Reactivos GPL

Barcelona, España

CE

- CRP TURBI -

CRP
TURBILATEX

Store at: +2+8º C.

Presentation:
Cod. TL030 CONT: R1 45 ml / R2 5 ml. / CAL 1 ml.
Cod. TL030-2 CONT: R1 2 x 45 ml / R2 2 x 5 ml. / CAL 1 ml.

Procedure

Diagnostic reagent for qualitative measurement of CRP.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY

The CRP-Turbilatex is a quantitative turbidimetric test for measurement C-reactive protein (CRP) in human serum or plasma. Latex particles coated with specific human anti-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 COMPOSITION

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Latex (R2)	Suspension of latex particles coated with anti-human CRP, pH 7.3. Sodium azide 0.95 g/L.
CRP-CAL (R3)	Human serum. C-Reactive protein concentration is stated on the vial label.
CRP CONTROL Optional	Ref.: TL012 Control ASO/CRP/RF Level L. Ref.: TL022 Control ASO/CRP/RF Level H.

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY

Working reagent (WR): Shake gently the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 9 mL Diluent. WR: Stable for 1 month at 2-8º C. Anyway it is recommended to prepare a fresh Working Reagent based on its workload.

CRP Calibrator: Ready to use and stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-*8º C.* Carefully invert the bottles before use.

Do not freeze; frozen reagents could change the functionality of the test.

Signs of reagent deterioration**:**

- Particles and turbidity indicates contamination or reagents deterioration.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store at tightly closed at 2-*8º C.* Do not use reagents over the expiration date.

CALIBRATION

The assay is calibrated to the Reference Material CRM 470/RPPHS. The use of other commercially available CRP calibrators is not recommended.

SPECIMEN

Fresh serum. Stable: 7 days at 2-8º C or 3 months at –20º C.

The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized or lipemic samples.

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED

- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 540 nm filter.
- Cuvettes with 1 cm light path.

General laboratory equipment

TEST PROCEDURE

Calibration Curve (range up to 90 mg/L):

Prepare the following CRP calibrator dilutions in ClNa 9 g/L as diluent. Multiply the concentration of the CRP calibrator by the corresponding factor to obtain the CRP concentration of each dilution.

The Standard dilutions must be isued for measurement within 24 hours.

Calibrator 1	100 µL Calibrator CRP*
Calibrator 2	100 µL Calibrator 1 + 100 µL ClNa 9 g/L
Calibrator 3	100 µL Calibrator 2 + 100 µL ClNa 9 g/L
Calibrator 4	100 µL Calibrator 3 + 100 µL ClNa 9 g/L
Calibrator 5	100 µL ClNa 9 g/L
*See the values on the label. Multiply by the appropriate factor	

Manual Procedure

1. Bring the working reagent and the photometer to 37º C.
2. Set spectrophotometer wavelength to 540 nm and adjust to zero absorbance against water.
3. Pipette into a Cuvette:

	Calibrator	Sample	Blank
Working reagent (µL)	500	500	500
Calibrator (µL)	3	--	--
Sample (µL)	--	3	--
Distilled water (µL)	--	--	3

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

CALCULATIONS

Multipoint Calibration:

1- Calculation of sample concentration is against interpolation of the absorbance ($A_2 - A_1$) in the calibration curve.

2- Calibration Curves are stable for 10 days, after which a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed or QC so indicate.

One point calibration:

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

QUALITY CONTROL

Controls Ref.: TL012 and Ref.: TL022 are recommended to monitor the performance.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Up to 6 mg/L.

It is suggested that each laboratory establish its own reference range.

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 by more than 300 mg/L in 12-24 h.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- *Linearity limit:* Up to 90 mg/L[(note1)] (calibration curve) (under the described assay conditions)n and Up to 80 mg/L[(note1)] (one point calibration).
- *Prozone effect:* No prozone effect was detected upon 430 mg/L.
- *Detection limit:* Values less than 2 mg/L give non-reproducible results.
- *Sensitivity:* Δ 4,2 mA.mg/L.
- *Precision:*

	Intra-assay n= 10			Inter-assay n= 10		
Mean (mg/L)	8.6	16.9	50.5	8.6	16.8	50.5
SD	0.56	0.61	0.97	0.74	1.11	3.2
CV	6.5	3.6	1.9	7.7	6.6	6.3

- *Accuracy:* Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 25 samples ranging from 1 to 90 mg/L CRP were assayed. The correlation coefficient (r) was 0.991 and the regression equation was y=1.08x -3.4
  The results of the performance characteristics depend on the used analyzer.

INTERFERING SUBSTANCES

Do not interfere:

– Bilirubin (20 mg/dL)
– Lipemia (10 g/L)
– Rheumatoid factors (300 IU/mL)

Interfere:

– Hemoglobin (≥ 5 g/L)

Other substances may interfere[7]

NOTES

1- 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. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

BIBLIOGRAPHY

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.

CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nau J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75

GPLBTLDTT01-I
Rev. 01/2012