

## 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

### 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).  
Polyethylene 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 °C). Open vial is stable for 3 months when stored at 2-8 °C.

SYMBOLS IN PRODUCT LABELLING			
	Authorised Representative		Use by/Expiration Date
	For in-vitro diagnostic use		CAUTION. Consult instructions for use
	Batch Code/Lot number		Manufactured by
	Catalogue Number		(Xi) - Irritant
	Consult instructions for use		
	Temperature Limitation		

### 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.

### 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 °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
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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  $\Delta$  absorbance of the sample and each standard as following:

$\Delta$  absorbance of sample = (A2 - A1) sample  
 $\Delta$  absorbance of each standard = (A2 - A1) for each standard  
Plot the calibration curve and obtain the result.

### Quality Controls

Control serum 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.

**Performance characteristics**

**Detection limit**

0.1 mg/dL

**Precision**

	CV (%)	
	Intra-Run	Inter-Run
<b>Low</b>	1.13	2.31
<b>Medium</b>	1.65	0.98
<b>High</b>	1.17	1.01

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
588 001	100 test
588 002	200 test

**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

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