SEROCON®

CRP LATEX

(Slide Agglutination Method)

BEACON®

Code	Product Name	Pack Size
SE022A	CRP Latex(Slide Agglutination Method)	25 T
SE022B	CRP Latex(Slide Agglutination Method)	50 T
SE022C	CRP Latex(Slide Agglutination Method)	100 T
SE022D	CRP Latex(Slide Agglutination Method)	250 T

Qualitative determination of C-Reactive Protien (CRP)

Store at 2-8°C

Principle of The Method

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.

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.

Reagents

Reagent 1: CRP Latex Suspension	Latex particle coated with goat IgG anti-human CRP, pH 8.2. Preservative
Reagent 2: Positive Control	Positive control with preservative
Regent 3: Negative Control	Negative control with preservative

Accessories :

Disposable Plastic Droppers, Disposable Applicator Sticks, Rubber Teat, Disposable Plastic Slides

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 ERMDA 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 2-8°C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.

Reagents deterioration: Presence of particles and turbidity.

Additional Equipment

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.

Samples

Fresh serum. Stable 7 days at 2-8°C or 3 months at –20°C.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized 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 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 (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 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

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.
2. Prozone effect: No prozone effect was detected up to 1600 mg/L (Note 1).
3. Diagnostic sensitivity: 95.6 %.
4. Diagnostic specificity: 96.2 %.

Interferences

Bilirubin (20 mg/dL), hemoglobin (10 g/L) and lipids (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL) interfere. Other substances may interfere.

Notes

1. High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
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

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 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 Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984: 138:

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/CRL/SE/IFU Ver-03
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