Reactivos GPL

Barcelona, España

CE

- CRP TURBI -

CRP
TURBILATEX

Store at: +2+8º C.

Presentation:

Cod. TL035	*CONT: R1 1 x 40 ml / R2 1 x 10 ml. / CAL 1 ml.*
Cod. TL036	*CONT: R1 2 x 40 ml / R2 2 x 10 ml. / CAL 1 ml.*
Cod. TL037	*CONT: R1 4 x 40 ml / R2 4 x 10 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. 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.
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

CRP Calibrator: Reconstitute (→) with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use.
Stable for 1 month at 2-8ºC or 3 months at -20ºC.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.
Signs of reagent deterioration:

- Presence of particles (R1, R2) and turbidity (R1)

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.

CALIBRATION

Use CRP Calibrator.
The sensitivity of the assay and the target value of the calibrator have been standardized against the Reference Material ERM-DA 474/IFCC.
The 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.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED

- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostable at 37ºC with a 540 nm filter.

General laboratory equipment

TEST PROCEDURE

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

		Micro Test
Diluent R1	800 µL	400 µL
Latex R2	200 µL	100 µL
Calibrator or sample	5,0 µL	2.5 µL

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

CALCULATIONS

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

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

Normal 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.

REAGENT PERFORMANCE

- *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 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.
- *Detection limit:* Values less than 1 mg/L. give non-reproducible results.
- *Prozone effect*: No prozone effect was detected upon 800 mg/L.
- *Sensitivity:* Δ 4,2 mA.mg/L.
- *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%

- *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 results of the performance characteristics depend on the used analyzer.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL) and lipemia (10 g/L) do not interfere.
Haemoglobin (≥ 5g/L), interferes. Other substances may interfere[7].

NOTE

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