SLIDE TEST FOR C – REACTIVE PROTEIN

BACKGROUND

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 septicemia and meningitis where standard microbiological investigations are difficult.
Its use in post-operative 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 post-operative complications.
Serum CRP measurement also provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and creatine phosphokinase (CPK).

ASSAY PRINCIPLE

Vitro CRP slide test for detection of CRP is based on the principle of agglutination. The test specimen (serum) is mixed with Vitro 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.

REAGENTS

1. Vitro 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.
2. Positive control, reactive with Vitro CRP reagent.
3. Negative control, non-reactive with Vitro CRP reagent.

REAGENT STORAGE AND STABILITY

a) Store the reagents at 2-8°C. DO NOT FREEZE.
b) The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

SPECIMEN

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 upto a week. Do not use hemolysed serum.

PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

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

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2, 1:4, 1:8, 1:16, and so on.
2. Pipette each dilution of the test specimen onto separate reaction circles.
3. Add one drop of Vitro CRP latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
5. 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 the 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 amount of CRP in mg/dl present in the specimen.

Concentration of CRP can be calculated as follows:

CRP(mg/dl) = S x D

Where,

S = Sensitivity of the reagent i.e. 0.6 mg/dl.
D = Highest dilution of serum showing agglutination.

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REMARKS

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1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. CRP is found to be present after the first trimester of pregnancy and persists until delivery.
4. CRP levels increase in women who are on oral contraceptives.
5. 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 up to 3000 times.
6. Do not read results beyond indicated testing time limits.
7. 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.
8. In cases where an increase in CRP levels is suspected, but the screening test shows a negative result, semiquantitation should be done to rule out prozone effect.

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.

NOTES

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents 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.
3. Reagent contains 0.1% Sodium azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. 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 supplied with the kit.
5. Shake the Vitro CRP latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

BIBLIOGRAPHY

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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).**
5. **Data on file: Vitro Diagnostics.**

SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
	Batch code (Lot #)
	Catalog number
	Temperature limitation
	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
4021	50 TEST
4022	100 TEST
4031	100 TEST+ Controls
4032	50 TEST+ Controls

*All kit sizes are available with or without accessories which include:

- Positive Control.
- Negative Control.
- Slide.
- Mixing Staws.

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