












ThyroScreen™ PROFESSIONAL

Rapid screening test for Thyroid Stimulating Hormone

Whole blood rapid one-step TSH assay for primary hypothyroidism screening in adults
For Professional use only

REF	PD11008 ThyroScreen™ Professional 20 tests	 
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Key to Symbols

 For in vitro diagnostic use	 Consult instructions for use	 Storage temperature +4 to 30°C
 Expiry date	 Manufactured by	 CE mark
 Do not re-use	 Lot number	 Catalogue number

Intended Use

The ThyroScreen™ Professional rapid one-step TSH assay for hypothyroidism screening in adults is a lateral flow immuno-chromatographic assay for qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, plasma or serum. It is intended for use by healthcare professionals to screen for primary hypothyroidism in adults. It is not intended as a screening test for hypothyroidism in neonates.

Summary and explanation of the test

Human thyroid stimulating hormone (TSH), or thyrotropin is a glycoprotein secreted by the thyrotroph cells in the anterior pituitary gland¹. TSH is the principal physiological regulator of thyroid gland function. Its production and release is stimulated by the hypothalamic thyrotropin-releasing hormone (TRH) and controlled by circulating levels of the thyroid hormones, thyroxine (T4) and triiodothyronine (T3) through feedback to the pituitary gland and possibly the hypothalamus. Serum TSH levels are raised in cases of primary hypothyroidism. A diagnosis of hypothyroidism is made when low total or free levels of T4 are found, and confirmed by a raised TSH level. In cases of mild primary hypothyroidism levels of total and free T4 can sometimes still fall within the normal range so in these cases raised TSH levels is particularly useful in the diagnosis of the condition. In hyperthyroidism levels of triiodothyronine and T4 are raised whilst the TSH level is suppressed.

Principle of the test

The ThyroScreen™ Professional one-step TSH test uses 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 test 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 and produces a pink coloured band when the TSH concentration is higher than or equal to 5 µIU/ml. In the absence of TSH, there is no line in the reaction zone. The mixture continues flowing through the absorbent device past the reactive zone and control zone. Unbound conjugate binds to the reagents in the control zone, producing a pink coloured band and demonstrates that the reagents are functioning correctly.

Reagents and materials provided

Before performing the test please review the contents of the kit first and read the instructions carefully.

• ThyroScreen™ test cassettes - wrapped in a foil pouch	20
• Disposable plastic pipettes :	20
• Diluent dropper containing 5 ml buffer diluent	1
• Instruction leaflet	1

Materials required but not provided

- Timer
- Lancets for finger prick sample
- Alcohol wipes
- Gauze pads and gloves

Reagents supplied separately

- **ThyroScreen™ Professional Control set**
A set of one positive and one negative control for quality control the system (see Quality Control section)

 PD11015 ThyroScreen™ Professional Control set - 2x0.25ml

Storage and stability

- The kit should be stored at room temperature (4 to 30°C). **Do not freeze the test kit**
- The kit is stable until the expiry date printed on the outer packaging and foil pouch
- Keep away from moisture, heat or direct sunlight
- The ThyroScreen™ Professional Control set should be stored at room temperature (4 to 30°C) and the controls are stable until the expiry date printed on the bottle labels. After reconstitution the controls should be stored at 2 to 4°C and used within 5 hours

Warnings and precautions

- This test is designed for *in vitro* diagnostic use and professional use only.
- Blood specimens may be potentially infectious. Avoid contact with skin by wearing gloves and protective clothing. Properly handle and discard all used test devices and blood specimens in an approved biohazard container.
- Wear protective clothing and disposable gloves while assaying samples.
- Do not eat or drink in the area where specimens and kit reagents are handled.
- Do not use the buffer or cassette after the expiration date printed on the bottle label and/or foil pouch.
- Do not mix devices and buffers from different batches.
- Test cassettes are single use only
- Do not use a test from a damaged protective wrapper.
- Test buffer contains a preservative that is a poison and maybe harmful if swallowed. Seek medical help if buffer is ingested
- Control material contains diluted human sera which have been tested and found negative for anti-HIV, anti-HCV and HBs antigen. However these products should be handled as if potentially infectious. The controls contain sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal flush with a large volume of water to prevent azide build up in the waste plumbing.

Quality Control

ThyroScreen™ Professional contains built-in quality control features. A pink coloured line in the zone marked 'Control' on the cassette should always be seen after the test is complete. It shows that sufficient volume of sample/buffer has been added and that proper flow has been obtained. If this line is missing the test was not run correctly or has failed to function correctly. Absence of the control line invalidates the test and the sample should be re-tested using a new cassette.

In addition to the built in control the manufacturer also recommends running positive and negative controls to validate the test procedure on a regular basis and with

- Each newly opened kit (20 tests)
- Each time a batch of kit changes
- Each new operator (person who has not run the test in 2 weeks)
- Monthly as a check on storage conditions
- Whenever problems are identified

The ThyroScreen™ Professional Control set provides a compatible positive and negative control that should be run in the same way as an unknown sample. If the controls do not give the expected positive or negative result, patient results are suspect and should not be reported. The test should be re-run and controls confirmed before further patient tests are performed.

