Reactivos GPL

Barcelona, España

CE

- CRP LATEX-

CRP LATEX
Agglutination test.

Store at: +2+8ºC.

Presentation:
Cod. SE005 50 Test.
Cod. SE006 100 Test.

Procedure

Diagnostic reagent for qualitative measurement of CRP (C-Reactive Protein).

Only for *in vitro use in clinical laboratory* (IVD)

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

REAGENTS COMPOSITION

Latex **Ref. SE007 - 5 mL**	Latex particles coated with goat IgG anti-human CRP, pH, 8.2. Sodium azide 0.95 g/L.
Control (+) **1 mL**	Human serum with a CRP concentration > 20 mg/L. Sodium azide 0.95 g/L.
Control (-) **1 mL**	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 and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY
All the components are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
If appear particles and turbidity do not use.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC,. Do not use reagents over the expiration date.

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

SPECIMEN
Fresh serum. Stable 8 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED
Mechanical rotator with adjustable speed at 80-100 r.p.m.

General laboratory equipment

TEST PROCEDURE
Qualitative method
1. Allow the reagents and sample 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 control into separate circles on the slide test.
3. Shake the CRP-latex reagent gently before using and add a drop of this reagent next to the sample to be tested.
4. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rotate the slide with 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 (Note 2, 3).

The titer, in 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 follow: 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.

Serum controls CRP are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES
Up to 6 mg/L.

It is suggested that each laboratory establish its own reference range.

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 by more than 300 mg/L in 12-24 hours.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

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

INTERFERING SUBSTANCES
Interferences:
- Do not interfere: Haemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L).
- Interfere: Rheumatoid factors (100 IU/mL).
- Other substances may interfere[7].

NOTES
1. High CRP concentration samples may give negative results (prozone effect). It is recommended to be retested using 20 µL of the sample.
2. The strength of agglutination is not indicative of the CRP concentration in the samples tested.
3. 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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