

TSH Test Kit (Dry Fluorescence Immunoassay) User Manual

[PRODUCT NAME]

TSH Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

5 Tests/Kit
25 Tests/Kit

[INTENDED USE]

TSH Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of TSH (Thyroid stimulating hormone) in human fingertip blood.

TSH is the main regulator of thyroid cell growth, thyroid hormone synthesis and secretion. TSH (MW 30kDa) is synthesized and secreted by TSH cells of pituitary gland, it has negative feedback on the synthesis and secretion process. The fluctuation of TSH is faster and more significant than thyroid hormones when thyroid function is changed. It is a sensitive biomarker of hypothalamic pituitary thyroid axis function, especially for diagnosis of subclinical hyperthyroidism and subclinical hypothyroidism.

[TEST PRINCIPLE]

TSH Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will diffuse forward due to capillary action, then the TSH of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody, and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. Test strip in a foil pouch with desiccant
2. QR code card for calibration
3. User manual
4. Sample diluent
5. Plastic transfer pipette (Optional).
6. Alcohol pad (Optional).
7. Safety Blood Lancet (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a shelf life of 24 months.
Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1100 Dry Fluorescence Immunoassay Analyzer
2. LS-2100 Dry Fluorescence Immunoassay Analyzer
3. LS-4000 Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **fingertip blood**. Other bodily fluids and samples may not get the accurate result. Use the materials in accessory kit A for

fingertip blood sampling.

2. At room temperature, the test should be performed immediately after the sample collection.
3. **Sample Volume: 30µL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample, test strip and sample diluent should be recovered to room temperature (15°C-30°C).

For LS-1100:

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press the "Test" icon to enter the testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to deliver 30µL of sample into the sample diluent. Mix gently and thoroughly. And then drop 100µL mixture into the sample port in the test strip.
7. **Reaction Time: 15 minutes**
For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click the "Test".
For panel outside: After reaction time 15 minutes is elapsed, insert the test strip into the analyzer and then click the "Test".
8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[REFERENCE INTERVAL]

Reference Range: 0.4-4.0µIU/mL

TSH concentration is determined using samples obtained from 200 apparently healthy individuals.
It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

If the test result of the sample is more than 60µIU/mL, the analyzer displays ">60µIU/mL", and if the result is less than 0.1µIU/mL, the analyzer displays "<0.1µIU/mL". Specific data can be exported through related software as needed.

[LIMITATION]

1. This kit is only for the human **fingertip blood**.
2. The test results of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Linearity Range: 0.1-60µIU/mL, r²0.990.
2. Lower Detection Limit: ≤0.1µIU/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation is

within ±15%.

4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. The hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

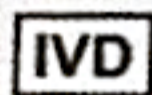



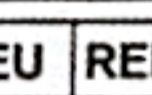
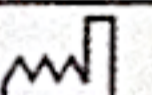
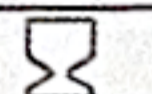

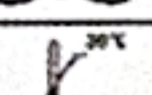
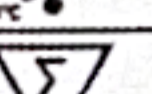
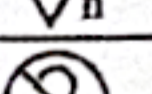


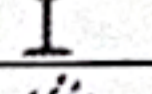
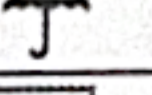
[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

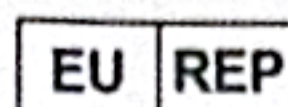
1. Fei Chengying. Serum TT3, FT3, TT4, FT4 and TSH detection significance. International Journal of laboratory medicine, 2010, 31(2): 121-122.
2. Liu Donggang, Ge Xiulan. Clinical value of serum TT3, TT4, FT3, FT4 and TSH in 200 cases. Journal of Hebei Medical University, 1995(4): 201-203.
3. Huang Jing, Zhang Wenjing, Wu Jingfang, et al. The value of thyroid stimulating hormone, thyroglobulin antibody, peroxidase antibody in the diagnosis of thyroid disease. Chongqing medicine, 2013(32): 3875-3877.

[SYMBOL DESCRIPTION]

	For in vitro diagnostic use only
	Catalog number
	Manufacturer
	Lot number
	EU Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store at 4°C-30°C
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion



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 Production date and expiration see the label.