

TT3 Rapid Quantitative Test

Catalog No.BT2209

INTENDED USE

The TT3 Rapid Quantitative Test is intended to quantify the concentration of total triiodothyronine in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of thyroid gland disease.

- Fluorescence immunoassay.
- Thyroid gland disease test.

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

INTRODUCTION

3,5,3'-triiodothyronine, abbreviated T3, is a hormone secreted from the thyroid gland and is synthesized in thyroglobulin together with thyroxine. Under normal circumstances, a small amount of T3 (about 20%) is derived from the direct secretion of the thyroid gland, while other is mostly derived from the deiodination of T4. The amount of T3 is about one-third of T4 in blood, and most of T3 (about 99.5%) binds to proteins such as TBG. The unbound T3 is named as free T3, which exerts the physiological effects of thyroxine. T3 concentration in blood reflects the functions of the thyroid surrounding tissues and the thyroid secretion status. When the thyroid gland is constantly stimulated by thyroid stimulating immunoglobulin, such as in Graves disease, the secretion of T3 is significantly increased, resulting in an elevation of T3 in blood, as well as the ratio of T3/T4.

T3 level is important to maintain normal thyroid functions. Quantification of T3 concentration in blood, combined with other tests, is widely used to screen thyroid diseases. Although the level of T3 alone cannot be used to diagnose hypothyroidism, in hyperthyroidism T3 level changes are more sensitive than thyroxine (T4). In T3-thyrotoxicosis, T3 level is elevated while total T4 and free T4 levels are normal. T3 elevation is widely found in various hyperthyroidisms. On the other hand, decreased T3 levels are found in primary hypothyroidism such as Hashimoto's thyroiditis and neonatal hypothyroidism or secondary hypothyroidism. In addition, certain physiological conditions, such as pregnancy, may impact capacities of thyroid hormone-binding proteins, which may result in changes of T3 levels^[1-3].

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method. While the sample and the buffer are mixed, T3 in specimen and mouse anti-T3 monoclonal antibody labeled with fluorescent microsphere(contain Europium) form a reaction complex .During lateral flow ,free labeled antibodies move along with the nitrocellulose membrane to a detection line (T-line:coated with T3 antigen). Free labeled antibodies are captured and gives fluorescent signal upon stimulation. Thus, the fluorescent signals are negatively correlated with the concentrations of TT3 in human serum. The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent concentration of TT3 in specimen.

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. Instruction for use 1 copy/kit

Material Required But Not Provided

1. Biotime FIA Analyzer
2. Transfer Pipette Set (5~50 uL and 10~100 uL size)
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 shall 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 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 timely, it can be stored in refrigerator at 2-8°C for 7 days, or at -20°C for 6 months. Samples must be recovered to 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°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 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 15 minutes.

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

REFERENCE INTERVAL

Normal Reference Value: 1.0-2.8nmol/L

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

Unit conversion formula: ng/mL*1.536=nmol/L

LIMITATIONS OF PROCEDURE

1. The test sample should be serum sample.
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

TT3 control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations are within ±15.0%.

Assay Range and Detection Limit

Assay Range: 0.5-10.0nmol/L

The Lowest Detection Limit: 0.5nmol/L

Linearity

A serial concentration of TT3 reference materials at 0.8-10.0nmol/L were tested, and the correlation coefficient (R) is ≥0.9900.

Precision

Intra-Lot Precision

Intra-lot precision was determined by testing of TT3 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 TT3 reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot).The C.V.is ≤ 20.0%.

Specificity:

The concentration of TT3 is not greater than 1.0nmol/L when the concentration of TT4 is 500.0ng/mL.

The concentration of TT3 is not greater than 1.0nmol/L when the concentration of rT3 is 50.0ng/mL.

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	2°C 8°C	Store at 2-8°C
	Do not re-use	2°C 30°C	Store at 2-30°C
	Authorized representative in the European		CE mark

BIBLIOGRAPHY OF SUGGESTED READING

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