C Reactive Protein (CRP)

Intended Use

In vitro diagnostic reagents for the quantitative determination of C Reactive Protein (CRP) in human serum by Immunoturbidimetric procedure.

Background

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.

Test 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 and Warnings

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.

Material Required

Automatic analyzer.
Saline solution.
Calibrator.
Controls.

Storage and Stability

The CRP reagents should be stored tightly capped at (2 - 8 ºC) when not in use. Do not freeze. Reagents in the original vials are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

The CRP latex reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

The CRP buffer 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 discarded.

Specimen Collection and Preparation

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

System Parameter

Wavelength

550 nm

Optical path

1 cm

Assay type

Turbidimetric

Temperature

37 ºC

Incubation time

5 min.

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/Buffer reagent: 250 µl

Volume R2/Latex reagent: 50 µl

Volume sample: 3 µl

Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.

Step 2: after 5 min read 2nd reading.

Note: 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 and Quality Control

Standardization: use Spectrum Calibrator. The method was standardized against the CRM 470 international standard

For quality control use Spectrum 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.

Expected 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.

References


Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 - 224

ORDERING INFORMATION

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