If the test does not show a control line or test line in the cassette window, or the line is smudged or partially visible, the test cassette should be discarded. Do not report the results and then re-run the test with a new cassette and follow the procedure exactly. If the second test does not show the lines please contact our Technical Services on 0044 1306 644099 (9am to 5.30pm GMT)

Specimen Collection and preparation

The ThyroScreen™ Professional test can be performed with fresh human whole blood, plasma or serum. Whole blood samples should be tested immediately. Plasma and serum samples should be refrigerated immediately after collection and separation at 2-8°C and tested within 3 days. If the plasma or serum samples contain precipitates they may interfere with the test and should be removed. **Do not use heparinised plasma samples.**

To collect finger-stick blood:

1. Rub the chosen finger towards the tip and wipe the end of the finger with an alcohol pad
2. Let the finger dry thoroughly. Alcohol will affect the test
3. Stick finger tip with a lancet and wipe away the first drop of blood
4. Rub the finger towards the tip for a second drop
5. Draw sufficient for two drops of whole blood into the pipette making sure that there are no air bubbles trapped

Test procedure

1. Allow the ThyroScreen™ Professional test cassette and diluent to come to room temperature prior to testing.
2. Remove the cassette from the foil pouch by tearing along the side slot. Do not remove the desiccant pack and discard the pouch.
3. Label the cassette with the patient's name or control number.
4. Place the cassette on a hard flat surface with the window facing up.
5. Add 2 drops (50 µl) of whole blood directly into the well marked 'Sample' on the test cassette. Discard the pipette after use into a suitable waste container (see Picture A).
6. Add six (6) drops of test diluent (200 µl) into the Sample well on the test cassette using the dropper bottle (see Picture B).
7. Set a timer for 10 minutes. Do not move the cassette during this time
8. At the end of the 10 minutes read the line(s) in the window of the cassette. Do not move the cassette until you have read the result. Do not read results after 12 minutes



Picture A

Add 2 drops of whole blood in Sample well



Picture B

Add 6 drops of diluent in Sample well

Reading test results

Negative: One pink coloured line appears in the window near to the 'Control' mark. No coloured line near the 'Test' mark means the TSH level is below the cut-off level of 5µIU/ml, and the test is negative.

Positive: Two pink coloured lines appear; one near the 'Control' mark and the second near the 'Test' mark result, which means the TSH level is above the cut-off level of 5µIU/ml, and the test is positive.

Please note: In addition to the pink line by the 'Control' mark, ANY pink line seen near the 'Test' mark of the cassette at the 10 minute time is considered POSITIVE. The intensity of the line does not matter

Invalid: A pink coloured line should always appear near the 'Control' mark. If there is no pink coloured line near this mark the test is invalid even if a line appears near the 'Test' mark. Do not report the result. In this case the test should be repeated with a new cassette.



Negative



Positive



Invalid



Invalid

Reporting results

The results of this test should be reported to a doctor for individual interpretation and management of symptoms

Limitations of the test

1. Follow the instructions exactly
2. Running the test above or below normal room temperature (15-30°C) may affect the results. Ensure both cassette and diluent are at room temperature before running the test.
3. The blood sample must be dispensed immediately after filling the pipette. If blood is clotted collect a new sample and re-test.
4. ThyroScreen™ Professional is designed to show a positive result for TSH concentrations of 5 µIU/ml or higher with a range 4 to 6 µIU/ml.
5. TSH elevations have been reported concomitant to hyperthyroidism in patients with neoplasia of the pituitary.
6. Very rare cases of hypothyroidism with an associated low level of TSH or hyperthyroidism with an associated high level of TSH have been reported.

7. As with all screening assays, results should be considered presumptive until confirmed. Results obtained with this kit should be used only as a companion to other diagnostic procedures and information available to the doctor.
8. To avoid incorrect readings do not interpret the test result after 12 minutes
9. In early pregnancy, high level of TSH could be detected.
10. High levels of RF (Rheumatoid factor), HAMA (Human anti-mouse antibodies) or CRP (C-reactive protein) may give a false positive result with the test.

Performance characteristics

Sensitivity and Specificity

The analytical sensitivity of the ThyroScreen™ Professional test is 5 µIU/ml with a tolerance +/- 20% of the cut-off (4 µIU/ml to 6 µIU/ml).

A correlation study was performed on 289 pre-tested whole blood samples with the AXSYM analyser (Abbott Laboratories). Based on the results of this study ThyroScreen™ Professional shows the following performance specifications

Sensitivity	81.3%
Specificity	97.3%
Accuracy	95.5%

Interference data

Anticoagulants

Citrate and EDTA plasma do not interfere with this assay but heparin inhibits the detection method and so interferes strongly.

Hormones and substances

Hormones and commonly encountered substances were tested to demonstrate that these substances do not interfere with the test results.

No cross reaction was obtained with the following hormone concentrations

- HCG : 500 to 500,000 mIU/ml
- LH : 500 mIU/ml
- FSH : 250 mIU/ml

Table 1 : Results of potential interference from hormones

Hormone	References	Concentration	TSH Negative <5 µIU/ml	TSH Positive >5 µIU/ml
hCG	WHO 1st IRP	200,000 mIU/ml	Negative	Positive
FSH	WHO 2nd IRP	250 mIU/ml	Negative	Positive
LH	WHO 68/38	500 mIU/ml	Negative	Positive

Table 2 : Results of potential interference from common substances

Substances	Concentration	TSH -ve < 5 µIU/ml	TSH +ve > 5 µIU/ml
Acetaminophen	20 mg/dl	Negative	Positive
Acetylsalicylic 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
Tetracycline	20 mg/dl	Negative	Positive
Haemoglobin	1 mg/dl	Negative	Positive
Haematocrit Range	20 - 50	Negative	Positive

Literature

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Pathway Diagnostics Ltd

Curtis Road, Dorking, RH4 1EJ, UK

Tel: 0044 1306 644099

www.personaldiagnosics.co.uk

