Human Thyroid Stimulating Hormone CLIA Kit

Chemiluminescence Immunoassay for the quantitative determination of Thyroid Stimulating Hormoneinin human serum

REF SKT-015 CE IVD 100,150 +2 +8 °C

INTENDED USE

Human Thyroid Stimulating Hormone CLIA Kit is a Chemiluminescence Immunoassay (CLIA) intended for the quantitative measurement of human Thyroid Stimulating Hormone in serum.

For in-vitro diagnostics purposes only

SUMMARY OF PHYSIOLOGY

Thyroid-stimulating hormone (TSH, thyrotropin) levels serve as a primary measure in thyroid diagnostics. Even slight changes in the concentrations of free thyroid hormones directly influence TSH levels. Accordingly, TSH is a very sensitive and specific parameter for assessing thyroid function and is particularly suitable for early detection or exclusion of disorders in the central regulating circuit between the hypothalamus, pituitary and thyroid. TSH is a 30kDa glycoprotein hormone consisting of 2 subunits. The alpha subunit is similar to those of follicle-stimulating hormone, humanchorionic gonadotropin, and luteinizing hormone. The beta subunit is different from those of theother glycoprotein hormones and confers its biochemical specificity.[1,2]

TSH is synthesized and secreted by the anterior pituitary in response to a negative feedback mechanism involving concentrations of free triiodothyronine and free thyroxine. Additionally, the hypothalamic tripeptide, thyrotropin-releasing hormone, directly stimulates TSH production.

The TSH test is mainly used for clinical evaluation of thyroid function. It can be used to determine if the patient suffers from hyperthyroidism, for the evaluation of hypothalamic-pituitary-thyroiddys function, and the screening of thyroid diseases. In the evaluation of thyroid function, the quantitative determination of TSH concentration in the circulatory system is of great significance.

The concentration of TSH increases significantly in patients with primary hypothyroidism and decreases in patients with secondary (pituitary) or tertiary (hypothalamic) hypothyroidism. By observing the changes of TSH concentration in patients and the stimulation of thyrotropin releasing hormone, secondary or tertiary hypothyroidism can be determined. Normally, TSH does not respond to the stimulation of thyrotropin releasing hormone in patients with secondary hypothyroidism while it will have a normal (or increased) response in patients with tertiaryhypothyroidism.[3]

ASSAY PRINCIPLE

The Human Thyroid Stimulating Hormone CLIA Kit is designed, developed, and produced for the quantitative measurement of human TSH level in serum samples. The TSH assay is a two-site sandwich assay to determination the level of follicle-stimulating hormone.

Assay calibrators, controls, or patient serum samples are added directly to a reaction vessel together with streptavidin coated magnetic particles and biotinylated anti- TSH polyclonal antibody. The magnetic particles capture the biotin antibody as well as an immune-complex in the form of “magnetic particles–biotin TSH antibody–TSH–acridinium ester TSH antibody”. Materials bound to the solid beads are held in a magnetic field while unbound materials are washed away. Then trigger solutions are added to the reaction vessel, and light emission is measured with the ECL100 analyzer. The relative light units (RLU) are proportional to the concentration of a TSH in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve and reported in serum TSH concentration.

REAGENTS: PREPARATION AND STORAGE

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.It can be stored for 1 month at 2℃~8℃ after kit opening.

1. TSH Magnetic Particle Solution (01501)
Qty: 6.0mL (100/kit),8.5mL (150/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

2.Biotin TSH antibody (01502)
Qty: 6.0mL (100/kit),8.5mL (150/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

3. Acridinium ester TSH antibody (01503)
Qty: 11.0mL (100/kit),16.0mL (150/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

4.TSH Calibrators (01506-01507)
Qty: 2x vials
Storage: 2 – 8°C
Preparation: Ready to Use
After the first use, it is recommended to storage at 2 - 8℃ and can be used within one month. Do not freeze.

5.TSH Controls (01508-01509)
Qty: 2 x vials
Storage: 2 – 8°C
Preparation: Ready to Use
After the first use, it is recommended to storage at 2 - 8℃ and can be used within one month. Do not freeze.

