CRP TURBILATEX

Latex Turbidimetry

IVD CE

PRODUCT CODE
TL002

INTENDED USE
The CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C-Reactive Protein in human serum or plasma.

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.

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.

REAGENTS

Diluent(R1)	Tris buffer 20 mmol/L, pH 8,2. Preservative.
Latex(R2)	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.

PREPARATION
CRP Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature 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 2-8ºC and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use; they must be stored refrigerated at 2-8ºC. 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 (R1, R2) and turbidity (R1).
CRP Calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC

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.

SPECIMEN AND SAMPLE PREPARATIONS
Fresh serum or plasma. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolyzed or lipemic samples.

PROCEDURES
1. Bring the reagents and the photometer (cuvette holder) to 37ºC
2. **Assay conditions:**
   Wavelength: 540 nm (530-550)
   Temperature: 37 ºC
   Cuvette light path: 1 CM
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 (A_1) and after 2 minutes (A_2) of the sample addition.

CALCULATIONS

$$\frac{(A_2\text{-}A_1)\ \text{sample}}{(A_2\text{-}A_1)\ \text{calibrator}} \times \text{Calibrator concentration} = \text{mg/l CRP}$$

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures.

REFERENC RANGE
Normal value upto 6 mg/dL
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 as 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 1 mg/L give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 800 mg/L.
4. **Sensitivity:** Δ 4.2 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	16.8 mg/L	57.97 mg/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 $(r)^2$ was 0,99 and the regression equation $y = 1{,}101x + 2{,}518$.

The result of the performance characteristics depends on the analyzer used.

INTERFERENCE
Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere[7].

NOTES
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

SYMBOL ON LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
Σ	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

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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.
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Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany