# C-Reactive Protein Assay Kit (CRP)

**Method: Immunoturbidimetric Method**

| Cat .No. | Package Size | Analyzer |
|---|---|---|
| EGS9621M /S | R1:3×20 ml R2:1×20 ml | For Hitachi 7070 &OlympusAU640/400/600 |
| EGB9620M /S | R1:3×20 ml R2:1×20 ml | For Hitachi 7060/7150 &ShimadzuCL7200/8000 |
| EGD9621M | R1:24×3.8 ml R2:12×2.6 ml | For Siemens Dupont/Siemens Behring Series |
| EGCRP460 BS | R1:1×18 ml R2:1×6 ml | For Mindray BS120/180/190/200/220 /230/240/430/460/830 |
| EGGCRP | R1:1×18 ml R2:1×6 ml | For Semi Auto Analyzer |

**INTENDED USE**

For in vitro quantitative determination of C-reactive protein in human serum or plasma.

**CLINICAL SIGNIFICANCE**

CRP (C-reactive protein) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infectious, histolytic disease and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now come to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious disease.

**ASSAY PRINCIPLE**

The sample is combined with CRP-specific antibodies to produce a precipitate. The turbidity is measured at 340 nm, and a concentration-absorbance standard curve is established to measure the CRP concentration in the sample.

**REAGENT COMPOSITION**

| Contents | Concentration |
|---|---|
| **Reagent 1 (R1)** | |
| Tris buffer<br>Stabilizer<br>Preservative | 20mmol/L |
| **Reagent 2 (R2)** | |
| Goat anti-human CRP antiserum solution<br>Stabilizer<br>Preservative | 13% (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.
4.Reagents should not be contaminated.

**APPLICABLE INSTRUMENT**

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

**SAMPLE COLLECTION AND PREPARATION**

Serum or plasma sample(Heparin anticoagulation or EDTA anticoagulation).
Sample can be stored at 2℃～8℃ for 5 days, and it can be stored at (-15)℃-(-25)℃ for 3 months.

**ASSAY PROCEDURE**

Test Condition(Hitachi 917)

| | | | |
|---|---|---|---|
| Main wavelength | 340 nm | Sample (S) | 13 μl |
| Secondary wavelength | 700 nm | Reagent 1 (R1) | 180μl |
| Reaction temperature | 37℃ | Reagent 2 (R2) | 60μl |
| Cuvette diameter | 1cm | Reaction type | Two point end method |

Operate procedure

| | |
|---|---|
| Add into cuvette： | |
| Sample (S) | 13μl |
| Reagent 1 (R1) | 180μl |
| Mix well and incubate for 5 minutes at 37℃, read initial absorbance A1; | |
| Reagent 2 (R2) | 60μl |
| Mix well and incubate for 5 minutes at 37℃, read final absorbance A2;<br>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 trace to the international reference material 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. Disposal of calibrator: the calibrator is liquid for use, and the zero-point calibrator is ultrapure water.
3. Calibration mode: six-point nonlinear calibration.
2 Requirements for calibration and frequency: It is recommended to do a five-point calibration 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.

Beijing Strong Biotechnology, 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

5 Check the validity of the kit.

**CALCULATIONS 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 of the test substance in the sample.

**REFERENCE RANGE**

Adult: <8mg/L (0.8mg/dL)

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

**INTERFERENCE**

The effect of VC≤150 mg/dL, DB≤50 mg/dL, Hb≤100 mg/dL, Heparin Sodium≤500 mg/dL, RF≤500 IU/ml, Intralipid≤4 mmol/L, is less than 10%.

**ACCURACY**

The kit is tested with ERM-DA474/IFCC international reference material. The deviation of the results should ≤ ±10%.

**SENSITIVITY**

When the sample concentration is 4.0 mg/dL, the absorbance change should between 0.05～0.50.

**LINEARITY**

In the range of [0.7,20] mg/dL, the linearity correlation coefficient r ≥ 0.990. In the range of [0.7,2.5] mg/dL, the absolute deviation should ≤ ± 0.25 mg/dL; In the range of (2.5,20] mg/dL, the relative deviation should ≤ ±10%.

**PRECISION**

According to CLSIEP5-A2, 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 5 days, and each batch was measured for 5 times.The results are as follows:

a)Repeatability precision (N=20)

| | Mean (mg/dL) | CV(%) |
|---|---|---|
| Level 1 | 2.49 | 0.9 |
| Level 2 | 5.35 | 0.7 |

b) Intermediate precision(N=25)

| | Mean (mg/dL) | CV(%) |
|---|---|---|
| Level 1 | 2.57 | 0.9 |
| Level 2 | 5.42 | 0.7 |

**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. Calibrator and control use human matrix serum, passed the detection of HIV (HIV 1, HIV 2) antibodies, hepatitis B surface antigen (HbsAg) and hepatitis C virus (HCV). All of them are negative. Although the detection method is highly accurate, it can not be guaranteed that all infected donors are found, so the control should also be treated as infectious specimens.

**REFERENCES**

1. Ng, P.C. et al. Archives of Disease in Childhood (1997), 77(3):221-227.
2. Han Zhijun, Huang Zhifeng, etc. Automatic analysis method for common clinical chemistry items, third edition, Liaoning Science and Technology Press, 2005.8, Chapter Three, Chapter 16, Section 4, Determination of Blood C-Reactive Protein (Immune Turbidimetric Method).

**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 European Company |

Beijing Strong Biotechnology, 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