The Wide Range C-Reactive Protein (wr-CRP) Turbidimetric Immunoassay Kit

Catalogue number: 51120

For the quantitative determination of C-reactive Protein
in human serum and plasma

This package insert must be read in its entirety before using this product
Use only the current version of product data sheet enclosed with the kit

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FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

Version: 3.1

TABLE OF CONTENT

PACKING SPECIFICATION

Cat. No.	Size	Approximately tests
51120-05	R1: 15ml, R2: 5ml	100
51120-10	R1: 30ml, R2: 10ml	200
51120-20	R1: 60ml, R2: 20ml	400
51120-50	R1: 150ml, R2: 50ml	1000
51120-100	R1: 300ml, R2: 100ml	2000

INTRODUCTION

C-Reactive Protein (CRP), also known as PTX1, and pentraxin-related, is an annular pentameric protein produced from hepatic. The mechanism is when the body is infected or the tissue is damaged, macrophages and T cells are activated, producing interleukin-6, interleukin-1, tumor necrosis factor and other cytokines and mediators. Factors and mediators reach the liver, stimulating the synthesis of CRP by hepatocytes and epithelial cells. CRP is used mainly as an inflammation marker. Apart from liver failure, there are few known factors that interfere with CRP production.

Many pharmacological studies demonstrated that this protein possesses potent anti-diabetic, anti-atherogenic and anti-inflammatory functions. Supplement of adiponectin protein can decrease blood glucose, improve insulin sensitivity, alleviate fatty liver and prevent atherosclerosis. Decreased circulating levels of plasma adiponectin (hypoadiponectinaemia) are associated with increased body mass index (BMI), and decreased insulin sensitivity.

PRINCIPLE OF THE ASSAY

This assay is a turbidimetric immunoassay for the quantitative measurement of CRP in human serum and plasma. A standard or sample is added into a cuvette and mixed with the reaction buffer R1. After a short incubation, the test reagent R2, which is a suspension of microparticles coated with CRP antibodies, is added into the cuvette and mixed. The presence of CRP in the standard or sample causes the immune-particles to aggregate. The extent to which the microparticles aggregate is quantified by the amount of light scattering measured as absorbance by a chemistry analyzer. The concentration of CRP in unknown samples can be interpolated from a reference curve using the standards provided.

REAGENTS SUPPLIED

R1 – Reaction buffer, 30 ml, a ready-to-use buffer solution containing salt, polyether compound and preservative

R2 – Test reagent, 10 ml, a ready-to-use suspension of polymer microparticles coated with rabbit anti-ADPN polyclonal antibodies in storage buffer

OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

1. Clinical chemistry analyzer
2. CRP calibrators (provided separately, Cat. #51120-S1)
3. CRP controls (optional, provided separately, Cat. #51120-C1)
4. Deionized water
5. Analyzer-specific reagent containers for R1 and R2

STORAGE

The kit should be stored at 2-8°C upon receipt. Once opened, the reagents may be stored at 2-8°C for up to 4 weeks.

SAMLE HANDLING

This kit can be used to determine CRP in human serum and plasma samples. Blood specimens should be collected aseptically into appropriate tubes. Plasma should be prepared by standard techniques for laboratory testing. The prepared specimens should be stored in closed vessels. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at −20°C or below. For long-term storage of specimens, −70°C or below is recommended. To avoid freeze-thaw cycles, specimens should be aliquoted. Do not use hemolyzed, hyperlipemic, heat-treated or contaminated specimens. No dilution of the sample is required in this assay.

ASSAY PROCEDURE

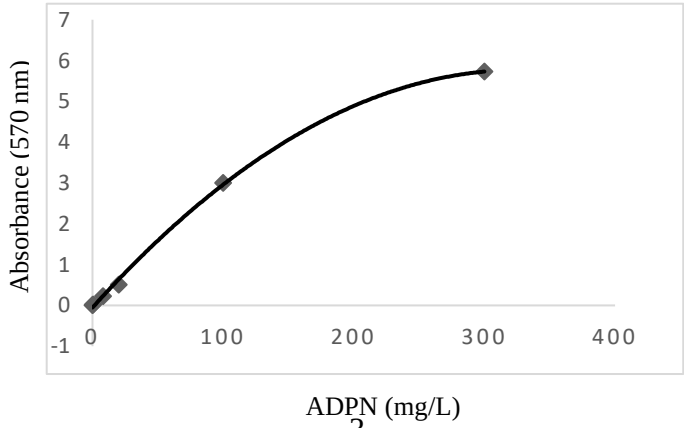
Assay procedures may vary depending on the automated chemistry analyzer to be used. A general example of assay procedures is stated as follow:

1. Dispense 300µl of R1 into a clean cuvette
2. Add 2µl of sample and incubate at 37˚C for 5 minutes
3. Further add 100µl of R2
4. Read change of absorbance at Main Wavelength 570 nm and Sub Wavelength 800 nm for 8 minutes after the addition of R2
5. Calculate the concentration of CRP in unknown sample by interpolation from a reference curve using the standards provided

TYPICAL STANDARD CURVE

The following standard curve is provided for demonstration only. A standard curve should be generated for each assay.

CRP (mg/L)	Absorbance
0	0
0.5	0.020
8	0.221
20	0.504
100	2.997
300	5.726



CALCULATION

1. Subtract the absorbance of the blank from that of standards and samples.
2. Generate a standard curve by plotting the absorbance obtained (y-axis) against CRP concentrations (x-axis). The best fit line can be generated with any curve-fitting software by regression analysis. 4-parameter curve fitting can be used for calculation.
3. Determine CRP concentration of samples from standard curve.

ASSAY CHARACTERISTICS

A. Sensitivity

The sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus three times the SD obtained from the blank sample. The sensitivity of CRP assay is 0.1mg/L.

B. Precision

The precision of the CRP assay is < 10% CV. Four samples consisting of two CRP controls and two serum based panels were assayed 20 times separately.

Sample	Mean CRP (mg/L)	SD (mg/L)	CV
Low Control	8.5	0.4	3.51%
High Control	20.1	0.7	1.72%
Panel 1	92.1	4.4	4.81%
Panel 2	43.5	1.3	2.90%

C. Linearity

The CRP assay is linear between 0.1 mg/L to 300 mg/L.

D. Interference

No interference was detected with hemoglobin up to 5 g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5g/L lipid emulsion.

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