TRUEchemie CRP (C-Reactive Protein) TEST KIT

(Latex Agglutination Method)

for the qualitative and semi-quantitative determination of CRP in serum

INTENDED USE

The TRUEchemie CRP test for the qualitative and semi-quantitative determination of CRP in serum.

INTRODUCTION

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 C-carbohydrate of Pneumococcus. Elevated CRP levels 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 septicemia 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 result. If CRP is absent, there will be no agglutination, indicating a negative test result.

PACK SIZE

Kit Size	**25 T**	**50 T**	**100 T**
Cat. No.	**ADX811**	**ADX812**	**ADX813**
Kit Contents			
1) CRP Latex Reagent	1 x 1 ml	1 x 2 ml	2 x 2 ml
2) CRP Positive Control	1 x 0.250 ml	1 x 0.250 ml	1 x 0.250 ml
3) CRP Negative Control	1 x 0.250 ml	1 x 0.250 ml	1 x 0.250 ml
Accessories Reusable Plastic Slides Disposable Plastic Droppers Disposable Plastic Sticks Rubber Teat			

STORAGE AND STABILITY

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

REAGENT PREPARATION

Ready to use reagents.

SAMPLE / SPECIMEN AND STORAGE

Fresh serum. In case of a delay in testing, store at 2-8°C. Plasma or hemolysed / lipaemic serum should not be used.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Bring all the reagents and samples to RT before use.
3. **Do not freeze the Latex Reagent.**
4. Do not use hemolysed or turbid specimen.
5. The Latex Reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
6. The source material used in the manufacturing of Positive & Negative Controls is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety these controls should be handled with proper care.
7. While dispensing Latex Reagent, hold the glass dropper vertically to ensure uniform drop size.
8. The disposal of the residues has to be done as per local legal regulations.

TEST PROCEDURE

(A) QUALITATIVE TEST:

1. Place one drop (0.040 ml) each of specimen, Positive Control and negative Control in separate circles of the slide using the plastic droppers provided.

2. Add one drop (0.040 ml) of Latex Reagent in each of these circles.

3. Mix the content of each circle separately and spread it in the entire circle.
   Rock the slide gently for 2 minutes and look for agglutination

INTERPRETATION:

Agglutination with Positive Control and no agglutination with Negative Control validate test results.
Agglutination within 2 minutes is a 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.

DO NOT OBSERVE RESULTS BEYOND 2 MINUTES

(B) SEMI QUANTITATIVE TEST:

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

2. Place one drop of each diluted serum sample using plastic droppers in each circle of slide & proceed further as in Qualitative Test (A).

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

CRP in mg/L = D x S

D= Highest dilution showing clear-cut agglutination.
S= Sensitivity of the test is 6 mg/L.

QUALITY CONTROLS

Positive & Negative Controls are used to validate the kit performance.

INTERFERENCES

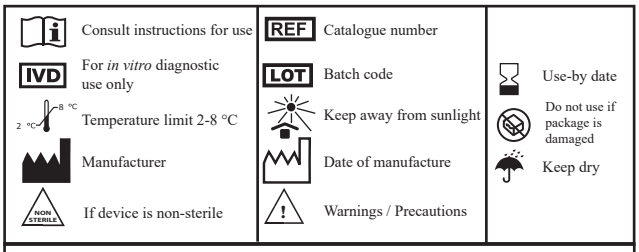
High CRP concentration samples may give negative results (prozone effect). Retest the sample again using a sample drop of 20 µL. Haemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere.

NOTES

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