C-Reactive Protein Assay Kit

(HCRP)

Method: Latex Immunoturbidimetric Method

Cat. No.	Package Size	Analyzer
EGS3621M	R1: 3×20 ml R2: 1×20 ml	For Hitachi 917 Olympus AU640/400/600
EGB3620M	R1: 3×20 ml R2: 1×20 ml	For Hitachi 717 Shimadzu CL7200/8000
EGH3621M	R1: 3×20 ml R2: 1×20 ml	For Hitachi 902
EGD3621M	R1: 12×4.2 ml R2: 6×2.9 ml	For Siemens Dupont Siemens Behring Series
EGHCRP4603	R1: 1×18 ml R2: 1×6 ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGHCRP3	R1: 1×18 ml R2: 1×6 ml	For Semi Auto Analyzer

INTENDED USE

For in vitro quantitative determination of CRP in human serum or plasma.

CLINICAL SIGNIFICANCE

CRP is an acute phase response protein. When the body becomes inflamed, the CRP in the patient's serum increases. In particular, many diseases such as pneumococcal infection and tissue infection have increased significantly. In 1930, CRP was found in the serum of patients with acute infection by Tillet et al. Now CRP has become a sensitive indicator for detecting infection and inflammation. It also helps to monitor patients during surgery and early diagnosis of infant infection.

The study also found that high levels of CRP within the normal range are related to the mortality of cardiomyopathy and are an independent risk factor for cardiovascular disease.

ASSAY PRINCIPLE

The CRP in the sample reacts with the hypersensitized anti-CRP antibody latex particle reagent to form an immune complex. The turbidity change was detected at a wavelength of 570nm, and the degree of change was a function of the CRP content in the sample.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Amino acetic acid buffer	50mmol/L
Reagent 2 (R2)	
Latex particles of sensitized CRP antibody liquid	0.20% (w/v)

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. The production date and expiry date are shown on the label.
3. Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering wavelength of 570nm.

It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh Serum or Plasma (EDTA or Heparin)

Sample CRP could be stable for 6 days at 2-8°C.

ASSAY PROCEDURE

Test Condition (Hitachi 917)

Main wavelength	570 nm	Sample(S)	2 μl
Secondary wavelength	800 nm	Reagent 1 (R1)	150 μl

Beijing Strong Biotechnologies, Inc.

Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China

Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn

Reaction temperature	37℃	Reagent 2 (R2)	50 μl
Cuvette diameter	1cm	Reaction type	Two Point End

Operation Procedure

Add into Cuvette:	
Sample (S)	2 μl
Reagent 1 (R1)	150 μl
Mix well and incubate for 5 minutes at 37℃,	
Reagent 2 (R2)	50 μl
Mix well and incubate 30s at 37℃, read A1; Incubate another 180s, read A2. calculate △A=A2-A1.	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use Gcell CRP calibrator. Calibrator traces to the international reference materials ERM-DA474/IFCC.

1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.

2. Requirements for calibration and frequency: It is recommended to calibrate at least once every two weeks. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

It is recommended to use Gcell CRP control. The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:

1. Check the parameter setting and light source.
2. Check the cleanliness of the cuvette and sampling needle.
3. Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4. Check the reaction temperature.
5. Check the validity of the kit.

CALCULATION RESULT

According to the project-specific calibration mode, after the instrument automatically generates a calibration curve, the content of the test substance is calculated from the change in absorbance.

REFERENCE RANGE

Serum: 0.0-0.6mg/dL

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of intralipid ≤ 3000 mg/dL, hemoglobin ≤ 500 mg/dL, bilirubin ≤ 30 mg/dL, ascorbic acid ≤ 50 mg/dL, RF ≤ 500IU/ml is less than 10%.

ACCURACY

The kit is tested with ERM-DA474/IFCC international reference material. The deviation of the results should ≤± 15%.

SENSITIVITY

When the sample concentration is 0.5 mg/dL, the change of absorbance should between 0.05-0.50.

LINEARITY

In the range of [0.05, 32] mg/dL, the linearity correlation coefficient r≥0.990. In the range of [0.05, 1] mg/dL, the absolute deviation should ≤ ±0.2 mg/dL. In the range of (1, 32] mg/dL, the relative deviation should ≤ ±10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches per day, and each batch was measured for 2 times separately in morning

and afternoon, for total 20 days. The results are as follows:

a) Repeatability (N=20)

	Mean (mg/dL)	CV %
Level 1	0.92	2.9
Level 2	2.34	2.4

b) Intermediate precision (N=80)

	Mean (mg/dL)	CV %
Level 1	0.92	5.0
Level 2	2.34	4.0

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.

2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.

3. Do not mix or exchange reagents with different batches in the process of detection.

4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.

5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.

6. The calibrator and quality control product contain human serum. It has been tested for antibodies against HIV (HIV1, HIV2), hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV), and they are all negative. Although the detection method is highly accurate, there is no guarantee that all infected donors can be found, so quality control products should also be treated as infectious specimens.

REFERENCES

1. Claus, D.R., Osmaud, A.P., Gewurz, H; J. Lab. Clin. Med 87, 120-128 (1976).

2. Shire, B., de Beer, F.C., Pepys, M.B.; Clin. Chim. Acta 117, 13-23 (1981).

INDEX OF SYMBOLS


Manufacture

Catalogue Number

Lot number


Date of manufacture

Use by(Expiration date)

For In-Vitro Diagnostic use only


Stored at 2-8℃


Attention: See instruction for use

Authorized Representative in the

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