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 rinciple. Total duration of assay: 18 minutes

1st incubation: a sample, biotinylated monoclonal TSH-specific antibody and monoclonal TSH-specific antibody labeled with a ruthenium complex react to form a sandwich complex.

2nd incubation: After addition of streptavidin-coated microparticles, the complex binds to the solid phase via interaction of biotin and streptavidin.

Measurement: 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 calibration and a master curve provided via the reagent barcode.

【Main Component】

The reagent pack consists of MB, RA, RB, calibrators and control materials, different lots cannot be used at the same time or mixed up together.

Components	Ingredients	Volume (1×50T)	Volume (2×50T)	Volume (1×100T)	Volume (2×100T)
(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
(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
(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
Calibrator (High)	0.1M PBS, ProClin 300	1×1.5 mL	2×1.5 mL	1×1.5 mL	1×1.5 mL
Calibrator (Low)	0.1M PBS, ProClin 300	1×1.5 mL	2×1.5 mL	1×1.5 mL	1×1.5 mL
Control Material (High)	0.1M PBS, ProClin 300	1×2.0 mL	2×2.0 mL	1×2.0 mL	1×2.0 mL
Control Material (Low)	0.1M PBS, ProClin 300	1×2.0 mL	2×2.0 mL	1×2.0 mL	1×2.0 mL

The assignment of calibrators value complies strictly with ISO 17511:2003, and this method can be traced back to 3rd WHO reference material 81/565.

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

Materials and instruments required but not provided:

- Auffer
- Buffer
- Concentrated Washing Buffer
- Automated eCL Analyzer
- Assay Cup

【Storage and Shelf Life】

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.

【Applicable Instrument】

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

【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 in suggestion. It is recommended to complete the test in time after sample collection. Samples can stable for 24 hours at 18~28℃, 7 days at 2~8ºC, 28 days at -25ºC~-15℃, 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.

The sample volume required for each TSH test is 100 µL.

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

In order to ensure the reliability of test results, it's recommended to test the control materials every 24 hours. After each calibration, reagent lot change, maintenance or failure repairment, quality control is recommended. The quality control results should fall within the scope of local regulations. If beyond, the analyzer status, reagents, calibration and other factors should be checked.

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 593 asymptomatic human (male 247, female 346) in Guangdong Province, P. R. China, the percentile 2.5 to 97.5 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 , lipid ≤ 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 (repeatibility 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) is less than 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

【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. The preservative ProClin™ 300 contains 3% 2-methyl-4-isothiazolin-3-one (MIT) and 5-chloro-2-methyl-4-isothiazolin-3-one (CMIT), will be harmful if inhalation, contact with skin and/or swallow, and may be toxic to aquatic organisms; thus, proper personal protection should be adopt while handling the reagent, and abandoned reagents should be dealed with in compliance with local regulations.

【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

【Reference】

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7. Ladenson PW. Clin Chem 1996, 42(1):183-7.
8. Nicoloff JT and Spencer CA. J Clin Endocr Metab 1990, 71: 553-8.

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【Version and Revision】

Version: A0

Issue Date:20 AUG 2020