AeHealth

CE IVD

T3 (Total Triiodothyronine) Rapid Quantitative Test (Immunofluorescence Assay)

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

PRODUCT NAME

T3 (Total Triiodothyronine) Rapid Quantitative Test (Immunofluorescence Assay)

SPECIFICATION

1 test/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 50 tests/kit, 100 tests/kit;

INTENDED USE

The TT3 (Total Triiodothyronine) Rapid Quantitative Test along with Aehealth FIA Meter is intended for vitro quantitative determination of Total Triiodothyronine (TT3) in human serum or plasma. The test is used as an aid in the functional diagnosis of thyroidea.

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.

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

PRINCIPLE OF THE PROCEDURE

The Aehealth TT3 Rapid Quantitative Test is based on fluorescence immunoassay technology. The Aehealth TT3 Rapid Quantitative test usesuses 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 antigen in blood specimen, the less complexes accumulated on test strip. Signal intensity of detector antibody reflects the amount of T3 captured and Aehealth FIA Meter shows TT3 concentrations in blood specimen.

COMPONENT

Test cassette	IC card	Instructions for use	Buffer
25 tests	1	1	25
For each test card bag, it contains one test card and one package of desicant.			

STORAGE AND STABILITY

1. Store the detection buffer at 2 ~ 30℃. The buffer is stable up to 18 months.
2. Store Aehealth TT3 rapid quantitative test cassette at 2 ~ 30℃, shelf lifeis up to 18 months.
3. Test cassette should be used within 1 hour after opening the pack.

MATERIALS SUPPLIED

- Test cassette
- Test cassette IC card
- Buffer (sample diluent)

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10 μL, 100 μL size)
- Specimen Collection Containsers
- Alcohol Pads
- Centrifuge (for Plasma/Serum only)
- Timer

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use test cassette if its lot # does not match with IC card # that is inserted onto the equipment.
5. The Aehealth TT3 rapid quantitative test kit is only operational in the Aehealth FIA meter.
6. Do not use the test cassette if the pouch is punctured or not well sealed.
7. The test cassette and meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detection buffer vials for different specimens.
9. Blood specimens, used test cassettes, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. 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°C～8°C for up to 3 days. For longterm storage, specimens should be kept below -20°C.

TEST PROCEDURE

Refer to Aehealth FIA meter operation manual for the complete instructions on use of the test. The test should be operated in room temperature.

Step1: Preparation

Check/ swipe the IC card information to the equipment.

Step2: Sampling
Draw 40 μL of serum/plasma 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 100 μL of sample mixture and load it onto the sample well of the test cassette.

Step5: Testing
Quick Test: After 15 minutes of sample adding reaction, insert the detection card into the carrier of the fluorescence immunoassay analyzer, click the “Test” button on the “Quick test” page, enter the information, and click “test” the instrument will automatically detect and print the results;

Timming Test: Insert the detection card into the carrier of the fluorescence immune analyzer immediately after adding the sample, double click the "Timing test" button, enter the information and click “test”, after the automatic incubation countdown is over, click test, automatically detect, give the test results and print.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human serum and plasma specimen.
2. The results of Aehealth TT3 Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If TT3 test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Aehealth TT3 Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Detection Limit : 0.5 nmol/L ;
Linear Range: 0.5～10 nmol/L;
Linear correlation coefficient R ≥ 0.990;
Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when the accuracy calibrator prepared by TT3 national standard or 1.0mg/Land 10.0mg/L standardized accuracy calibrator are tested.

BIBLIOGRAPHY OF SUGGESTED READING

1.Han Xueqi. Clinical significance of T3, T4, FT3, FT4 and TSH.RIA in 252 patients with thyroid disease[J].J of Qilu Medical Laboratory, 2004, 15(2).
2.Demers LM, Spencer CA, eds. Laboratory medicine practice guidelines: laboratory

INDEX OF CE SYMBOLS

IVD	In Virto Diagnostic medical Device		Do Not Reuse
	Expiration Date		Consult Instructions For Use
2℃ 30℃	Store at 2-30°C		Date of Manufacturer
	Manufacturer	LOT	Batch Code
	Warning, please refer to the instruction in the annex		Keep Dry
	Avoid overexposuer to the sun	CE	CE Mark
	Don’t use the product when the package is damaged		Biological Risks
EC REP	Authorized Representative in the European Community		

Please read this user manual carefully before operating to ensure proper use.
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BASIC INFORMATION

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