CRP-Turbilatex

Latex turbidimetry

Quantitative determination of C - reactive protein (CRP).
IVD.Store 2-8°C.

PRINCIPLE OF METHOD:

CRP-Turbilatex is a quantitative turbidimetric test for the measurement of Creactive 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

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.90 g/L. Merthiolate 0.05 g/L.
Latex (R2)	Latex particles coated with goat IgG anti-human CRP, pH 7.3. Sodium azide 0.90 g/L. Merthiolate 0.05 g/L.
CRP-CAL	Calibrator. C - reactive protein concentration is stated onthe vial label.
Optional	Control ASO/CRP/RF Level L. Control ASO/CRP/RF Level H.

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-DA472/IFCC.
The on board 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

Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows:
4 mL Diluent + 1 mL Latex Reagent

CRP Calibrator: Ready to use vaiue mention on vial in mg/L

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 are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: Presence of particles and turbidity.
Working reagent: Stable for 30 days at 2-8°C.
CRP Calibrator: Stable for 1 month at 2-8°C or 3 months at -20°C.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT

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

SAMPLES:

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

GENERAL SYSTEM PARAMETERS:

Reaction type	Fixed Time
Wave length	540 nm (530-550)
Light Path	1 Cm
Reaction Temperature	37°C
Blank/Zero Setting	Distilled Water
Reagent Volume	1ml
Sample Volume	10 µl
Delay/Lag Time	5 Sec.
Read Time	120 Sec.
Calibrator Concentration	Stated on Vial Label
Normal Value	Up to 6 mg/L
Linearity (One Point Calibration)	150 mg/L

PROCEDURE

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

Working Reagent (mL)	**1.0**
Calibrator or sample (µL)	**10µl**

5. Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

CALCULATIONS:

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

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 800 mg/L.
4. Sensitivity: A4.2 mA.mg/L.
5. 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	16.8mg/L	57.97mg/L
Total	7.3%	6.9%	5.9%
Within Run	2.8%	3.1%	2.9%
Between Run	6.1%	4.7%	3.9%
Between Day	3.0%	4.0%	3.4%

6. 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) was 0.99 and the regression equation y = 1.101x + 2.518.
The results of the performance 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.

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