# Instruction for Triiodothyronine (T3) Test Kit (Immunofluorescence)

**1. Product Name**

Generic name: T3 Test Kit (Immunofluorescence)

Trade name: T3.

**2. Package**

Specification 1: 25T/kit REF: 52026050

Specification 2: 50T/kit REF: 52027050

Quality Control (optional):

Level 2: 0.5mL × 1 REF: 52105052

**3. Intended Use & Indication**

For *in vitro* quantitative determination of T3 content in human serum, plasma or whole blood.

It is mainly used to assist in the diagnosis of thyroid diseases.

Products for professional use only.

**4. Test Principle**

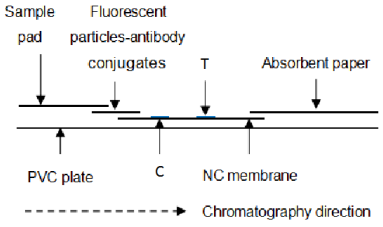
Mix the blood sample with the diluent, then add mixture onto the sample port of the test card, T3 in the sample binds with anti-T3 monoclonal antibody, which is coupled to fluorescent particles, to form a fluorescent particles - antibody - antigen complex. This immune complex migrates along the nitrocellulose membrane and reaches the test area (T). The fluorescent particles – antibody which didn't bind with the antigen will then bind the pre-coated T3 conjugated antigen. The fluorescence intensity is thus inversely proportional to the T3 content in the sample. The remaining antibody coupled with fluorescent particles reaches the quality control area (C) and binds pre-coated Rabbit IgG for the control purpose.

**5. Main components & Additional Required Equipment**

The test kit consists of test card, magcard, sample diluent and the instruction.

(1) The test card consists of the shell and test strip. Test strip contains a sample pad, glass fiber (coated with fluorescent particles-T3 antibody conjugates), nitrocellulose (NC) membrane (test area (T) is coated with T3 conjugated antigen, quality control area (C) is coated with Rabbit IgG, blotting paper and PVC plate.

Diagram is as follows:




Schematic diagram of test strip

(2) Magcard: loaded with calibration curve and information of reagents with this batch.

(3) Sample diluent: the main component is Tris-HCl buffer.

(4)Equipment: applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

**6. Accessories Required But Not Provided**

(1) Pipettes and pipette tips: 100 μL.

(2) Timer

**7. Special Storage & Transport Conditions**

(1) The test kit is kept in sealed aluminum foil bag and can be stored at 2-30℃. The unopened pack is valid for 18 months from the date of manufactured. Once opened, if the temperature is 18-30℃, and the humidity is 40%-85%. The validity period is 1 hour.

(2) Transport at 2-30℃.

**8. Sample Requirements**

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results for other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8℃ for not more than 1 days and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, or stored at 2-8℃ for more than 1 days.

(3) Bring the samples to room temperature before test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeatedly freezing and thawing.

(4) Human serum is recommended to be used for testing. EDTA-$K_2$ and EDTA-$Na_2$ is recommended to be used as the coagulant.

**9. Test Procedure**

Carefully read the reagent instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (25±2℃) before use.

(1) Startup: Click "STD Mode" in the main menu to enter the measurement interface, click "Type" to select the sample type.

(2) Click "Lot No." to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a "di" sound, the magcard is swiped successfully. Make sure the magcard and the test card are from the same batch (Note: reagents are pre-calibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.).

(3) Sampling:

Add 100μL serum, plasma or whole blood into the container with 200μL sample diluent, mix thoroughly for 30s-1min. Take 100μL diluted sample, drop vertically to the sample port on the test card directly and start timing.

(4) Insert it into the analyzer's test slot (the sample port end toward the inside). Click "Measure", the instrument will automatically detect and print out the results after 15 minutes (If using "Fast Mode", keep it for 15 minutes and quickly insert into the analyzer's test slot).

**10. Reference Interval**

Reference range: 1.3-3.1 nmol/L

**11. Explanation for Test Results**

(1) When fluorescent strips appears on the control area (C), the analyzer will automatically capture and analyze the fluorescence light signals and provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer will not detect the fluorescence but will alarm automatically, indicating that either the operation

is incorrect or the test card is damaged. In this case, carefully read the instructions again and re-test with a new test card. If the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the sample test results are more than 10 nmol/L, the instrument displays > 10 nmol/L, when the test results are less than 0.6 nmol/L, the instrument displays <0.6 nmol/L.

(4) This test kit does not produce Hook Effect within 10 nmol/L.

**12. Detection Limit**

(1) This test kit is for *in vitro* diagnostic use only.

(2) Sensitivity of this method is 0.6 nmol/L, not recommended for the early diagnosis of indications.

(3) Diagnosis and treatment can not only rely on this test result, it should be taken into account the patients' clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

**13. Interfering Substance**

(1)High concentrations of hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibodies, and rheumatoid factors in the sample interfere with the assay results.

**14. Product Performance Indicators**

(1) Analysis sensitivity: ≤ 0.6 nmol/L

(2) Linearity range: 1-10 nmol/L (Linear correlation coefficient: r ≥ 0.990)

(3) Measurement precision: Within run repeatability: CV ≤ 12%,

Between run repeatability: CV ≤ 15%

(4) Accuracy: -15% ≤ Bias% ≤ +15%

(5)The Interference test result: TT4 at a concentration of 500 ng/mL and rT3 at a concentration of 50 ng/mL is tested less than 2 ng/mL (3.07 nmol/L) on this kit.

**15. Precautions**

(1) Once opened, use the test cards as soon as possible, otherwise it may cause moisture. Do not re-use the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

**16. Explanation of graphic symbol**

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| | Consult Instructions for use | | Temperature Limitation |
| LOT | Lot No. | | Expiry Date |
| IVD | *In Vitro* Diagnostic Reagent | CE | CONFORMITE EUROPEENNE |
| | Production Date | | Biohazard |
| | Manufacturer | | Volume |
| Σ | Contains sufficient for < n>tests | | Keep away from sunlight |
| | Do not re-use | | Dark dry preservation |
| EC REP | Authorized representative in the European community | REF | Catalogue number |

**17. Reference**

(1) Wang Z, Lao HM, Liu T, et al. Labelled antibody-based one-step time-resolved fluoroimmunoassay for measurement of free thyroxine in serum. Ann Clin Biochem. 2011,48(6):550-7.

(2) Oppenheimer JH. Role of plasma proteins in the binding, distribution and metabolism of the thyroid hormones. N Engl J Med. 1986;278:1153-62.

**18. Metrological Traceability**

The kit was traceable to the certified reference material IRMM-469.

**19. Help Information**

If you need help please contact after sales.

**20. Manufacturer**

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China

**21. Instruments & Applications**

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

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