

ATLAS C-REACTIVE PROTEIN (CRP) LATEX KIT

For the qualitative and semi-quantitative measurement of C-reactive protein (CRP) in human serum.

IVD For in -vitro diagnostic and professional use only

2°C  8°C
Store at 2-8°C

INTENDED USE

Atlas C-Reactive Protein (CRP) is used to measure the CRP in human serum qualitatively and semi- quantitatively.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assays have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radical immunodiffusion.

The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is the rapid two (2) minute reaction time.

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. When serum containing greater than 6 mg/L CRP is mixed with the latex reagent, visible agglutination occurs.

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: A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum: A stabilized pre-diluted animal serum.
- Glass Slides.
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Positive and negative controls prepared using human serum found negative for hepatitis B surface antigen (HBsAg) by FDA required test; however, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper provided with the latex and hold perpendicularly when dispensing.
- Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2 - 8°C). **DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.

- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8 °C and for 3 months at -20°C.
- For longer periods the sample must be frozen.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- Do not use plasma.

PROCEDURE

A.QUALITATIVE TEST:

1. Allow the reagents and samples to reach 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 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 (40 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.

B.SEMI-QUANTITATIVE TEST:

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.

QUALITY CONTROL

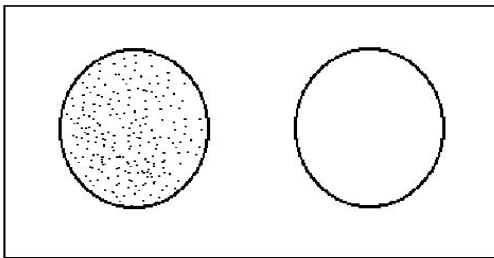
Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. All result different from the negative control result, will be considered as a positive.

INTERPRETATION OF RESULTS

A.QUALITATIVE TEST:

A **negative** reaction is indicated by a uniform milky suspension with no agglutination as observed with the CRP Negative Control.

A **positive** reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the CRP Negative Control (Fig. 1).



Positive Negative

Figure 1

B. Semi-QUANTITATIVE TEST:

The approximate CRP concentration in the patient sample is calculated as follow:

$6 \times \text{CRP titer} = \text{mg/L}$

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl)
- 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.

LIMITATIONS

1. Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
2. Freezing the CRP Latex Reagent will result in spontaneous agglutination.
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.

REFERENCE VALUES

Up to 6 mg/L. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- **Sensitivity:** 6(5-10) mg/L
- **Prozone effect:** No prozone effect was detected up to 1600 mg/L
- **Diagnostic sensitivity:** 95.6 %.
- **Diagnostic specificity:** 96.2 %.

REFERENCES

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ATLAS MEDICAL














**William James House,
Cowley Road, Cambridge,
CB4 0WX, UK**

Tel: +44 (0) 1223 858 910

Fax: +44 (0) 1223 858 524

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 REF	Catalogue Number		Store at
 IVD	For In-Vitro Diagnostic use		Caution
 Σ	Number of tests in the pack		Read product insert before use
 LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		