CRP LATEX SLIDE

INTENDED USE
BIOLINE CRP LATEX SLIDE TEST reagent is for the Qualitative determination of CRP in human serum.

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

METHOD AND PRINCIPLE
The CRP-latex is a slide agglutination test for the qualitative and semiquantitative 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.

REAGENT COMPOSITION
Latex Reagent: *Latex particles coated with goat IgG anti-human CRP, pH, 8,2. Preservative*
Positive control: Human serum with an CRP concentration more than 6mg/l.
Negative control : Animal serum. Preservative

WARNINGS AND PRECAUTIONS
1. For *in vitro* diagnostic use.
2. 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.

REAGENT PREPARATION
Reagent and controls (Positive and Negative) are ready to use.

REAGENT 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 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
--Mix reagents gently before use.

REAGENT DETERIORATION
Presence of particles and turbidity.

SPECIMEN COLLECTION AND STABILITY
Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged.
Do not use highly hemolyzed or lipemic samples.

INTERFERENCES
Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere.

MANUAL 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. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (Approx 50 µL) next to the sample 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 an CRP concentration equal or greater than 6mg/l.
The titer, 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 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.
All result different from the negative control result, will be considered as a positive.

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

PERFORMANCE CHARACTERISTICS
1.Analytical sensitivity: 6 (5-10) mg/L, under the described assay conditions
1. Prozone effect: No prozone effect was detected up to 1600 mg/L.
2. Diagnostic sensitivity: 95.6 %.
3. Diagnostic specificity: 96.2 %.

LIMITATIONS OF THE PROCEDURE

- False positive results may be obtained in conditions such as, reumatoide arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 5 years may cause false negative results.
- A single CRP determination does not produce much information about the actual state of the disease. Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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