SPECTRUM

The Creative Approach to Bioscience

C Reactive Protein (CRP) Turbi Latex

REF: 560 001	**100 test**	REF: 560 002	**200 test**
R1 Buffer	2 x 20 ml	R1 Buffer	4 x 20 ml
R2 Latex	1 x10 ml	R2 Latex	2 x 10 ml
Calibrator	1 Vial	Calibrator	1 Vial

REF: 560 003 **100 test** (without calibrator)

SYMBOLS IN PRODUCT LABELLING

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

Intended Use

In vitro diagnostic reagents for the quantitative determination of C Reactive Protein (CRP) in human serum by means of particle-enhanced turbidimetric 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 as 2000-fold. A rapid fall of CRP levels indicates recovery.

Test Principle

This CRP test is based upon the reaction between C reactive protein (CRP) and latex covalently bound human CRP antibodies .
CRP values are determined photometrically.

Reagents

R1 Buffer reagent
TRIS buffer 20 mmol/L, pH 8.2, and 0.95 g/L sodium azide.

R2 Latex reagent
Latex particles coated with goat IgG anti-human CRP, pH 7.3 and Sodium azide 0.95 g/L.

Calibrator
CRP concentration is stated on the vial label.

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.

Storage and Stability

Reagents in the original vial are 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 stability. Do not freeze reagents. Open vial is stable for 3 months when stored at 2 - 8 ºC

Deterioration

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 diluent reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

Reagent Preparation and Stability

Working Reagent is prepared with 1 part of Latex Reagent and 4 parts of Buffer Reagent . Prepare a fresh Working reagent based on its workload. Shake gently the reagents before pipetting. e.g. 400 µl Buffer Reagent + 100 µl Latex Reagent.

stability : 1 month at 2 - 8 ºC.

CRP Calibrator: Reconstitute with 1 ml distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

Stability: 1 month at 2 - 8 ºC or 3 months at -20 ºC.

Specimen Collection and Preparation

Fresh or deep frozen serum CRP remain stable for 8 days at (2 - 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. The cleared patient serum sample must be used on the same day, as turbidity may reoccur.

Procedure

1 - Bring the reagents and the photometer to 37ºC

2 - Assay conditions:

Wavelength	540 nm (530 -550 nm)
Temperature	37ºC
Cuvette	1cm light path

3 - Adjust the instrument to zero with distilled water .

4 - Pipette into a cuvette :

Working Reagent	500 µl
Calibrator or Sample	5 µl

5.Mix and read absorbance (A_1) immediately . After 2 minutes of the sample addition, read (A2).

Calculation

$$\frac{(A_2\text{-}A_1)\text{sample}}{(A_2\text{-}A_1)\text{calibrator}} \times \text{Calibrator concentration} = \text{mg/L CRP}$$

Expected Values

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

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

Quality Control

Control sera are recommended to monitor the perfomance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Performance characteristics

Detection limit

Values less than 1 mg/L give non-reproducible results.

Prozone effect

No prozone effect was detected upon 800 mg/L.

Precision

The reagent has been tested for 20 days, using three different CRP concentrations in a EP5-based study.

EP5	CV (%)		
	9.2 mg/L	**16.8 mg/L**	**57.97 mg/L**
Total	7.3%	6.9 %	5.9%
Within Run	2.8%	3.1%	2.9 %
Between Run	6.1 %	4.7%	3.9 %
Between Day	3.0%	4.0 %	3.4%

Accuracy

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 50 samples of different concentrations of CRP were assayed. The correlation coefficient (r)2 was 0.99 and the regression equation y = 1,101x + 2,518. The results of the performance characteristics depend on the analyzer used.

Sensitivity

Minimum detection limit of the assay is 2 mg/L

Linearity

Up to 100 mg/L.
Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Waste disposal

Disposal of all waste materials should be in accordance with local guidelines.

References

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

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

3-Okamura JM, Miyagi JM, Terada K, Hokama Y. Potential clinical applications of C-reactive protein. J Clin Lab Anal 1990; 4:231-5.

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

5-Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.

6-Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods.

7-Application of linear regression procedures for method comparison studies. Part I. J Clin Chem Clin Biochem 1983; 21:709-20.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
560 001	100 test
560 002	200 test
560 003	100 test (without calbrator)

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