HS-TSH-CHECK-1

High Sensitive Quantitative determination of Thyroid Stimulating Hormone in whole blood, plasma or serum samples

FOR EASY READER® AND EASY READER+® USE ONLY

Ref: HS21091

I- PRINCIPLE

Human thyroid stimulating hormone (TSH) is a glycoprotein secreted by the thyrotroph cells in the anterior pituitary (1).

The primary function of TSH is to regulate the release and to control the synthesis of the major thyroid hormones. When circulating thyroid hormone levels fall below normal, the pituitary secretes TSH. This in turn acts on the thyroid gland to produce and release more thyroid hormones. However, when circulating thyroid hormone levels rise above normal, the pituitary responds by releasing less TSH, causing the thyroid gland to decrease production and secretion of thyroid hormones.

Measurement of basal serum concentration of TSH is an essential test in the investigation of suspected hypothyroidism (abnormally low levels of thyroid hormones). A raised concentration of TSH confirms a primary cause of the disease, while a normal or low concentration excludes it or, more rarely, indicates a pituitary or hypothalamic cause (1, 2).

Since the development of highly sensitive TSH immunometric assays, it is widely believed that measurement of TSH in serum probably represents the best single assessment of thyroid function. As well, measurement of TSH after injection of exogenous TRH is useful in the differentiation of secondary and tertiary (hypothalamic) hypothyroidism (3, 4, 5).

The HS-TSH-CHECK-1 is a rapid quantitative assay for the detection of TSH in serum, plasma or whole blood to be used as a screening test **for hypothyroidism diagnosis**. **Under no circumstances, HS-TSH-CHECK-1 must be used for detection of hyperthyroidism in patient.** The method employs a unique combination of monoclonal dye conjugate and polyclonal-solid phase antibodies to identify TSH in the test samples with a high degree of specificity.

As the sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the TSH forming an antibody-antigen complex. This complex binds to the anti-TSH antibody in the reaction zone (T) and produces a pink colour band. In the absence of TSH, there is no line in the reaction zone (T). The mixture continues flowing through the absorbent device past the reactive zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a pink colour band and demonstrating that the reagents are functioning correctly.

II- HS-TSH-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

1- HS-TSH-CHECK-1 reaction devices:	10	20
2- Disposable plastic pipettes:	10	20
3- Diluent in a dropper bottle:	2.5mL	5mL
4- Instruction leaflet:	1	1

5- Controls (Optional):

Positive control (ref. V2500HS) and Negative control (ref. V2501HS): a freeze-dried preparation of a non-infectious compound in diluted Human serum tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide and optionally available as a positive and negative control (1x 0.25 mL). The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All HS-TSH-CHECK-1 kit components should be stored at room temperature (+4°C to +30°C) in the sealed pouch.

2- ***Do not freeze the test kit.***

3- The HS-TSH-CHECK-1 kit is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.

2- Read carefully the instructions before using this test.

3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.

4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.

5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.

6- Avoid any contact between hands and eyes or nose during specimen collection and testing.

7- Do not use beyond the expiry date which appears on the package label.

8- Do not use a test from a damaged protective wrapper.

V- SPECIMEN COLLECTION AND PREPARATION

1-HS-TSH-CHECK-1 test is to be performed on human serum, plasma or whole blood.

2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).

3- Each specimen should be treated as if potentially infectious.

4- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.

5- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.

6- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

VI- ASSAY PROCEDURE

a) Control testing

- Wait for 15 minutes after freeze-dried dissolving.
- Add the requested volume (25µL) with **lab pipette (disposable tips)** into the sample well of the cassette and proceed in the same way as for a patient's sample.
- The concentration range (**in mIU/L**) is indicated on the vial label and obtained result must be within the specified range. The confidence range can change slightly depending on lot number.

