

# **C-REACTIVE PROTEIN**

Cat. No.	Pack name	Packaging (Content)
BLT20009	CRP	5 x 25 ml CRP Buffer 1 x 10 ml CRP Antiserum 1 x 1 ml CRP Calibrator
BLT20010	CRP	2 x 25 ml CRP Buffer 1 x 5 ml CRP Antiserum 1 x 1 ml CRP Calibrator



#### INTENDED USE

Diagnostic reagent for in vitro quantitative determination of C-Reactive Protein (CRP) in human serum by turbidimetric immunoassay

## DIAGNOSTIC IMPLICATIONS

C-Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more guickly than the red cells sedimentation rate. CRP lacks diagnostic value when the patients illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases

# METHOD

Measurement of antigen-antibody reaction by the end-point method.

## REAGENTS PROVIDED

#### Buffer

Phosphate buffered saline (pH 7.43) Polvethylene alvcol (40 a/l) Sodium azide (0.09 %)

#### Antiserum

Phosphate buffered saline (pH 7.43) Polyclonal goat anti-human CRP (variable) Sodium azide (0.09 %)

#### Calibrator Pooled human serum, diluted with high levels of CRP with phosphate buffered saline, liquid and stabilized Contains 0.09 % sodium azide as preservative. Concentration : see bottle label

## PREPARATION AND STABILITY OF REAGENTS

Reagent Preparation Liquid reagents, ready for use.

#### Stability and Storage

The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

#### REAGENTS REQUIRED BUT NOT SUPPLIED

Saline (9 g/l NaCl)

#### SAMPLE COLLECTION

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

# AUTOMATION

Application procedures on clinical chemistry analyzers are available upon request.

#### Manual Procedure

Sample/Control dilution: None

Reference curve: Generate a reference curve by successive 1:2 dilutions of Calibrator High in saline or use the ready for use calibrator set. Use saline as zero point.

Test: Mix 60 µl of calibrators and samples with 1000 µl of buffer. Read optical density (OD1) of calibrators, controls and samples at 340 nm. Add 100 µl of CRP antiserum. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of calibrators, controls and samples at 340 nm. Calculate  $\triangle OD$ 's, plot a calibrator curve and read the concentration of controls and samples.

## **Reference Values**

0 - 10 ma/l (IFCC).resp. 0-1 ma/dl

This range is given for orientation only. Each laboratory should establish its own reference values

## PERFORMANCES

The performance characteristics for the CRP reagents were measured on a clinical chemistry analyzer (Cobas Mira).

Measuring Range: 0 - 220 mg/l (resp. 0-22 mg/dl) Detection Limit: 5 ma/l (resp. 0.5 ma/dl) Hook Effect: > 840 mg/l (resp. 84 mg/dl) Sensitivity: 0.0094 ABS units/concentration unit

Precision: [%CV]

	Low	Medium	High
Intra-Run	4.06	2.57	3.44
Inter-Run		4.29	6.60

Cy	а	11	ε	20	10	4
	n	d	1		n	
	n	d	1	nd	n	'n

Control	Assigned	Measured	
ERBA	19.2 (16.3-22.1)	20.9	
Biorad	25.9 (20.7-31.0)	27.8	

Interferences: No interference for : Hemoglobin (250 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (20 mg/dl), Triglyceride (1000 mg/dl)

Limitations: None

- Comparison with nephelometry:
- v = 0.9981x + 0.0142r = 0.9917

## PRECAUTIONS AND WARNINGS

1. In vitro diagnostic use only.

2.Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide

#### 3.Polvethyleneglycol is not biohazardous

4.Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

# Also available Calibrators and Controls

Cat. No.	Product name	Pack name	Content
BLT00012	CRP CALIBRATOR	CRP CAL H	1 x 1 ml
BLT00013	CRP CONTROL	CRP CON H	1 x 1 ml
BLT20014	CRP CONTROL	CRP CON L	1 x 1 ml
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1	1 x 1 ml
BLT20035	MULTICONTROL LEVEL 2	MULTICON L2	1 x 1 ml

## REFERENCES

1. Manack, J.R. and Richards, CB., J. Immunol, 20, 1019 (1971)

2. Ritchie, RF., J. Lab. Clin. Med. 70, 512 (1967)

3. Pepys MB, et al., Ann, NY Acad, Sci. 389, 459 (1982)





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