Instruction For Use

【Product Name】

Thyroglobulin Antibody (Electrochemiluminescence Immunoassay)

【Order Information】

REF NO.	Package Size
690043	50T
690068	2×50T
690036	100T
690035	2×100T

【Intended Use】

Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. Determination of Anti-TG is used as an aid in the detection of autoimmune thyroid diseases.

【Summary】

Elevated serum concentrations of antibodies against Tg are found in subjects with autoimmunity-based thyroiditis, chronic lymphocytic-infiltrative thyroiditis (Hashimoto's disease) and Graves' disease. The Anti-TG assay can provide useful information for monitoring the course of diseases and for differential diagnosis. Anti-TG has also been reported as a useful surrogate diagnostic marker for differentiated thyroid cancer when serum Tg is negative and for ruling out interference by TG autoantibodies when measuring serum Tg using a Tg test.

【Test Principle】

Competition principle. Total duration of assay: 18 minutes.

- 1st incubation: Sample are incubated with biotinylated thyroglobulin antigen (Tg) and the antibodies of the sample bind the antigen.
- 2nd incubation: After addition of Anti-TG antibodies labeled with ruthenium complex and streptavidin-coated microparticles, the immunocomplex produced 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 and a master curve provided via the reagent barcode.

【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 (2×50T)	Volume (100T)	Volume (2×100T)
Magnetic Beads (MB)	Streptavidin-coated microparticles; preservative	1×1.8 mL	2×1.8 mL	1×3.5 mL	2×3.5 mL
Reagent B (RB)	Tg~Biotin: 0.05M HEPES, preservative	1×3.5 mL	2×3.5 mL	1×7.0 mL	2×7.0 mL
Reagent A (RA)	Anti-TG~Ru(bpy)$^{2+}_3$: 0.05M HEPES, preservative	1×3.0 mL	2×3.0 mL	1×6.0 mL	2×6.0 mL
Calibrators	Human Anti-TG, Bovine serum, preservative	High: 1×1.0 mL Low: 1×1.0 mL			
Control Materials (Optional)	Human Anti-TG, Bovine serum, preservative	High: 1×1.0 mL Low: 1×1.0 mL			

Traceability: This method can be traceable to the NIBSC (National Institute for Biological Standards and Control) 65/093 standard material.

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 [illegible], 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 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 Sodium heparin, EDTA-K3 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. Samples would better to be tested in 8 hours after collection, otherwise, should be stored 2~8ºC for no more than 3 days or -20ºC for 1 month. Freezing and thawing cycle is permitted 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 Anti-TG test according to the operational manual.

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

The sample volume required for each Anti-TG test is 40 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 (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) quality control findings outside the defined limits.

Quality control

For quality control, use Anti-TG 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 give conversion formula for IU/mL to kIU/L.

【Biological reference interval】

According to serum test results of 388 healthy human serum samples (male 170 and female 218, aged between 19 and 70), the percentile 95 gives reference range <105.89 IU/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.

The measured Anti-TG value of a patient's sample can vary depending on the testing procedure used. The laboratory finding must therefore always contain a statement on the Anti-TG assay method used. Anti-TG values determined on patient samples by different testing procedures cannot be directly compared with one another and could be the cause of erroneous medical interpretations. If there is a change in the Anti-TG assay procedure used while monitoring therapy, then the Anti-TG values obtained upon changing over to the new procedure must be confirmed by parallel measurements with both methods.

【Limitations】

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

When the sample has bilirubin ≤75 mg/dL, hemoglobin ≤0.5 g/dL, triglyceride ≤2000 mg/dL, biotin ≤22.5 ng/mL, total protein ≤125 mg/mL, rheumatoid factor ≤415.8 IU/mL, the interference deviation of the measurement results is within ±10%.

【Measuring Range】

The measuring range of the kit is 10~ 4000 IU/mL. For samples with Anti-TG content below the lower detection limit, the results are reported as <10 IU/mL; If the Anti-TG content is above the upper detection limit, ,the results are reported as > 4000 IU/mL.

【Analytical Performance】

Lower limits of measurement

Limit of Blank (LoB) is 5 IU/mL.

Accuracy

The relative bias of measuring Anti-TG national reference materials should be within ±10% .

Linearity

The correlation coefficient (Pearson's r) is not less than 0.9900 in the interval of 10~ 1000 IU/mL.

Within-run precision (repeatability)

The coefficient of variation (CV) ≤ 8.0%.

Between-lot precision

The coefficient of variation (CV) ≤ 10.0%.

Analytical specificity

Test results of blank samples spiked with analogs below are lower than 50 IU/mL.

Analog	Concentration
Anti-TPO	1400 IU/mL

Homogeneity of calibrators and control materials

Within-bottle homogeneity: The coefficient of variation (CV) ≤ 10.0%.

Between-bottle homogeneity: The coefficient of variation (CV) ≤ 10.0%.

Method comparison

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

Number of serum samples measured: 116

Linear regression:

y=1.0762x+11.3140

r = 0.987

The sample concentrations were between approx 10.02 and 3416 IU/mL

【Precaution and Warning】

The measured Anti-TG value of a patient's sample can vary depending on the testing procedure used. The laboratory finding must therefore always contain a statement on the Anti-TG assay method used. Anti-TG values determined on patient samples by different testing procedures cannot be directly compared with one another and could be the cause of erroneous medical interpretations. If there is a change in the Anti-TG assay procedure used while monitoring therapy, then the Anti-TG values obtained upon changing over to the new procedure must be confirmed by parallel measurements with both methods.

The kit is only used for in vitro diagnostics.

When using the kit, it's necessary to exercise the normal precautions 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 should be 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.

【Symbols Explanation】

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

【Reference】

1. AJJAN RA, WEETMAN AP. Pathogenesis of autoimmune thyroid disease. In :Paul S (edit). Contemporary Immunology: Autoimmune Reactions. 1999: 31-59.
2. Pfannenstiel P, Saller B. Schilddrüsenkrankheiten - Diagnose und Therapie, 2nd edition. Berliner Medizinische Verlagsanstalt. 1995; 28-30, 141, 169-172,200-201.
3. McIntosh RS, Asghar MS, Weetman AP. The antibody response in human autoimmune thyroid disease. Clin Sci 1997; (92)6: 529-541.
4. LUBIN E, MECHLIS-FRISH S, ZATZ S, et al, Serum thyroglobulin and iodine-131 whole body scan in the diagosis and assessment of treatment for metastatic differentiated thyroid cancer. J Nucl Med, 1994, 35: 257-262.

【Manufacturer】

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