Atlas Medical

ATLAS C-REACTIVE PROTEIN (CRP) LATEX KIT

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

IVD *For In-Vitro and professional use only*

Store at 2-8°C

INTENDED USE

Atlas C-REACTIVE PROTIEN (CRP) is used to measure the CRP in human serum qualitatively and 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 l,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 PRIVIDED

- CRP Latex Reagent: A suspension of uniform polystyrene particles coated with monospecific antihuman CRP (goat) in saline solution , pH 7.5 ± 0.5. Reagent sensitivity is adjusted to approximately 6(5-10) mg / L **mix well before using**.
- CRP Positive Control Serum: A stabilized prediluted human serum containing >20mg/L CRP
- CRP Negative Control Serum: A stabilized prediluted human.
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.
- Reaction Slide
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer.
- Test Tubes.
- Test Tube Rack.
- Serological pipettes.

PRECAUTIONS

- Reagents containing sodium azide may combine 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 sera 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 (40(L). 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 stated expiration 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.
- Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

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. Bring reagents and specimens to room temperature before use.
2. Place one drop (40 µl) of CRP Positive Control on field #1 of the reaction slide. Place one drop (40 µl) of the CRP Negative Control on field #2. Using a serological pipette place (40µl) of undiluted test sample to field #3. Continue likewise with additional unknowns. Use different pipette tips for different samples.
3. Gently resuspend the CRP Latex Reagent and add one drop to each test field.
4. Mix well with the provided stirring sticks.
5. Rotate the slide for 2 minutes and read immediately under an oblique indirect light.

B. Semi-Quantitative Test:

1. Set up at least five test tubes: 1:2, 1:4, 1:8, 1:16, 1:32, etc..
2. Dilute sample according to dilution factor on each test tube with saline solution.
3. Place one drop of each of positive and negative controls on to the slide ring. Place one drop of each dilution on successive fields of the reaction slides.
4. Gently resuspend the CRP Latex Reagent and add one drop to each test field.
5. Mix well with the provided stirring sticks. Gently rock the slide for two (2) minutes and read immediately under direct light.

QUALITY CONTROL

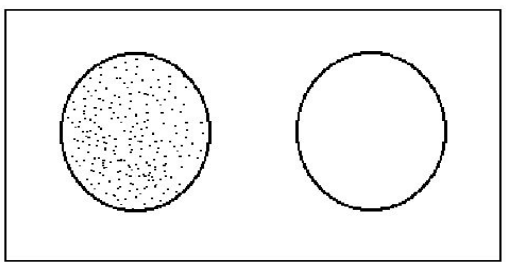
1. CRP Positive and Negative Control should be included in each test batch.

2. Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the CRP Negative Control and agglutination with large aggregates is observed with the CRP Positive Control

INTERPRETATION

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×CRP titer = mg/L

INTERFERENCES

NON 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 .Re – test 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.

EXPECTED VALUES

1. CRP in healthy individuals is approximately 0.02-1.35mg(dl. The mean value in adults is 0.047mg(dl.
2. A weak positive correlation was found between CRP and age.
3. It is important to determine the level of CRP for monitoring patient progress. This is due to :
    1. The concentration of CRP is an index of tissue damage incurred .
    2. Increasing or decreasing levels of CRP (e.g. daily) indicate the progress of inflammatory process.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
- Freezing the CRP Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.
- 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 Saline Solution.

PERFORMANCE

1. Sensitivity: 6 (5-10) mg/L
2. Comparison:

A.Qualitative Results:

A study performed using CRP Latex Reagent and a commercially available product yielded 98% accuracy. The discrepant results were obtained in samples with titers near the limit of sensitivity of the reagents.

B. Semi-Quantitative Results

A panel of 10 known CRP positive serum samples were quantitated on three (3) consecutive days. The results of the study indicated that CRP Latex Reagent has 100% precision.

REFERENCES

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ATLAS MEDICAL

William James House, Cowley Rd,

Cambridge, CB4 4WX, 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		