BIOBASE

C-Reactive Protein（CRP）Test Kit

(Immunoturbidimetric)

【NAME】

C-Reactive Protein（CRP）Test Kit (Immunoturbidimetric)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of C-Reactive Protein（CRP） in human serum.

CRP is a kind of acute phase reaction protein. In the state of inflammation, serum CRP of patients will increase, especially in pneumococcal infection, infection and other diseases increased significantly. Now CRP has become a sensitive indicator of infection and inflammation. And it is significant to the surgical patients monitoring and early diagnosis of infant infection. The study also found that the normal range of the high level of CRP has relation to cardiac disease mortality, and it is an independent risk factor for cardiovascular disease.

【METHODOLOGY】

CRP and super sensitized CRP antibody latex particle reagent is reaction, And generate immune complex. Detection of the turbidity of change at 570nm, the degree of change is proportional to the CRP levels in the samples.

【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;

Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 month.

Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh serum or heparin anticoagulant blood plasma.

Serum stability:2℃~8℃preservation stability in 6 days;

When the bilirubin concentration of sample≤100μmol/L, hemoglobin hemoglobin≤5.0mg/dL, was not observed clearly disturbance.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer

【SYSTEM PARAMETERS】

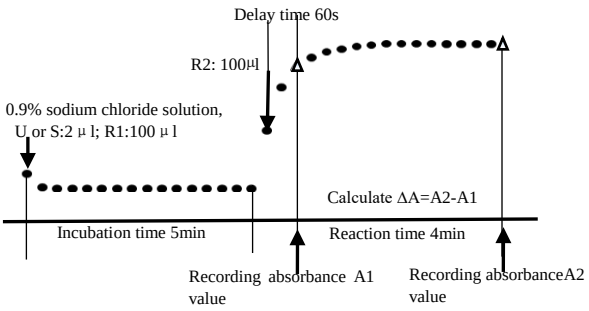
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	570 nm
Secondary Wavelength	800nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	1:50:50
eg : Sample Vol.	2μL
Reagent1 Vol.	100 μL
Reagent2 Vol.	100 μL
Linearity	0～32 mg/dL
Testing	Deducting the reagent blank

【OPERATION STEPS】

Double reagent operation:

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample



【CALCULATION】

ΔAbs = [（A2- A1）Calibrator or Sample] － [（A2- A1）Blank]

According to the calibration requirements, with different levels of calibration solution, together with 9 g/L sodium chloride solution as the blank. After measurement,the instrument automatic synthesize calibration curve for the calibration response quantity through the appropriate mathematical model (such as Logit/ Spline).Using CRP calibration values to calibrate instrument ,within the scope of the reportable results,the instrument directly report reliable test results.

【REFERENCE RANGE】

0 ~ 0.6mg/dL

By clinical trials, choose no less than 100 healthy men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range

Recommendation: The laboratory set up its own reference range!

【THE LIMITATIONS OF TESTING RESULTS】

CRP testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】

1. Reagent blank absorbance≤1.0000 (37℃,570nm，lcm Light path).
2. Precision: repeatability CV≤10％,Batch difference R≤10％.
3. Accuracy: Relative deviation≤10％.
4. The linear range: 0～32 mg/dL，R≥0.990;

【ATTENTION】

1. Reagent containing sodium azide (toxic), strayed into the eyes, mouth or contamination to the skin, please immediately rinse thoroughly w with water, if necessary to the hospital.
2. The maximum linearity is 32 mg/dL. If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3. Reagent opened shall be sealed by the specified method
4. Test tubes and other equipment which have been exposed to the test sample shallbe disposed of according to the medical waste disposal method.
5. Do not mix different batches of reagents, replacing the reagent lot, please recalibration!

Biobase Biodustry(Shandong)Co.,Ltd

Add: BIOBASE Biological industrial park, Mingshui Economic development zone, Jinan, China, 250200

Tel: 0086-0531-91219801 Fax: 0086-0531-81219804