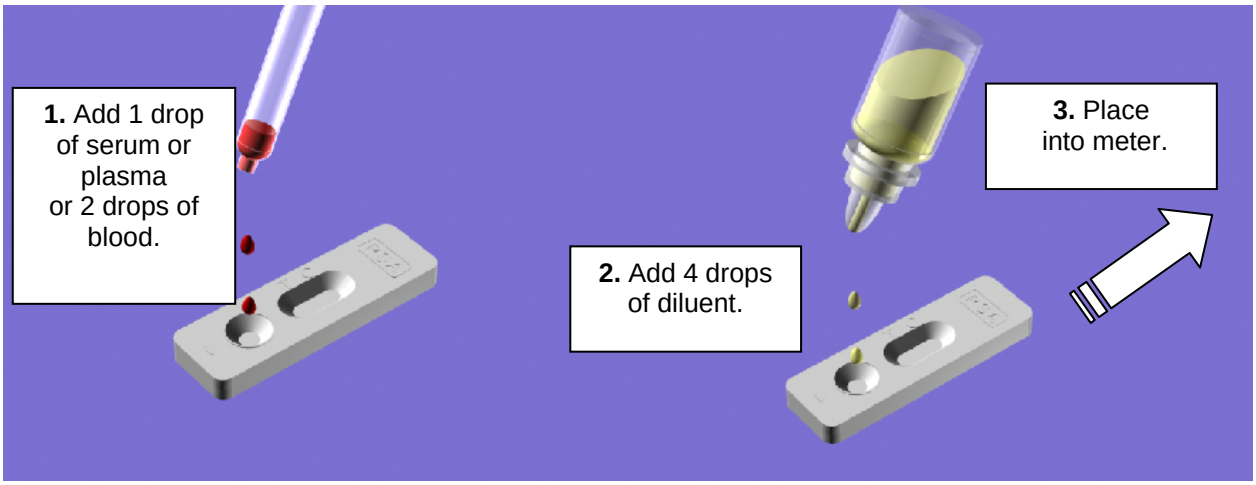
- The reconstituted vial should be kept between +2°C and +8°C and should be used within 14 days after reconstitution.

b) Samples testing

Follow the below instructions or refer to the picture n°1.

1- Allow samples and HS-TSH-CHECK-1 test devices to come to room temperature prior to testing.
2- Remove the reaction device from its protective wrapper by tearing along the split.
3- Label device with the patient's name or control number.
4- Fill the serum dropper with specimens (serum, plasma or whole blood) and by holding it vertically, dispense one drop (25 µL) into sample well. If whole blood is used, dispense 2 drops (50 µL) into sample well (▷) **and wait for the blood sample to be completely absorbed before adding diluent**.
5- Hold the dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device (▷) with an interval of 2-3 seconds between each drop.
6- Read the result **(in mIU/L**) after 15 minutes either using the immediate or countdown reading mode (see corresponding leaflet).

For general instructions describing how to use the VEDALAB's rapid test readers, refer to the corresponding leaflet.



Picture n° 1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 1– 80mIU/L.
For TSH concentration below 1mIU/L, the result will be given as "< 1mIU/L".
For TSH concentration over 80mIU/L, the result will be given as "> 80mIU/L".
For samples whose concentration is higher than 80 mIU/L, dilute with saline and repeat the assay as per instructions of Part. VI.

b) Accuracy

A study has been performed using serum samples obtained from dilutions of TSH W.H.O. reference material n°81/565. Covering a range of 0 to 80 mIU/L. Optical densities expressed as a function of TSH concentrations are described by following polynomial curve:

$$Y = -12.8249 + 10.0488\ x - 0.0654x^2$$

The results show a good correlation (r >0. 99) of the values obtained with HS-TSH-CHECK-1 on VEDALAB's reader.

c) Sensitivity

Concentrations close to 0.5mIU/L are detected by HS-TSH-CHECK-1 test. In these cases, results will be rendered as "< 1mIU/L".
Levels higher than 5mIU/L are generally considered as abnormal values.

d) Precision

Comparative studies were performed on a panel of 48 human sera using either the Roche Modular® or Cobas Elecsys® analysers. Results showed a coefficient of correlation of respectively 97.3% with the Modular® instrument and 99.1 % with the Cobas® instrument.

e) Cross reaction with homologous hormones

Homologous hormones were tested either without any added TSH or with added TSH (33mIU/L). Results are summarized in table I and showed no cross reaction.

