Finecare™

T4 (Thyroxine) Rapid Quantitative Test

Catalog No. W232

INTENDED USE

The Finecare™ T4 (Thyroxine) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of Thyroxine (Total T4) in human whole blood, serum or plasma. The test is used as an aid in the functional diagnosis of thyroidea .

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

SUMMARY

The determination of serum or plasma levels of Thyroxine (T4) is recognized as an important measurement in the assessment of thyroid function. Thyroxine (T4) is one of two major hormones produced by the thyroid gland (the other is called triiodothyronine, or T3), T4 and T3 are regulated by a sensitive feedback system involving the hypothalamus and the pituitary gland. Approximately 99.97% of the T4 circulating in the blood is bound to plasma proteins: TBG (60-75%), TTR/TBPA (15-30%) and Albumin (~10%). Only 0.03% of circulating T4 is free (unbound) and biologically active. Total T4 is a useful marker for the diagnosis of hypothyroidism and hyperthyroidism.

PRINCIPLE

The Finecare™ T4 (Thyroxine) Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ T4 (Thyroxine) Rapid Quantitative Test uses a competitive immunodetection method, when sample is added to the sample well of the Test Device, the fluorescence-labeled detector T4 antibody binds to T4 antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the antigen-antibody complexes can't be captured to T4 antigen that has been immobilized on test strip, but the rest of fluorescence-labeled antibody is captured. Thus the more antigen in blood specimen, the less complexes accumulated on test strip. Signal intensity of detector antibody reflects the amount of T4 captured. The working range and the detection limit of the T4 Test system are 12.87~300 nmol/L and 12.87nmol/L respectively.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Please make sure that test device lot No., buffer lot No. and ID Chip lot No. are the same before use.
5. The Finecare™ T4 (Thyroxine) Rapid Quantitative Test is only operational in the Finecare™ FIA Meter. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.
6. The test device should remain in its original sealed pouch until ready to use. Do not use the test device if the pouch is punctured or not well sealed. Discard after single use.
7. The Test Device and Meter should be used away from vibration and magnetic field. During normal usage, the Test Device may introduce minute vibration, which should be regarded normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tips and detector buffer vials should be used for one specimen only. Discard after single use.
9. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
10. Blood specimens, used test devices, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The Finecare™ T4 (Thyroxine) Rapid Quantitative Test should not be used as absolute evidence for functional diagnosis of thyroidea. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

1. 25 Individual sealed pouches, each containing:
   - Test Device
   - Desiccant Pouch
2. One Test Device ID Chip
3. Leaflet with instructions for use.
4. 25 tubes of detector buffer

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set
3. Specimen Collection Containers
4. Centrifuge (for Plasma only)
5. Timer

STORAGE AND STABILITY

1. Store Finecare™ T4 (Thyroxine) Rapid Quantitative Test at 4～30℃ up to the expiration date.
2. If removed from refrigerator, allow the test for 30 minutes to return to room temperature before testing.
3. Do not remove the device from the pouch until ready to use. The Test Device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma or whole blood.

For Whole Blood:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2~8℃.
3. It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 7 days.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2~8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

The Finecare™ T4 (Thyroxine) Rapid Quantitative Test should be used with Finecare™ FIA Meter.

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/insert ID Chip into the equipment.

Step2: Sampling

Draw 75 µL of serum/plasma/whole blood with a transfer pipette and add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4:Loading

Take 75 µL of sample mixture and load it onto the sample well of the Test Device. leave the sample-loaded Test Device at room temperature for 15 minutes.

Step5:Testing

1. Finecare™ FIA meter:

Standard test: Insert the Test Device onto the Test Device Holder and click "Test". 15 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Device on the operation platform.15 minutes later, insert the Test Device onto the Test Device Holder and click "Test". The result will show in the display and print out when click "Print".

2. Finecare™ multi-channel FIA meter:

Insert the Test Cartridge onto the Test Cartridge Holder. 15 minutes later, the result will show in the display and print out when click “Print”.
Please refer to the Operationin user manual of Finecare™ FIA Meter for details.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meter calculates T4 test results automatically and displays the concentration of T4 on the screen as form of XX.XX nmol/L. For further information, refer to the Operation Manual for the Finecare™ FIA Meter.

Reference Value: 66-181 nmol/L (5.1~14.1ug/dL)
■ Conversion factor as unit of nmol/L
- 1ug/dL =12.87 nmol/L

Note: Recommend that each laboratory formulates its own Reference Range according to actual situation.

QUALITY CONTROL

Each Finecare™ T4 (Thyroxine) Rapid Quantitative Test device contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The results of Finecare™ T4 (Thyroxine) Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If T4 test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results include cross-reactions with some components of whole blood from individual to antibodies; and non-specific adhesion of some components in human whole blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of T4 antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
4. Other factors may interfere with Finecare™ T4 (Thyroxine) Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 300 human blood samples, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ T4 (Thyroxine) Rapid Quantitative Test and the Roche T4 Reagent Kit for the 300 clinical samples, the Correlation Coefficient is ≥0.950.

Assay Range and Detection Limit

- **Assay Range**: 12.87~300 nmol/L (1~23.31 ug/dL)
- **Detection Limit (Analytical Sensitivity):** 12.87 nmol/L

Cross-Reactivity

The following substances do not interfere with the T4 test results at the indicated concentrations: L –T3 at 500ng/mL,R –T3 at 100 ug/dL , 3’5’ L – T2 at 5000 ug/dL and 3’5’L-tyrosine at 5000 ug/dL

Linearity

A serial concentration of T4 controls at 21.46 nmol/L, 115.1 nmol/L, 245.4 nmol/L were each tested for three times, the Correlation Coefficient (R) is ≥0.990.

Precision

Intra-Lot Precision
Within-run precision has been determined by using 10 replicates for the same lot of T4 specimen of 245.4 nmol/L.C.V. is ≤15%.
Inter-Lot Precision
Between-run precision has been determined by using 3 replicates for each of three lots using T4 specimen levels at 245.4 nmol/L. C.V. is ≤ 15%.

Bibliography Of Suggested Reading

1. Yong S，Chen Y，Lee TK，et al． Determination of total thyroxine in human serum by hollow fiber liquid-phase microextraction and liquid chromatography-tandem mass spectrometry[J]. Talanta，2014，126（1）：163-169.
2. Milinkovi N，Ignjatovi S，Zarkovi M，et al． Indirect estimation of reference intervals for thyroid parameters[J]. Clin Lab，2014，60（7）：1083-1089.
3. Huang Y. The quality control and standardization of labeled immunoassay(Ⅱ)[J]. Label Immunoassays & Clin Med，2006，13（4）：240-243.
4. Oppenheimer JH. Role of plasma proteins in the binding, distribution and metabolism of the thyroid hormones[J]. N Engl J Med. 1986; 278 :1153-62.2003; 111:1805-1812.

INDEX OF SYMBOLS

IVD	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse	REF	Catalog #
30°C 4°C	Store between 4～30℃				

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Version: 20/05/2016