

SBio CRP

Slide Test for C-Reactive Protein

REF	90420050	90420100
50 T	100 T	



Temperature Limitation	Manufacturer	This side up	EC REP Authorised Representative	Xn NaN, R22 S23-46-61
Use by (Last day of stated month)	Consult Instructions for use		CONTROL + Positive control	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Date of Manufacture	REF Catalogue Number		CONTROL - Negative control	
LOT Batch Number	IVD In vitro Diagnostic Medical Device		REAGENT Description of reagent	
		Contains sufficient for <n> tests		

SUMMARY

C-reactive protein (CRP) is a serum protein, which is synthesized in the liver. Its rate of synthesis and secretion increases within hours of an acute injury or the onset of inflammation and may reach as high as 20 times the normal levels.

Elevated serum concentration of CRP is an unequivocal evidence of an active tissue damage process and CRP measurement thus provides a simple screening test for organic disorders. Apart from indicating inflammatory disorders, CRP measurement helps in differential diagnosis, in the management of neonatal septicaemia and meningitis where standard microbiological investigations are difficult.

Its use in postoperative surveillance is of great importance. CRP levels invariably rise after major surgery but fall to normal within 7-10 days. Absence of this fall is indicative of possible septic or inflammatory postoperative complications.

Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and Creatinine phosphokinase (CPK).

SBio CRP is a latex agglutination slide test for the detection of C-reactive protein.

REAGENTS

- SBio CRP reagent: A uniform suspension of polystyrene latex particles coated with Anti-CRP antibodies. The reagent is standardized to detect CRP concentrations greater than 0.6 mg/dl. The standardization of detection limit of SBio CRP is traceable to the W.H.O., International reference Standard (85/506) for Human C-reactive protein.
 - Positive control, reactive with SBio CRP reagent.
 - Negative control, non-reactive with SBio CRP reagent.
- Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE.

The shelf life of the reagent is as per the date mentioned on the reagent vial label. Do not use reagents after the expiry date.

PRINCIPLE

SBio CRP slide test for detection of CRP is based on the principle of agglutination. The test specimen (serum) is mixed with SBio CRP latex reagent and allowed to react. If CRP concentration is greater than 0.6 mg/dl a visible agglutination is observed. If CRP concentration is less than 0.6 mg/dl, then no agglutination is observed.

NOTE

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The reagents that are derived from human source have been

tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious. The reagents contain 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.

- The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls provided with the kit.
- Shake the latex reagent well before use to disperse the latex particles uniformly and improve test readability.
- Only a clean and dry slide must be used. Clean the slide with distilled water and wipe dry.
- Accessories provided with the kit only must be used for optimum results.
- Do not use damaged or leaking reagents.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques.

Only serum must be used for testing. Should a delay in testing occur, store the sample at 2-8°C. Samples can be stored for up to a week.

ADDITIONAL MATERIAL REQUIRED

Stop watch, Test tubes, A high intensity direct light source, Isotonic saline.

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Qualitative Method

- Pipette one drop (40 µl) of test specimen (serum) on the slide using disposable pipette provided with the kit.
- Add one drop of SBio CRP latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
- Using a mixing stick, mix the test specimen and SBio CRP latex reagent uniformly over the entire circle.
- Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

- Using isotonic saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.
- Pipette one drop (40 µl) of each dilution of the test specimen onto separate reaction circles on the slide.
- Add one drop of SBio CRP latex reagent to each drop of test

- specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
- Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
 - Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two** minutes.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of detectable levels of CRP in the test specimen.
No agglutination is a negative test result and indicates absence of detectable levels of CRP in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of CRP in mg/dl present in the test specimen.

Concentration of CRP can be calculated as follows:

$$\text{CRP (mg/dl)} = S \times D$$

Where, S = Sensitivity of the reagent i.e. 0.6 mg/dl.

D = Highest dilution of serum showing agglutination.

REMARKS

- Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
- Use of plasma rather than serum can lead to false positive results.
- CRP is found to be present after the first trimester of pregnancy and persists until delivery.
- CRP levels increase in women who are on oral contraceptives.
- CRP response is not affected by the commonly used anti-inflammatory or immunosuppressive drugs, including steroids, unless the disease activity is affected and it covers an exceptionally broad incremental range upto 3000 times.
- Do not read results beyond indicated testing time limits.
- Since CRP production is a non-specific response to tissue injury, it

is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

- In cases where an increase in CRP levels is suspected, but the screening test shows a negative results, semiquantitation should be done to rule out prozone effect.

PERFORMANCE CHARACTERISTICS

- The performance characteristics of SBio CRP were evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers latex slide test reagent having similar performance characteristics.

	Total	SBio CRP	
		Positive	Negative
CRP +ve samples	33	33	0
CRP -ve samples	80	0	80
	113	33	80

Sensitivity: 100% Specificity: 100%

- Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of CRP negative and CRP positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Andersen H.C., McCarthy M., Am. J. Med., 8, 445 (1950). (2) Ward A. N., Cooper E. M., Clin. Chem. Acta, 81, 75 (1977). (3) Fisher C. L., Nakamura R., Am. J. Clin. Path., 66, 840 (1976). (4) Connell E. B., Connell J., Am. J. Obs. Gynaec, 110, 633 (1971).

 Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:


Singapore Biosciences PTE Ltd.

11 Yishun Street 51, #04-23,
The Criterion, Singapore 767971

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain