



**Thyroid Stimulating Hormone (TSH)
ELISA Test Kit
(Serum/Plasma)
Package Insert**

For in vitro diagnostic and professional use only.

PRODUCT NAME

TSH ELISA Test Kit (Serum/Plasma)

INTENDED USE

This kit is a quantitative detection of human serum/plasma of Thyroid Stimulating Hormone (TSH). The reagent is suitable for clinical screening and diagnosis of thyroid stimulating hormone in human serum/plasma.

TSH ELISA Kit is intended for professional use as an aid in the diagnosis of thyroid dysfunction. TSH values should not be the only factor in the determination of thyroid status, and all other available clinical and epidemiological information should be considered for an accurate diagnosis.

Recommended for use:

Any person presenting with signs or symptoms of hypo or hyperthyroidism

Any person presenting with an enlarged thyroid gland (goiter)

Pregnant women for first trimester screening

Any person requiring regular monitoring of treatment

Normally, thyroid function is first assessed by detection of TSH levels in the blood.

The monoclonal anti-TSH antibody coated on the surface of the microwells specifically recognizes the junction between the α and β subunits. The HRP-conjugated monoclonal anti-TSH antibody detects the β subunit only.

Combining the measurement of TSH with the thyroid hormones (T3/T4) can provide more information for the determination of thyroid status.

PRINCIPLE

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The system of the TSH ELISA test is founded on the solid phase, double antibody sandwich method. When TSH is present, it combine with monoclonal anti-TSH pre-coated in microwells. Then combine with monoclonal anti-TSH antibody conjugated to horseradish peroxidase (HRP-Conjugate). In the course of washing, any unbound HRP-Conjugate is removed. After chromogen solutions A and B are added into the wells and during incubation, stopped with sulfuric acid. Then read the result with microplate reader, and calculate the content.

MAIN COMPONENTS

Materials provided with the kit:

Components	96T		480T	
coated Microtiter plate	1 bag	12*8	5 bags	12*8
Conjugate	1 vial	6.5 mL	5 vials	6.5 mL
Wash Buffer (40X)	1 vial	20 mL	5 vials	20 mL
Substrate A	1 vial	7 mL	5 vials	7 mL
Substrate B	1 vial	7 mL	5 vials	7 mL
Stop Solution	1 vial	6 mL	5 vials	6 mL
Control S0 (0 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Control S1 (0.2 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Control S2 (1 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Control S3 (5 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Control S4 (10 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Control S5 (40 uIU/mL)	1 vial	0.5 mL	5 vials	0.5 mL
Closure plate membrane	2 sheets		10 sheets	

Note: different batches of reagent kit, and different component cannot be exchanged for use. Once open, stable for 3 months at 2-8°C.

SAMPLE REQUIREMENT

- Specimen Collection:** No special patient's preparation required. Collect the specimen in accordance with the normal laboratory practice. Either fresh serum/plasma specimens can be used with this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum must be separated from the clot as early as possible to avoid hemolysis of the RBC. Care should be taken to ensure that the serum/plasma specimens are clear and not contaminated by microorganisms.
- Highly lipaemic, icteric, or hemolytic specimens should not be used** as they can give false results in the assay. **Do not heat inactivate specimens.** This can cause deterioration of the target analyte. Samples with visible microbial contamination should never be used.
- TSH ELISA is intended ONLY for testing of individual serum samples. Do not use the assay for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
- Transportation and Storage: Store specimens at 2-8°C. Specimens not required for assaying within 3 days should be stored frozen (-20°C or lower). Multiple freeze-thaw cycles should be avoided. For shipment, samples should be packaged and labeled in accordance with the existing local and international regulations for transportation of clinical samples and ethological agents.

TEST PROCEDURE

- All reagents should be allowed to reach room temperature for 15 minutes before use.
- Dilute the wash buffer at the rate of 1:40 dilution with distilled water before use.
- The sample adding should be corresponding to the number of micro plate. (The number of well is determined by reference material and sample)

Note: Use a separate disposal pipette tip for each specimen, each control as to avoid cross contamination.

- Add 50 μ L sample in the corresponding well, add 50 μ L each control S0, S1, S2, S3, S4, S5 respectively to corresponding well.
- Respectively adding conjugate 50 μ L. Shake gently to mix for 30s (An important step). Incubate at

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37 °C for 60 minutes with the sealing plate membrane sealing the plate.

6. At the end of the incubation, remove and discard the plate cover. Take out, add wash buffer to each well for 10 seconds. Repeat 5 times. After the final washing cycle, turn the plate over onto blotting paper or clean towel, and tap it to remove any remainders.

7. Add Substrate A (50µL) and Substrate B (50µL). Incubate at 37 °C for 10 minutes with the sealing plate membrane sealing the plate.

8. Add 50µL Stop Solution to each well. Mix gently by shaking, read the absorbance within 10 minutes after stopping the reaction. Read the absorbance value at 450nm/ 630nm with microplate reader. Calculate the concentration and evaluate the results.

DATA HANDING

Fit Type: 4 parameters Logistic

Coordinate Choice: X-Y

REFERENCE VALUE (OR RANGE)

TSH normal concentration (Just for reference): 0.26~4.2uIU/mL

This normal concentration should be build by themselves during the long time practice for each test room.

INTERPRETATION OF RESULTS

Chronometry: Read the sample's optical density (OD) at 450nm with a microplate reader.

The detection limit is higher than 0.05uIU/mL. If the determination value is higher or lower than normal range, it means there is an abnormal result. The final result should be diagnosed with clinical symptom and other diagnose method.

Some result out of this detect range calculated through reference curve extension can not be used as accurate quantitative result. The result of high concentration sample out of detection range should be detected after diluted.

LIMITATIONS

1. It is no insignificance for positive results must be confirmed with another available method, and it should be interpreted in conjunction with the patient clinical information.
2. This reagent is only used for the detection of human serum samples.

PERFORMANCE CHARACTERISTICS

1. Dosage reflected the curve linear

Correlation coefficient of the standard curve (r) should be ≥0.990.

2. Applicable Limit about Floor Level

It should not be higher than 0.05uIU/mL for this test kit.

3. Precision

Intra-assay: CV%≤15%; Inter-assay: CV%≤20%

4. Accuracy

Test it with TSH national standards which concentration is 5 uIU/mL for 10 times; bias% ≤10%.

PRECAUTIONS

1. Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
2. Make sure that all reagents are within the validity indicated on the kit box and of the same lot. Never use reagents beyond their expiry date stated on labels or boxes.

3. Allow the reagents and specimens to reach room temperature before use. Shake reagent gently before use.

4. Concentrated washing liquid will produce crystal at room temperature, should be diluted completely before use.

5. Please put the unused plate back into the bag, and store at 2~8°C.

6. Operate strictly according to the instruction, control of reaction time and temperature strictly.

7. Never reuse microplate sealing membrane. If the external of the microplate contact with water when warm bath, results will be better.

8. Use sufficient volume of washing liquid in the washing steps. Fail to do so may cause color deepening.

9. TSH reference material is limited to use in this ELISA kit but sales alone.

10. Sample with interference substance of 400mIU/mL LH or 800mIU/mL FSH has no effect on test result of this test kit.

STORAGE AND EXPIRY

1. Store at 2-8°C. DO NOT FREEZE.

2. Once open, stable for 3 months at 2-8°C. Other liquid components have the same validity period with the reagent box.

BIBLIOGRAPHY

[1] Pharmacopoeia of the People's Republic of China.











[2] Requirements for Biologics of the People's Republic of China.

MANUFACTURER

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between		Batch number
	Do not re-use		IVD product
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests