

CRP Turbilatex

Code	Product Name	Pack Size
SE028A	CRP Turbilatex	50 ml

Intended Use

For the quantitative determination of C-reactive protein in human serum.

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.
Reagent 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



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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. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed 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 lighth 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

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

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.

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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: $\Delta 4.2$ mA. mg/L.

5. Precision:

Intra-assay precision Within run (n=20)	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	44.18	0.67	1.51
Sample 2	9.69	0.40	4.11

Inter-assay precision Run to run (n=20)	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	42.891	0.72	1.69

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 65 samples ranging from 1 to 150 mg/L of CRP were assayed. The correlation coefficient (r) was 0.999 and the regression equation $y = 1.0039x + 0.0049$ mg/L.

The results of the performance characteristics depend on the analyzer used.

Interferences

Bilirubin (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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5. Werner Muller et al. Journal of Immunological Methods 1985; 80: 77 — 90.
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Symbols Used On Labels



Catalogue
Number



Manufacturer



See Instruction
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/CRT/SE/IFU Ver-02
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