Finecare™

T3 (Triiodothyronine) Rapid Quantitative Test

Catalog No. W231

INTENDED USE

The Finecare™ T3 (Triiodothyronine) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of Triiodothyronine (Total T3) in human serum, plasma and whole blood.
-Fluorescence immunoassay
-Provide 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 Triiodothyronine (T3) is recognized as an important measurement in the assessment of thyroid function. Its effects on target tissues are roughly four times more potent than those of T4. Of the thyroid hormone that is produced, just about 20% is T3, whereas 80% is produced as T4. T3 and T4 are regulated by a sensitive feedback system involving the hypothalamus and the pituitary gland. Approximately 99.7% of the T3 circulating in the blood is bound to plasma proteins: TBG (30-80%), TTR/TBPA (9-27%) and Albumin (11-35%). Only 0.3% of the circulating T3 is free (unbound) and biologically active. T3 plays an important role in the maintenance of the euthyroid state. Total T3 measurements can be a valuable component in diagnosing certain disorders of thyroid function.

PRINCIPLE

The Finecare™ T3 (Triiodothyronine) Rapid Quantitative Test is based on fluorescence immunoassay technology. Finecare™ T3 (Triiodothyronine) Rapid Quantitative Test uses a competitive immunodetection method, when sample is added to the sample well of the test Device, the fluorescence-labeled detector T3 antibody binds to T3 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 T3 antigen that has been immobilized on test strip, but the rest of fluorescence-labeled antibody is captured. Thus the more antigens in blood specimen, the less complexes accumulated on test strip. Signal intensity of detector antibody reflects the amount of T3 captured. The working range and the detection limit of the T3 Test system are 0.61~9.22 nmol/L and 0.61 nmol/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™ T3 (Triiodothyronine) 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 produce minor vibration, which should be regarded as 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™ T3 (Triiodothyronine) 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™ T3 (Triiodothyronine) 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. If collecting plasma use a blood collection tube containing suitable anticoagulant (Sodium Citrate 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℃.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (Sodium Citrate 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.

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™ T3 (Triiodothyronine) 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 in room temperature.

Step1: Preparation
Check/insert ID Chip into the equipment.
Step2: Sampling
Draw 75 μL of serum/plasma or whole blood with a transfer pipette andadd it to the detector buffer tube.
Step3: Mixing
Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4:Loading

TTake 75 μL of sample mixture and load it onto the sample well of the Test Device.

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 Device onto the Test Device 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 T3 test results automatically and displays the concentration of T3 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: 1.3~3.1 nmol/L (0.8~2.0 ng/mL)

■ Conversion factor as unit of nmol/L

- nmol/L(SI unit) = 1.54 x ng/mL

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

QUALITY CONTROL

Each Finecare™ T3 (Triiodothyronine) 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 serum, plasma (Sodium Citrate recommended), whole blood (Sodium Citrate recommended) specimen only.
2. The results of Finecare™ T3 (Triiodothyronine) Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If T3 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/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 captured by the antibodies; instability of T3 antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies. 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™ T3 (Triiodothyronine) Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as interference substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study has been performed using 248 human blood samples, T3 concentrations ranging from 0.33 nmol/L to 9.91 nmol/L, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ T3 (Triiodothyronine) Rapid Quantitative Test and the Roche Elecsys® T3 Reagent Kit for the 248 clinical samples, the Correlation Coefficient is ≥0.940.

Assay Range and Detection Limit

- **Assay Range**: 0.61~9.22 nmol/L (0.4 ~ 6.0 ng/mL)
- **Detection Limit (Analytical Sensitivity):** 0.61 nmol/L (0.4 ng/mL)

Cross-Reactivity

The following substances do not interfere with the T3 test results at the indicated concentrations: L –T4 at 500ng/mL, D –T4 at 500ng/mL, R– T3 at 50 ug/dL.

Linearity

A serial concentration of T3 controls at 0.95 nmol/L, 2.12 nmol/L, 5.34 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 T3 specimen of 2.12 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 T3 specimen levels at 2.12 nmol/L. C.V. is ≤ 15%.

Bibliography Of Suggested Reading

1. Ekins RP. Methods for the measurement of free thyroid hormones. In: Free Thyroid Hormones: Proceedings of the International Symposium Held in Venice, December 1978. Amsterdam: Excerpta Medica; 1979:72-92.
2. Robbins J, Rall JE. The iodine-containing hormones. In: Gray CH, James VHT, eds. Hormones in Blood. Vol 1. 3rd ed. London: Academic Press, 1979;632-667.
3. Demers LM, Spencer CA, eds. Laboratory medicine practice guidelines: laboratory support for the diagnosis and monitoring of thyroid disease. Thyroid. 2003;13:3-126.

INDEX OF SYMBOLS

IVD In Vitro Diagnostic Use	See Instruction for Use	Expiry Date
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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CE EC REP

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