C-REACTIVE PROTEIN (CRP) Latex

C-REACTIVE PROTEIN (SLIDE LATEX AGGLUTINATION TEST)

Intended Use

The reagents are for *in-vitro* diagnostic use only.

Principle

The CRP Reagent is a suspension of polystyrene latex particles coated with the gamma globulin fraction of anti-human CRP Specific serum. When CRP is present in the sample, presence of agglutination indicates a content of CRP equal or greater than 6mg/L, without previous sample dilution.

Reagent provided

1. Reagent 1- Latex CRP in suspension (contains Sodium Azide 0.1%).
2. Reagent 2-Positive Control containing at least 6mg/L of CRP.* Human Serum(Contains Sodium Azide 0.1%).
3. Reagent 3- Negative Control containing less than 6mg/L of CRP.* Human Serum. (Contains Sodium Azide 0.1%).

*The human sera used in the controls has been tested and found negative for HBsAg and HIV. However a careful handling is always recommended.

Reagent storage and stability

Shake the Reagent 1 (CRP Latex) before use. After that it must be uniform and without visible clumping. The test sensitivity depends on the drop volume (40 µl).Do not use droppers other than those provided in the kit and place the dropper perpendicular to the slide surface.
The Reagents, if stored at 2-8°C are stable till the expiry date stated on the label. DO NOT FREEZE.

Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Haematic, lipaemic or contaminated sera must be discarded.

Procedure

- Before using the kit, allow the components to reach room temperature.
- Gently shake the reagent to disperse the latex particles.

A. Qualitative Test

1. Check the reagent against the positive and negative controls (as follows).
2. Place a drop (40 µl) of UNDILUTED serum into a circle of the slide.
3. Add a drop (40 µl) of the Reagent 1 (CRP Latex) next to the drop of serum.
4. Mix both drops spreading them over the full surface of the circle.
5. Rotate the slide, manually or with a mechanical rotor at 80-100 rpm for two minutes. Read the presence or absence of visible agglutination in this period of time. ***Unspecific agglutination could appear if the test is read later than two minutes.***

Reading

- Presence of agglutination indicates a content of CRP in the sample equal or greater than 6 mg/L.
- The lack of agglutination indicates aCRP level lower than 6mg/L in the sample.

B. Semi-Quantitative Test

The test will be performed in the same way as qualitative test but using dilution of the serum sample in saline (NaCl 9g/l) PBS or glycine buffer.

Dilutions	1:2	1:4	1:8	1:16
Sample Serum	100 µl	-	-	-
Saline	100 µl	100 µl	100 µl	100 µl
		→ 100 µl	→ 100 µl	→ 100 µl
Volume of above diluted sample	40 µl	40 µl	40 µl	40 µl

The titer will be the highest dilution with positive result.

Concentration will be the reciprocal of positive reading dilution

6 x n (Ratio of Dilution)	6x2	6x4	6x8	6x16
mg/L	12	24	48	96

Normal Range

Adults: < 6 mg/L.

CRP is a portion where serum level increases significantly in an acute phase status as it happens in the most forms of different tissue injuries. It was described the presence of such protein in normal persons at a titer not exceeding 6 mg/L.However the increase occurs in a non specific way in different aggressions like malignant tumor, rheumatic fever, myocardial infarct, inflammations, etc.

References

1Warworth, E.Wadsoth, Ch. Clin. Chim. Acta 138 (1984).
2. Pepys M.B., Dash A.C., Ashley M.J., Clin. Exp.Immunol, 30, 32-37 (1977).
3. Deyo, R.A.,Pope, R.M., Perrsellin, R.H., J.Rheumatol.279 (1980)

Symbols

IVD In Vitro Diagnostics. Caution. Keep away from sun light. Date of Manufacture.

LOT Batch No. Read Instructions. Fragile. Product Expiry Date.

CONT Content. Storage Temperature. Keep Dry. Manufactured By.

REF Catalogue No.

KEE DIAGNOSTICS PVT LTD
CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.
NEW DELHI-110028.
W. www.keediagnostics.com
E. info@keediagnostics.com, T. 011 43136000.