SCREEN IFA TEST TSH
(Serum/Plasma)
Package Insert

REF: SC-1378	English

A rapid test for detecting TSH quantitative in serum or plasma that with the use of SCREEN® Fluorescence Immunoassay Analyzer

INTENDED USE

TSH Test Cassette (Immunofluorescence Assay) is intended for in vitro quantitative determination of Thyroid Stimulating Hormone (TSH) in 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.

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 (T_4), and then triiodothyronine (T_3) 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),”

PRINCIPLE

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 SCREEN® Analyzer to show TSH concentration in specimen

REAGENTS

The test include TSH antibody coated particles and TSH antibody coated on the membrane.

PRECAUTIONSI

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 SCREEN® FIA 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. 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.

SPECIMEN 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**.

The diluted sample can then be used immediately or stored for up to 8 hours

MATERIALS

Materials Provided
• Test Cassettes • Specimen Collection Tubes with buffer
• ID Card • Package Insert
Materials Required But Not Provided
• Timer • Centrifuge • SCREEN® Fluorescence Immunoassay Analyzer
• Pipettes • Specimen Collection Container

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 °C) prior to testing.

1. Turn on the Analyzer power. Then according to the need, select “Standard test” or “Quick test” mode.
2. Remove the ID card and insert it into the Analyzer port.
3. **Serum or plasma:** Pipette **75 µL serum or plasma** into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette **75 µL** diluted specimen into the sample well. Start the timer at the same time.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.
   “**Quick test**” mode: Insert the test cassette into the Analyzer at **15 minutes** after sample application click “**QUICK TEST**”, fill the test information and click **"NEW TEST"** immediately. the Analyzer will automatically give the test result after a few seconds.
   “**Standard test**” mode: Insert the test cassette into the Analyzer immediately after sample application, click “**STANDARD TEST**”, fill the test information and click **"NEW TEST"** at the same time, the Analyzer will automatically counting down **15 minutes**. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for TSH is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyze.
Working range of TSH is 0.1-100 µIU/mL.

QUALITY CONTROL

Each TSH Test Cassette contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated.

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 SCREEN® Fluorescence Immunoassay Analyzer are only for the analysis of the results on the rapid tests. It should not be used as the sole criteria for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

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 ≤ ±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%。

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.

LEGENDA SIMBOLI

	Consult Instructions for Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

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