LH Rapid Quantitative Test

Catalog No.BT2206

INTENDED USE

The Biotime LH Rapid Quantitative Test is intended to quantify the concentration of LH 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

LH is a protein secreted by anterior pituitary, which consist of α subunits and β subunits with molecular weight of 30,000 Da. LH secreted intermittently stimulates leydigcells to manufacture testosterone in male, while the concentration of LH is changed with menstrual cycles and ovulation periods in female. In menstrual cycles, the peak of the releasing of LH is closely related to ovarian oviposit. Once the peak of the releasing of LH emerges, there is an ovarian oviposit after the 24th to the 26th hour. The best time to conceive can be insured by monitoring the concentration of LH. In other conditions, an increase of the concentration of LH is observed, such as hypogonaddism, early testicles incomplete, renal insufficiency, cirrhosis, hashitoxicosis and severe hunger.
In patients with early testicular insufficiency and klinefelter syndrome, renal insufficiency, cirrhosis, hyperthyroidism and severe starvation, there was an increase of concentration of LH. Faced female immature ovarian, early ovarian insufficiency, polycystic ovarian disease or menopausal steroid hormone decreasing, secretion of LH was irregular.
In other hand, male have a similar situation. The decline of pituitary anterior lobe secreting and secretion GnRH of by hypothalamus and pituitary anterior lobe dysfunction can cause the concentration of LH decrease. Pituitary and hypothalamus dysfunction should do other tests to diagnose hypothalamus, pituitary or gonadal dysplasia. The function of hypothalamus-pituitary-gonadal axis should be examined in combination with other tests, such as the LH-RH stimulation test and the detection of other hormone levels [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 LH in the sample and the mouse anti-LH 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 LH 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 LH 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 LH 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. 2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. 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 should 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 to 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 20 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value

Sex	Stage	Normal reference interval(mIU/mL)
Mature male	/	**1.50-9.25**
Mature female	Follicular phase	1.25-11.80
	Ovulatory period	13.15-94.75
	Luteal phase	1.05-14.50
	Mneopause	7.70-64.20

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

LIMITATIONS OF PROCEDURE

1. The test sample should be serum.
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
Test cartridges from same lot were tested with LH control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15%.
Assay Range: 1.0-200.0mIU/mL
The Lowest Detection Limit: 1.0mIU/mL
Linearity
A serial concentration of LH controls at 1.0-200.0mIU/mL were tested, the Correlation Coefficient (R) is≥0.9900.
Precision
Intra-Lot Precision
Intra-lot precision was determined by testing of LH 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 LH reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 20%.
Specificity:
The concentration of LH is not greater than 1.00mIU/mL when the concentration of HCG is 20000.00mIU/mL.
The concentration of LH is not greater than 1.00mIU/mL when the concentration of FSH is 500.00mIU/mL.
The concentration of LH is not greater than 1.00mIU/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	2℃ 8℃	Store at 2-8℃
	Do not re-use	2℃ 30℃	Store at 2-30℃
EC REP	European authorized representative	CE	CE mark

BIBLIOGRAPHY OF SUGGESTED READING

1. Tang Zhixian, Jin Weixin, Li Xin, etc. FSH, LH diagnosis in male infertility and sexual dysfunction [J] Shandong Medical, 1990, 30 (4): 19.
2. Yan Renying. Perinatal medical foundation [M] Beijing & People's Medical Publishing House, 1989, 10-13.
3. Li Mei jia. Contemporary immunology technology and application [M] Beijing & Beijing Medical University Peking Union Medical University Joint Publishing House. 1998, 549-561.
4. Hansen JH, et al. HAMA Interference with Murine Monoclonal Antibody-Based Immunoas says[J]. J of Clin Immunoassay, 1993, 16: 294-299.
5. Levinson SS. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference[J]. J of Clin Immunoassay, 1992, 15: 108-114.

Xiamen Biotime Biotechnology Co., Ltd.
Address: 2F/3F/4F/5F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.

EC REP
Lotus NL B. V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

Version: A/05
Issuing date: 2022-07-01