GP

CE IVD

TSH

Fast Test Kit

(Immunofluorescence Assay)

IF1024 for Getein1100
IF5024 for Getein1160
IF3024 for Getein1180
REF IF4024 for Getein1200
IF2024 for Getein1600

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.

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

The test uses an anti-human TSH monoclonal antibody conjugated with fluorescence latex and another anti-human TSH monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human TSH monoclonal antibody binds with the TSH in sample and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human TSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of TSH in sample.

Insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of TSH in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein-1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) TSH test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein TSH test cards
2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human TSH monoclonal antibody, the test line is coated with another anti-human TSH monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: 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

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma samples. Samples should be free of hemolysis.
2. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated samples.
5. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 100 μL***.

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample well on the test card.
5. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table,horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 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 printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein-1180/Getein1200/Getein1600.

Others: Measuring range of the test kit is 0.10 μIU/mL~50.00 μIU/mL, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 4 times.

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 μIU/mL~4.20 μIU/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 μIU/mL~ 50.00 μIU/mL
Lower Detection Limit	0.10 μIU/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric Thyrotropinassay 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.

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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing TSH Fast Test Kit (Immunofluorescence Assay).
Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF26-S-11

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054