Substances	References	Concentration	TSH Negative: <1 mIU/L	TSH Positive: 33 mIU/L
hCG	W.H.O 07/364	50,000 mIU/mL	<1	
		10,000 mIU/mL		35.1
FSH	W.H.O 83/575	250 mIU/mL	<1	34
LH	W.H.O 80/552	1000 mIU/mL	<1	31.7

Table I: Hormones interference results

f) Interferences

1-Anticoagulants

Citrate, EDTA and heparin were not showing any interference.

2- Substances

Commonly encountered substances were tested, either with or without added TSH, to demonstrate that these substances do not interfere with HS-TSH-CHECK-1 results. (Table II).

Substances	Concentration	TSH Negative < 5 mIU/L	TSH Positive > 5 mIU/L
Acetaminophen	20 mg/dL	Negative	Positive
Acetylsalicyclic Acid	20 mg/dL	Negative	Positive
Ampicillin	20 mg/dL	Negative	Positive
Ascorbic Acid	20 mg/dL	Negative	Positive
Atropin	20 mg/dL	Negative	Positive
Caffeine	20 mg/dL	Negative	Positive
Gentisic Acid	20 mg/dL	Negative	Positive
Glucose	2 mg/dL	Negative	Positive
Paracetamol	20 mg/dL	Negative	Positive
Tetracycline	20 mg/dL	Negative	Positive
Hemoglobin	1 mg/dL	Negative	Positive
Hematocrit Range	20 – 50 %	Negative	Positive

Table II: Common substances interference results

g) Intra-assay reproducibility

Within run precision was evaluated by using 20 replicates of 3 samples containing 2.13, 6.98 and 49.14 mIU/L of TSH as determined with quantitative HS-TSH-CHECK-1 for Easy Reader®.

The obtained CVs (coefficient of variation) were respectively equal to 14.55, 9.87 and 13.36%.

h) Hook effect

No hook effect was observed up to a TSH concentration of 1,000mIU/L. The reader result was: "> 80mIU/L".

VIII- LIMITATIONS

1- As for any diagnostic procedure, the physician should confirm the data obtained using this test by other clinical methods.

2- HS-TSH-CHECK-1 rapid test is designed to quantify TSH within 1 to 80 mUI/L concentration range. Therefore, TSH-CHECK-1 rapid test must only be used to detect hypothyroidism and not hyperthyroidism for which very low level of TSH (<0.1 mIU/L) must be measured. In the case that hyperthyroidism is suspected, TSH assay must be performed using a suitable specific test.

3- Very rare cases of hypothyroidism with an associated low level of TSH or hyperthyroidism with an associated high level of TSH have been reported.

4- In early pregnancy, high level of TSH could be detected.

5- **When the test is performed with whole blood, only fresh samples should be used (< 4hours). Finger prick samples should be assayed just after collection.**

6- As it is true for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.

7- High level of RF (Rheumatoid factor) or HAMA (Human anti-mouse antibodies) could give false positive result.

8- High level of CRP (C-reactive protein) indicates inflammatory process related to infection and thus increased concentration in poly-specific antibodies that could give false positive result in some cases.

9- This format of test is to be only used with VEDALAB's rapid test readers.

10- If the reading time (15 minutes) is not strictly respected, wrong results will be obtained.

11- This format of test should not be used for visual reading.

IX- BIBLIOGRAPHY

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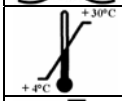
3- Thornes, HM, Mcleod, DT and Carr D (1987), Economy and efficiency in routine thyroid function testing: Use of a sensitive immunometric assay for thyrotropin in a general hospital laboratory. Clin Chem 33, 1635-1638.
4- Klee, GC and Hay, ID (1987), Assessment of sensitive thyrotropin assays for an expanded role in thyroid function testing: Proposed criteria for analytic performance and clinical utility. J Clin Endocrin Metab, **64**, 461 –471.
5- Synder, PJ and Utiger, RD (1972), Response to thyrotropin releasing hormone (TRH) in normal man. J. Clin Endocrin Metab, 3 4, 380-385

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

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