

Instruction For Use

【Product name】

Total Triiodothyronine Kit(Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
690048	50T
690049	2×50T
690050	100T
690051	2×100T

【Intended use】

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

【Summary】

Triiodothyronine (T3) is the hormone principally responsible for the development of the effects of the thyroid hormones on the various target organs. T3 (3,5,3'-triiodothyronine) is mainly formed extrathyroidally, particularly in the liver, by enzymatic 5'-deiodination of T4. Accordingly, the T3 concentration in serum is more a reflection of the functional state of the peripheral tissue than the secretory performance of the thyroid gland.

A reduction in the conversion of T4 to T3 results in a decrease in the T3 concentration. It occurs under the influence of medicaments such as propranolol, glucocorticoids or amiodarone and in severe non-thyroidal illness (NTI), and is referred to as "low T3 syndrome". As with T4, over 99 % of T3 is bound to transport proteins. However, the affinity of T3 to them is around 10-fold lower.

The determination of T3 is utilized in the diagnosis of T3-hyperthyroidism, the detection of early stages of hyperthyroidism and for indicating a diagnosis of thyrotoxicosis factitia.

【Test principle】

Competition principle. Total duration of assay: 18 minutes.

1st incubation: 30 µL of sample and anti-T3-specific antibody labeled with a ruthenium complex; bound T3 is released from the binding proteins in the sample by ANS.

2nd incubation: After addition of streptavidin-coated microparticles and biotinylated T3, 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 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 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	1×1.5 mL	2×1.5 mL	1×3.0 mL	2×3.0 mL
Reagent B (RB)	Monoclonal anti-T3-antibody(sheep) labeled with ruthenium complex 60 ng/mL; 0.1M PBS; preservative	1×3.3 mL	2×3.3 mL	1×6.5 mL	2×6.5 mL
Reagent A (RA)	Biotinylated T3 1.0 ng/mL; 0.1M PBS; preservative	1×3.3 mL	2×3.3 mL	1×6.5 mL	2×6.5 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 back to the T3 international standard IRMM-469.

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] 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 2°C~8°C.

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 2°C~8°C	18 months
Store at 2°C~8°C after opening	8 weeks
on the analyzers at 2°C~15°C	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 2°C~8°C	18 months
Store at 2°C~8°C 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. It is recommended to complete the test in time after sample collection. Samples can be stable for 8 hours at 18~28°C, 7 days at 2~8°C, 28 days at -25°C~-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 total triiodothyronine (T3) determination procedure.

Before the reagent is used, the multi-agent bottle is put into the analyzer to automatically stir the magnetic beads at least 30 min before testing 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 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

For quality control, use T3 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 nmol/L or ng/mL:

$$\text{nmol/L} \times 0.651 = \text{ng/mL}$$

$$\text{nmol/L} \times 65.09998 = \text{ng/dL}$$

$$\text{ng/mL} \times 1.536 = \text{nmol/L}$$

Sample dilution

Not necessary due to the broad measuring range.

Expected values

According to serum test results of 280 healthy human (male 141, female 139), using statistical methods take its percentile 2.5th to 97.5th percentile, draw a T3 kits reference range of 0.70 ~ 1.96 ng/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 0.20-6.5 ng/mL. Values below the limit of blank are reported as <0.20 ng/mL. Values above the measuring range are reported as >6.5 ng/mL.

When the concentration of bilirubin samples in 40 mg/dL or less, triglyceride concentration of 1800 mg/dL or less, concentration of biotin 10 ng/mL or less, hemoglobin concentration of 1000 mg/dL or less, the interference of the determination results deviation within ±10%. Undisturbed by the type rheumatoid factor (800IU/mL).

Product performance

Lower limit of measurement

Analytical sensitivity not great than 0.20 ng/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 0.2~6.5 ng/mL.

Within-run precision

The coefficient of variation (CV) ≤ 7.5%.

Analytical specificity

Measuring the following cross-reactivities: L-T4 (500 ng/mL or less), rT3 (50 ng/mL or less), 3-iodo-L-tyrosine (1000 ng/ml or less) and 3,5-diiodo-L-tyrosine (50 ng/mL or less), the result were less than 2.0 ng/mL.

Method comparison

A comparison of the Lifotronic T3 assay (y) with the Roche Elecsys T3 Method (x) using clinical samples gave the following correlations:

Number of serum samples measured: 220

Linear regression:

$$y = 1.0191x + 0.116$$

$$r = 0.977$$

The sample concentrations were between approx 0.286 ng/mL and 6.406 ng/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		Material code
	Warning		Date of manufacture
	Unique device identifier		

Manufacturer

Shenzhen Lifotronic Technology Co., Ltd.

Lifotronic Tower, No. 8, Qiuzhi East Road, Guancheng Community, Guanhu Street, Longhua, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Email: inter-service@lifotronic.com

European Representative

Shanghai International Holding Corp. GmbH (Europe)

Eiffelstrasse 80, 20537 Hamburg, Germany

Tel. +49-40-2513175 Fax. +49-40-255726

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