FSH Rapid Quantitative Test

Catalog No.: BT2205

INTENDED USE

The Biotime FSH Rapid Quantitative Test is intended to quantify the concentration of FSH in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of infertility
-Fluorescence immunoassay
-Infertility
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

FSH Rapid Quantitative Test is used to detect the concentration of the FSH in human serum.
FSH is a glycoprotein hormone secreted by antepituitary basophil cell, which consists of an α peptide chain and a β peptide chain through covalent bond. FSH, controlled by hypothalamic gonadotropin, promotes the function of maturation of follicle in female, while it promotes the formation and maturation of the seminiferous duct in male. The increase of the concentration of FSH can forecast ovulation according to the peak of the FSH and LH emerging at the same time at the mid-menstrual. It is important to process of the maturation of follicle. It can promote maturation of follicle, cell proliferation in granular layer, active the aromatizing enzyme and increase the secreting estriol. Furthermore, the formation of the follicle is due to the coordinating role of the estriol and a few Luteinizing hormones[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 FSH in the sample and the mouse anti-FSH 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 FSH 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 of the concentration of FSH in human serum.

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 FSH 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 one-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 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. 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 2-8℃, 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.
2. The specimen collection container should be immune tube or pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, 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 must be recovered to the room temperature before tests.
4. Separate the serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the 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 20μL 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 test results.

Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 20 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Sex	Stage	Normal reference interval(mIU/mL)
Mature male	/	1.25-13.5
Mature female	Follicular phase	2.45-15.55
	Ovulatory period	5.35-24.80
	Luteal phase	1.65-10.25
	Mneopause	24.60-135.75

Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. This test kit is only applicable to human serum specimen.
2. Human anti-mouse antibody (HAMA) may be present 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, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
FSH control materials with two different concentrations were tested by every batch of Test Cartridges, and the deviations were within ±15%.
Assay Range: 0.30-200.00mIU/mL
The Lowest Detection Limit: 0.30mIU/mL
Linearity
A serial concentrations of FSH reference materials at 1.00-200.00mIU/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of FSH reference materials using 10 test cartridges from the same batch. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of FSH reference materials using 30 test cartridges from 3 consecutive lots randomly (10 test cartridges from each batch).The C.V. is ≤ 20%.
Hook effect
There is no hook effect when the concentration of FSH is 500.00mIU/mL
Specificity
The concentration of FSH is not greater than 2.00mIU/mL when the concentration of HCG is 20000.00mIU/mL.
The concentration of FSH is not greater than 2.00mIU/mL when the concentration of LH is 500.00mIU/mL.
The concentration of FSH is not greater than 2.00mIU/mL when the concentration of TSH is 1000.00μIU/mL.

SYMBOLS

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

	Date of manufacture		Keep dry
	Expiry date		Keep away from sunlight
	Manufacturer		Store at 2-8℃
	Do not re-use		Store at 2-30℃
	European authorized representative		CE mark

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