CRP

REF 710L

CE

IVD For in vitro medical deviace

Use

The reagent CRP are intended for the quantitative determination of C-Reactive Protein in serum.
Turbidimetryc method.

Summary

The CRP measurements are used for following-up and monitoring such illnesses, as well as for the differential diagnosis in certain cases.
C-reactive protein is frequently found in the sera of normal persons in very low concentrations, in most cases not exceeding a level of 6 mg/l.
However, during the inflammatory process, whether of an infectious or other nature, the titers of C-reactive protein can reach levels that are far above normal values.
In these cases C-reactive protein titers increase and decrease more quickly than the red cells sedimentation rate.
The increase of C-reactive protein occurs in a non specific way in different kinds of tissular aggression, as for example in infectious states, rheumatic fever, rheumatoid arthritis, peritonitis, burns, myocardic infarct, etc.
For this reason a high C-reactive protein concentration in serum lacks diagnostic value when the patients illnesses is not defined.

Principle

The CRP reagents is a suspension of polystyrene latex particles of uniform size coated with IgG anti-human CRP. When a sample containing CRP is mixed with the reagent, a clear agglutination occurs, which can be measured by turbidimetry.

Reagents

CRP R1 TRIS buffer pH 8.2 20 mmol/l
Sodium azide < 0.1%
CRP R2 Suspension of polystyrene latex particles coated with IgG anti-human CRP. in a buffer .
Sodium azide < 0.1%
CRP CAL Calibrator. C-Reactive protein concentration is stated on the vial label

Reagent Preparation

Working reagent: Swirl the latex vial gently before use.Prepare the necessary amount as follows:
1 ml Latex reagent + 9 ml Diluent
CRP Calibrator : recostituite with 1 ml of distilled water. Mix gently and incubate 10 minuts at room temperature before use.

Storage And Stability

- Store the kit at 2-8°C. Do not freeze the reagents.
- After opening, the vials R1and R2 are stable until the expiration date if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Working reagent: stable for 30 days at 2-8°C.
CRP Calibrator: stable for 1 month at 2-8°C or 3 month at -20°C.

Precaution In Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contacting with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Sample

- Fresh Serum.
- CRP is stable in the samples up to 7 days at 2-8°C or 3 month at -20°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedure

Wavelength	λ: 540 nm
Working Temperature	37°C
Optical Path	1 cm
Reaction	"end point"

Bring the reagents at 15-25°C before use them.

	STD	Sample
Working reagent	1000µl	1000µl
Sample	–	5 µl
Standard	5 µl	–

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

Calculations

CRP [mg/L] =
$\Delta A_{sample} / \Delta A_{standard}$ **x Conc. STD**

The reagent performances are related to 37°C, 1 cm and 540 nm

Reference Values

Serum	0.0 - 6.0 mg/l

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 150 mg/l Samples with values exceeding 150 mg/l must be diluted with saline solution. Multiply, then, the result for diluting factor.

Precision

Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN [mg/dl]	N =18	H = 71.4
C.V.%	N = 1.7	H = 1.4

Analytical sensitivity

The test sensitivity in terms of detection limit is 3 mg/l

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor
r = 0.987

Interferences

No interference was observed by the presence of

Bilirubin	≤ 20 mg/dl
Triglycerides	≤ 340 mg/dl
Haemoglobin	≤ 800 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young et al.

Quality Controls

It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.:"Clinical Chemistry", Mosby Ed. (1996).
Clinical Chemistry publication "Effects of Disease on Clinical Laboratory Tests"
Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Symbols

CE	CE Mark (98/79 CE regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Product by Spain