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】

Competition method. Total duration of assay： 18 minutes.

15 µL of sample was incubated with anti-T3-specific antibody labeled with a ruthenium complex. 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.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 pack consists of MB, RA, RB, calibrators and control materials (Optional). Different batch of reagent components should not be used interchangeably.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles；0.1M PBS ； preservative.	1×1.8 mL	2×1.8 mL	1×3.5mL	2×3.5 mL
Reagent B (RB)	Biotinylated T3；5mM PBS; preservative.	1×3.5 mL	2×3.5mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	Anti-T3-Ab~Ru(bpy)$^{2+}_3$; 5mM PBS；preservative.	1×3.5 mL	2×3.5mL	1×7.0 mL	2×7.0 mL
Calibrators	0.1M PBS, preservative	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	0.1M PBS, preservative	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traced to Roche Elecsys FT3.

See the control material value sheet for the target values and ranges of control materials.

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:

- REF 679005, Auffer, 480 mL, or REF 679004, Auffer, 6×480 mL
- REF 679007, Buffer, 480 mL, or REF 679006, Buffer, 6×480 mL
- REF 679009, Concentrated Washing Buffer, 1 L, or REF 679008, Concentrated Washing Buffer, 6×1 L
- REF 679011, Assay Cup, 300 T, or REF 679012, Assay Cup, 3000 T

Additional materials for Automated ECL Immunoassay Analyzer eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p:

- REF 0320501804, Auffer, 2×1 L, or REF 0320501805, Auffer, 4×1 L
- REF 0320501904, Buffer, 2×1 L, or REF 0320501905, Buffer, 4×1 L
- REF 0320507502, PreClean, 2×800 mL, or REF 0320507503, PreClean, 4×800 mL
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 032120111, Assay Cup/Assay Tip, 12×2×105

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

- REF 0320501801, Auffer, 2×2 L, or REF 0320501806, Auffer, 4×2 L
- REF 0320501901, Buffer, 2×2 L, or REF 0320501906, Buffer, 4×2 L
- REF 0320507501, PreClean, 2×2 L, or REF 0320507504, PreClean, 4×2 L
- REF 0320510001, Assay Cup/Assay Tip, 6×6×105, or REF 0320510002, Assay Cup/Assay Tip, 1×6×105

【Storage conditions and expiration date】

Store at 2ºC-8ºC.

Do not freeze.

Store the reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the reagents	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks
on the analyzers at 2ºC~15ºC	8 weeks

The calibrators and control materials are stable up to the stated expiration date.

Stability of the calibrators and control materials	
Unopened store at 2ºC~8ºC	18 months
Store at 2ºC~8ºC after opening	8 weeks

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

Damaged, expired or contaminated reagents should be discarded.

【Appropriate instrument】

Automated ECL Immunoassay Analyzers: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL8600, eCL8600i, eCL8600p, eCL8800, eCL8800i, eCL8800p, eCL9000, eCL9600, eCL9900, eCL9900i.

【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 18~28ºC, 7 days at 2~8ºC, 28 days at -25ºC~-15ºC. 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.

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

For quality control, use FT3 control materials.

In addition, other suitable control material can be used.

Control materials for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits.

Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.
If necessary, repeat the measurement of the samples concerned.
Follow the applicable government regulations and local guidelines for quality control.
Please make sure that the correct values are used.

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】

According to serum test results of 254 healthy human (male 126, female 128), using statistical methods take its percentile 2.5th to 97.5th 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, triglyceride 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】

Lower limit of measurement

Analytical sensitivity is 0.28 pg/mL.

Accuracy

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

Linearity

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

Within-run precision

The coefficient of variation (CV) ≤ 7.5%.

Analytical specificity

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

Cross-reactant	Concentration (pg/mL)	Cross-reactivity %
L-T4	300000	0.0020%
D-T4	625000	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%

Method comparison

A comparison of the Lifotronic FT3 assay (y) with the Roche Elecsys FT3 Method (x) using clinical samples gave the following correlations:
Number of paired values: 218
Linear regression:
Y=1.0205X+0.169
r = 0.993
The sample concentrations were between approx 0.82 pg/mL and 29.74 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;
Any serious incident that would be occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
The preservative ProClin™300 which contain Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): May cause an allergic skin reaction. thus, proper personal protection should be adopt while handling the reagent: avoid breathing dust/fume/gas/mist/vapours/ spray, wear protective gloves and contaminated work clothing should not be allowed out of the workplace. If skin irritation or rash occurs: get medical advice/attention, take off contaminated clothing and wash it before reuse, and dispose of contents/container to an approved waste disposal plant.

【Symbols Explanation】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Consult instructions for use
	Use-by date		In vitro diagnostic medical device
	Batch code		Sufficient for <n> tests
	Serial number		Biological risks
	Temperature limit		This way up
	Authorized representative in the European Community		Indicates this device is in compliance with Europe Directive.
	Catalogue number	P/N	Material code
	Warning		Date of manufacture
	Unique device identifier		

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd.
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【Version and Revision】

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