Lifotronic

CE

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 bloodsteram by the thyroid gland and play a vital role in regulating the blood'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 identifypatients 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 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.

3rd incubation: The reatction mixtrue 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；5mM PBS; preservative.	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
(RA)	Anti-T3-Ab~Ru(bpy)$^{2+}_3$；5mM PBS；preservative.	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
Calibrator (High)	0.1M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Calibrator (Low)	0.1M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (High)	0.1M PBS, preservative	1×1.0 mL	2×1.0 mL	1×1.0 mL	1×1.0 mL
Control Material (Low)	Bovine, 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 ISO 17511:2003, and can be traced to Roche Elecsys FT3.

Quality control target and scope see quality control card.

Materials required (but not provided)

（1）Auffer

（2）Buffer

（3）Concentrated Washing Buffer

（4）Automated ECLAnalyzer

（5）Assay cup

【Storage conditions and expiration date】

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

Opened reagents can be stored for 28 days in machine (temperature 4℃~15℃), or stored for 28 days in 2 ℃~ 8℃.

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

Damaged, expired or contaminated reagents should be discarded.

【Appropriate instrument】

Automated ECLAnalyzer: eCL8000, eCL 8000i, CL 8000p, eCL 8000x.

【Specimen collection and preparation】

Human serum and plasma added with heparin lithium, heparin sodium and EDTA-K2, EDTA-K3 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℃, 7 days at 2~8ºC, 28 days at -25ºC~-15℃, 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 m atching calibrators to obtain the standard curve tested by the current system (the analyzer can automatically determine the validity of the standard curve accordi ng 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 our-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%. Undisturbed by the type rheumatoid factor (600IU/mL).

【Analytical Performance】

Analytical sensitivity

Limit of detection=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%

Analytical specificity

The following cross-reactivities were found, tested with two different FT3 concentration samples.

Cross-reactant	concentration	Cross-reactivity %
L-T4	300000 pg/mL	0.0020%
D-T4	625000 pg/mL	0.0050%
3-iodo-L-tyrosine	50000000	0.000001%
3,5-diiodo-L-tyrosine	100000000	0.000015%
3,3',5,5'-tetraiodothyroacetic acid	1000000	0.0001%

【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.

【Symbol】

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

【Manufacturer】

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【Version and Revision】

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