NS Bio-Tec

CRP

A rapid latex slide test for detection of C-reactive protein in serum

REF: CRP – MA -100 (100 test)
CRP – MA -050 (50 test)
CRP – MA -100 L (100 test)
CRP – MA -050 L (50 test)

INTENDED FOR USE

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of C-reactive protein (CRP) in serum.

PRINCIPLE

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

SPECIMEN COLLECTION

The test should be performed on serum. Specimens can be drawn by venipuncture or convenient fingertip method. Plasma should not be used because fibrinogen may cause nonspecific agglutination of the latex particles.

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

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

REAGENT COMPOSITIONS

1-Latex Reagent: a suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.2. The latex particles are coated with monospecific anti-human **CRP**, produced in laboratory animals
2- positive control .
3- negative control .
All components contain 0.1% sodium azide as preservative
4- slides .

PACKAGE: COLLECTION AND STORAGE.

All reagents are stable up to the expiration date specified when stored at 2 - 8°C. Do Not Freeze. Avoid extended exposure of reagents to elevated temperatures.

PRECAUTIONS & WARNING

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HbsAg) and HTLV-lll antibodies by an FDA approved procedure and found to be non-reactive. No known test method for HbsAg or HTLV-lll antibodies offers total assurance that a human derived product will not transmit hepatitis orHTLV-lll virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.
The reagents in each kit are matched. Reagents from different kits must not be interchanged or pooled. If the kit does not yield expected results when controls are tested, the kit should be discarded. Mix the reagents well before use. Use clean equipment. Traces of detergent to dried reactants on the test slide may adversely affect test performance and results.

REAGENT PREPARATION & STABILITY

Expiration date is specified on the kit label. Biological indication of product instability is evidence by inappropriate reaction of the latex reagent with the corresponding positive control serum

REQUIRED MATERIALS NOT PROVIDED

Pipettes (serological)
Lab rotator.
Laboratory timer.

PROCEDURE

1.Bring all reagents and specimens to room temperature.
2.Shake the CRP test reagent gently, expel contents of dropper and refill, then place one drop (50 µl) onto glass slide. Using pipette, add one drop of the patient serum (50 µl) onto the glass
slide, and mix both together with the flat end of the dispensing pipettes.
3.Continue to mix for about 2 minutes with rotator or by hand and observe for macroscopic clumping using the indirect oblique light source.
4.Positive control should be run with each series to test sera. The positive control supplied is to be used exactly as outlined in steps 1 through 3 above.
5.The reaction of the test serum is compared to the CRP positive control serum and negative control**.**

WASTE DISPOSAL

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL

A positive control will produce, usually within 1 minute, coarse agglutinated flocs against a clear background, as demonstrated by the positive control.
If the indicated results, using the positive controls not obtained, the CRP kit should not be used.

RESULT

Negative result: No agglutination of the latex particle suspension will occur within two minutes.
Positive result: An agglutination of the latex particle suspension will occur within two minutes, showing a CRP level of more than 6 mg/dl. Since negative results may be caused by antigen excess, the test should be repeated using a diluted serum.

Same as described in screening test.

RESULTS

The serum CRP concentration can then be calculated approximately by multiplying the dilution factor (i.e. 2, 4, etc) by the detection limit (6 mg/L).
e.g. if the agglutination titer appears at 1:4 the approximate serum CRP level is 4 x 6 = 24 mg/L

LIMITATIONS

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 seras-by retesting at a 1:10 dilution. Reaction times longer than specified (4 minutes) may produce apparent false reactions due to a drying effect. Strongly lipemic or, contaminated sera can cause false positive reactions.

Normal adult levels of CRP are reported to be less than 6 mg/dl 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 children and healthy adults.

PERFORMANCE

In comparing CRP tests, it must be remembered that the different 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. 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/dl or 14 mg/dl while the content of normal serum is less than 6 mg/dl.

REFERENCES

1. Tillet, W.S. & T. Francis: J. Exper.Med. 52, 561, 1930.

2. Fischel, E:E., in: Cohen. A.A. (Editor) Laboratory Diagnostic Procedures in Rheumatic Disease. Little Brown & C. Boston, P. 70, 1967.

3. MacLeod, C.M., & O.T. AVERY: J. Exper.Med. 73, 191, 1950

	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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