PATHOZYME DIAGNOSTICS

RAPICHEK CRP LATEX

(SLIDE AGGLUTINATION)

CAT No.: CRP

Latex slide test for the qualitative and semi-quantitative determination of C-Reactive Protein (CRP) in Serum.

DIAGNOSTIC SIGNIFICANCE:

C-Reactive Protein (CRP) is a normal alpha globulin which increase in inflammatory processes. The name CRP is derived from the fact that this protein has the capacity to precipitate the somatic C-Carbohydrate of Pneumococcus. Elevated CRP level are usually observed in a variety of infections and inflammatory conditions where there is tissue destruction. The CRP level measurement is useful in differential diagnosis of neonatal septicaemia and meningitis. CRP levels are always elevated after myocardial infarction and surgery. The CRP test can also help in determining postsurgical complications.

PRINCIPLE:

This test based on the immunologic reaction between CRP as an antigen and latex particles have been coated with monospecific anti-human CRP and sensitized to detect levels greater than 6µg/ml CRP.

SPECIMEN COLLECTION:

Fresh serum, in case of a delay in testing, store at 2-8^{0}C. Hemolysed / lipaemic serum should not be used.

KIT PRESENTATION:

PACK SIZE	25 Test	50 Test	100 Test
Latex Reagent	1 Vial	1 Vial	1 Vial
Positive Control	1 Vial	1 Vial	1 Vial
Negative Control	1 Vial	1 Vial	1 Vial
Glass Slide	1 No	1 No	1 No
Mixing Sticks	25 Nos	50 Nos	100 Nos
Sample Dropper	25 Nos	50 Nos	100 Nos
Latex Dropper	1 No	1 No	1 No

REAGENT STORAGE & STABILITY:

All reagents included in the kit are stable at 2-8^{0}C until the expiry date stated on the label.

PRECAUTION:

1. Bring all the reagents and samples to RT before use.
2. Do not freeze the Latex reagent.
3. Do not use haemolysed or turbid specimen. The use of plasma instead of serum could lead to erroneous results. Drying of the mixture at the periphery of the circle could lead to erroneous results.
4. The Latex reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
5. The source material used in the manufacturing of Positive control is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety the control should be handled with proper care.
6. While dispensing Latex reagent, hold the glass dropper vertically to ensure uniform drop size.
7. Positive Control is ready to use & should not be diluted while using in test procedure.
8. Contaminated sera and a longer reaction time beyond 2 minutes may lead to false positive results.
9. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.
10. Elevated CRP levels may also be found during pregnancy as well as in women who are on oral contraceptives.

PROCEDURE:

(A) Qualitative Method:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place one drop of the sample and one drop of each positive and negative controls into separate circles on the slide test.
3. Swirl the CRP-latex reagent gently before using and add one drop next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rock the slide gently to and fro for 2 minutes and examine for macroscopic agglutination under direct light source. **Do not examine beyond 2 minutes.** False positive results could appear if the test is read later than two minutes.

Interpretation Of Results:

Agglutination within 1-2 minutes is positive test and indicates presence of CRP in the test specimen, no agglutination up to 2 minutes is a negative test and indicates absence of CRP in the test specimen.

(B) Semi-quantitative Method:

1. Dilute the specimen serially 1:2, 1:4, 1:8. 1:16 using normal saline.
2. Proceed for each dilution as in the qualitative method.

Interpretation Of Results:

The highest dilution shows positive reaction within 2 minutes indicates the CRP titre. The approximate CRP concentration can be obtained by multiplying titre by sensitivity of the test.

CRP in µg/ml = D X S

D - Highest dilution showing positive reaction

S = Sensitivity of the test is 6 µg/ml.

SENSITIVITY:

The reagent has a sensitivity of **6 µg/ml (0.6 mg/dl or 6 mg/L)** serum.

INTERFERENCES:

Bilirubin (20 mg/dL), Hemoglobin (10 g/L), Rheumatoid Factors (300 IU/mL) do not interfere other substances may interfere.

REFERENCE:

1. Kidmark, C.O. 91972) Scand.J.Clin. Invest.29, 407.
2. Clyde, W.A., Jr.: Immunology, 1964.
3. Deya, R.A., Pope, R. M., Perselin, R. H. (1980).J. Rheumatol, 7, 279.

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