SPECTRUM

The Creative Approach to Bioscience

C REACTIVE PROTEIN (CRP) Immuno-Turbidimetry

REF: 588 001	**100 test**
R1 Buffer Reagent	2 x 20 ml
R2 Antiserum	1 x 4.2 ml
Standard	1 x 0.2 ml
REF: 588 002	**200 test**
R1 Buffer Reagent	2 x 40 ml
R2 Antiserum	1 x 8.2 ml
Standard	2 x 0.2 ml

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	Manufactured by
REF Catalogue Number	(Xi) - Irritant
Consult instructions for use	
Temperature Limitation	

Intended Use

In vitro diagnostic reagents for the quantitative determination of C Reactive Protein (CRP) in human serum by 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 C reactive protein (CRP) antigen-antibody reaction.

Reagents

R1 Buffer Reagent
Phosphate buffered saline(pH 7.43).
Polyethelene glycol (40 g/L).
Sodium azide (0.95 g/L).

R2 Antiserum
Phosphate buffered saline(pH 7.43).
Polyclonal goat anti-human CRP (variable).
Sodium azide (0.95 g/L).

Standard
CRP concentration is stated on the vial label.

Materials required but not provided with the kit

Controls

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. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Reagent Preparation, Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date stated on the vial label when capped and stored at (2 - 8 ºC).Open vial is stable for 3 months when stored at 2-8 ºC.

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CRP Standard
The Standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).
Once opened the Standard is stable for 6 weeks if stored tightly closed at 2 - 8 ºC after use.

Deterioration

Reagent 1 appears as colorless solution while the latex reagent (**R2)** has white, turbid appearance free of granular particulate. Any change in appearance may be a sign of deterioration.

Specimen Collection and Preparation

Fresh or deep frozen serum. CRP remain stable for 2 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. 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 room temperature

2 - Assay conditions:

Wavelength	340 nm
Temperature	room temperature
Cuvette	1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

	Standard	Sample
Reagent (R1)	400 µl	400 µl
Standard	25 µl	-----
Sample	-----	25 µl
Mix and record 1st reading (A1).		
Reagent (R2)	40 µl	40 µl

After addition of **R2,** incubate at room temperature and after 5 minutes record 2nd reading (A2)

Calculation

Generate a reference curve by successive 1 : 2 dilutions of standard in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each standard as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each standard = (A2 - A1) for each standard
Plot the calibration curve and obtain the result.

Quality Controls

Control seraum 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

0.1 mg/dL

Precision

	CV (%)	
	Intra-Run	**Inter-Run**
Low	1.13	2.31
Medium	1.65	0.98
High	1.17	1.01

Interferences

No interference for :
Hemoglobin (250 mg/dL)
Na-citrate (1000 mg/dL)
Heparin (50 mg/dL)
Bilirubin (20 mg/dL)
Triglyceride (2500 mg/dL)

EDTA (5 mg/dL) and has interferences for: Turbidity (> 1.25%).

Sensitivity

1 mg/L

Linearity

Up to 220 mg/L.

Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Expected Values

0 - 10 mg/L .

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

Waste Disposal

Disposal of all waste materials should be done in accordance to local guide lines.

References

1. Ritchie, RF., J. Lab clin. Med. 70, 512 (1967)
2. Pepys MB. et al., Ann. NY Acad. Sci, 389, 459 (1982)
3. Manack, J.R. and Richards, CB., J. Immunol. 20, 1019

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
588 001 588 002 588 002-1	100 test 200 test 200 test (without standard)

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