

Diagnostic Kit for Thyroid Stimulating Hormone (Fluorescence Immunochromatographic Assay)

Instructions for Use

INTENDED USE

This kit is intended for in vitro quantitative detection on the thyroid-stimulating hormone (TSH) existing in the human serum/plasma/whole blood/fresh finger terminal blood samples and is used for evaluating the pituitary-thyroid function. This kit only provides the test result of thyroid-stimulating hormone (TSH), and the obtained result shall be analyzed in combination with other clinical information. This kit is for healthcare professionals.

SUMMARY

Thyroid-stimulating hormone (also known as thyrotropin, thyrotropic hormone, TSH, or hTSH for human TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4) and triiodothyronine (T3) by the thyroid gland, thereby stimulating metabolism in almost all tissues in the body. TSH is produced when the hypothalamus releases a substance called thyrotropin-releasing hormone (TRH). It is a glycoprotein hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid. The determination of TSH levels is recognized as an important measurement in the assessment of thyroid function.

PRINCIPLE OF DETECTION

This reagent kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively test the thyroid-stimulating hormone (TSH) in the human serum/plasma/whole blood/fresh finger terminal blood samples. Test strip contains anti-TSH antibody pre-immobilized on the test line (T) of the membrane and goat anti-chicken IgY antibody in the control line (C). The labeling pad contains pre-coated fluorescently labeled anti-TSH antibody and chicken IgY antibody. In the detection of samples, TSH antigen in the samples firstly binds to fluorescently labeled anti-TSH antibody to form an immune complex. Under the immunochromatographic effect, the complex and the sample flow in the inside nitrocellulose membrane towards the absorbent paper. The complex binds with the coated anti-TSH antibody while it passes through test line (T), to form "anti TSH antibody-TSH antigen-fluorescence-labeled anti TSH antibody" complex and thus aggregate. When passing through the control line (C), the fluorescently labeled chicken IgY antibody binds to the coated goat anti-chicken IgY antibody to form a "goat anti-chicken IgY antibody-fluorescently labeled chicken IgY antibody" complex and agglutinates. The TSH concentration in the sample is positively correlated with the fluorescence intensity, and the concentration of TSH in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

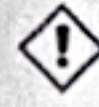
Catalogue number	52221001	52221005	52221020	52221025
Specification	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Components				
Test Device	1	5	20	25
Sample Diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1. Test line (T line): T line area of nitrocellulose membrane is coated with anti-TSH antibody.
2. Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-chicken IgY antibody.
3. Labeling pad: Anti-TSH antibody and chicken IgY antibody labeled with fluorescent

microspheres are coated.

4. Main component of sample diluent is 20mM, pH7.4 PBS solution.



Warning: The diluent includes 0.1% Proclin300

- H317: May cause an allergic skin reaction.
- H412: Harmful to aquatic life with long lasting effects.
- P280: Wear protective gloves/protective clothing/face protection.
- P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.
- P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2°C~30°C. The shelf life of the kit is 24 months.
2. Do not use the kit after the expiration date.

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedures.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2°C~8°C for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2°C~8°C for 7 days. If frozen below -15°C, samples can be stores for 6 months.
6. Fresh terminal blood of fingertips should be used immediately after collection.
7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.
8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

I -1: Drip the sample into the test device

- (1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;
- (2) Take out sample diluents, add 20µL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;
- (3) Add 80µL of above mixed solution into the sample hole of test device;
- (4) Start stopwatch and wait for 15 minutes.

Igloo Reader Pro Procedure

1. To turn the reader on - press the power button on the circle-shaped rubber bottom of the device.
2. Press the button new measurement. Fill in Patient Identifier and other required data. Configure measurement timer and click Next.
3. As soon as the testing is completed, place the test cassette into the Adaptor supplied with Reader. Please check the "Correct Orientation" marked on the Adaptor for the test cassette.
4. Insert the adaptor with the test cassette into Reader to start the measurement. Please do it quickly so the measurement timer works correctly.
5. Measurement is now under way. Please make sure not to reject the adaptor or cassette during measurement.
6. Your first measurement is complete. Each test result can be exported or printed. *Advanced units of measurement may vary depending on the test.

REFERENCE INTERVAL

1. Study of TSH reference interval is conducted through referring to C28-A2 document published by US Clinical and Laboratory Standards Institute (CLSI)- How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition and WST 402-2012. Define and determine the reference intervals of test items in clinical laboratory. Conduct a study of the TSH reference area, the obtained reference interval of TSH is: 0.5-5µIU/mL.
2. Due to difference in geography, race, age etc., each laboratory is suggested to establish reference interval of TSH that is suitable for local populations and has clinical significance.

