Diagnostic Kit for TSH

A test for detecting TSH quantitative in serum or plasma that with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

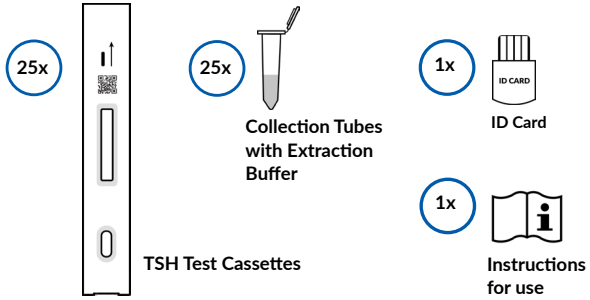
PACKING SPECIFICATION
25 Tests/ Kit (07TSH5025)

INTENDED USE
The TSH Test Cassette (Immunofluorescence Assay) is intended for *in-vitro* quantitative determination of Thyroid Stimulating Hormone (TSH) in human serum, plasma. Measurement of TSH is useful to aid in the screening the adult population for primary hypothyroidism by medical professionals. It could also be used in screening neonates for hypothyroidism. The test is intended for healthcare professionals use.

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 then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body.[1] It is a glycoprotein hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid.[2,3] TSH (with a half life of about an hour) stimulates the thyroid gland to secrete the hormone thyroxine (T4), which has only a slight effect on metabolism. T4 is converted to triiodothyronine (T3), which is the active hormone that stimulates metabolism. About 80% of this conversion is in the liver and other organs, and 20% in the thyroid itself.[1] Laboratory testing of thyroid stimulating hormone* levels in the blood is considered the best initial test for hypothyroidism.[4] It is important to note the statement from the Subclinical Thyroid Disease Consensus Panel: "There is no single level of serum TSH at which clinical action is always either indicated or contraindicated. The higher the TSH, the more compelling is the rationale for treatment. It is important to consider the individual clinical context (e.g. pregnancy, lipid profile, ATPO antibodies).[5]

PRINCIPLE
The TSH Test Cassette is based on fluorescence immunoassay technology. TSH Test Cassette (Serum/Plasma) detects Thyroid Stimulating Hormone through Immunochromatographic quantitative detection technology. The sample moves through the strip from sample pad to absorbent pad by the chromatographic force. If the test sample contains TSH, it attaches to the TSH antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane (Test line). The concentration of TSH in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of TSH in the sample can be calculated by the Immunofluorescence Analyzer to show TSH concentration in specimen.

REAGENTS
The test include TSH antibody coated particles and TSH antibody coated on themembrane.

MATERIALS PROVIDED


MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Timer
- Specimen Collection Containers

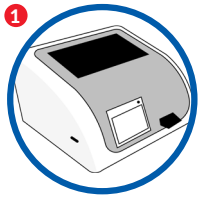
PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The TSH Test Cassette is only operational in the Immunofluorescence Analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.

STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

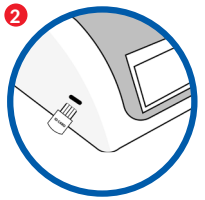
SAMPLE COLLECTION AND PREPARATION
Blood Sample Taking
1. Collect the specimens according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2 - 8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA, Heparin sodium, can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability
1. Transfer **75 µL of serum or plasma** to the buffer tube with the micro pipette.
2. Close the tube and shake the sample by hand forcefully for approximately **10 seconds** so sample and dilution buffer mix well.
3. Let the diluted sample rest for approximately **1 minute**.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

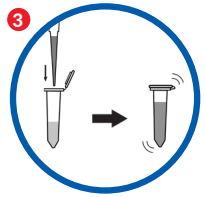
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



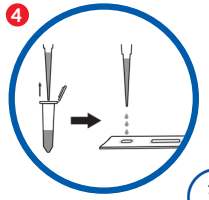
Turn on the Analyzer power.



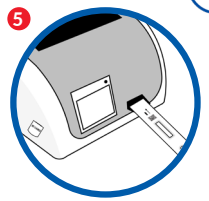
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



Serum or plasma: Pipette **75 µL of serum or plasma** into the buffer tube, mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Pipette **75 µL of diluted specimen** into the sample well. Start the timer at the same time.



Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for TSH is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Working range of TSH is 0.1 - 100 µIU/mL.

QUALITY CONTROL

Each TSH Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The TSH Test Cassette (Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of TSH.
2. The TSH Test Cassette (Serum/Plasma) will only indicate the presence of TSH antigen in the specimen and should not be used as the sole criteria for evaluating thyroid function.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of Immunofluorescence Analyzer are only for the analysis of the results on the tests. It should not be used as the sole criteria for treatment decisions.
5. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
<20 µIU/mL	Normal Neonatal
<10 µIU/mL	Normal Children
<5 µIU/mL	Normal Adult

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation is ≤±15%.

2. Assay Range and Detection Limit

- Assay Range: 0.1 - 100 µIU/mL.
- Detection Limit (Analytical Sensitivity): 0.1 µIU/mL.

3. Linear range

0.1 - 100 µIU/mL, R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 5.0 µIU/mL and 20 µIU/mL of TSH. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 5.0 µIU/mL and 20 µIU/mL of TSH. C.V. is ≤15%.

5. Method comparation

The assay was compared with Roche electrochemical luminescence Assay test with 100 samples. The correlation coefficient(r) is 0.984.

BIBLIOGRAPHY

1. Merck Manual of Diagnosis and Therapy, Thyroid gland disorders.
2. The American Heritage Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company. 2006. ISBN 0-395-82517-2.
3. Sacher R, Richard A. McPherson (2000). Widmann's Clinical Interpretation of Laboratory Tests, 11th ed. F.A. Davis Company. ISBN 0-8036-0270-7.
4. So, M; MacIsaac, RJ; Grossmann M (August 2012). "Hypothyroidism". Australian Family Physician 41 (8): 556–62.
5. Surkset. al.,JAMA 291:228, 2004.

SYMBOLS

	Consult Instructions For Use		Catalogue Number
	For *In-vitro* Diagnostic use		Authorized Representative
	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
	Lot Number		European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date		Tests per Kit
	Unique Device Identifier		

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