Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

TSH

Thyroid Stimulating Hormone Test Kit
(Fluorescence Immunoassay Method)

Instructions for Use

Version:A/3

REF HP-Palm-TSH-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name: Thyroid Stimulating Hormone Test Kit (Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit

Note: other specifications are available, 10Tests/Kit, 50 Tests/Kit, 100 Tests/Kit.

Intended Use

The Thyroid Stimulating Hormone (TSH) Test Kit is intended for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum, and plasma (EDTA and lithium heparin) or whole blood, using the fluorescence immunoassay analyzer. Measurements of the thyroid stimulating hormone protein are used in diagnosis of thyroid or pituitary disorders.

For in vitro diagnostic use only .

For prescription use only.

Test Principle

The TSH test kit is a rapid quantitative assay based on the principle of double antibodies sandwich fluorescence immunoassay.

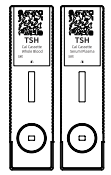
Thyroid Stimulating Hormone Protein antigen in the sample reacts with mouse anti-human TSH antibody in the pad, to form antigen-antibody complexes. The complexes migrate upward, firstly captured by mouse monoclonal anti-TSH antibody on the T line and then by polyclonal goat anti-mouse IgG antibody on the C line coated in the membrane. After the reaction, the fluorescence immunoassay analyzer calculates the TSH concentration according to the fluorescence intensity of T and C line.

Material Provided

Component	25Kits
Sample Diluent	25
Calibration Cassette	2
Test Cassette	25
Instructions for Use	1
Disposable tube with 60μL	50

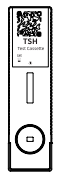
Sample Diluent

Calibration Cassette



QR code is with built-in parameter for each assay.

Test Cassette



Disposable tube with 60μL

Volume 60μL

Material Needed but Not Provided

Timing device

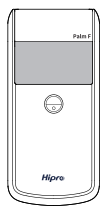
Storage&Validity

Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument



Palm F Fluorescence Immunoassay Analyzer

Specimen type

The specimen type of Hipro TSH test kit is human serum, plasma (EDTA or lithium heparin) or whole blood -Take blood samples in observance of the standard precautions for the withdrawal of biological fluids.

1. Do not use samples that have remained at room temperature for more than 8 hours.
2. Freeze the sample at -20°C or lower temperature if dosage is not performed within 72 hours.
3. Due to possible evaporation effects, samples on the analyzer should be measured within 2 hours.

Storage

Fresh collected specimens are stable if stored at 2°C-8°C for up to 24 hours. For longer storage, aliquot, cap tightly, and freeze at -20°C for up to 3months.

Avoid repeated freezing and thawing.

Avoid hemolysate.

Required volume

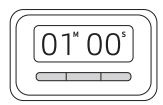
60μL is required for serum, plasma or whole blood, used for dilution. 60μL is required of diluted sample for each determination. This volume does not include the dead volume (unusable volume in the sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

TSH Test Kit Instructions Guide

Before You Begin

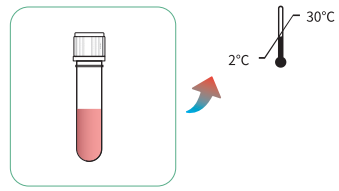
1a Please read the TSH IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

1b A timing device (phone, clock or timer) is required but not provided.



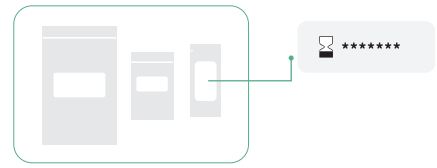
Before You Begin

1c Allow the sample back to room temperature.



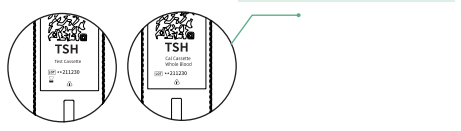
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

1e Check on the expiration date on labels of different component.



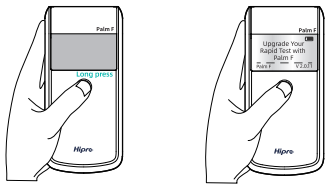
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.

