CRP

Latex Slide Agglutination Method

INTENDED USE

For the Qualitative and Semi-Quantitative determination of C-Reactive Protein in Human Serum.

SUMMARY & CLINICAL IMPORTANCE

C-Reactive Protein (CRP) is a Normal Alpha Globulin, which increases in Inflammatory Processes. The name CRP is derived from the fact that this protein has the capacity to precipitate the somatic Ccarbohydrate of Pneumococcus. Elevated CRP levels are usually observed in a variety of infectionsand 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 Post-Surgical complications.

PRINCIPLE

Uniform Latex particles are coated with Anti-Human CRP. The specimen containing CRP on mixing with Latex Reagent agglutinates, showing a positive test results, If CRP is absent, there will be no agglutination, indicating a negative test result.

STORAGE & STABILITY

All the reagents are stable at 2-8°C till the expiry date mentioned on the labels.

SPECIMEN

Fresh Serum is the preferred Specimen. In case of delay in testing, store the Serum at 2-8°C. Plasma or Hemolysed / Lipaemic Serum should not be used.

PRECAUTIONS

1. **Do not read results after 2 minutes.**
2. Bring all the reagents to RT before use.
3. Do not freeze the Latex Reagent.
4. Do not use Hemolysed or Turbid Specimen.
5. The Latex Reagent (1) should be shaken well before use to ensure a homogeneous suspension of latex particles.

CRP

Latex Slide Agglutination Method

6. The source material used in the manufacture of Positive and Negative Controls is tested for HBsAg and HIV antibodies and are found to be negative. However, for better safety these controls should be handled with proper care as If they are potentially dangerous.
7. While dispensing Latex Reagent, hold the Latex dropper vertically to ensure uniform drop size.

PROCEDURE

A. QUALITATIVE TEST

1. Place one drop (Approximately 50µL) of specimen, Positive Control and Negative Control in separate circles of the glass slide by using the Sample droppers provided.
2. Add one drop of (Approximately 50µl) Latex Reagent in each of these circles with the Latex dropper.
3. Mix the content of each circle separately and spread it in the entire circle with the mixing sticks provided in the kit.
4. Rock the slide gently for 2 minutes and look for any agglutination.
5. Do not read results after 2 minutes.

INTERPRETATION OF RESULTS

Agglutination with Positive Control and no agglutination with Negative Control validate the test results. Agglutination within 2 minutes is a positive test and indicates presence of CRP in the test specimens.

No agglutination up to 2 minutes is a negative test and indicates absence of CRP in the test specimen.

DO NOT OBSERVE RESULTS AFTER 2 MINUTES

B. SEMI QUANTITATIVE TEST

1) Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline.

2) Place one drop each of diluted serum samples using sample droppers in each circle of the glass slide and proceed further as in Qualitative Test (A).

INTERPRETATION

The highest dilution, which shows clear-cut aggulination within 2 minutes, indicates the CRP titre the approximate CRP concentration can be obtained by multiplying titre by sensitivity of the test.

CRP

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CRP in mg/dL = D x S
D = Highest dilution showing clear cut aggulation.
S = Sensitivity of the test 6 mg/L.

PRODUCT FEATURES

- Detects CRP as low as 6 mg/L. (Cut off Sensitivity 0.6 mg/dL)
- Uniform and Homogenous Latex Particles ensure clear Agglutination.
- Qualitative and Semi Quantitative procedures included in the same kit.
- Positive and Negative Controls are provided for the proper validation of the kit.
- Positive and Negative Controls provided in the kit are free from HIV & HbsAg and are safe touse.
- Sample dilution is not required unlike conventional procedures.
- Incorporates Six Sigma methodologies throughout the manufacturing processes wherein the product under goes various stringent process checks like Defining, Measuring, >>Analyzing, Improving and Controlling. (DMAIC)
- Avid Agglutination ensures proper discrimination between positive and negative results.
- Cut off sensitivity 6 mg/L is determined in correlation with Quantitative Turbidometry.
- Latex Reagent Sensitivity 6 mg/L is calibrated against WHO calibrators.
- Optimum Anti CRP Antibody concentration coated on to the Latex particles overcomes Prozone Effect.

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NOTES

- Do not read results after 2 Minutes.
- Positive and Negative Controls are ready to use and should not be diluted while using in test procedure.
- Improper mixing and drying of reagents may lead to erroneous results.
- Contaminated sera and longer reaction time may lead to false positive results.
- As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms and findings.
- Elevated CRP levels may also be found during pregnancy as well as in woman who are on oral contraceptives.

REFERENCES

1. Kidmark, C.O. (1972) Scand J. Clin. Invest 29, 407
2. Deya, R.A, Pope, R.M, Perselin, R.H. (1980), J. Rheumatol 7, 279.

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