Instruction For Use

【Product Name】

Thyroxine-binding Globulin (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
690064	50T
690065	2×50T
690066	100T
690067	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of Thyroxine-binding Globulin (TBG) in human serum and plasma. The results can be used in assisting diagnosis of thyroid diseases.

【Test Principle】

Competitive principle. Total duration of assay: 18 minutes.

30 µL of sample, biotinylated anti-TBG antibody react to form a complex. After addition of streptavidin-coated microparticles and TBG antigen labeled with ruthenium complex, the complex binds to the solid phase via interaction of biotin and streptavidin. After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. 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. Results are determined via a calibration curve which is instrument specifically generated by 2-point calibration and a master curve provided via the RFID.

【Main Component】

The reagent pack consists of MB, RA, RB, calibrators and control materials (Optional). Different batch of reagent components should not be used interchangeably.

Component	Ingredients	Volume (50T)	Volume (100T)	Volume (2×50T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles: preservative	1×1.8 mL	1×3.5 mL	2×1.8 mL	2×3.5 mL
Reagent B (RB)	Anti-TBG-Ab~biotin, HEPES, preservative	1×3.8 mL	1×7.5 mL	2×3.8 mL	2×7.5 mL
Reagent A (RA)	TBG~Ru(bpy)32+, HEPES, preservative	1×3.5 mL	1×7.0 mL	2×3.5 mL	2×7.0 mL
Calibrators	HEPES, preservative, lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	HEPES, preservative, lyophilized	High: 1×1.0 mL Low: 1×1.0 mL			

This method can be traceable to Thyroxine - binding globulin. WHO International Standard (88/638).

See the control material card for the target value and permissible range of quality control.

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 and Shelf Life】

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 reconstituted	8 hours
Store at -25ºC~-15ºC after reconstituted	3 months (freeze-thawed only once)

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

Damaged, expired or contaminated reagents should be discarded.

【Applicable Instrument】

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

【Specimen collection, handling and storage】

It is recommended to use serum samples or plasma samples collected from EDTA-K2, EDTA-K3, heparin lithium, heparin sodium blood collection tubes.

Blood samples should be collected by standard operation of venous puncture; after complete coagulation, the tangible component should be removed by centrifugation.

The sample should avoid bubbling during testing. Lipid layer floating on the upper of the sample should be removed.

Samples would better to be tested in 8 hours after collection, otherwise, should be stored 2~8°C for no more than 24 hours or -20°C, 90 days. Freezing and thawing cycle is permitted only once.

【Assay Procedure】

Testing procedures and precautions

Previous to operation, users should read the operational manual carefully to obtain system operation procedure, sample processing, security precaution, maintenance and other related information.

Set up TBG test according to the operational manual.

Put the TBG rackpack into the correct analyzer slot to automatically suspend magnetic beads at least 30 min before testing.

Recommended ambient temperature:10°C ~ 30°C; Relative humidity:≤80%.

Calibration

Calibration should be performed using lot-matching reagent and calibrators.

Before calibration, the reagent and main curve information should be imported into the analyzer via radio frequency identification (RFID) reagent card(refer to instrument user manual). The analyzer adjusts the main curve to produce working curve according to the calibrator results, and identifies validity of the working curve automatically.

Recalibration is recommended when:

(1) the reagents of different lot are used;

(2) the same lot of reagents were used on the analyzer beyond 28 days;

(3) As required: if the control material results exceed the specified limit.

Quality control

For quality control, use TBG 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.

Pre-treatment of lyophilized calibrator and control material:

Accurately add 1.0 mL of deionized water, and cover it at room temperature for 20 minutes to reconstitute the contents of the bottle. Mix well and avoid air bubbles. The calibrated product or control product after mixing is marked and dispensed. If you do not test immediately, you need to quickly transfer to -20ºC storage.

Calculation

The system software automatically calculates the analyte concentration using particular algorithm, and the result unit is µg/mL or nmoL/L : 1 × 18.5 µg/mL=1nmol/L.

【Biological reference interval】

According to serum test results of 418 healthy human (147 male aged 13-85, 146 non-pregnant female aged 13-75, 125 pregnant female aged 20-38), the percentile 2.5 to 97.5 gives healthy male and non-pregnant female reference range of 11 ~ 30 µg/mL and healthy pregnant female reference range of 46~ 58 µg/mL.

Due to differences in the region, race, gender and age, laboratories are recommended to set up their own reference ranges.

【Result Interpretation】

For explaining the result, the patient's overall clinical manifestation should be referred to, including symptoms, medical history and other relevant data and information.

【Limitations】

Test results are used only for clinical reference and cannot be used as the basis for diagnosis or rule-out of diseases alone.

The measuring range of the kit is 0.5~95 μg/mL. Values below the limit of blank are reported as < 0.5μg/mL. Values above the measuring range are reported as > 95 μg/mL.

When the sample containing bilirubin ≤ 200 mg/dL, triglyceride ≤ 3000 mg/dL, hemoglobin ≤ 76.8 mg/dL, biotin ≤ 60 ng/mL, HAMA ≤100 ng/mL, interference deviation to the test result lies within ±10%. When the RF concentration in the sample is ≤ 1000 IU/mL, the relative recovery of the test results is between 90% and 110%.

【Analytical Performance】

Lower Limits of measurement

Lower detection limit is 0.5 μg/mL (repeatability study, n = 20).

Accuracy

When measuring the appropriate concentration of the added sample, the recovery ratio should be in the range of 90% to 110%. Or measuring the metrologically traceable trueness control materials, the relative deviation of the measurement results shall be within the range of ±10%.

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 3.5~ 80 μg/mL.

Within-run imprecision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Between-lot imprecision

The coefficient of variation (CV) ≤ 10%.

Homogeneity of calibratiors and control materials

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

Method comparison

A comparison of the Lifotronic TBG assay (y) with the SIEMENS TBG assay Method (x) using clinical samples gave the following correlations:
Linear regression:
Number of samples measured: 220
y=1.0490x-2.6693
r = 0.978
The sample concentrations were between approx 4.65 and 77.4 μg/mL.

【Precaution and Warning】

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to comply with regulations in the laboratory.

All reagents and samples including specimen, calibrators and control materials, should avoid foaming before and during test.

Test results of the kit are for clinical reference only, and clinical evaluation of patients should be combined with their symptoms and signs, medical history, other laboratory examination results and treatment responses.

Due to factors such as methodology or antibody specificity, testing identical samples with reagents from different manufacturers may get different results, and the results from different kits should not compare directly, lest cause the wrong medical explanation; It's suggested that laboratorians should point out the characteristics of used reagent in the test report to the clinician. In serial monitoring, if the reagent type is changed, a continuous parallel test should be performed and comparison of the results to the former to determine a new baseline value.

This product contains animal-sourced materials and may have potential biological risk. All samples and test wastes should be treated as the source of infection, and all wastes must be disposed 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.
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)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel. +49-40-2513175 Fax. +49-40-255726

【Version and Revision】

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