effect: No prozone effect was 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 triglycerides (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere.

BIBLIOGRAPHY

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