



TSH

Fast Test Kit

(Immunofluorescence Assay)

IF1024 for Getein 1100
 IF5024 for Getein 1160
 IF3024 for Getein 1180
 IF4024 for Getein 1200
 IF2024 for Getein 1600

Instructions for Use



INTENDED USE

TSH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of thyroid-stimulating hormone (TSH) in human serum and plasma samples. This test is used in the screening, clinical diagnosis, prognosis and therapeutic effect evaluation of thyroid diseases. For professional and laboratory use only.

SUMMARY

TSH is the main regulator of thyroid cell growth, thyroid hormone synthesis and secretion. TSH (MW 30 kDa) is synthesized and secreted by TSH cells of pituitary gland, it has negative feedback to the synthesis and secretion process. The fluctuation of TSH is faster and more significant than thyroid hormones when thyroid function was changed, it is a sensitive biomarker of hypothalamic-pituitary-thyroid function.

PRINCIPLE

TSH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence-labelled TSH monoclonal antibody binds with the TSH in sample and forms a marked antigen-antibody complex. This complex moves to the detection zone of the test card by capillary action, where it is captured on the test line by another TSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the

amount of TSH in the sample. The intensity of the fluorescent signals can be analyzed with an appropriate device, enabling the quantitative detection of TSH in the sample.

APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
TSH test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*TSH test card

A test card consists of: Fluorescence-labelled TSH monoclonal antibody, TSH monoclonal antibody.

Consumables for Getein 1200/Getein 1600

-Box with pipette tips (96 tips/box)

-Mixing plate (1 piece/box)

Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months.

The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- Serum and plasma can be used as samples in the assay.
- Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma. hemolyzed specimens should not be used.
- This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
- It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days at 2~8°C and 6 months at -20°C.

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180

immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1600/Getein 1200:

- 1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- 2) Put the consumables at the correct position in Getein 1200/Getein 1600.
- 3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

RESULTS

TSH Fast Test Kit (Immunofluorescence Assay) results are provided in $\mu\text{IU/mL}$.

Others: Measuring range of the test kit is $0.10 \mu\text{IU/mL}$ – $50.00 \mu\text{IU/mL}$, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 4 times.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Hemoglobin	5 g/L
Triglyceride	25 g/L
Bilirubin	0.1g/L

EXPECTED VALUE

The expected normal value for TSH was determined by testing samples from serum of 391 apparently healthy individuals. The reference range of TSH is $0.27 \mu\text{IU/mL}$ – $4.20 \mu\text{IU/mL}$ calculated by using normal distribution methods (95% confidence interval). It is recommended that each laboratory should establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	$0.10 \mu\text{IU/mL}$ ~ $50.00 \mu\text{IU/mL}$
Limit of Detection	$0.10 \mu\text{IU/mL}$
Within-Run Precision	$\leq 10\%$
Between-Lot Precision	$\leq 15\%$

REFERENCES

1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric Thyrotropin assay to subnormal assessment. ClinEndocrinolMetab. 1990, 70(2):453-460.
2. Sakai H, Fukuda G Suzuki N, et al. Falsely Elevated Thyroid-Stimulating Hormone (TSH) Level Due to Macro-TSH. Endocr J. 2009, 56(3):435-440.
3. Abalovich M, Amino N, Barbour LA, et al. Management of thyroid dysfunction during pregnancy and postpartum: an Endocrine Society Clinical Practice Guideline. J ClinEndocrinol Metab. 2007, 92(8):1-47.
4. Spencer C A, Takeuchi M, Kazarosyan M. Current status and performance goals for serum thyrolobulin assays. Clin Chem. 1996, 42(1):164-173.
5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for

professional use.

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TSH Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using TSH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

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