C-REACTIVE PROTEIN (CRP) LATEX KIT

IVD *For In-Vitro and professional use only*
Store at 2- 8°C

INTENDED USE

C - reactive protein (CRP) latex kit is intended to be used to measure the CRP in human serum based on the slide agglutination test for qualitative and semi- quantitative detection.

INTRODUCTION

C-reactive protein (CRP) which is synthesized by hepatocytes, is an acute-phase present in normal serum and can increase significantly in response to tissues injury, bacterial or virus infection. The clinical measurement of CRP in serum is effective for screening test of organic disease and sensitivity index of disease activity in inflammatory, infective and ischemic conditions. Antibody produced against purified CRP found to be a more sensitive test than the C-polysaccharide assay according to MacLeod and Avery. Since that time a number of immunological assays have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radical immunodiffusion.
As described by Singer and Plotz, the measurement of CRP in serum is based on the principle of the latex agglutination assay and the rapid two (2) minute reaction time adding the major advantage of this method.

PRINCIPLE

The CRP reagent kit is based on an immunological reaction between CRP Antisera bound to biologically inert latex particles and CRP in the test specimen. A visible agglutination appears when serum CRP equal or greater than the Reagent sensitivity (Indicated on the label of the latex vial).

STORAGE AND STABILITY

- The reagents should be stored refrigerated at 2 - 8°C. **DO NOT FREEZE**. Slight sedimentation should be considered normal when stored refrigerated.
- These reagents are stable until the expiry date stated on the product label. Do not use the reagents past the expiration date.
- The reagent should be uniform without visible clumping once shaken.
- Avoid using the latex reagents and controls if contamination occurred.
- The vials must always be in an upright position. If changes of position occurred, gently mix to dissolve aggregates that may present.
- Presence of particles and turbidity will result in reagents deterioration.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If testing is delayed, specimen can be stored for 7 days at 2-8^{0}C or up to 3 months at -20^{0}C.
- Make sure the samples with presence of fibrin is centrifuged before testing. Avoid using highly hemolysed or lipemic samples.
- Do not use plasma.

MATERIALS

MATERIALS PROVIDED

- CRP Latex Reagent: Latex particles coated with goat IgG anti-human CRP, pH 8.2 **MIX WELL BEFORE USE.**
- CRP Positive Control Serum (Red cap): A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum (Blue cap): A stabilized pre-diluted animal serum.
- Glass Reaction Slide.
- Stirring Sticks.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipette 50 µL.
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.

PROCEDURES

A.QUALITATIVE TEST

1. Bring the reagents and samples to reach to room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Mix the CRP-latex reagent or using vortex mixer and add one drop (40 µL) next to the samples to be tested.
4. Use stirrer to mix the drops and spreading them over the entire surface of the circle. Do not use the same stirrer for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. Avoid reading the test after more than two minutes since it may cause false positive results.

B. SEMI-QUANTITATIVE TEST

The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.

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

Interpretation of results is carried out by macroscopically observe the presence of any visible agglutination immediately after removing the slide from the rotator. Visible agglutination of latex particles constitutes a positive result and indicates that a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).
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:

Sensitivity (Indicated on the label of the latex vial) x CRP Titer =mg/L

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10 g/dl)
- Bilirubin (20 mg/dl)
- Lipids (10 g/L)

Other substances interfere, such as RF (100IU/ml).

NOTE

High CRP concentration samples may give negative results .Retest the sample again using a drop of 20µl. 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 LIMITATION

1. Reaction time is critical. False positive result may occur if the reaction time exceeded 2 minutes due to reaction mixture may dried up.
2. Spontaneous agglutination may occur if the CRP Latex Reagent is stored in freezing condition.
3. Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.
4. A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all negative sera by retesting at a 1:10 dilution with glycine buffer.

QUALITY CONTROL

It is recommended to use the positive and negative controls to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. The results are considered as a positive if all the result are different from the negative control result.

REFERENCE VALUES

Up to the reagent sensitivity (Indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:
Refer to vial label.

PROZONE EFFECT
No prozone effect was detected up to 1600 IU/ml.

SENSITIVITY
95.6%.

SPECIFICITY
96.2%

PRECAUTIONS

- The reagents contain sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. When drained, flush with a large volume of water to prevent azide build up.
- Make sure to wear protective clothing when handling the reagents, such as disposable gloves and a laboratory coat.
- When the testing is completes, wash hands and clean the test table top with water and soap.
- The kit is for in vitro diagnostic use only.
- Materials used to produce the kit were prepared using human serum found to be negative for hepatitis B surface antigen (HBsAg), HCV and antibody HIV (1/2) by FDA required test. Care must be taken in the use and disposal of each vial and its contents as it is potentially infectious.
- Use provided dropper and hold perpendicularly when dispensing as the drop size of the latex reagent (40µl) will determine the accuracy of the test.
- For each use, make sure to rinse the slide test thoroughly with water and wiped with lint-free tissue.
- Use provided controls to check reactivity of the reagent.

REFERENCES

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REF Catalogue Number	Temperature limit	Manufacturer fax number	Fragile, handle with care
IVD *In Vitro* diagnostic medical device	Caution	Manufacturer telephone number	Use-by date
Contains sufficient for <n> tests and Relative size	Consult instructions for use (IFU)	Keep away from sunlight	Date of Manufacture
LOT Batch code	Manufacturer	Do not use if package is damaged	Keep dry