TT4 Rapid Quantitative Test

Catalog No.BT2210

INTENDED USE

The Biotime TT4 Rapid Quantitative Test is intended to quantify the concentration of total thyroxine in human serum or plasma on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of thyroid gland disease.
-Fluorescence immunoassay.
-Thriod gland disease test.
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

T4 is produced by the thyroid gland. Adults bodies normally produce about 80-100μg per day. 99.96% of the T4 in the blood exists as protein-bounding form, 90% of which binds to thyroid hormone binding globulin (TBG).
Quantification of TT4 helps to evaluate thyroid functions. Blood TT4 levels elevate in patients with hyperthyroidism and decrease in patients with hypothyroidism. In patients with declined thyroid functions, TT4 levels are also lower than normal conditions.
TT4 measurements is related to the concentrations of its carrier proteins. Thus evaluation of T4 binding capacity to its carrier proteins is necessary. TT4 diagnostic results should also be combined with other laboratory test or clinical examines to evaluate thyroid functions[1-3].

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.
While the sample and the buffer are mixed, T4 in specimen and mouse anti-T4 monoclonal antibody labeled with fluorescent microsphere(contain Europium) form a reaction complex. During lateral flow, free labled antibodies move along with the nitrocellulose menbrane to a detection line (T-line:coated with T4 antigen). Free labeled antibodies are captured and gives fluorescent signal upon stimulation. Thus, the fluorescent signals are negatively correlated with the concentrations of TT4 in human plasma or serum.
The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent concentration of TT4 in specimen.

PRECAUTIONS

1. This reagent is used for in vitro diagnostic use 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. Detection 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 (5~50uL and 10~100uL 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 plasma or serum.
2. The collection of sample container should be heparin anti-coagulant tube for plasma 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 timely, it must 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 plasma or 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 instrument.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 40μL of plasma or 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:58.0-140.0nmol/L
Note: Individual reference range is suggested to be established for each laboratory..
Unit conversion formula: ng/mL*1.287=nmol/L

LIMITATIONS OF PROCEDURE

1. The test sample should be plasma or 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
TT4 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: 10.0-320.0nmol/L
The Lowest Detection Limit: 10.0nmol/L
Linearity
A serial concentration of TT4 reference materials at 20.0-320.0nmol/L were tested,and the correlation coefficient (R) is≥0.9900.
Precision
Intra-Lot Precision
Intra-lot precision was determined by testing of TT4 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 TT4 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 TT4 is not greater than 15nmol/L when the concentration of TT3 is 500.0ng/mL.
The concentration of TT4 is not greater than 15nmol/L when the concentration of rT3 is 50.0ng/mL.

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

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Version: A/09
Issuing date: 2022-07-01