C REACTIVE PROTEIN (CRP) (TURBI-LATEX)

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 . 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%.
- Calibrator

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 ,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 °C - + 8 °C . 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.

Working reagent : shake Latex vial gently before use , prepare the necessary amount as follow : **1 ml Latex Reagent + 9 ml buffer reagent**

Specimens

Fresh or deep frozen serum. CRP remains stable for 8 days at + 2 °C - + 8 °C. 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

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

	Calibrator	Sample
Working reagent	500 µ	500 µ
Calibrator	5 µ	----
Sample		5 µ

4- Mix and read the absorbance immediately (A1) of Calibrator & sample. exactly 2 minutes later, read absorbance (A2) of Calibrator & sample.

Calculation

$$\frac{(A2\text{-}A1)\ \text{Sample}}{(A2\text{-}A1)\ \text{Calibrator}} \times \text{Calibrator Conc.}$$

Calibration. Quality Control

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

For quality control use BIOMED 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.

Reference Values

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

Values < 6 mg/l.

Linearity up to 150 mg/l

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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Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 ñ 22