

Cenogenics

C·R·P·A[®] Latex Test Set

INTENDED USE

Rapid latex agglutination test for the qualitative determination of C-reactive protein.

SUMMARY AND EXPLANATION

C-reactive protein usually appears in the sera of patients in the acute stages of a number of inflammatory, most bacterial and some viral infections; acute rheumatic fever with or without carditis; rheumatoid arthritis and most other collagen diseases; and in a number of other conditions characterized by inflammation. C-reactive protein can usually be demonstrated in cases of acute myocardial infarction and in several types of malignancies particularly those that are metastatic².

Since the discovery that rabbits form precipitating antibodies against CRP³, various immunoprecipitation techniques have been applied for its detection. The C.R.P.A. LATEX TEST is based on the latex agglutination method introduced by Singer et al, in 1957⁴. The C.R.P.A. LATEX TEST has the advantage of rapid performance in comparison to other tests for the detection of CRP. The results are readable after 1 - 2 minutes reaction time.

Only serum should be tested. Strongly lipemic sera can cause false positive reactions. The results should be read within 1 - 2 minutes. A longer reaction time may cause false positive results. If CRP level is very high (in the range of 20 mg%), agglutination may fail to appear due to antigen excess (prozone).

When serum is drawn from a patient and tested at appropriate time intervals, changes in the level of C-reactive protein can be used as an index of recovery. The use of C-reactive protein test to measure the effectiveness of therapy is of great clinical significance, particularly in the management of patients with acute rheumatic fever.

PRINCIPLES OF THE PROCEDURE

The test is based on an immunologic reaction between CRP as an antigen and the corresponding antibody coated on the surface of biologically inert latex particles.

REAGENTS

C.R.P.A. LATEX REAGENT is a suspension of polystyrene latex particles in glycine-saline buffer, pH 8.4 \pm 0.2. Latex particles are coated with monospecific anti-human CRP produced in laboratory animals.

GLYCINE-SALINE BUFFER (20X) CONCENTRATE, pH 8.4 \pm 0.2, is to be diluted 1:20 with distilled water.

POSITIVE CONTROL SERUM is a stabilized human serum containing CRP as an antigen.

NEGATIVE CONTROL SERUM is a stabilized human serum nonreactive with the latex particles.

All reagents are preserved with sodium azide (1 mg/ml).

WARNING

For in vitro diagnostic use.

STORAGE CONDITIONS

Store at 2°—8° C. Do not freeze.

STABILITY

Expiration date is specified on the kit label. Biological indication of product instability is evidenced by inappropriate reaction of the latex reagent with the corresponding positive and negative control sera.

SPECIMEN

Collection and Preparation:

Specimen can be drawn by venipuncture or convenient fingertip method. After complete clot retraction, the serum is separated for testing.

Interfering Substances:

Strongly lipemic sera and/or bacterial contamination may cause false positive agglutination.

Storage Conditions:

The serum specimens should be stored refrigerated. If testing is to be prolonged in excess of 24 hours, serum should be frozen. Bacterial contamination may cause protein to denature.

PROCEDURE

Materials supplied with C.R.P.A. LATEX TEST SET:

- C.R.P.A. Latex Reagent
- Glycine-Saline Buffer 20X Concentrate
- Positive Control Serum
- Negative Control Serum
- Disposable Pipettes
- Applicator Sticks
- 6-Well Glass Slide

Materials required, but not provided:

- Test tube (for dilution)
- Pipettes (serological)
- Lab rotator (optional)
- Laboratory timer

METHOD

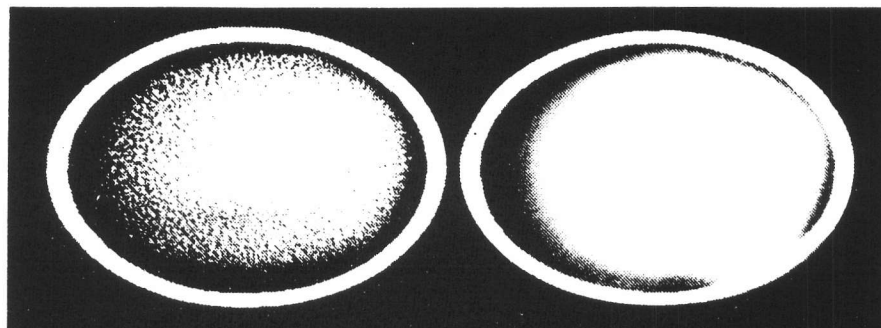
1. Bring all reagents and serum samples to room temperature.
2. Using a disposable pipette provided, place one drop of patient's serum on the test slide.
3. Mix the C.R.P.A. Latex Reagent well. Expel contents of dropper, refill and add one drop to each of the serum drops to be tested. Mix each unknown well with a separate applicator stick, spreading the mixture over the field and then tilt the slide through several planes for 2 minutes. A rotary shaker may be used.
4. Positive and negative controls should be run with each series of test sera. The controls supplied by CENOGENICS are to be used exactly as outlined in steps 1 thru 3.
5. The reaction of the test serum is compared to the CRP positive and negative control sera.

QUALITY CONTROL PROCEDURE

A positive control will produce, usually within one minute, coarse agglutinated flocs against a clear background.

A negative control will produce no agglutination. It should be used for a basis of comparison. The relative degree of smoothness of the C.R.P.A. Reagent itself should be considered and incorporated in reading the result.

If the indicated result using the positive and negative controls are not obtained, the C.R.P.A. kit should not be used.



Coarse Agglutination =
Positive

No Agglutination =
Negative

RESULTS

An agglutination of the latex particle suspension is a positive result. Since negative results may be caused by antigen excess, the test should be repeated using a diluted serum.

LIMITATIONS OF PROCEDURE

The strength of the agglutination reaction is not indicative of the CRP concentration. Weak reactions may occur with slightly elevated or markedly elevated concentrations. A prozone phenomenon (antigen excess) may cause false negatives. It is advisable, therefore, to check all negative sera by retesting at a 1:10 dilution. Reaction times longer than specified may produce apparent false reaction due to a drying effect. Strongly lipemic or contaminated sera can cause false positive reactions.

If quantitative determination of CRP is desired after receiving a positive result with CENOGENICS' latex slide test, the CENOGENICS' C-Reactive Protein Antiserum or a single radial immunodiffusion method¹⁴ is recommended.

EXPECTED VALUES

Normal adult levels of C-reactive protein are reported to be less than 1.2 mg/100ml when they can be detected. Recent refined techniques, however, have shown the routine appearance of trace amounts of the protein in the sera of apparently normal children⁶ and healthy adults⁷.

SPECIFIC PERFORMANCE CHARACTERISTICS

The different CRP techniques vary in sensitivity. The latex agglutination technique is more sensitive than precipitation in capillary tubes or in agar gel and gives positive results at lower CRP concentrations^{8,9,10}. For this reason, the latex agglutination test usually gives a higher percentage of positive results than the other methods. Expressed in absolute terms, the amount of C-reactive protein in serum from patients with strongly positive CRP reactions is given by different workers as 33 mg/100 ml¹², while the content of normal serum is less than 1.2 mg/100 ml¹³.

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Registered to ISO 9001 and ISO 13488

Morganville, N.J. 07751

Printed in U.S.A.
PG-0240-03