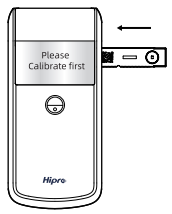


Test Procedures

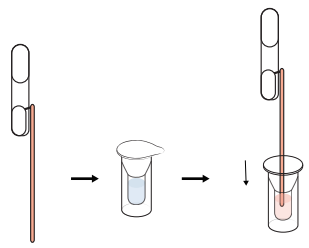
2a Turn on the applicable instrument according to the User Manual.



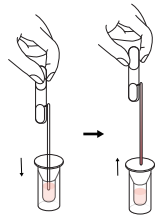
2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.



3a Use the disposable tube to collect and add 60μL specimen(serum/plasma/whole blood) into the sample diluent.



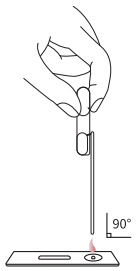
3b Repeated squeezing and absorbing to mix the samples.



Note:Do not make the liquid entering into the balloon interior during the squeezing and absorbing process.

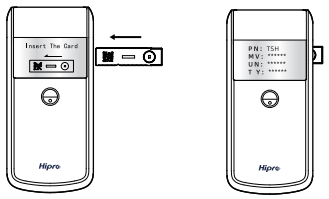
Test Procedures

3c Use a new disposable tube to add 60μL mixed liquid onto the sample well of test cassette.



3d Wait for 15 minutes .

3e Insert the test cassette into the analyzer and the analyzer will display the results automatically.



! Avoid bubbles when collecting samples.

Reference Value

The normal reference range is 0.55-4.78mIU/L.

159 healthy patients were measured and the results (95%) meet the linearity range 0.55-4.78mIU/L.

The value is indicative only and may differ from other published values as a result of differences in methods and in the population being studied. It is recommended that each laboratory establish its own reference range.

Performance Characteristics

1. **Strip width**

   The width of strip should be ⩾2.5mm.
2. **Liquid flow speed**

   The speed should be ⩾10mm/min.
3. **Linearity**

   Within range 0.3-100mIU/L, the correlation coefficient (r) should be ⩾0.990.
4. **Within-lot precision**

   The coefficient of variation (CV) should be ⩽15%.
5. **Between-lot precision**

   The coefficient of variation (CV) should be ⩽20%.
6. **Accuracy**

   The relative deviation should be ⩽15%.
7. **Limit of blank(LoB)**

   The LoB should be ⩽0.3mIU/L.

Precautions and limitations

For in vitro diagnostic use

Only experienced laboratory personnel should use this test and handling all laboratory reagents should be based on normal precautions required.

Safety precautions

1. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
2. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
3. Disposal of all waste material should be in accordance with local guidelines.
4. Avoid electromagnetic or vibration environment for analyzer.
5. Do not insert the polluted cassette into analyzer.

Potential biohazard warning

Some reagents of Hipro test kits contain material of animal origin, even if they are certified as deriving from healthy animals, it is recommended to handle them with the same precaution used for potentially infectious samples.

Limitations-interference

As with all immunoassays, the results of this test can be influenced by factors present in some patients' specimens. The factors include hemoglobin>5g/L, triglyceride>10mmol/L, bilirubin>200μmol/L, For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

When the TSH concentration ⩽300mIU/L, there will not be Hook effect.

Safety Phases

S 37 Wear suitable gloves

S 60 This material and /or its container must be disposed of as hazardous waste.

Symbols used on labels

Symbol	Usage
	Use-By date
LOT	Batch code
	Manufacturer
	Keep Away from Sunlight
2°C 30°C	Temperature Limit
IVD	In Vitro Diagnostic Medical device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instructions for use
	Do not freeze
Σ	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

Reference

1.Liu Chao，Wu Xiaohong: the clinical significance of TSH detection 2003,2(2)： 98-101.

2.Biondi B,Palmieri EA,Klaim M.Schlumberger M.Filetti S Lombardi G.Subclinical hyperthyroidism:clinical featears and treatment options.Eur J Endocrinol,2005,152(1):1-9.

Approval Date &Revision Date

Approval Date: Sept 9,2019

Revision Date: Jul 15,2021

Revision Date: Jul 25,2023

Revision Date: Dec 22,2023

CE IVD

工艺：70g双胶纸，双面印刷，横向4折页，竖向对折　展开尺寸：32*25cm