

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL

	Temperature Limitation		Date of Manufacture
	In vitro Diagnostic Device		Batch Code
	Company name & address		Refer Operating Instructions
	Use by		Company name
	Authorised Representative in European Community		Do Not Reuse
	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE
	NEGATIVE CONTROL		POSITIVE CONTROL

C Reactive Protein (CRP)



For Professional Use

Test for the detection of C-reactive Protein (CRP) in human serum.



Read Pack Insert before use provided along with the kit

CRLA

INTENDED USE :

CRP latex slide test is a latex agglutination test for qualitative and semi quantitative in vitro determination of C-Reactive Protein (CRP) in human serum.

INTRODUCTION :

C-Reactive protein is a serum protein synthesized by hepatocytes. Normally it is present in trace amounts in serum, but it can increase by as much as 1,000 fold within hours of an acute injury or onset of inflammation. Its use in post operative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7 to 10 days. Absence of this fact is indicative of possible septic or inflammatory post operative complications. Serum CRP measurement also provides useful information in patients with myocardial infarction, these being an excellent correlation between peak levels of CRP and creatinine phosphatase.

PRINCIPLE:

The CRP test is based on passive latex agglutination. Polystyrene latex particles are coated with purified CRP antibodies. When serum containing greater than 0.6 mg/dl CRP is mixed with the suspension of coated latex particles, visible agglutination occurs.

STORAGE AND STABILITY :

Storage :

Store the reagents at 2 to 8°C. Do not use the reagent beyond the expiry date mentioned on it. Before performing the test bring all the reagents to Room temperature. Replace the reagents to 2 to 8°C soon after performing the test.

DO NOT FREEZE THE REAGENTS.

Stability :

1. The unopened kit is stable for 24 months from the date of manufacturing as indicated on the package.

2. The opened kit is stable for 6 months from the date of opening.

3. Repeated freeze thaw of reagents from 2-8°C to Room temperature several times will reduce the stability of the kit.

PACK SIZE : Available in packs of 25,50,&100 Tests.

CONTENTS OF THE KIT :

Materials	25 Tests	50 Tests	100 Tests
CRP Positive Control serum	0.3 ml	0.3 ml	0.3 ml
CRP Negative Control serum	0.3 ml	0.3 ml	0.3 ml
CRP Latex Reagent	0.8 ml	1.6 ml	3.2 ml
Glass slide	1 No.	1 No.	1 No.
Disposable applicator sticks	25 Nos.	50 Nos.	100 Nos.
Disposable plastic dropper with rubber teat	25 Nos.	50 Nos.	100 Nos.
Product pack insert	1	1	1

SPECIMEN:

Use fresh serum for testing. The specimen should be Non-hemolysed and free from contamination. The specimen may be stored at 2-8°C for up to 8 days and at -20°C for up to 4 weeks.

SPECIMEN COLLECTION AND HANDLING :

Collect blood in a clean sterilized vial and allow it to clot. Separate the serum by centrifugation at 10000 rpm for 10 minutes at room temperature. It is recommended that fresh samples should be used. If serum is not used for testing immediately it should be stored at 2 to 8°C or Frozen at -20°C. Bring specimen to room temperature, and specimen should be mixed properly and centrifuged before use. Do not heat or repeatedly freeze thaw the specimens.

PRECAUTIONS :

1. For *in vitro* diagnostic use only.



Manufactured in India by :

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- Bring all reagents and specimens to Room temperature, prior to testing.
- Avoid using lipemichaemolysed or contaminated specimen.
- All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the center for disease control/National Institute of Health Manual "Biosafety in Microbiological and Biomedical Laboratories", 1984.
- Never pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling specimens and kit reagents. Afterwards wash hands carefully.
- Avoid splashing or forming aerosols.
- Discard all materials and specimens as if capable of transmitting infection. The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid waste containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500mg/l available chlorine. Allow 30 minutes for decontamination to be completed.

NOTE :

- Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.
- Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to bio hazardous waste matter for proper disposal.
- Deterioration is indicated by a significant decrease by weak agglutination.
- Do not use reagents after the expiration date printed on the label.
- When removing reagents from the bottles, use aseptic technique to avoid contamination.
- Mix the reagent bottle gently before use.
- Do not use contaminated serum sample for testing.
- Ensure used glass slide is disinfected, washed thoroughly and rinsed free of detergents.

