

TSH Rapid Quantitative Test

Catalog No.: BT2204

INTENDED USE

The Biotime TSH (Thyroid-Stimulating Hormone) Rapid Quantitative Test is intended to quantify the concentration of TSH in human serum or plasma on Biotime FIA Analyzers by fluorescent immunoassay. The test is used as an aid detection of hyperthyroidism or hypothyroidism.

-Fluorescent immunoassay

-Hyperthyroidism, hypothyroidism

For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Thyroid-Stimulating Hormone, also known as thyrotropin, thyrotropic hormone or TSH, is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body. It is a glycoprotein hormone produced by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid. Abnormal TSH levels indicate thyroid functional disorders. Combined with thyroid hormone levels, hyperthyroidism or hypothyroidism can be diagnosed^[1].

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 TSH in the sample and the mouse anti-TSH 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 TSH 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 TSH in human serum or plasma.

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 TSH in human serum or plasma.

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 tube/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 10–100μL)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8°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 can be performed with serum or plasma.
2. The specimen collection container should be EDTA-K2 anticoagulant tube for plasma and 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°C for no more than 7 days, or at -20°C for no more than 6 months. Samples must be recovered to the room temperature before tests.

4. Separate the serum or plasma 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°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

Take 40μL of serum or plasma 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 20 minutes.

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

REFERENCE INTERVAL

Normal reference interval: 0.5-5.0μIU/mL

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

LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma.
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

TSH control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations were within ±15%.

Assay Range and Detection Limit

Assay Range: 0.4-100.0μIU/mL

The Lowest Detection Limit: 0.4μIU/mL

Linearity

A serial concentrations of TSH reference materials at 0.5-100.0μIU/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.

Precision

Intra-lot Precision

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

Specificity

The concentration of TSH is not greater than 0.50μIU/mL when the concentration of HCG is 1800mIU/mL.

The concentration of TSH is not greater than 0.50μIU/mL when the concentration of FSH is 300mIU/mL.

The concentration of TSH is not greater than 0.50μIU/mL when the concentration of LH is 500mIU/mL.

Unit Conversion

1μIU/mL (General unit) = 1mIU/L (SI unit)

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 2-8°C
	Do not re-use		Store at 2-30°C
	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 Immunoassay [J].J of Clin 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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