FT4 Rapid Quantitative Test

Catalog No.BT2215

INTENDED USE

The Biotime FT4 Rapid Quantitative Test is intended to quantify the concentration of FT4 in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of hyperthyroidism.
-Fluorescence immunoassay
-hyperthyroidism
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3) it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system[1]. T4 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T4 (fT4) is the unbound and biologically active form, which represents only 0.03% of the total T4. The remaining T4 is inactive and bound to serum proteins such as thyroxine binding globulin (TBG) (75%), pre-albumin (15%), and albumin (10%)[2-5]. The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T - uptake, TBG) is therefore unnecessary. Thus free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status.

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.

While the sample and the pretreated buffer are mixed, FT4 forms a reaction complex with sheep anti-FT4 antibody labeled with fluorescent microsphere (contain Europium). While the reaction complex and residual labled antibodies moving to T line(coated with T4 antigen), the residual labled antibodies are captured and gives fluorescent signal upon excitation. Thus fluorescent signals are negatively correlated with the concentrations of FT4.

The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent the concentration of FT4 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. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1copy/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 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 Biotime FIA Analyzer Operation Manual for the complete instructions on use of the Test. 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 40uL 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.

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 interval: 12-22 pmol/L.
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.
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 FT4 control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15.0%.

Assay Range: 0.3~100pmol/L

The Lowest Detection Limit: 0.3pmol/L

Linearity
A serial concentrations of FT4 controls at 0.3~100pmol/L were tested, the Correlation Coefficient (R) is≥0.9900.

Precision

Intra-Lot Precision
Intra-lot precision C.V. is ≤ 15.0%.

Inter-Lot Precision
Inter-lot precision was determined by testing of FT4 reference materials. The C.V. is ≤ 15.0%.

Specificity
The following cross-reactivities were found, tested with FT4 concentrations of approximately 13 pmol/L and 39 pmol/L :

Cross-reactant	Concentration testedng/dL	Cross-reactivity%
L-T3	50000	0.005
D-T3	50000	0.002
rT3	190000	0.007
3-iodo-L-tyrosine	10000000	0.000
3,5-diiodo-L-tyrosine	10000000	0.000
3,3',5-triiodothyroacetic acid	100000	0.000
3,3',5,5'-tetraiodothyroacetic acid	100000	0.001

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℃	Temperature limit
	Do not re-use	2℃ 30℃	Temperature limit
EC REP	Authorized representative in the European Community	CE	CE mark

BIBLIOGRAPHY OF SUGGESTED READING

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