

CRP Rapid Quantitative Test

Catalog No.: BT2302

INTENDED USE

The Biotime CRP Rapid Quantitative Test is intended to quantify the concentration of CRP, including high-sensitivity CRP(hsCRP) and normal CRP in human serum, plasma or whole blood on Biotime FIA Analyzers by fluorescent immunoassay. The test is used as an aid detection of infectious processes, hsCRP is also used as an aid detection of cardiovascular disease.

- Fluorescent immunoassay
- Infectious process, cardiovascular disease
- For in vitro diagnostic use only. For professional use only.

INTRODUCTION

C-reactive protein (CRP) is an annular (ring-shaped), pentameric protein found in blood, whose levels rise in response to inflammation. It is an acute-phase protein of hepatic origin that increases following interleukin-6 secretion by macrophages and T cells. It's physiological role is to bind to lysophosphatidylcholine expressed on the surface of dead or dying cells (and some types of bacteria) in order to activate the complement system via C1q. In healthy adults, the normal concentrations of CRP is less than 10 mg/L. When there is a stimulus, the CRP level can rise several to hundreds folds rapidly and star to drop once stimulus subside. Thus the normal CRP detection is not only applied to monitor various inflammatory processes, bacterial infection, tissue necrosis, injury and recovery, but also to evaluate the disease and judge the curative effect^[1].

Although CRP may be only a moderate risk factor, recent researches suggest that patients with elevated basal levels of CRP are at an increased risk of cardiovascular disease. hsCRP is therefore used to evaluate cardiovascular disease along with other test.

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the CRP in the sample and the mouse anti-CRP monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with CRP specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of CRP in human serum, plasma or whole blood. The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of CRP in human serum, plasma or whole blood.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and strong electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Otherwise, it may cause damages to the instrument.

MATERIAL

Material Provided

1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided

1. Biotime FIA Analyzer
2. Transfer Pipette Set and pipette tips (range 0.5~10µL and 10~100µL)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30°C, the shelf life is 24 months.
2. Store the test cartridge at 2-30°C, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test should be performed with serum, plasma or whole blood.
2. The sample collection container should be immune tube or pro-coagulant tube for serum

- and EDTA-K2 anti-coagulant tube for plasma or whole blood.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the serum or plasma sample can't be detected in time, it can be stored in refrigerator at 2-8°C for no more than 7 days, or at -20°C for no more than 6 months. Samples should be recovered to the room temperature before test.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURES

Please refer to operation manual of Biotime FIA analyzers for details. The test should be operated at room temperature (~25°C).

Step 1: Preparation

Check/insert SD card into the equipment.

Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling

For serum or plasma: take 3µL of serum or plasma with a transfer pipette and add it into the buffer tube.

For whole blood: take 5µL of whole blood with a transfer pipette and add it into the buffer tube.

Step 3: Mixing

Mix well the specimen with detection buffer by tapping or inverting the tube.

Step 4: Loading

Take 80µL of sample mixture and load it into the well of the test cartridge.

Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.

Step 5: Testing

Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 3 minutes.

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value

hsCRP: <1.0mg/L; CRP: < 10.0mg/L.

Note: If the CRP test result is below 5mg/L, it will be shown in the hsCRP result. Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum, plasma or whole blood.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [2-3].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same lot were tested with CRP control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15%.

Assay Range and Detection Limit

Assay Range: 0.5-200.0mg/L

The Lowest Detection Limit: 0.5 mg/L

Linearity

A serial concentration of CRP controls at 0.5-200.0mg/L were tested, the Correlation Coefficient (R) is ≥0.9900.

Precision

Intra-Lot Precision

Intra-lot precision was determined by testing of CRP reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%

Inter-Lot Precision

Inter-lot precision was determined by testing of CRP reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.

SYMBOLS

Symbol	Description	Symbol	Description
	Catalogue number		In vitro diagnostic medical device
	Batch code		Consult instructions for use
	Date of manufacture		Keep dry

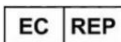
	Use-by date		Keep away from sunlight
	Manufacturer		Store at 2-30°C
	Do not re-use		Authorized representative in the European
	CE mark		

BIBLIOGRAPHY OF SUGGESTED READING

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2. Hansen JH, et al. HAMA Interference with Murine Monoclonal Antibody-Based Immunoassays [J].J of Clinical Immunoassay, 1993, 16:294-299.
3. Levinson SS. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference[J].J of Clin Immunoassay,1992,15:108-114.



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