

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

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 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).

Materials required but not provided with the kit

1- Standard

CRP concentration is stated on the vial label.

2-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. 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.

Reagent Preparation, Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 °C).

CRP Standard:

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

SYMBOLS IN PRODUCT LABELLING

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

For further storage at - 30 °C divide Standard into aliquots. Stability 3 months. once thawed never freeze again.

Specimen Collection and Preparation

Fresh or deep frozen serum. CRP remain stable for 2 days at (2 - 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. 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 calibrator in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each calibrator as following:

Δ absorbance of sample = (A2 - A1) sample

Δ absorbance of each calibrator = (A2 - A1) for each standard

Plot the calibration curve and obtain the result.

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 \times 5).

Quality Controls

Control sera are recommended to monitor the performance 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.

Expected Values

0 - 10 mg/L .

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

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	100 test



Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4665 1848 - Fax: +202 4665 1847

www.spectrum-diagnostics.com

E-mail:info@spectrum-diagnostics.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



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