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A Division of Orchard Medical

C-Reactive Protein (CRP)

IVD

Order Information

Cat. No.	Kit Configuration
OMR1068	Reagent 1: 1 x 40 mL
	Reagent 2: 1 x 10 mL
	Calibrator: 1 x 1 mL

Summary

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

Method

Turbidimetric method

Principle

CRP-Turbilatex is a quantitative turbidimetric test for the measurement of C-reactive protein (CRP) in human serum or plasma. Latex particles coated with specific anti- human CRP are agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change, dependent upon the CRP contents of the patient sample that can be quantified by comparison from a calibrator of known CRP concentration.

Reagent Storage instruction and stability

The reagent is stable until the expiration date on the label when stored tightly closed at 2°-8°C.
If found Particles and Turbidity is observed means reagent deterioration.
Do not freeze; frozen Latex or Diluent could change the functionality of the test
All the components of the kit are stable until the expiration date on the label when stored tightly.
Reagent 1: Diluent
Reagent 2: Latex
Solution
Calibrator: Lyophilized serum – Separate pack

Composition

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with goat IgG anti-human CRP and Preservative.
Calibrator: Lyophilized Serum (CRP Value on Label)

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 and 2 are ready to use.
CRP Calibrator: Reconstitute with 1.0 mL of distilled water. Mix gently and incubate 10 minutes at room temperature before use. Calibrator Stable for 1 month at 2°-8°C or 3 months at –20°C. (Freeze only Once!)

Calibration Curve (For Fully Automated Analyzers)

Prepare dilutions of the Calibrator using NaCl 9 g/L as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the CRP concentration of each point of the curve.

Calibrator dilution	1	2	3	4	5	6
Calibrator CRP (µL)	--	25	50	100	200	400
NaCl 9 g/L (µL)	0	375	350	300	200	-
Factor	0	0.0625	0.125	0.250	0.50	1.00

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7 days at 2° –8°C
60 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength: 540 nm (530-550)
Temperature: 37°C
Cuvette light path: 10 mm

	Sample/ Calibrator
Reagent 1	800 µl
Reagent 2	200 µl
Sample /Calibrator	5 µl
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

Calculations

$$\text{CRP mg/L} = \frac{(A2\text{-}A1)\ \text{sample}}{(A2\text{-}A1)\ \text{calibrator}} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics and Measuring Range

The test has been developed determine CRP activities within a measuring range from 2 - 200 mg/L. If such value is exceeded the sample should be diluted 1 + 4 with NaCl solution (9 g/L) and results multiplied by 5.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/L.

Linearity

The higher limit of detection is 200 mg/L.

Precision

Intra-assay n = 20	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	14.96	0.56	3.77
Sample 2	55.40	1.28	2.31

Inter-assay n = 20	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	28.05	1.11	3.95
Sample 2	96.97	1.13	1.16

Method Comparison

A comparison of Nucleus Diagnosys C-reactive protein (CRP) (y) with a commercially available test (x) using 15 samples gave following results:
y = 1.005x - 0.149; r2 = 0.989.

Reference Range

Adults < 5 mg/L, Newborn up to 3 weeks < 4.1 mg/L, Infants and children < 2.8 mg/L
Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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