CRP-turbilatex

Latex turbidimetry

CE

Determination of CRP in human serum or plasma.
Store at 2-8 °C.

REF: KCRP-T43B14 / KCRP-T43B24

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:

Latex particles coated with specific anti- human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

Composition:

R1 (diluent): Tris buffer - 20 mmol/L, pH 8,2. Preservative
R1 (Latex): Latex particles coated with goat IgG anti-human CRP, pH 7,3. Preservative.
CRP-CAL: Calibrator. C-Reactive protein concentration is stated on the vial label.

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:

Use CRP Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material ERM-DA 474/IFCC.
The calibration is stable for 1 month.
Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

Preparation:

CRP Calibrator: Reconstitute (→) with 1,0 mL of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

Storage and Stability:

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations prevented during their use. Reagents should not be left inside the analyzer after use, they must be stored refrigerated at 2-8°C. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date. Do not freeze; frozen Latex or Diluent could change the functionality of the test.
Reagent deterioration: Presence of particles and turbidity.
ASO Calibrator: Stable for 1 month at 2-8°C or 3 months at –20°C.

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 hemolized or lipemic samples.

Equipment:

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

Procedure:

1. Bring the reagents and the photometer (cuvette holder) to 37°C.

2. Assay conditions:
Wavelength: . . . . . 540 nm (530-550)
Cuvette: . . . . . 1 cm. light path
Temperature: . . . . . 37°C

3. Adjust the instrument to zero with distilled water.

4. Pipette into a cuvette:
Diluent R1: 800 µL
Latex R2: 200 µL
Calibrator or sample: 5 µL
5. Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

Calculations:

$$\frac{(A2\text{-}A1)\ \text{Sample}}{(A2\text{-}A1)\ \text{calibrator}} \times \text{Concentration of Calibrator} = \text{mg/L CRP}$$

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 recommandations.

Reference values:

Normal values up to 6 mg/L.
Each laboratory should establish its own reference range.

Performance characteristics:

Linearity:
Up to 150 mg/L, under the described assay conditions.
Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

Detection limit:
Values less than 1 mg/L give non-reproducible results.

Prozone effect:
No prozone effect was detected upon 800 mg/L.

Sensitivity:
Δ 4,2 mA.mg/L.

Precision:
The reagent has been tested for 20 days, using three different CRP concentrations in a EP5-based study.

EP5	%CV		
	9,2 mg/L	16,8 mg/L	57,97 mg/L
Total	7.3	6.9	5.9
Intra-assay	2.8	3.1	2.9
Inter-assay	6.1	4.7	3.9
Inter-day	3	4	3.4

Accuracy:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 50 samples of different concentrations of CRP were assayed. The correlation coefficient (r)2 was 0,99 and the regression equation:
y = 1,101x + 2,518.
The results of the performance characteristics depend on the analyzer used.

Interferences:

Bilirubin (20 mg/dL) and lipemia (10 g/L) do not interfere. Hemoglobin (≥ 5 g/L), interferes. Other substances may interfere.

Notes:

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 Infect Diseases 1997; 10: 196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 – 144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1: 15 – 27.
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606 – 607.
5. Werner Müller et al. Journal of Immunological Methods 1985; 80: 77 – 90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121 – 2124.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Sorachim