AeHealth

CE IVD

TSH (Thyroid Stimulating Hormone) Rapid Quantitative Test (Immunofluorescence Assay)

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

PRODUCT NAME

TSH (Thyroid Stimulating Hormone) Rapid Quantitative Test (Immunofluorescence Assay)

SPECIFICATION

1 test/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 50 tests/kit, 100 tests/kit;

INTENDED USE

The TSH (Thyroid Stimulating Hormone) Rapid Quantitative Test along with Aehealth FIA Meter is intended for vitro quantitative determination 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 .

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.

Normal Reference Value: 0.3~4.2 mIU/L;
Note: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE OF THE PROCEDURE

The Aehealth TSH Rapid Quantitative Test is based on fluorescence immunoassay technology. The Aehealth TSH Rapid Quantitative test uses a sandwich immunodetection method, when sample is added to the sample well of the test Cartridge, the fluorescence□labeled detector TSH antibody 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 and TSH are captured to TSH antibody that has been immobilized on test strip. Thus the more TSH 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 and Aehealth FIA Meter shows TSH concentrations in blood specimen.

STORAGE AND STABILITY

1. Store the detection buffer at 2～30°C. The buffer is stable up to 18 months.
2. Store Aehealth TSH rapid quantitative test cassette at 2～30°C, shelf lifeis up to 18 months.
3. Test cassette should be used within 1 hour after opening the pack.

MATERIALS SUPPLIED

- 25 Test Cassette
- 1 Test cassette IC card
- 1 Tube Whole Blood Buffer
- 1 Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10 μL, 100 μL size)
- Specimen Collection Containsers
- Sterile Lancets (for Fingerstick Whole Blood only)
- Alcohol Pads
- Centrifuge (for Plasma/Serum only)
- Timer

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use test cassette if its lot # does not match with IC card # that is inserted onto the equipment.
5. The Aehealth TSH rapid quantitative test kit is only operational in the Aehealth FIA meter.
6. Do not use the test cassette if the pouch is punctured or not well sealed.
7. The test cassette and meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detection buffer vials for different specimens.
9. Blood specimens, used test cassettes, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

SPECIMEN COLLECTION AND PREPARATION

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

For Whole Blood Collected by Venipuncture:

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 storing at 2°C～8°C for more than 2 days.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. 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°C～8°C for up to 3 days. For longterm storage, specimens should be kept below -20°C.

TEST PROCEDURE

Refer to Aehealth FIA meter operation manual for the complete instructions on use of the test. The test should be operated in room temperature.

Step1: Preparation

Check/ swipe the IC card information to the equipment.

Step2: Loading

Serum / plasma: take 100μL of serum or plasma samples, load it onto the sample well of the test cassette;

Whole blood: take 120μL of whole blood sample, load it onto the sample well of the test cassette, immediately add a drop of whole blood buffer to the sample well;

Step3: Testing

Quick Test: After 15 minutes of sample adding reaction, insert the detection card into the carrier of the fluorescence immunoassay analyzer, click the “Test” button on the “Quick test” page, enter the information, and click “test” the instrument will automatically detect and print the results;

Timming Test: Insert the detection card into the carrier of the fluorescence immune analyzer immediately after adding the sample, double click the "Timing test" button, enter the information and click “test”, after the automatic incubation countdown is over, click test, automatically detect, give the test results and print.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Aehealth TSH 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 may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Aehealth TSH Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Detection Limit: 0.1 mIU/L;
Linear Range: 0.1-100mIU/mL;
Linear correlation coefficient R ≥ 0.990;
Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when the accuracy calibrator prepared by TSH national standard or standardized accuracy calibrator are tested.

BIBLIOGRAPHY OF SUGGESTED READING

1.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.
2.Ladenson PW. Optimal laboratory testing for diagnosis and monitoring of thyroid nodules, goiter and thyroid cancer. Clin Chem 1996;42:1,183-187.

INDEX OF CE SYMBOLS

IVD	In Virto Diagnostic medical Device		Do Not Reuse
	Expiration Date		Consult Instructions For Use
2℃ 30℃	Store at 2-30°C		Date of Manufacturer
	Manufacturer	LOT	Batch Code
	Warning, please refer to the instruction in the annex		Keep Dry
	Avoid overexposuer to the sun	CE	CE Mark
	Don’t use the product when the package is damaged		Biological Risks
EC REP	Authorized Representative in the European Community		

Please read this user manual carefully before operating to ensure proper use.
Document No: 30900050 Version: 1.0

BASIC INFORMATION

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