Ferritin Rapid Quantitative Test

Catalog No.: BT2701

INTENDED USE

The Biotime Ferritin Rapid Quantitative Test is intended to quantify the concentration of ferritin in human serum on Biotime FIA Analyzers by fluorescent immunoassay. The test is used as an aid detection of anemia.
-Fluorescent immunoassay.
-Anemia.
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Ferritin Rapid Quantitative Test is used to detect the concentration of ferritin in human serum. Ferritin is a universal intracellular protein that stores iron and releases it in a controlled fashion. The protein is produced by almost all living organisms. In humans, It acts as a buffer against iron deficiency and iron overload. Ferritin is found in most tissues as a cytosolic protein, but small amounts are secreted into the serum where it functions as an iron carrier. Plasma ferritin is also an indirect marker of the total amount of iron stored in the body, hence serum ferritin is used as a diagnostic test for iron-deficiency anemia. Recent study suggests that ferritin provides a more sensitive, specific and reliable measurement for determining iron deficiency at an early stage. On the other hand, patients with ferritin levels that are higher than the reference range may be indicative of conditions such as iron overload, infections, inflammations, collagen diseases, hepatic diseases, neoplastic diseases and chronic renal failure[1-3].

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 ferritin in the sample and the mouse anti-ferritin 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 ferritin specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final sandwich-like raction complex. Thus the fluorescent signal on detection line is positively correlated with the concentration of ferritin in human serum.
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 ferritin in human serum.

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 and pipette tips (range 5~50μL and 10~100μL)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, 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 serum specimen.
2. The specimen collection container should be immune tube or pro-coagulant tube for serum.
3. Sample collection: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, 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. Samples should be recovered to the room temperature before tests.
4. Separate serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to operation 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
Take 10μL of serum 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 15 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: Female: 10.0-125.0ng/mL; Male: 16.0-220.0ng/mL.
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum 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
Ferritin control materials of two different concentrations were tested by every lot of Test Cartridges, and the deviations are within ±15.0%.
Assay Range: 1.0-1000.0ng/mL
The Lowest Detection Limit: 1.0ng/mL
Linearity
A serial concentrations of ferritin reference materials at 2.0-1000.0ng/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of ferritin 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 ferritin 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℃ 8℃	Store at 2-8℃
	Do not re-use	2℃ 30℃	Store at 2-30℃
EC REP	Authorized representative in the European	CE	CE mark

BIBLIOGRAPHY OF SUGGESTED READING

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