INTERPRETATION OF THE RESULT

1. For the reference intervals established based on the above data of test kit, it is recommended that each laboratory establish the reference intervals based on the clinical significance of the population in its region.
 2. If the TSH measured concentration of sample is higher than the reference value range, the physiological change or stress response and other states shall be excluded. Tangible abnormal should be diagnosed in combination with clinical symptoms. Above result is only for reference.
 3. Test result of this method is only applicable to evaluation using the reference value established in this method and cannot be directly compared with result of other method.
 4. Other factors that may cause wrong test result include technical reason, operation error and other simple factors.
- Invalid result: If the assay result is invalid, the Igloo Reader Pro will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result persists, please contact the device manufacturer.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not

- use if the aluminum foil bags are damaged or if the test reagents are wet.
- For all components of the kit, it is recommended not to mix or interchange different batches.
 - Excessive or insufficient sample may lead to deviation of result.
 - Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
 - Test method should strictly follow the instruction for use.
 - For specific explanation of test result, analysis shall be performed in combination with clinical information.
 - The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
 - Desiccant in aluminum foil bag is inedible.
 - Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
 - During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal enterprise reference, that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

- Reportable range of the reagent (kit) is 0.2μIU/mL~1000.0μIU/mL.
- Linear range: Linearity of reagent (kit) is within the range of 0.2μIU/mL to 100μIU/mL. The correlation coefficient (r) of linearity should be ≥ 0.9900.
- Accuracy: The relative deviation is within ± 15%.
- Limit of detection: ≤ 0.1μIU/mL.
- Repeatability: CV ≤ 15%.
- HOOK effect: When TSH concentration is ≤ 1000.0μIU/mL, there is no HOOK effect.
- Specificity: The following substances are tested at the concentrations indicated in the table and do not produce non-specific reactions.

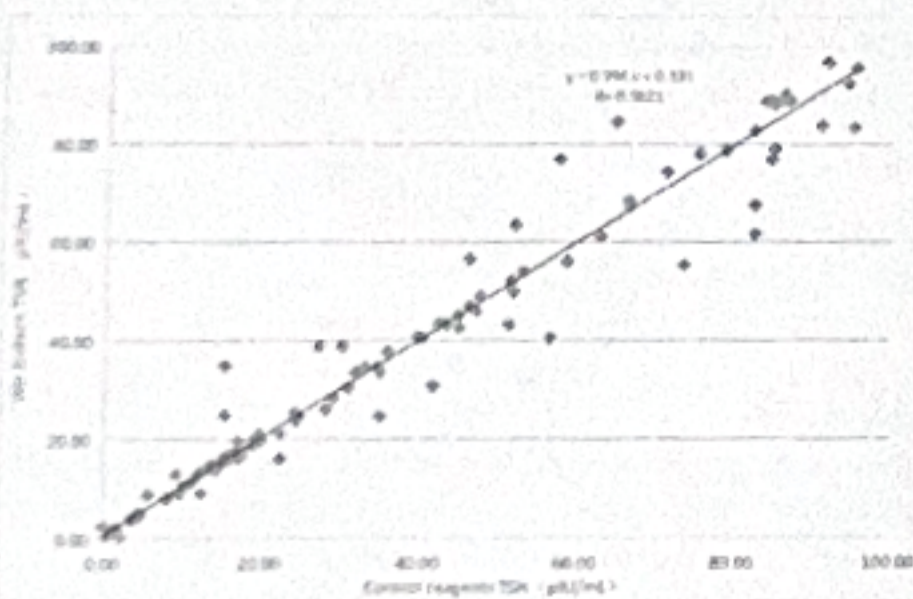
Material	Concentration	Material	Concentration
HCG	1000mIU/mL	LH	200mIU/mL
FSH	200mIU/mL	-	-

8. Interfering substance: Following substances are tested at the given concentration with no interference.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2.0 mg/mL	Triglyceride	40.0 mg/mL
Hemoglobin	10.0 mg/mL	Rheumatoid factor	1500.0IU/mL

9. Clinical performance

Clinical evaluation performance of the product is assessed through collecting 168 clinical samples. The results are compared by using the corresponding kit of marketed chemiluminescence method as the reference reagent. Their comparability is studied by linear regression. The correlation coefficients of the two tests are $y = 0.998x + 0.331$ and $R = 0.9821$, respectively.



LIMITATION

- This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
- Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
- Test shall be carried out at normal room temperature (18°C~25°C).
- Linearity range of this kit is 0.2μIU/mL~100.0μIU/mL. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the maximum dilution multiple of this kit is 10 times and the reportable range is 0.2μIU/mL ~ 1000.0μIU/mL.
- Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
- Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
- This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
- If the obtained result is questionable, immediately re-test or use other method to test the sample.
- Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

- [1] Fitzgerald SP, Bean NG. Thyroid stimulating hormone (TSH) autoregulation reduces variation in the TSH response to thyroid hormones. *Temperature (Austin)*. 2018;5(4):380-389. Published 2018 Oct 8.
- [2] Estrada JM, Soldin D, Buckley TM, Burman KD, Soldin OP. Thyrotropin Isoforms: implications for thyrotropin analysis and clinical practice. *Thyroid*. 2014;24(3):411-423.
- [3] Golbert L, de Cristo AP, Faccin CS, et al. Serum TSH levels as a predictor of malignancy in thyroid nodules: A prospective study. *PLoS One*. 2017;12(11): e0188123. Published 2017 Nov 16.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2°C ~ 30°C		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		

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