CRP Turbilatex

Code	Product Name	Pack Size
SE028A	CRP Turbilatex	50 ml

BEACON

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

Principle of The Method
CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C- reactive protein (CRP) in human serum or plasma.
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.

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.

Reagents

Reagent 1: Diluent	Tris buffer 20 mmol/L, Preservative.
Reagent 2: Latex Antigen	Latex particles coated with goat IgG anti-human CRP, Preservative.
Regent 3: CRP Calibrator	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 Provided with kit. The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material ERM-DA472/IFCC.

Preparation
CRP Calibrator: Ready to 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. 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.

Additional Equipment

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

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.

Procedure
1. Bring the reagent and photometer (cuvette holder) to 37°C.
2. Assay conditions:
   Wavelength : 540 nm (530-550)
   Temperature : 37°C
   Cuvette ligth path : 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Diluent R1	900 µl
Latex R2	100 µl
Calibrator or sample	5 µl

5. Mix and read the absorbance immediately (A_1) and after 2 minutes (A_2) of the sample addition.

Calculation

$$\frac{(A_2\text{-}A_1)_{Sample}}{(A_2\text{-}A_1)_{Calibrator}} \times \text{Calibrator Concentration} = \text{mg/L CRP}$$

Quality Control
Control sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

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

Performance Characteristics

1. **Linearity limit:** 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 the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. **Detection limit:** Values less than 2 mg/L give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected up to 400 mg/L.
4. **Sensitivity:** Δ4.2 mA. mg/L.
5. **Precision:**

	Intra-assay (n=10)		
Mean (mg/L)	8.6	16.8	50.5
SD	0.56	0.61	0.97
CV	6.5	3.6	1.9

	Intra-assay (n=10)		
Mean (mg/L)	8.6	16.8	50.5
SD	0.74	1.11	3.2
CV	7.7	6.6	6.3

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similer characteristics. 65 samples ranging from 1 to 150 mg/L of CRP were assayed. The correclation coefficient(r) was 0.98 and the regression equation y = 0.892 x +0.282.
   The results of the perfomance characteristics depend on the analyzer used.

Interferences

Bilirrubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL), 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.

Bibliography

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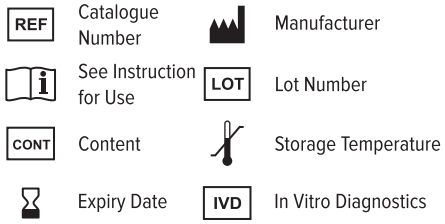
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139 — 144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1: 15 — 27.
4. Kari Pulki et al. Sacand J Clin Lab Invest 1986; 46: 606 — 607.
5. Werner Muller et al. Journal of Immunological Methods 1985; 80: 77 — 90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121 — 2124.

Symbols Used On Labels



BEA/24/CRT/SE/IFU-01 08/01/2022