QUALITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IVD

ORDER INFORMATION

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CLINICAL SIGNIFICANCE

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase by as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assay have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radial immunodiffusion. The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is rapid two (2) minute reaction time.

PRINCIPLE

The CRP reagent contains latex particles coated with Anti - Human CRP antibody. When the reagent is mixed with serum containing CRP at a level greater than 0.6 mg/dl the particles will agglutinate.

TEST SENSITIVITY

The sensitivity is of 0.6 mg/dl of C-reactive protein according to the World Health Organisation (WHO) International Reference preparation.

REAGENT COMPOSITION

Reagent 1 : CRP Late Reagent
Reagent 2 : Positive Control Sera
Reagent 3 : Negative Control Sera

ACCESSORIES

Slides, Stirrer rods, Droppers

SAFETY PRECAUTIONS AND WARNINGS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2).

However handle cautiously as potentially infectious.

SAMPLE COLLECTION AND PRESERVATION

Serum

REAGENT PREPARATION AND STORAGE

All reagents are ready to use.

REAGENT STABILITY

All reagents and controls are ready for use and stable up to the expiry date when stored at 2-8°C

ASSAY PROCEDURE

QUALITATIVE DETERMINATION

Add in different circles of the slide :

- Serum to be tested  1 drop
- Positive Control  1 drop
- Negative Control  1 drop
- In all circles add : CRP latex Reagent  1 drop

Mix and spread with the stirring rod to fill the test circle. Rotate the slide and observe for any agglutination which should occur within two minutes.

INTERPRETATION OF THE RESULTS

All the positive samples should be tested by a semiquantitative method

SEMI-QUANTITATIVE DETERMINATION

Prepare sample dilutions with saline 1:2, 1:4, ..., 1:64. Test each dilution according to the qualitative procedure until no further agglutination is observed. The CRP concentration can then be estimated from the last dilution with the visible agglutination.

CALCULATION

CRP (mg/dl) = Highest dilution with positive reaction x reagent sensitivity (0.6 mg/dl).

QUALITY CONTROL

Accutestrol N - H

REFERENCE INTERVAL

< 0.6 mg/dl

BIBLIOGRAPHY