SAFETY PRECAUTIONS

The reagents must be used in a professional laboratory environment and are for in vitro diagnostic use. Source material which contains reagents of bovine serum albumin was derived in New Zealand. It was obtained only from healthy donor animals, maintained under veterinary supervision, and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they were potentially infectious. Avoid contact with reagents containing hydrogen peroxide. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Exercise Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. ECL100 Immunoassay Analyzer (ECL100) or ECL25 Immunoassay Analyzer (ECL25)
2. CL011 Cuvettes (for ECL100) or CL010 Cuvettes (for ECL25)
3. EDI™ Wash Reagent (P-594)
4. EDI™ Trigger Solutions A and B (P-595A, P-595B)

The instrument must operate using materials supplied by Epitope Biotechnology, Co.,Ltd. or Epitope Diagnostics, Inc. When materials sourced from third-party suppliers are being used, Epitope Biotechnology, Co.,Ltd. and Epitope Diagnostics, Inc. take no responsibility for the validity of obtained results. Materials are available to purchase from Epitope Biotechnology, Co.,Ltd. and Epitope Diagnostics, Inc. Please contact your distributor for more information.

SPECIMEN COLLECTION AND PREPARATION

1. Blood sample should be collected under sterile conditions.
2. For human serum samples only; other body fluids and samples may not yield accurate results.
3. Clinical samples should be tested within 2 hours after collection. If the measurement cannot be completed within 2 hours, please store under the following conditions:
    - storage at low temperature and away from light (2℃~8℃) for 7 days,
    - storage at -20℃ or below for 30 days,
    - Freeze and thaw three times
4. Avoid heat-inactivated samples. Mixed, contaminated and hemolysis samples should be discarded.
5. Samples should be restored to room temperature before testing. Frozen samples should be completely melted and mixed well before use. Due to possible volatilization, samples, calibrators and controls on the ECL platform should be tested within 2 hours.
6. Some substances in the samples will interfere with the test results. The common interfering substances and maximum allowable concentrations are as follows:
    - bilirubin: 10 mg/dL
    - triglyceride: 1800 mg/dL
    - hemoglobin: 500 mg/dL
    - biotin: 220 nmol/L
    - For patients receiving high-dose biotin therapy (5 mg/ day), samples must be collected 8 hours after taking the last dose of biotin.
7. A single assay of this item requires 50 µL of sample. This quantity does not include the amount of dead volume in the sample container, the capacity required for retesting, and other measurement items. For the definition of minimum required sample size, refer to the equipment manual.

CALIBRATION

An active calibration curve is required for all tests. Calibration is required for the first time use of a reagent lot and every 28 days thereafter or when either kit control is out of range. Refer to appropriate system manuals for configuring calibrators.

QUALITY CONTROL

The characteristics of patient samples are simulated through controls and are critical to validate the performance of CLIA assays due to the random access format. Use of controls is left to the discretion of the user based on good laboratory practices, requirements, and applicable laws. We suggest performing a control test once every day. Quality control results that do not fall within acceptable ranges may indicate invalid test results.

ASSAY PROCEDURE

1. Reagents from different kit lot numbers should not be combined or interchanged. Make sure that there are no air bubbles in any reagents, calibrator and control vials.

2. Reagent Preparation

2.1 Remove reagent cartridges from packaging and replace the solid caps with the provided soft caps for ECL100. For ECL25, carefully remove the aluminum foil seal on each container on the cartridges.

2.2 For the ECL100, take out the Magnetic Particle bottle make sure to roll between hands and gently but thoroughly mix until the magnetic particle solution is homogenous. The solution should be uniform with no clumps of magnetic particles visible; this step is vital for assay performance. For ECL25, mix the magnetic beads by moving back and forth the bottom part of the cartridge at upright position. Make sure to look inside the cartridge until the solution is uniform with no clumps of magnetic particles visible and no air bubbles. Recap the bottle. Open the top soft cap of all reagent bottles, leaving only the hollow soft rubber. The reagents are now ready to be loaded into the ECL100 or ECL 25 for calibration.

3. Assay Program

The following table illustrates the protocol used by the ECL100 or ECL25 for instrument operation.

Component	Quality Control Hole (µL)	Sample Hole (µL)
TSH Controls (01509-01510)	50	-
Samples	-	50
Biotin TSH antibody (01502)	50	50
Acridinium ester TSH antibody (01503)	100	100
TSH Magnetic Particle Solution (01501)	50	50
Incubate at 37°C for 30 minutes		
Wash the reaction cuvette 3 times with wash reagent.		
Trigger Solution A (P-595)	100-200	100-200
Trigger Solution B (P-595)	100-200	100-200

NOTE FOR ASSAY PROCEDURE

All the reagents in this kit are ready-to-use. Make sure that there is no air bubble in any reagents, calibrator and control vials. Reagents from different kit lot numbers must not be combined or interchanged.

