Cys-C Rapid Quantitative Test

Catalog No.: BT2602

INTENDED USE

The Biotime Cys-C (Cystatin C) Rapid Quantitative Test is intended to quantify the concentration of Cys-C in human plasma or whole blood on Biotime FIA Analyzers by fluorescent immunoassay. The test is used as an aid detection of kidney function.
-Fluorescent immunoassay.
-Kidney Function.
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Cys-C Rapid Quantitative Test is used to detect the concentration of Cys-C in human plasma and whole blood.
Cys-C is a kind of cysteine protease inhibitors and also named gamma trace or post-gamma-globulin. In humans, all cells with a nucleus produce cystatin C as a chain of 120 amino acids. It is found in virtually all tissues and body fluids. Cystatin C has a low molecular weight (approximately 13.3 kilodaltons), and it is removed from bloodstream by glomerular filtration in the kidney. If kidney functioin and glomerular filtration rate decline, the blood level of cystatin C in human blood rises. The concentration of Cys-C in human blood is only determined by glomerular filtration rate instead of age, gender or diet. Cys-C is a valuable biomarker in diagnosing early kidney injury. What's more, Cys-C can be used to detect kidney injury due to acute rejection reaction and medicine treatment, which is a useful and sensitive biomarker for diagnosing diabetic nephropathy[1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer is mixed and applied into the test cartridge, the Cys-C in the sample and the mouse anti-Cys-C 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 Cys-C specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final sandwich-like reaction complex. Thus the fluorescent signal on detection line is positively correlated with the concentration of Cys-C in human plasma or whole blood.
The fluorescent signal from microspheres of T line will be detected and calculated according to the calibration curve (in SD card provided with the reagent) to represent the concentration of Cys-C in human 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 cartridge that is 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. Detector 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 (range 5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, 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 can be performed with plasma or whole blood .
2. The specimen collection container should be anticoagulant heparin tube or K 2 EDTA anticoagulant tube for plasma or whole blood.
3. Sample collection: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, For plasma, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for no more than 7 days，or at -20℃ for no more than 6 months. For whole blood, if the sample can't be detected timely, it only can be stored in refrigerator at 2-8℃ for no more than 3 days. Samples should be recovered to the room temperature before tests.
4. Separate plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operational manual of Biotime FIA analyzers for details.
The test should be operated at room temperature(~25℃).
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 plasma: Take 10μL of plasma with a transfer pipette and add it into the buffer tube.
For whole blood: Take 15μL of whole blood with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with 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 5 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: <1.2 mg/L.
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be plasma or whole blood specimen.
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 [4-5].
3. Other factors also can induce the false results, including technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Cys-C control materials of two different concentrations were tested by every lot of Test Cartridges, and the deviations are within ±15.0%.
Assay Range: 0.2-8.0mg/L
The Lowest Detection Limit: 0.2mg/L
Linearity: A serial concentrations of Cys-C reference materials at 0.4-8.0mg/L were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Inter-Lot Precision
Intra-lot precision was determined by testing of Cys-C reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15.0%.
Inter-Lot Precision
Inter-lot precision was determined by testing of Cys-C reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20.0%.

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use

	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Store at 2-30℃
	Do not re-use	CE	CE mark
EC REP	Authorized representative in the European		

BIBLIOGRAPHY OF SUGGESTED READING

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EC REP

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