ASTAM DIAGNOSTICS

PRODUCT INSERT

REF CRPS

PRATHAM®
CRP Test (Latex)

INTENDED USE

PRATHAM® CRP Test (Latex) slide test is used for the qualitative and semi-quantitative determination of C-reactive protein (CRP) in human serum.

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 by as much as 1000-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. It has been 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. The major advantage of this method is the rapid three (3) minute reaction time.

TEST PRINCIPAL

PRATHAM® CRP Test (Latex) slide test for qualitative and semi-quantitative detection of C- reactive protein (CRP) in human serum. Latex particles coated with gaot igG anti-human CRP are agglutinated when mixed with samples contacting CRP.

KIT COMPONENTS

1. Latex Reagent
2. Positive Control
3. Negative Control
4. Test Slide
5. Mixing Sticks
6. Sample Droppers
7. Product Insert

MATERIAL REQUIRED BUT NOT PROVIDED

Micro pipettes, Vortex mixer, Tissue paper, Normal saline, Test Tube, Centrifuge Marker, Timer, Specimen Collection Device.

STORAGE AND STABILITY

PRATHAM® CRP Test (Latex) slide test components are stable up to expiry date indicated on the component label/box label. CRP kit needs to be stored at 2-8º C.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2-8º C for no longer than 48 hours after collection. For longer periods the sample must be frozen.
3. As in all serological tests, hemolytic or contaminated serum must not be used.
4. Do not use plasma.

WARNING AND PRECAUTION

- Cap the vial properly after use to avoid drying of the latex reagent. Do not freeze the latex reagent.
- Positive & negative controls are ready to use & should not be diluted while using in test procedure.
- As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
- Drying of the specimen and latex reagent mixture at the periphery of the circle could lead to erroneous results.
- In addition to Rheumatoid Arthritis, positive result may also be found in Syphilis, Systemic Lupus, Erythematosus, Hepatitis,

Hypergammaglobulinema etc.

- This package insert must be read completely before performing the test. Failure to follow the insert may give inaccurate test results.
- Do not use expired test kit.
- Bring all components to room temperature (15º C-30º C) before use.
- Do not use the components of any other type of test kit as for the components in this kit.
- Apply standard bio-safety precautions for handling and disposal of potentially infective material.
- Do not smoke, drink or eat in areas where specimens or kit is being handled.
- Handle all specimen as potentially infections.
- Wear gloves while handling specimens and performing the test.
- Avoid splashing and aerosol formation.
- Clean up spills throughly using an appropriate disinfectand.
- Do not use if the product has been exposed to excessive heat.
- Dispose off all specimens and materials used to perform the test as bio- hazardous waste.
- Firmly shake the latex reagent vial properly to get the homogenous latex particles before testing.

TEST PROCEDURE

A. QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperature.
2. Place 50µl of the sample with the help of specimen dropper and one drop of each positive and negative controls into separate circle on the test slide.
3. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (50µl) to each test circle.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Gently rock the slide for two (2) minutes and read agglutination reaction if any immediately under direct light.

B. SEMI-QUANTITATIVE TEST:

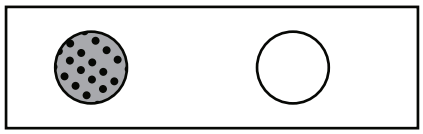
1. Make serial two fold dilutions of the sample in normal saline solution (9 g/L).
2. Proceed for each dilution as in qualitative method.

INTERPRETATION OF RESULTS

1. QUALITATIVE TEST:

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed and compose 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.



2. SEMI-QUANTITATIVE TEST:

The approximate CRP concentration in the patient sample is calculated as follows:
mg.dL of serum = Factor of 0.8 x Reciprocal of last dilution showing a positive result.

Dilution	Reciprocal	Conc. of serum (mg/dL)
1:2	2	1.6
1:4	4	3.2
1:8	8	6.4

INTERFERENCES

NONE INTERFERING SUBSTANCES:

Hemoglobin (10 g/dl)
Bilirubin (20 mg/dl)
Lipids (10 g/L)
Other substances interface, 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.

INTERNAL QUALITY CONTROL

1. Positive and negative controls should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension with no agglutination in observed with the CRP Negative Control and agglutination with large aggregates is observed with the CRP Positive Control.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity: Greater than 0.8mg/dL or 8mg/dL.
PROZONE EFFECT: No prozone effect was detected up to 1500 IU/ml.
SENSITIVITY 95%.
SPECIFICITY 96%.

LIMITATION OF THE TEST

1. Freezing the CRP Latex Reagent will result in spontaneous agglutination.
2. Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.
3. Reaction time is critical. If reaction time exceeds two (2) minutes drying of the reaction mixture may cause false positive results.
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.
5. Reagents determination: Presence of particles and turbidity.
6. Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.

DISPOSAL

Consider all test run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

The manufacturer and distributors of this product shall not be liable for any losses, liability, claims, coasts or damages whether direct or indirect or consequential out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. MacLeod, C.M., et. al.. J. Exp. Med 73:191 (1941).
2. Wood, HF., et. al.. J. Clin. Invest. 30: 616 (1951).
3. Mancini, G., et. al. Immunochemistry 2:235 (1965).
4. Singer, J.M., et. al.. Am. J. Med 21: 888 (1956).
5. Fischer, C.L., Gill,.C.W.. In Serum Protein Abnormalities. Boston, Little, Brown and Co., (1975).
6. Pepys, M.B.. Lancet 1:653 (1981).
7. Werner, M..Clin.Chem. Acta 25:299 (1969).

SYMBOLS

	See instruction for use		Storage temeprature		For in-vitro diagnostic use
	Expiry date		Catalogue number		Manufactured by
	Keep away from sunlight		Manufacturing date		No. of tests
	Do not reuse				

Manufactured By:

ASTAM DIAGNOSTICS PVT. LTD.

Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
For feedback/queries contact customer care : 011-27358101

ASTAM DIAGNOSTICS