One Step Test for TSH (Colloidal Gold)
For in vitro Diagnostic Use

Cat.# CG1024

User Manual

INTENDED USE

One Step Test for TSH (Colloidal Gold) is intended for in vitro quantitative determination of thyroid-stimulating hormone (TSH) in serum, plasma or whole blood. This test is used in the screening, clinical diagnosis, prognosis and therapeutic effect evaluation of thyroid diseases.

SUMMARY

Thyroid-stimulating hormone (TSH) is the main regulator of thyroid cell growth and thyroid hormone synthesis and secretion. This 30KD protein TSH is synthesized and secreted by tsh cells of pituitary gland, and it can have 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 two high specificity and high sensitivity antibodies, the anti-human TSH monoclonal antibody I conjugated with colloidal gold coated on the sample pad and the anti-human TSH monoclonal antibody II coated on the test line. Rabbit anti-mouse IgG antibody coated on the control line. The sample moves by suction of absorbent paper when added to the test strip, the gold-labeled anti-human TSH monoclonal antibody I binds with the TSH in sample and forms an antigen-antibody complex. In the detection zone, marked antigen-antibody complex will be captured on the test line by the anti-human TSH monoclonal antibody II and forms a double-antibody sandwich.

Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereafter referred to as FIA8000), the concentration of TSH in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein TSH test card in a sealed pouch with desiccant…… 25
2. Disposable pipet (optional)…… 25
3. User manual …… 1
4. SD card …… 1
5. Whole blood buffer…… 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, colloidal gold pad (coated with gold-labeled anti-human TSH monoclonal antibody I) and nitrocellulose membrane (the detection zone is coated with the anti-human TSH monoclonal antibody II, and the control zone is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 18 months.
Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma, whole blood. Heparin, EDTA and sodium citrate should be used as the anticoagulant for plasma and whole blood sample. Samples should be free of hemolysis.
2. Serum or plasma are suggested for better result.
3. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃or stored at -20℃for 6 months before test (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature (15~30℃) and be homogeneous before test. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME: 100 µl.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should reach to room temperature (15~30℃) before test. Use test card within 1 hour to avoid moisture.
3. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual). Make sure that SD card lot No. is in accordance with test kit lot No..
4. Take out the test card from the sealed pouch before use. Label the test card with patient or control identification and put it on a clean and horizontal table.
5. Using sample transfer pipette, deliver 100 µl of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card. (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
6. Reaction time: 15 minutes. Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.

Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

Others: Measuring range of the test kit is 0.05µIU/mL~50.0µIU/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 0.27µIU/mL~ 4.20µIU/mL calculated by using normal distribution methods giving a level of confidence of approximately 95 %. The reference range of TSH in plasma and whole blood sample is the same. It is recommended that each laboratory should establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.05µIU/mL~50.00µIU/mL
Lower Detection Limit	0.05µIU/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%
Repeatability	≤10%

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. Samples containing interferents 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

3. TSH reach up to concentration of 500μIU/ml do not cause Hook effect.

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 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for TSH (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing One Step Test for TSH (Colloidal Gold).
Please read this user manual carefully before operating to ensure proper use.
Version: TS.1.0

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.bio-GP.com.cn