Please read the reagent instructions and equipment instructions carefully before using this kit and perform the test according to relevant requirements. When reagents are loaded, the equipment will automatically stir the magnetic particles to resuspend them. Allow the regent to mix for minimum 15 min before starting the assay program.

INTERPRETION OF RESULTS

1. The default unit for the TSH project is µIU/mL..
2. Due to methodological differences or antibody specificity, there may be deviations between the test results of reagents from different manufacturers. Therefore, direct comparisons should not be made to avoid false interpretation.

3. When the concentration of TSH in the sample exceeds 100.0 μIU/mL,the sample can be diluted before measurement.
4. When the sample concentration of TSH is lower than the detection lower limit, the test result can be reported as < 0.05μIU/mL. When the sample concentration is higher than the detection upper limit, it can be reported as >100.0μIU/mL.

EXPECTED VALUES

Reference for this test is 0.27-4.20 μIU/mL, determined by results from 528 specimen of healthy people (2.5%-97.5% confidence limit).

Note: each Laboratory is recommended to determine and establish its own reference range with local population.

LIMITATIONS OF THE PROCEDURE

1. This product is for use on the ECL100 Immunoassay Analyzer or ECL 25 Immunoassay Analyzer only. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, operation, system performance, instructions, calibration, precautions, hazards, maintenance, and troubleshooting.
2. Reagents from different kit lot numbers should not be combined or interchanged.
3. Test results obtained from the proposed kit should not be served as a sole basis for clinical diagnosis or patient management.
4. If the test sample result is higher than the upper limit of the calibration curve, it is recommended to re-measure after dilution according to a certain ratio. The measured value is recalculated according to the dilution ratio to ensure the accuracy of the result.

PERFORMANCE CHARACTERISTICS

1. Hook Effect:
   - The assay showed no hook effect up to 1000 μIU/mL.
2. Limit of Detection(LoD):
   - 0.05μIU/mL.
3. Linearity:
   - 0.05μIU/mL to 100.0μIU/mL,
   - linearity correlation coefficient R ⩾0.990.
4. Accuracy:
   - relative deviation within ±10%.
5. Precision:
   - Intra-assay repeatability: CV≤8%;
   - Inter-assay reproducibility: CV≤15%.

NOTES

1. Read the instructions carefully and gently but thoroughly mix the reagent before use. Remove any air bubbles before loading the reagents onto the equipment.
2. Keep the reagent in the storage conditions indicated in this IFU and on the reagent label. Do not freeze reagents.
3. Avoid contact with skin, eyes and mucous membrane. Upon contact, flush the area with clean water immediately.
4. All patient samples must be treated as potential infectious material.
5. Components in different kits cannot be mixed.
6. All waste must be disposed of in compliance with local regulations and laws.

WARRANTY

This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Biotechnology Co,Ltd and its distributors DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Biotechnology Co,Ltd.. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state.

REFERENCE

1. Watts NB, Keffer JH. Practical endocrine diagnosis. 3rd ed. Philadelphia: Lea and Febiger, 1982, 77–96.
2. Fernandez-Ulloa M, Maxon HR. Thyroid. In: Kaplan LA, Pesce AJ, editors. Clinical chemistry: theory, analysis,
and correlation. 2nd ed. St. Louis: CV Mosby, 1989, 620–637.
3. White GH. Recent advances in routine thyroid function testing. Crit Rev Cl Lab Sci, 1986, 24(4): 315-362.
4. Guofeng ZHANG, Rui GUO, Haixia GUAN. Information other than laboratory results should be valued when
diagnosing thyroid diseases: Lessons from the misdiagnosis of Graves ′ hyperthyroidism in a woman taking biotin
[J]. China Journal of endocrinology and metabolism. 2017, 33(9): 723-725.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or to place an order, please contact Epitope Diagnostics, Inc. in USA at +1 858-693-7877 or email to cs@epitopediagnostics.com

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GLOSSARY OF SYMBOLS (EN 980/ISO 15223)

IVD In Vitro Diagnostic Device	CE European Conformity	LOT Lot Number
REF Catalog Number	Read Instructions before Use	Σ Number of Tests
Store at	Use by	Keep Away from Heat and Direct Sun light
Manufacturer	EC REP Authorized Representative in Europe	Distributor