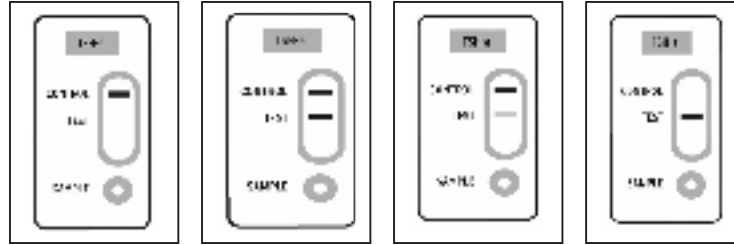


PLEASE NOTE: In addition to the pink/purple line by the Control mark **ANY PINK/PURPLE** line that is seen near the Test mark of the cassette at the 10-minute time is considered a positive result. The intensity of the line does not matter.



Negative

Positive

Positive

Invalid



Whole Blood One-Step Rapid TSH Assay for Hypothyroidism Screening in Adults

For Detection of TSH in Whole Blood:

For Professional Use

Manufactured for
ThyroTec, Inc.
1801 Horseshoe Pike, Suite 1
Honey Brook, PA 19344

Marketed by
Wampole Laboratories, LLC
2 Research Way
Princeton, NJ 08540

www.thyrottest.com

1020QR-C April 2005



**QUICK REFERENCE INSTRUCTIONS
FOR THYROTEST® TSH CASSETTE**

**For Detection of TSH in Whole Blood:
For Professional Use**

Whole Blood One-Step Rapid TSH Assay for Hypothyroidism Screening in Adults

The ThyroTest® one-step, rapid TSH assay for hypothyroidism screening in adults is a lateral flow chromatographic immunoassay for the qualitative determination of human thyroid stimulating hormone (TSH) in whole blood.

Before you start, review the contents of the kit first and read the instructions carefully and understand how to use this test before you begin. More detailed information is available in the package insert.

KIT STORAGE

- The test kit may be stored at room temperature (15 – 30°C; 60 – 86°F); **do not freeze.**
- Do not use the test cassette after the date printed on the foil pouch.
- Keep away from moisture, heat, or direct sunlight.

- Controls are stored at 15-30° C (60-86° F) and are stable until the expiration date on the vial. After opening, the vials should be used at room temperature. The stability after opening is 30 days.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Read instructions for use carefully before performing this test.
3. For professional use only.
4. Use only with finger stick blood drops using the pipette provided.
5. Blood specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and discard all used test devices in an approved biohazard container.
6. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch.
7. Test cassettes are single use only.
8. Test buffer and controls contain a preservative that is a poison and may be harmful if swallowed. Seek medical help if buffer is ingested.

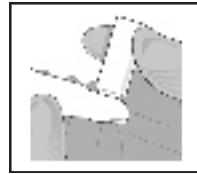
BLOOD COLLECTION

Each **ThyroTest**® is run with two drops of fresh whole blood. Samples should be tested immediately after collection into the pipette. If the blood appears to be clotted in the pipette, a new, fresh blood sample should be taken.

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 dry thoroughly. Alcohol will affect the test.
3. Stick finger tip with a lancet. Follow instructions for use. **(Picture A)**
4. Wipe away first drop of blood.
5. Rub the finger towards the tip for a second drop.
6. Hold the pipette flat and touch end of the pipette (included in the pouch) to the drop of blood. **(Picture B)**

7. Let blood fill to the line on the pipette. The pipette will fill to the line by itself.
8. It may be necessary to rub the finger for an additional drop of blood to fill to the line.



A



B

QUALITY CONTROL

If you are testing under CLIA waived status, the manufacturer recommends running Controls of each new lot. The Positive and Negative controls included in the kit should be run according to laboratory requirements. These controls should be run like an unknown sample. If the controls do not give expected results (Positive or Negative), patient results must not be reported, and the test should be re-run. It is recommended that the Controls be run with a minimum frequency, depending on number of tests run in the laboratory. Each laboratory should establish its own criteria (See package insert)

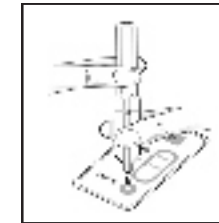
If the test does not show **any** (control or test) line in the window or a smudged or partial line, the test cassette should be discarded. Do not report the results. Run the test again with a new cassette and follow the procedure exactly. An invalid test may be caused by old or non-reactive cassette, not adding enough blood or buffer to the cassette, or not following directions. Use the Positive and Negative Controls in the kit and run the test again using a new cassette. If the second test does not show lines, please contact Wampole Technical Services at 800-257-9525.

TEST PROCEDURE

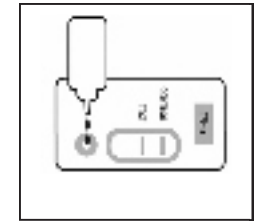
1. Remove the test cassette and pipette from the foil pouch by tearing at slot on the side of bag. Do not remove the desiccant pack. Discard the pouch.
2. Place the cassette on a hard flat surface with the window facing up.

3. Add 2 drops of whole blood directly into Sample well on the Test Cassette with the pipette provided in the pouch. Discard the pipette after use into a waste container when done. **(Picture A)**
4. Add six (6) drops of Test Buffer into the Sample well on the Test Cassette. **(Picture B)**
5. Set a timer for 10 minutes. Do NOT move the cassette during this time.
6. 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 checked the line(s). The test can be read up to 12 minutes.

IMPORTANT: Do not read after 12 minutes.



A



B

RESULTS

(see results pictures)

Negative: One pink/purple colored line appears in the oval window near the Control mark. No colored line near the Test mark means the TSH level is negative, and below the cut-off of 5 µIU/mL.

Positive: In addition to the pink/purple line by the Control mark, a second pink/purple colored line seen near the Test mark means the TSH level is positive, and above the cut-off of 5 µIU/mL.

Invalid: A pink/purple line should always appear near the Control mark. If there is no pink/purple line seen near the mark, the test is invalid. Do not report the result. In this case the test should be repeated with a new cassette or call Wampole Technical Services at 800-257-9525.