

C-reactive Protein (CRP) Diagnostic Reagent Kit (latex-enhanced immunoturbidimetry)

Product Instruction

Product name

Generic Name: C-reactive Protein (CRP) Diagnostic Reagent Kit (Latex-Enhanced Immunoturbidimetry)
Abbreviation: CRP

Intended use

C-reactive protein (CRP) diagnostic reagent is used for quantitative in vitro determination of C-reactive protein in human serum on photometric systems.

Package Specifications

R1	R2
40ml × 1	10ml × 1
800ml × 1	200ml × 1
8000ml × 1	2000ml × 1

Calibrator (liquid):

Specification 1 (0.5mL × 1; 6 levels);

Quality Controls (Liquid):

Specification 1 (0.5mL × 1; 2 levels);

Clinical significance

C-reactive protein (CRP) is an acute marker of inflammatory processes. In case of an acute inflammation the concentration of CRP increases and decreases more rapidly than the red cell sedimentation rate. The increase of CRP occurs in a non-specific way in different kinds of tissular aggression, as for example in infectious states, rheumatoid arthritis, myocardial infarction, malignant tumor, etc...

Principle

This method is based on the reaction of a sample containing human CRP and specific antiserum to form an insoluble complex which can be measured turbidimetrically at 546 nm.

Main ingredient

Composition	Main ingredients
R1	Phosphate buffer 50mmol/L
	Surfactant 3mL/L
	Polyethylene glycol 6000 5-20g/L
	Sodium chloride 30g/L
R2	Latex particles labeled with C-reactive protein antibody 1.5%
Calibration	Phosphate buffer 100mM, Sucrose 7%, BSA 6%, C reactive protein
Quality control	PBS buffer 50mM, Phosphate buffer 100mM, Sucrose 7%, BSA 6%, C reactive protein

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Fresh serum.

-20°C stable for 7 days.

Assay procedure

1. Reagent preparation

This reagent is liquid and can be used directly.

Main wavelength	546nm	Sample(S)	2μl
Sub wavelength	no	Reagent 1	160μl
Reation temperature	37°C	Reagent 2	40μl
Cuvette light path	1cm	Reaction type	Two Point End

Operation steps

Add to the cuvette:	
Sample(S)	2 μl
R1	160 μl
Mix well, incubate at 37°C for 5 minutes, then add	
R2	40 μl
Mix well, incubate at 37°C for 30 seconds, absorbance A1; incubate at 37°C for 4.5 minutes, absorbance A2 ΔA= A2- A1	

Calculations

Calculate and plot $\Delta A = (A2 - A1)$ of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in mg/L on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval

0-8.2 mg/L

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration

The assay requires the use of a Multi-immunoassay Calibrator. Recalibration is recommended at anytime if one of the following events occurs:

- The Lot number of reagents changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

Performance characteristics

1. Measuring range

0.5 mg/L - 150 mg/L

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity

When a control serum (20 mg/L) is used as a sample, the range of absorbance change is 0.05-0.2.

Precision

Within-Run	
n= 20	Level 1
Mean (mg/L)	15 ± 5
CV (%)	CV ≤ 5%

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30 mg/dl
Haemoglobin	5 g/L
VC	0.5 g/L
Heparin Sodium	100U/ml

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

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

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus,

etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters for analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	—
Wave Length Prim	600
ABS. Limit	32000
Sample Volume (uL)	3
R1 Volume (uL)	240
R2 Volume (uL)	0
R3 Volume (uL)	60
Calibration Type	SPLINE
Calibration Point	6
Span Point	4
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume (uL)	3
Sample DIL. VOL.	/
R1 Volume (uL)	240
R2 Volume (uL)	60
Reagent DIL. VOL.	/
Measure Wave 1	600
Measure Wave 2	—
METHOD	END
SLOPE	-
Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	

FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	300
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	6AB
Formula	spline
STD(1) Conc.#	*
Unit	mg/L

Dubai - Global Office**Xportin Global FZE**

Business Centre,
Sharjah Publishing City Free Zone,
Sharjah, United Arab Emirates
Formation No. 4307793.01
Mobile: +971 506938802 / +91 98241 88802
Email: xportinglobalfzelle@gmail.com
Website: www.xportin.com

India - Head Office:**Devasvi Enterprise LLP (Manufacturer)**

Navsari, Gujarat – 396445
Email: devashvienterprisellp@gmail.com