CRP Assay

Latex Immunoturbidimetric

CE REF C7100150A

C7101100A

IVD For in vitro medical device

Use

The reagent CRP are intended for the quantitative determination of C - reactive protein in serum. Turbidimetric 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 nonspecific way in different kinds of insular aggression, as for example in infectious states, rheumatic fever, rheumatoid arthritis, peritonitis, burns, myocardia infarct, etc. For this reason a high C-reactive protein concentration in serum lacks diagnostic value when the patient's 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 20.0 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

Reagents are liquid and ready to use. CRP R2: swirl before first use. Avoid foam formation. CRP Calibrator: Ready to 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.

Precaution in Use

The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification -packaging and labeling of dangerous substances.
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

- Serum.
- CRP is stable in the samples up to 7 days at 2-8°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.

Procedure

Wavelength	λ: 600 nm
Working Temperature	37°C
Optical Path	1 cm

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

Bireagent Procedure "substrate starter"

	CALIBRATORE	CAMPIONE
Reagent R1	800 µl	800 µl
Reagent R2	200 µl	200 µl
Mix,incubate a 37°C for 30", then add:		
Sample	--	6 µl
Calibrator	6 µl	–

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

Calculation

$$\text{CRP[mg/L]} = \frac{(A2-A1)\ \text{sample}}{(A2-A1)\ \text{calibrator}} \times \text{Calibrator}$$

Reference values

Serum	0.0 – 10.0 mg/l

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population.

Measurement range

2-90 mg/l, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again.

Precision

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

MEAN [mg/l]	N =16.8	H = 57.9
C.V. %	N = 3.1	H = 2.9

Analytical sensitivity

The test sensitivity in terms of detection limit is 2mg/l

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor
r = 0.99 y=1.1x + 2.5

Interferences

No interference was observed by the presence of

Bilirubin	≤ 20 mg/dl
Triglycerides	≤ 10 g/L
Haemoglobin	≤ 5 g/L

Calibration

It is recommended to use the CRP Calibrators for calibration. Dissolve the lyophilized CRP calibrator with 1ml distilled water, and dilute to 6 calibrators as follows,

Dilute	1	2	3	4	5	6
CAL µl	200	100	50	25	12.5	0
Normal Saline	0	100	150	350	375	200
ratio	1	1/2	1/4	1/8	1/16	0

Calibration Method:
Spline or other non-linear method

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.

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