BIOLATEX, S.L.
POL. INDUSTRIAL LA PORTALADA
CALAHORRA, 4 · PAB. 6
26006 LOGROÑO (SPAIN)
TEL.: (34) 941 270 047
FAX: (34) 941 271 077
INFO@BIOLATEX.COM

C REACTIVE PROTEIN (CRP)

REF: L-9510T
B-9410T

Product for In Vitro Diagnostic use. The product should be used for the quantitative determination of C Reactive Protein in human serum by the immunoturbidimetric procedure.

Diagnostic Relevance

C- reactive protein (CRP) is one of the acute phase proteins being synthesised by hepatocytes. The serum concentration of CRP increases during acute stages of diverse diseases associated with inflammation and tissue injury. Elevated CRP has been demonstrated in nearly all bacterial and fungal infections. In addition, it has been shown to be increased in other diseases as neoplasia, and rheumatic diseases as well as in major surgery.The diagnosis usefulness of CRP is based on the velocity and on the magnitude of its increase. Serum concentrations are raised within hours of disease onset and the increase can be as much 2000-fold. A rapid fall of CRP levels indicates recovery.

Principle

This CRP test is based upon the reactions between C reactive protein (CRP) in the sample and latex-covalently bound antibodies against human CRP. CRP values are determined turbidimetrically using fixed-time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range between 0 and 100 mg/L. The measuring temperature is 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

Buffer: TRIS(0.05 M, pH 8.2), and < 0.1% of sodium azide as preservative.

Latex Reagent: polystyrene particles coated with goat antibodies anti-human-CRP, containing NaCl and bovine serum albumin. Preservative: sodium azide 0.1%.

Precautions

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Materials required

Automatic analyzer. Saline solution. Calibrator. Controls.

Storage and Stability

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at +2…+8ºC. Do not freeze.

The CRP buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

The CRP latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarted.

Specimens

Fresh or deep frozen serum. CRP remains stable for 8 days at +2 to +8ºC. If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolysed or contaminated samples.

Heavily lipaemic sera and turbid frozen serum samples must be cleared with a delipidating agent. Delipidation of samples do not affect the results of CRP in serum samples. The cleared patient serum sample must be used on the same day, as turbidity may reoccur. Fresh or deep frozen serum. CRP remain stable for 8 days at +2 to +8ºC. If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolysed or contaminated samples. Heavily lipaemic sera and turbid frozen serum samples must be cleared with a delipidating agent. Delipidation of samples do not affect the results of CRP in serum samples. The cleared patient serum sample must be used on the same day, as turbidity may reoccur.

Procedure

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use. Follow the instructions of the operator's manual to load the cartridge, technique programation, calibration, sample measurement and control

Volume R1/working reagent:	Volume R2/start reagent:	Volume sample:
250 µl	50 µl	3 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 5 min after read 2nd reading.		
Wavelength: 550 nm	Incubation Time at 37º C: 5 min	

** Volume, time and wavelength are recommended. Adjust them depending of analyser features.*

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

Calibration. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material. The method was standardized against the International Standard CRM 470.

For quality control use Biolatex Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Calculation

The turbidimetric analysers automatically calculate the CRP concentration of each sample.

Conversion: mg/l = µg/ml.

Reference Values

Each laboratory should establish an expected range for the geographical area in which it is located.

Values < 6 – 8 mg/l are within the normal range.

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers or in manual procedures.

Specific Performance Characteristics*

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, this data must be calculated by each instrument.

(*) Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

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Hessian PA, Palmer DG. The presence and possible significance of C-Reactive protein in rheumatoid inflammation. J Rheumatol 1985 1985; 12:871-5.

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Müller M, Mierau R, Wohltmann D. Interference of IgM rheumatoid factor with nephelometric C-reactive protein determinations. J Immunol Methods 1985; 80: 77-90.

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BL, SL. C/Calahorra 4 – 6.26006 LO-Spain

CE

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Significados de los símbolos indicados en las etiquetas. Explanation of symbols used on labelling. Explication des symbols figurant sur les etiquettes. Spiegazione dei simboli utilizzati sull'eticheta. Significado dos símbolos indicados nas etiquetas. Erläuterung der symbole auf den etiketten.

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