SPECTRUM

The Creative Approach to Bioscience

CRP/hs(C- Reactive protein)

REF: 545 001 50 test

R1 Buffer 1 x 20 ml
R2 Latex 1 x 4 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Intended Use

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

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) and latexcovalently bound antibodies against human CRP. CRP values are determined turbidemetrically.

Reagents

Buffer R1
TRIS buffer, pH: 6.5, and 0.09 % sodium azide as preservative.
Latex reagent R2
Polystyrene particles (0.5%) coated with goat antibodies anti-human-CRP serum in aglycine buffer (0.1 M, pH: 8.2), containing NaCL (0.15 M) and bovine serum albumin (0.5%). Preservative: Sodium azide 0.075%
Calibrator
Human - based reference fluid. Preservative: sodium azide, 0.075%
Stability 4 weeks after opening.
All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

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 but not provided

Spectrophotometric analyzer.
Saline solution.
Controls.

Storage and Stability

Reagents in the original vial is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC). Immediately following the completion of an assay run, the reagent vial should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at (2 - 8 ºC) after use. Do not freeze reagents.
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 discarded.
The CRP buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.
WR is stable for up to one month at 4ºC. It is recommended that each Laboratory prepares a fresh Working Reagent based on its workload.

Reagent Preparation

All reagent are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial lable when capped and stored at (2 - 8 ºC).

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. Heavily lipaemic sera and turbid frozen serum samples must be cleared with a delipidating agent. Delipidation of
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.

Calibration curve

Calibrator 1	100 µl of Spectrum CRP Calibrator*
Calibrator 2	100 µl of Calibrator 1 + 100 µl of Saline Solution
Calibrator 3	100 µl of Calibrator 2 + 100 µl of Saline Solution
Calibrator 4	100 µl of Calibrator 3 + 100 µl of Saline Solution
Calibrator 5	100 µl of Saline Solution

(*) See values on the label . Multiply by the appropriate factor.

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..

Procedure

Wavelength 550 nm
Temperature 37ºC
Cuvette 1cm light path
Measurement against distilled water blank.
Bring the reagents at 37ºC and pipette:

	Blank	Calibrator	Sample
Buffer R1	375 µl	375 µl	375 µl
Latex Reagent R2	75 µl	75 µl	75 µl
Mix, Incubate one minute.			
Distilled Water	5 µl	---	---
Calibrator	---	5 µl	---
Sample	---	---	5 µl

Mix and measure absorbance immediately (A_1) , then incubate 5 min (37ºC), after incubation read absorbance (A2).

Calculation

Plot the calibration curve and the sample concentration is obtained by interpolation the sample absorbance (A_2-A_1) in the calibration curve.
If is an one point calibration:

$$\frac{(A_2\text{-}A_1)\text{sample} - (A_2\text{-}A_1)\text{blank}}{(A_2\text{-}A_1)\text{calibrator} - (A_2\text{-}A_1)\text{blank}} \times \text{Calibrator concentration}$$

Linearity

Up to 50 mg/L.

Expected Values

Values < 6 - 8 mg/L are within the normal range.

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

References

Hokama Y, Nakamura RM. C-Reactive protein: current status and future perspectives. J Clin Lab Anal 1987; 1: 15-27

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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ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
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