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KST72116GP

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Intended Use

The PreventID® TSH is a rapid test for the determination of thyroid stimulating hormone (TSH) in serum, plasma or whole blood (with heparin as anti-coagulant). The test sensitivity is 5 µ IU/ml.

Introduction

TSH is a hormone of the pituitary front lobe. With the help of the releasing hormone thyreoliberine (TRH), the hypothalamus stimulates the secretion of TSH from thyrotropic cells. TSH then stimulates the formation of iodine-containing thyroid hormones thyroxine (T4) and triiodothyronine (T3) in the thyroid gland. It also promotes the conversion of T4 into the more potent T3 in the periphery. Conversely, thyroid hormones inhibit the secretion of TSH from the pituitary front lobe as part of the thyrotropic regulatory circuit so that, finally, constant and demand-adapted equilibrium levels of the involved hormones are achieved.

The TSH determination is a meaningful parameter for the determination of hypothyroidism. Thyroid hypofunction usually increases TSH levels in the blood.

Test Principle

The PreventID® TSH test is a sandwich immunoassay test. The test cassette contains a nitrocellulose membrane strip with an immobilised Anti-TSH antibody in the test reaction zone (T). Another antibody, a goat-anti-mouse antibody is immobilised in the control reaction zone (C) on the nitrocellulose membrane.

Serum or blood sample is added into the sample application window. A blood separation pad (for whole blood tests) will trap the red blood cells and therefore avoids that the red blood cells will migrate into the membrane. The gold conjugate pad contains mouse anti-TSH which is coupled with Colloidal Gold. The analytes (TSH) in the blood react with the Colloidal Gold coupled anti-TSH-antibody of the Gold Conjugate Pad thus forming an antibody – antigen – Colloidal Gold complex while the liquid is moving along the membrane and transports these complexes along the membrane by capillary action supported by the Absorb Pad.

When the antibody – antigen – colloidal gold complexes are transported across the membrane and reach the respective immobilized anti-TSH-antibody on the membrane (T), they are trapped and will form a sandwich complex consisting of: immobilized antibody – antigen (analyte) – antibody – Colloidal Gold. Only when the applied blood sample contains a certain concentration of TSH, the formation of this sandwich complex will result in a visible purple colour line in the respective test region of the membrane. In case the TSH level concentration is less than the detection limit in the blood sample, the test region of the membrane will remain colorless (no test line visible).

The liquid continues to move to the control area (C) on the nitrocellulose membrane. There, this conjugate will form a complex with the immobilised anti-mouse antibody on the membrane resulting in the formation of a purple coloured control (C) test line. This indicates that the test has been performed correctly.

Materials

Materials Provided

- test devices (with sample dropper), individually packed **TEST**
- manual

Materials Required but not Provided: blood collection tubes with heparin, timer or stop watch

Storage and Stability

The PreventID® TSH test kit should be stored at 4–30 °C (40–86 °F). Do not freeze. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the pouch. Do not use it beyond the expiry date.

Precautions

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimen.
3. Wear protective gloves and wash hands thoroughly after performing the test.
4. Avoid splashing or aerosol formation while handling specimen and performing the test.
5. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
6. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged. Do not use the test after expiry date.
7. Read the instruction carefully before performing the test.
8. Do not mix reagents from different lots
9. If you have any questions please contact Preventis GmbH.

Specimen Collection and Specimen Preparation

1. Remove the test device from the pouch and place it on a flat, dry surface (Fig 1).
2. Collect a sample as serum, plasma or whole blood sample and use it inbetween 24 hours.

Test Procedure

Serum, plasma

For a TSH analysis in serum or plasma, **2 drops** of the sample are added to the sample application window.

Whole blood

For a TSH analysis in whole blood, **3 drops** of the sample are added to the sample application window.

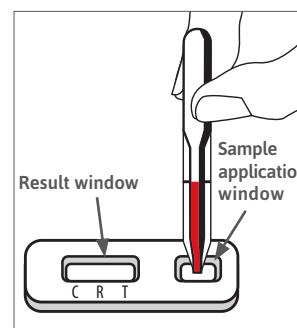


Fig. 1: Expelling the blood sample into the sample application window

As the test begins to work, you will see purple colour move across the result window in the center of the test device.

Interpret test results **at 10 minutes**. Do not interpret the test after 15 minutes.

Test Interpretation (Fig. 2)

A purple line will appear at the left section of the result window. This shows that the test is working properly. This line is the **control line (C)**.

The right section of the result window indicates the test results. If another color line appears at the right section of the result window, this line is the **test line (T)**.

Positive Result

The presence of two coloured lines (T and C) within the result window regardless of which line appears first indicates a positive result (Fig. 2a).

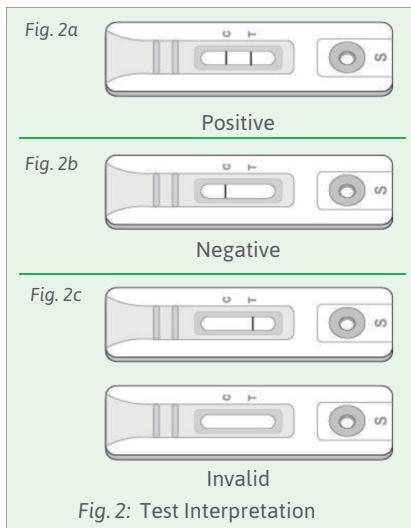
Note: Generally, the higher the analyte level in the specimen, the stronger the colour of the test line (T) will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the test line (T) will be very faint.

Negative Result

The presence of only one color band within the result window indicates a negative result (Fig. 2b).

Invalid Result

If after performing the test no colour line is visible within the result window or only the test line (T), this result is considered invalid (Fig. 2c). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be retested.



Please note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 10 minutes.

Sensitivity and Specificity

The PreventID® TSH test sensitivity is 5 µIU/ml TSH. The ability of the test to specifically detect TSH was challenged through cross-reaction studies on specimens containing known quantities of structurally and physiologically related hormone. Serum specimens spiked with 500 mIU/ml LH (Human Leutinizing Hormone), 1000 mIU/ml FSH (Follicle Stimulating Hormone), 200,000 mIU/ml hCG (human Chorionic Gonadotropin) show negative results.

Test Limitations

If the whole blood sample shows a high hematokrit, serum or plasma should preferably be used for the TSH test.

Although the PreventID® TSH test is very accurate in detecting TSH, a low incidence of false results can occur. Some serum specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.

Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

References

1. Martinez M, Derkson D, and Kapsner P, "Making Sense of Hypothyroidism. An Approach to Testing and Treatment," Postgrad Med, 1993, 93(6): 135-8, 141-5.
2. Sawin CT, Geller A, Hershman JM, et al, "The Aging Thyroid: The Use of Thyroid Hormone in Older Persons," JAMA, 1989, 261(18):2653-5.
3. Surks MI, "Guidelines for Thyroid Testing," Lab Med, 1993, 24(5):270-4.

Short instructions PreventID® TSH

1. Remove the test device from the pouch and place it on a flat, dry surface.
2. Prepare sample (serum, plasma or whole blood).
3. Apply **2 drops of serum or plasma or 3 drops of whole blood** into the sample application window.
4. Interpret test result at 10 minutes. Do not interpret the test after 15 minutes.



Status: 2018-12-04

US: all products: Research Use Only. Not for use in diagnostic procedures.

	Temperature limitation		Manufacturer
	In vitro diagnostic device		Lot number
	Catalogue number		Expiry date
	To be used with		Do not reuse
	Read user instructions		Contains sufficient for <n> tests
	Keep away from sunlight		

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