Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test

Catalog No. W220

INTENDED USE

The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of thyroid stimulating hormone (TSH) in human whole blood, serum or plasma. The test is used as an aid in the functional diagnosis of thyroidea.

For in vitro diagnostic use only. For professional use only.

SUMMARY

The determination of serum or plasma levels of thyroid stimulating hormone (TSH or thyrotropin) is recognized as an important measurement in the assessment of thyroid function. Thyroid stimulating hormone is secreted by the anterior lobe of the pituitary gland,and induces the production and release of thyroxine (T4) and triiodothyronine (T3) from the thyroid gland.

PRINCIPLE

The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test is based on lateral flow immunoassay. The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test uses a direct solid sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector TSH antibody on the membrane separately binds to TSH antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody with TSH are separately captured by TSH antibody that has been immobilized on test strip. Thus the more antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of TSH captured. The Finecare™ FIA Meter shows TSH concentration in blood specimen. The working range and the detection limit of the TSH Test system are 0.1~100 mIU/L and 0.1 mIU/L, respectively.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Please make sure that test device lot No., buffer lot No. and ID Chip lot No. are the same before use.
5. The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test is only operational in the Finecare™ FIA Meter. 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.
6. The test device should remain in its original sealed pouch until ready to use. Do not use the test device if the pouch is punctured or not well sealed. Discard after single use.
7. The Test Device and Meter should be used away from vibration and magnetic field. During normal usage, the Test Device may introduce minute vibration, which should be regarded normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tips and detector buffer vials should be used for one specimen only. Discard after single use.
9. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
10. Blood specimens, used test devices, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test should not be used as absolute evidence for functional diagnosis of thyroidea. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

1. 25 Individual sealed pouches, each containing:
   - ■ Test Device
   - ■ Desiccant Pouch
2. One Test Device ID Chip
3. Leaflet with instructions for use
4. 25 tubes of detector buffer

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set
3. Specimen Collection Containers
4. Centrifuge (for Plasma only)
5. Timer

STORAGE AND STABILITY

1. Store Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test at 4～30℃ up to the expiration date.
2. If removed from refrigerator, allow the test for 30 minutes to return to room temperature before testing.
3. Do not remove the device from the pouch until ready to use.

The Test Device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma or whole blood.

For Whole Blood:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2~8℃.
3. It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 7 days.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2~8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

The Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test should be uesd with Finecare™ FIA Meter.

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be in room temperature.

1. Set a Test Device on a dust-free clean place.
2. Check and insert ID Chip onto the instrument. Make sure that the Test Device lot No. matches with ID Chip lot No..
3. Draw 75 µL of whole blood/serum/plasma with a transfer pipette and add it to the buffer tube.
4. Mix well the specimen with Buffer for one minute by tapping or inverting the tube.
5. Take 75 µL of sample mixture and load it onto the sample well of the Test Device.
6. There are two test modes for Finecare™ FIA Meter, Standard Test mode and Quick Test mode. Please refer to the Section Ⅴ Operation in user manual of Finecare™ FIA Meter for details.

a) For Standard Test mode: If you select the Standard Test mode, immediately insert the Test Device onto the Test Device Holder of Finecare™ FIA Meter right after adding the sample mixture to the sample well, and click "Test".

b) For Quick Test mode: If you select the Quick Test mode, start the timer right after adding the sample mixture to the sample well, and leave the Test Device at room temperature for 15 minutes. Then immediately insert test device onto the holder of Finecare™ FIA Meter and click "Test". The instrument will automatically start to scan the Test Device immediately.

7. Read the results on the display screen of Finecare™ FIA Meter.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meter calculates TSH test results automatically and displays the concentration of TSH on the screen as form of XX.X mIU/L. For further information, refer to the Operation Manual for the Finecare™ FIA Meter.

Reference Value: 0.3~4.2 mIU/L

Note: Recommend that each laboratory formulates its own Reference Range according to actual situation.

QUALITY CONTROL

Each Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test device 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 Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The results of Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If TSH test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results include cross-reactions with some components of whole blood from individual to antibodies; and non-specific adhesion of some components in human whole blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of TSH antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
4. Other factors may interfere with Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 507 human blood samples, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ TSH (Thyroid-stimulating hormone) Rapid Quantitative Test and the Roche TSH Reagent Kit for the 507 clinical samples, the Correlation Coefficient is ≥0.970.

Assay Range and Detection Limit

- **Assay Range**: 0.1~100 mIU/L
- **Detection Limit (Analytical Sensitivity):** 0.1 mIU/L

Cross-Reactivity

The following substances do not interfere with the TSH test results at the indicated concentrations: FSH at 1000 mIU/mL, LH at 500 mIU/mL and HCG at130000 mIU/L.

Linearity

A serial concentration of TSH controls at 0.3mIU/L, 1.5 mIU/L, 5 mIU/L, 25 mIU/L, 50 mIU/L were each tested for three times, the Correlation Coefficient (R) is ≥ 0.990.

Precision

Intra-Lot Precision

Within-run precision has been determined by using 10 replicates for the same lot of TSH specimen of 1.5 mIU/L.C.V. is ≤15%.

Inter-Lot Precision

Between-run precision has been determined by using 3 replicates for each of three lots using TSH specimen levels at 1.5 mIU/L. C.V. is ≤ 15%.

Bibliography Of Suggested Reading Precision

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3. Surks MI, Chopra IJ, Mariash CN, Nicoloff JT, Solomon DH. American Thyroid Association Guidelines for the Use of Laboratory Tests in Thyroid Disorders. JAMA 1990;263:1529-1532.
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5. Ladenson PW. Optimal laboratory testing for diagnosis and monitoring of thyroid nodules, goiter and thyroid cancer. Clin Chem 1996;42:1,183-187.
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7. Tietz NW. Clinical Guide to Laboratory Tests, 3rd edition. Philadelphia, Pa. WB Saunders Co. 1995:594.
8. Passing H, Bablok W, et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790.

INDEX OF SYMBOLS

IVD In Vitro Diagnostic Use	See Instruction for Use	Expiry Date
Σ Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
Manufacturer	Do not reuse	REF Catalog #
30°C 4°C Store between 4～30℃		

Guangzhou Wondfo Biotech Co., Ltd.

CE EC REP

Version: 19/05/2016