

## Instruction For Use

### 【Product name】

Free Triiodothyronine Kit (Electrochemiluminescence Immunoassay)

### 【Order Information】

REF NO.	Package Size
690056	50T
690057	2×50T
690058	100T
690059	2×100T

### 【Intended use】

Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and plasma.

#### Summary

The thyroid hormones triiodothyronine (T3) and thyroxine (T4) are secreted into the bloodstream by the thyroid gland and play a vital role in regulating the body's metabolic rate, influencing the cardiovascular system, growth and bone metabolism, and are important for normal development of gonadal functions and nervous system.

T3 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T3 (FT3) is the unbound and biologically active form, which represents only 0.2-0.4% of the total T3. The remaining T3 is inactive and bound to serum proteins, while the distribution of T3 between these binding proteins (thyroxine binding globulin, pre-albumin, albumin) is controversially discussed.

The determination of free T3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore unnecessary. Therefore free T3 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. Free T3 measurements support the differential diagnosis of thyroid disorders, are needed to distinguish different forms of hyperthyroidism, and to identify patients with T3 thyrotoxicosis.

### 【Test principle】

The determination of free triiodothyronine was adopted by competition method. Total duration of assay: 18 minutes.

1st incubation: 15 µL of sample and anti-T3-specific antibody labeled with a ruthenium complex.

2nd incubation: After addition of biotinylated T3 and streptavidin-coated microparticles, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin.

Measurement: The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with Buffer. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

Result are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

### 【Main Components】

The reagent is consist of MB, RB, RA, calibrator and quality control materials.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
(MB)	Streptavidin-coated microparticles; 0.1M PBS; preservative.	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
(RB)	Biotinylated T3; 5 mM PBS; preservative.	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
(RA)	Anti-T3-Ab-Ru(bpy) <sub>3</sub> <sup>2+</sup> ; 5 mM PBS; preservative.	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
Calibrator (High)	T3 antigen, 0.1 M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Calibrator (Low)	T3 antigen, 0.1 M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (High)	T3 antigen, 0.1 M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (Low)	T3 antigen, 0.1 M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL

The assignment of calibrators value complies strictly with ISO17511:2020, and can be traced to Roche Elecsys FT3.

Quality control target and scope see quality control card.

Supporting instruments and materials required but not provided in this pack (provided by Lifotronic):

Additional materials for Automated ECL Immunoassay Analyzer eCL8000,

eCL8000i, eCL8000p, eCL8000x:

- Auffer, 480 mL, 6×480 mL
- Buffer, 480 mL, 6×480 mL
- Concentrated Washing Buffer
- Assay Cup

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i:

- Auffer, 2 L
- Buffer, 2 L
- Concentrated Washing Buffer
- Assay Cup, reaction cup
- Disposable Sampling Head, pipette tips
- PreClean, system wash solution
- Waste Bags, litter bags

### 【Storage conditions and expiration date】

Unopened reagent rackpack, calibrators and control materials should be placed at 2 ~ 8°C and will be valid for 12 months.

The reagents can be stored for 28 days in machine (temperature 4 ~ 15°C).

Opened reagents, calibrators and control materials should be used and stored at 2 ~ 8°C in 28 days, otherwise trashed.

The expiration date is labeled on the box, rackpack and bottles.

Damaged, expired or contaminated reagents should be discarded.

### 【Appropriate instrument】

Automated ECL Immunoassay Analyzer: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i.

### 【Specimen collection and preparation】

Human serum and plasma added with heparin lithium, heparin sodium and EDTA-2K, EDTA-3K anti-coagulants are recommended. Blood samples should be collected by standard operation of venous puncture; After the sample was completely coagulated, the residual cell types were removed by centrifugal operation. The sample should be free of air bubble during testing; If the upper layer of the centrifuge is covered with lipid layer, it should be removed. Samples with severe hemolysis are not recommended. It is recommended to complete the test in time after sample collection. Samples can stable for 8 hours at 18 ~ 28°C, 7 days at 2 ~ 8°C, 28 days at -25 ~ -15°C, Freeze only once.

### 【Test method】

#### Testing procedures and precautions

Before the test, should read carefully analysis instrument system operation manual, in order to obtain system operation procedures, sample management, security considerations, maintenance and maintenance and other related information, and ready to test the required materials. According to the system operation procedure call and set up the free triiodothyronine (FT3) determination procedure.

Before the reagent is used, the multi-agent bottle is put into the analyzer to automatically stir the magnetic beads to suspend the reagent.

The sample size required for each FT3 measurement is 15 µL

#### Calibration

Calibration tests should be performed using matching calibration products.

Before calibration, the reagent information and main calibration curve information of the kit (Radio Frequency Identification, inductive electronic chip card or near-receiving card) are required to be imported into the system. The analyzer adjusts the main calibration curve through the test results of the matching calibrators to obtain the standard curve tested by the current system (the analyzer can automatically determine the validity of the standard curve according to the adjustment results).

Recalibration is recommended when:

- (1) the lots of reagents are changed;
- (2) the same lot of reagents were used on the analyzer beyond 28 days;
- (3) quality control misses the target;
- (4) the lots of buffer are changed.

#### Quality control

In order to ensure the reliability of test results, it is recommended to check the quality control products of high and low levels every 24 hours. After each calibration, reagent batch, maintenance or failure repair, high and low quality control testing is recommended. The quality control test results should fall within the scope of the regulations. If it is beyond the prescribed scope, the equipment status, reagents, calibration products and other reasons should be checked for the reasons.

