

This diagnostic reagent kit is for In Vitro qualitative & semiquantative determination of C-reactive proteins in serum by Latex Agglutination method.

PRINCIPLE:

The CRP Latex Reagent consists of uniform Latex particles coated with antihuman - CRP. In presence of CRP in the specimen, visible agglutination is observed. Agglutination ensures the reaction of uniform Latex particle with CRP. No agglutination indicates absence of CRP in the specimen.

CLINICAL SIGNIFICANCE:

C-Reactive protein (CRP) is a normal alpha globulin type of serum protein synthesized in liver. Increased CRP levels are usually seen in infections, inflammatory conditions, in case of organic damage. Serum CRP levels facilitate useful information in the management of neonatal septicemia & meningitis, also seen in patients with myocardial infarction.

SAMPLE COLLECTION & STORAGE:

- Fresh clear serum is preferred.
- Store at 2-8°C
- Do not use plasma or hemolysed / lipaemic serum.

PRECAUTION:

- Bring all reagents and sample to room temperature before use.
- Do not freeze the latex reagent.
- Shake the Latex reagent well before use.
- Use of plasma can lead to false positive results
- Lipaemic, hemolysed & contaminated serum could produce non specific results.
- Drying of Reagent & improper mixing of reagent with sample can lead to erroneous results.
- Care should be taken to ensure uniform drop size while dispensing Latex Reagent & specimen
- Use of positive and negative control enables greater proficiency of results.

KIT CONTENTS:

(A) REAGENTS

- Reagent 1 Latex Reagent
- Reagent 2 Positive Control
- Reagent 3 Negative Control

(B) ACCESSORIES

- Glass Slide
- Plastic dropper
- Disposable Mixing sticks

REAGENT STORAGE AND STABILITY:

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the label.

PROCEDURE:

A) QUALITATIVE TEST:

- Place one drop of specimen, positive control, and negative control in the separate test circle of slide with the use of plastic dropper.
- Add one drop of CRP Latex reagent to the above drop & mix thoroughly with disposable applicator stick.
- Rock the slide gently for 2 min & look for agglutination

RESULT INTERPRETATION:

- Presence of CRP in the test specimen indicated by agglutination that confirms the positive test result.
- No agglutination within 2 minutes is a negative test result & indicates absence of CRP in the test specimen.

B) SEMI QUANTATIVE TEST:

- Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline
- Place one drop of diluted specimen in separate test circle of disposable slide.
- Add one drop of CRP latex reagent on the above drop, mix well with applicator stick.
- Rock the slide gently & look for agglutination till 3 min.

RESULT INTERPRETATION:

- Agglutination in the highest specimen dilution within 3 min corresponds to the approximate amount of CRP mg/dl present in the serum.
- Concentration of CRP can be calculated as follows
CRP (mg/dl) = D x S
- D = highest dilution of specimen showing clear cut agglutination.
- S = Sensitivity of the test 0.6 mg/dl.

LIMITATIONS:

1. As with all diagnostic test, the final diagnosis should be based on correlation of test result with other clinical symptoms & findings.
2. Increase in CRP level is generally associated with many conditions like Rheumatic diseases, Pregnancy, use of oral contraceptives, Myocardial infarction etc. so care should be taken before concluding the final result of the test.

REFERENCE VALUE:

<0.6 mg/dl

BIBLIOGRAPHY:

- Kidmarks, CO. (1972) ScandJ.Clin. Invest. 29, 407
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- Ward A.N. Copper E.M., Clin. Chem Ada, 81,75 (1977).

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 2-8°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by