

Qualitative determination of C-Reactive Protein (CRP)  
IVD Store at 2-8°C.

REF: KCRP-004B

## Summary:

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.

## Principle:

The CRP-latex is a slide agglutination test for the qualitative and semiquantitative detection of C- Reactive Protein (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP.

## Composition:

**Latex:** Latex particles coated with goat IgG anti-human CRP, pH, 8.2. Preservative

**Control + Red cap:** Human serum with a CRP concentration > 20 mg/L, Preservative

**Control - Blue cap:** Animal serum, Preservative

## Precautions:

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.

## Calibration:

The CRP-latex sensitivity is calibrated to the Reference Material ERMDA 474/IFCC.

## Storage and stability:

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Mix reagents gently before use.

**Reagents deterioration:** Presence of particles and turbidity.

## Samples:

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C.

Samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolysed or lipemic samples.

## Equipment:

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.

## Procedure:

### 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 50 µL of the sample (Note 1) and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the samples 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. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

### Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

## Reading and Interpretation:

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a CRP concentration equal or greater than 6 mg/L (Note 2 and 3). The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

## Calculations:

The approximate CRP concentration in the patient sample is calculated as follow:

$$6 \times \text{CRP Titer} = \text{mg/L}$$

## Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:

- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommendations.

## Reference values:

Up to 6 mg/L. Each laboratory should establish its own reference range.

## Performance characteristics:

### Prozone effect:

No prozone effect was detected up to 1600 mg/L.

### Sensitivity:

6 (5-10) mg/L, under the described assay conditions

### Diagnostic Sensitivity:

95.6 %

### Diagnostic specificity:

96.2 %

## Interferences:

Bilirubin (20 mg/dL), hemoglobin (10 g/L), and lipids (10 g/L), do not interfere. Rheumatoid factors (100 IU/mL), interfere. Other substances may interfere.

## Notes:

1. High CRP concentration samples may give negative results (prozone effect). Re-test the sample again using a drop of 20 µL.
2. The strength of agglutination is not indicative of the CRP concentration in the samples tested.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

## References:

1. Lars-Olof Hanson et al. Current Opinion in Infectious diseases 1997; 10: 196-201.
2. M.M. Pepys. The Lancet 1981; March 21: 653 – 656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
4. Yoshitsugy Hokama et al. Journal of Clinical Laboratory Status 1987; 1: 15 – 27.
5. Yamamoto S et al. Veterinary Immunology and Immunopathology 1993; 36: 257 – 264.
6. Charles Wadsworth et al. Clinica Chimica Acta; 1984; 138: 309 – 318.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACCC Press, 1995.