Instruction For Use

【Product Name】

Thyroid Stimulating Hormone(Electrochemiluminescence Immunoassay)

【Packaging specifications】

REF NO.	Package Size
690060	50T
690061	2×50T
690062	100T
690063	2×100T

【Intended Use】

Immunoassay for in vitro quantitative determination of thyrotropin in human serum and plasma. The results can be used in the preliminary screening test of thyroid function.

Thyroid stimulating hormone (TSH, Thyrotropin) is a stable glycoprotein hormone secreted by basophil cells of anterior pituitary, which exists freely in the blood. TSH is a dimer with molecular weight of ca. 30,000 daltons, consisting of an α and a β subunit[1]. TSH, as well as luteinizing hormone (LH), follicle-stimulating hormone (FSH), and human chorionic gonadotropin (HCG), shares similar α subunit, while their β subunit are distinctive[2-3].

TSH has influence on all phases of synthesizing and releasing thyroid hormones, involving short-term and long-term effect. First emerging effects involve hydrolysis of thyroglobulin and release of T3 and T4, subsequently uptake enhancement of iodine and syntheses of thyroid hormones. Long-time effect will induce thyroid cells proliferation and enlarge the gland[4].

Blood TSH level fluctuates significantly along with function change of thyroid gland. Hypothyroids behave probably increase of blood TSH, while patients with hyperthroidism or apituitarism present mostly decrease of TSH. Meanwhile, blood TSH level is a very important index of neonatal congenital hypothyroidism. As a first-class test item, TSH result would be considered first, then other thyroid function tests involved to give diagnosis. And accurate determination of TSH enables precluding most non-thyroid diseases[5-8].

【Test Principle】

Sandwich principle. Total duration of assay: 18 minutes.

100 µL of sample, biotinylated TSH-specific antibody, and TSH-specific antibody labeled with ruthenium complex react to form a sandwich complex. 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 system reagent. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

【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.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles, 0.75 mg/mL: 0.1M PBS; 0.05% ProClin 300	1×2.0 mL	2×2.0 mL	1×4.0 mL	2×4.0 mL
Reagent B (RB)	Anti-TSH-Ab~biotin, 2 mg/L: 0.1M PBS; 0.05% ProClin 300	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
Reagent A (RA)	Anti-TSH-Ab~Ru(bpy)$^{2+}_3$, 1.2 mg/L: 0.1M PBS; 0.05% ProClin 300	1×2.5 mL	2×2.5 mL	1×5.0 mL	2×5.0 mL
Calibrators	0.1M PBS, ProClin 300	High: 1×1.5 mL Low: 1×1.5 mL			
Control Materials (Optional)	0.1M PBS, ProClin 300	High: 1×2.0 mL Low: 1×2.0 mL			

Traceability: This method can be traced back to 3rd WHO reference material 81/565.

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 and Shelf Life】

Store at 2ºC-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 at 2~8°C	18 months
Store at 2~8°C after opening	8 weeks
on the analyzers at 2~15°C	8 weeks

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

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

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

Damaged, expired or contaminated reagents should be discarded.

【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】

Human serum and plasma added with heparin lithium, heparin sodium and EDTA-K2 anti-coagulants are recommended. 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 with severe hemolysis are not recommended. It is recommended to complete the test in time after sample collection. Samples can stable for 24 hours at 18~28°C, 7 days at 2~8ºC, 28 days at -25ºC~-15°C, Freeze only once.

【Assay Procedure】

Testing procedures and precautions

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

Set up Thyroid stimulating hormone (TSH) test according to the operational manual.

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

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. 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 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 TSH 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 system software automatically calculates the analyte concentration using particular algorithm, and the result unit is μIU//mL or mIU/L:
1 μIU/mL = 1 mIU/L.

Specimen dilution

Samples exceeding the measuring range would be manually diluted with TSH-negative serum.
The recommended dilution ratio is 1:10, the concentration of the diluted sample must be > 10 μIU/mL or mIU/L, and the diluted sample test results need to multiply dilution ratio.

【Biological reference interval】

According to serum test results of 659 healthy human (male 320, female 339), the percentile 2.5th to 97.5th gives reference range of 0.25 ~ 4.3 mIU/L.
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.
Even the concentration of TSH reached 1500 mIU/L, hook effect is unobservable.
When the sample containing bilirubin ≤ 60 mg/dL , triglyceride ≤ 2000 mg/dL , total protein ≤ 10 g/dL, biotin ≤ 25 ng/mL, or hemoglobin ≤1 g/dL, or HAMA (human anti-murine antibodies) ≤ 101.3 ng/mL, interference deviation to the test result lies within ±10%. The test result would not be interfered by rheumatoid factor (3250 IU/mL).

【Measuring Range】

The measuring range of the kit is 0.005 ~ 100 mIU/L. For samples with TSH content below the lower detection limit, the results are reported in < 0.005 mIU/L; If the TSH content is above the upper detection limit, then the sample should be diluted and re-tested. The results are reported after multiplying with the dilution factor.

【Analytical Performance】

Lower limit of measurement

The lower detection limit is 0.005 mIU/L (repeatability study, n = 20).

Functional sensitivity

Functional sensitivity is 0.02 mIU/L.

Accuracy

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

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 0.05 ~ 100 mIU/L.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 7.5%.

Analytical specificity

Test results of blank samples spiked with analogs below are lower than 0.005 mIU/L.

Analog	Concentration (IU/L)
LH	300
FSH	500
HCG	1000

Method comparison

A comparison of the Lifotronic TSH assay (y) with the Roche Elecsys TSH Method (x) using clinical samples gave the following correlations:
Number of samples measured: 133
Passing-Bablok regression:
y = 0.990x+0.000202
r = 0.999
The sample concentrations were between approx 0.009 and 95.57 mIU/L.

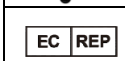
【Precaution and Warning】

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 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.

【Reference】

1. Pierce JG. Endocrinology 1971, 89:1331-44.
2. Morgan F and Canfield RC. Endocrinology 1971, 88(4): 1045-53.
3. Hertz R, Odell WD, and Ross GT. Ann Intern Med 1966, 65(4):800-20.
4. Fisher DA. Clin Chem 1996, 42(1):135-9.
5. Surks MI, Chopra IJ, Mariash CN, Nicoloff JT, and Solomon DH. JAMA 1990, 263: 1529-32.
6. Keffer JH. Clin Chem 1996, 42(1):125-35.
7. Ladenson PW. Clin Chem 1996, 42(1):183-7.
8. Nicoloff JT and Spencer CA. J Clin Endocr Metab 1990, 71: 553-8.

【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】

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【Version and Revision】

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