CRP-Latex

INTENDED USE

The CRP-latex is a slide agglutination test for the qualitative and semiquantitative detection of C-reactive protein in human serum.

METHOD

Latex Slide test

CLINICAL SIGNIFICANCE

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

Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP. If CRP concentration is greater than 6 mg/l a visible agglutination is observed. If CRP concentration is less than 6 mg/l, then no agglutination is observed.

REAGENTS

CRP Latex	A uniform suspension of polystyrene latex particles coated with goat IgG anti-human CRP, pH 8.2. The reagent is standardized to detect CRP concentrations greater than 6 mg/l.
Positive control	reactive with the Vitro CRP reagent.
Negative control	non-reactive with the Vitro 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 reagents at 2-8°C. DO NOT FREEZE.

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test. Mix reagents gently before use. Reagents deterioration: Presence of particles and turbidity.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged. Do not use highly hemolized or lipemic samples.

No special preparation of the patient is required prior to specimen collection by approved techniques. Do not use hemolyzed serum.

PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

1. Pipette one drop of serum onto the glass slide using the disposable pipette provided with kit.
2. Add one drop (50µl) of Vitro CRP latex reagent to the drop (50µl) 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 serum and Vitro CRP latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth or place the slide on a mechanical rotator at 80-100 r.p.m observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

Using isotonic saline prepare serial dilutions of the serum sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.

Pipette each dilution of the serum sample onto separate reaction circles. Start with the 1:2 diluted test specimen.

1. Add one drop of Vitro CRP latex reagent to each drop of the diluted serum sample on the slide. Do not let the dropper tip touch the liquid on the slide.
2. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
3. Immediately start a stopwatch. Rock the slide gently, back and forth or place the slide on a mechanical rotator at 80-100 r.p.m observing for agglutination macroscopically at **two minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates the presence of CRP in the test specimen.

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

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the CRP in mg/dl.

The concentration of CRP can be calculated as follows:

$$CRP\ (mg/l) = S \times D$$

where

S = Sensitivity of the reagent i.e., 6 mg/l.

D = Highest dilution of serum showing agglutination.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. All result different from the negative control result, will be considered as a positive.

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EXPECTED VALUES

Up to 6 mg/L. Each laboratory should establish its own reference range.

PERFORMANCE EVALUATION

1. Analytical sensitivity: 6 (5 - 10) mg/l, under the described assay conditions.
2. Prozone effect: No prozone effect was detected up to 1600 mg/l.
3. Diagnostic sensitivity: 95.6 %.
4. Diagnostic specificity: 96.2 %.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Serum samples having markedly higher protein content may produce non-specific reagent aggregation.
3. Use of plasma rather than serum can lead to false positive results.
4. Do not read results beyond two minutes.
5. It is recommended that all positive test results should be further tested with methods enabling quantitation of CRP titers.
6. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
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, semi-quantitation should be done to rule out prozone effect.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere[7]

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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SYMBOL DECLARATION

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

ORDERING INFORMATION

REF Complete Kit	SIZE	REF Latex Only
40201	100 tests	40203
40202	50 tests	40204

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

- Positive Control.
- Negative Control.
- Slide.
- Mixing Straws.

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