TEST PROCEDURE:

A. Qualitative Analysis :

Allow all reagents as well as the sample to attain room temperature.

- Using disposable plastic dropper place one drop of specimen in circled area of the slide provided in the kit.
- Add one drop of CRP latex antigen to the above drop and mix well with disposable applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination. Do not examine beyond two minutes. For Positive and Negative controls follow the same procedure as mentioned above by taking control serum from respective vials.

B. Semi quantitative Analysis :

- Dilute the Test serum serially 1:2,1:4,1:8,1:16,1:32 using normal saline.**
- Place one drop of diluted sample using plastic dropper in each circle of the glass slide.
- Add one drop of Latex reagent in each of these circles, mix well with applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination.

INTERPRETATION OF RESULTS :

Read the result under strong source of light.

A. Qualitative Analysis :

Positive : Any observable agglutination in the reaction mixture.

Negative : Uniform milky suspension with no agglutination.

B. Semi Quantitative Analysis :

Concentration of CRP in test serum can be estimated in mg/dl as follows. $CRP (mg/dl) = Sensitivity in mg/dlx Titre$ Where $sensitivity = 0.6 mg/dl Titre = Reciprocal of the highest dilution of serum which exhibits a positive reactions.$

FALSE POSITIVE	
Cause 1. Contaminated serum or reagents	Remedy Make sure that there is no contamination of serum or reagent. Use clean slide for testing. Do not read the result after 4 minutes.
2. Drying in slide test	Do not read the result after 4 minutes
3. Improper mixing of Latex Reagent	Mix the Latex reagent thoroughly before use.

FALSE NEGATIVE	
Cause 1. Contamination of serum or reagents	Remedy Make sure that there is no contamination of Serum or reagent Use clean slide for testing.
2. Improper mixing of Latex Reagent.	Mix the latex reagent thoroughly before use.

WEAKLY / DELAYED REACTION	
Cause 1. Improper mixing of Latex Reagent	Remedy Mix the Latex reagent thoroughly before use.
2. Expired reagent	Check the expiry date on the reagent
3. Improper storage conditions of the kit	The kit has to be stored at 2-8°C.

PERFORMANCE CHARACTERISTICS :

Accuracy : Bhat Bio-Scan® CRP Test meets the requirements when tested against DCI approved kits.

SPECIFICITY :

No. of Negative samples tested	No. of Negative by Bhat Bio-Scan® CRP Test	Specificity (%)
40	40	100

SENSITIVITY :

No. of Positive samples tested	No. of Positive by Bhat Bio-Scan® CRP Test	Sensitivity (%)
35	35	100

LIMITATIONS OF THE TEST :

- It is recommended that with every set of tests, positive and negative controls should be included. The result of positive and negative controls should be read before reading the test results. The satisfactory result of positive and negative Control indicates that the reagents are working well.
- Factors other than reagents, which might affect the performance of the test, include cleanliness of glassware, meticulous follow up of the procedure and rouleaux formation.
- Do not use lipaemic, haemolysed, or contaminated specimens.
- Mix Latex antigen gently before use.
- While dispensing reagents/specimen hold pipette/dropper vertically straight.
- Improper mixing of specimen/control with Latex may lead to erroneous results.
- Make sure that the cap of each reagent vial is properly and promptly applied to the same vial. Interchanging of the vial caps and or droppers will lead to contamination of reagents, which might lead to false results.
- The slide should be tilted back and forth gently to avoid disturbance to the reaction pattern
- Contaminated blood specimen or reagents may interfere with test results. Peripheral drying in slide test should not be misinterpreted as agglutination.
- Interpret results exactly at 2 minutes.
- The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membrane.

REFERENCE :

- Andersen H.C., Mc., Carthy M., Am.J.Med., 8,445 (1950).
- Connell E.B., Connell J.Am.J.obs.Gaynacc (1971).
- Fisher C.L. Nakamura R.Am.J.Clin.Path.66, 840 (1976).
- Ward A.N.Cooper E.M., Clin Chem.Acta.81.75 (1977).