#### Calculation

The analyzer automatically calculates the analyte concentration of each sample via the four-parameter logarithmic curve (4PLC), and the result unit is pg/mL, pmol/L or ng/dL:

pg/mL × 1.536 = pmol/L;

pg/mL × 0.1 = ng/dL.

#### Sample dilution

Samples for FT3 determinations cannot be diluted, as T3 in the blood is present in free and protein-bound forms which are in equilibrium. A change in the concentration of the binding proteins alters this equilibrium.

**【Biological reference interval】**

Through to the Guangdong area hospital, 254 cases (male 126, female 128) looks healthy human serum samples tested, using statistical methods take its percentile 2.5 to 97.5 percentile, draw a FT3 kits reference range of 1.92-4.44 pg/mL.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

**【Result explanation】**

In interpreting the results, the patient's overall clinical situation should be referred to, including symptoms, medical history and other relevant data and information.

**【Limitations】**

The test results are only for clinical reference and cannot be used as the basis for diagnosis or exclusion alone.

The measuring range of the kit is 0.28 ~ 32 pg/mL. Values below the limit of blank are reported as <0.28 pg/mL. Values above the measuring range are reported as >32 pg/mL.

When the concentration of bilirubin samples in 20 mg/dL or less, lipid concentration of 2000 mg/dL or less, concentration of biotin 70 ng/mL, or less hemoglobin concentration of 500 mg/dL or less, the interference of the determination results deviation within ±10%.When the concentration of rheumatoid factor in the sample is ≤ 600 IU/mL, the relative recovery of the test results is between 90% and 110%.

**【Analytical Performance】**

**Analytical sensitivity**

The lower detection limit is 0.28 pg/mL

**Accuracy**

The relative bias of measuring trueness control materials within ±15%.

**Linear**

The correlation coefficient (r) was not less than 0.9900 in the interval of 0.28~32 pg/mL.

**Within-run precision**

CV ≤ 7.5%

**Between-lot precision**

CV ≤ 10%

**Analytical specificity**

Tested the following FT3 analogs, the cross-reactivities should be not more than 10%. The test results are shown in the table Below:

Cross-reactant	concentration	Cross-reactivity %
L-T4	300000 pg/mL	0.0020%
D-T4	625000 pg/mL	0.0050%
3-iodo-L-tyrosine	5000000	0.000001%
3,5-diiodo-L-tyrosine	10000000	0.000015%
3,3',5,5'-tetraiodothyroacetic acid	1000000	0.0001%

**Homogeneity of calibrators Homogeneity of calibrators**

In-bottle homogeneity: coefficient of variation (CV) ≤ 7.5%.

Between-bottle homogeneity: coefficient of variation (CV) ≤ 10%.

**Method comparison**

A comparison of the Lifotronic FT3 assay (y) with the Roche Elecsys FT3 Method (x) using clinical samples gave the following correlations:

Linear regression:

$$y=1.0205x-0.16898$$

$$r = 0.993$$

The sample concentrations were between approx 1.2 and 29.6 pg/mL.

**【Precaution and Warning】**

This kit is for in vitro diagnostic use only;

When using this kit, it is necessary to observe the relevant matters in the laboratory.

The test results of this kit are for clinical reference only, and the clinical evaluation of patients should be combined with their symptoms/signs, medical history, other laboratory examination results and treatment reactions.

Due to reasons such as methodologies or antibody specificity, the use of reagents to test the same samples of different manufacturers may get different test results, the results with different kits should not compare directly, lest cause the wrong medicine explanation;It is suggested that the laboratory should indicate the characteristics of the reagent in the test report to the clinician.In the series monitoring, if the reagent type is changed, the continuity detection should be performed and parallel comparison with the results of the original reagent to determine the baseline value.

This product contains animal source material and may have potential biological risk.All samples and reaction wastes should be treated as the source of infection,

and all waste must be disposed of according to local regulations;Sodium azide may react with lead and copper pipe fittings, metal azide formation are at high risk of explosive, the dumping this liquid, should be in a lot of water to wash, to prevent a buildup of azide content.

**【Reference】**

- Linda M. Thienpont, Katleen Van Uytfanghe, Graham Beastall, Report of the IFCC Working Group for Standardization of Thyroid Function Tests; Part 2: Free Thyroxine and Free Triiodothyronine. Clinical Chemistry 2010,56:6,912-920.
- Ambrosio R, Sannino ML, Cortese L et al Validation and application of an immunofluorimetric assay for detection of serum free triiodothyronine and free thyroxine concentrations in buffalo (Bubalus bubalis) under various physiological conditions.J Vet Diagn Invest. 2009,21(5):668-73.
- Semlitsch G, Buchinger W, Reiterer E, et al Measurement of free triiodothyronine (FT3) using an electrochemiluminescence immunoassay in patients with autoantibodies to triiodothyronine. Acta Med Austriaca. 2000;27(2):54-55.

**【Symbol】**

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use by		In vitro diagnostic medical device
	Lot number		Sufficient for <n> tests
	Serial number		Biological risks
	Temperature limitation		This way up
	Authorized representative in the European Community		Indicates this device is in compliance with Europe Directive.
	Catalogue number		Material code

**【Manufacturer】**

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**【Version and Revision】**

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