

**QUICK REFERENCE INSTRUCTIONS  
THYROCHEK<sup>®</sup> TSH Cassette**

**for invitro diagnostic use**

A certificate of CLIA waiver is required to perform the testing in a waived setting. If the laboratory does not have a Certificate of Waiver, the Application for Certification (Form CMS-116), can be obtained at <http://www.cms.hhs.gov/clia/>. The form should be mailed to the address of the local State Agency of the State in which the laboratory resides (<http://www.cms.hhs.gov/clia/ssa-map.asp>).

Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. If the laboratory modifies the instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be high complexity and subject to all CLIA requirements.

Read the package insert and Quality Control procedures completely before using the product. Follow the instructions carefully when performing a test.

**INTENDED USE**

THYROCHEK is a lateral flow chromatographic immunoassay for the qualitative determination of human thyroid stimulating hormone (TSH) in whole blood samples of ambulatory adults. This test is intended to detect TSH at concentrations > 5 mIU/L. It is intended for use by medical professionals to screen an ambulatory adult population for primary hypothyroidism. It is not indicated for use screening neonates for hypothyroidism.

**STORAGE AND STABILITY**

1. The test kit may be stored at room temperature 15-30°C/ 60-86°F. **Do not freeze.**
2. Do not use the test cassette after the date printed on the foil pouch.
3. Keep away from moisture, heat or direct sunlight.
4. THYROCHEK TSH Controls are stored at 15-30°C/ 60-86°F and are stable until the expiration date on the vial. The stability after opening is 30 days, when stored at room temperature.

**WARNINGS AND PRECAUTIONS**

**CLINICAL:**

1. For *in vitro* diagnostic use.
2. A positive test must be confirmed using a quantitative laboratory TSH assay.
3. For professional use only.
4. Clinical judgment is necessary for interpreting the test results.
5. No treatment should be given based upon this qualitative TSH test result nor should any condition or treatment be monitored using this qualitative TSH test result.
6. False positive results can occur due to heterophilic (unusual) antibodies, and certain clinical conditions such as central hypothyroidism, TSH secreting tumors or thyroid hormone resistance.
7. A negative result does not rule out hypothyroidism as TSH > 5 mIU/L is not seen in secondary or tertiary hypothyroidism.
8. Test results can not be used to determine hyperthyroidism.

**TECHNICAL:**

1. 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.
2. Do not use test cassettes if foil pouches are opened or defective.
3. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch.
4. Test cassettes are single use only.
5. Adding sample and buffer to the wrong port will result in an incorrect result.
6. Test buffer contains sodium azide as preservative that is a poison and may be harmful if swallowed. Seek medical help if buffer is swallowed.
7. The control material has been found to be non-reactive for Hepatitis-B surface antigen. However, this product should be handled as potentially infectious. The controls contain sodium azide, which 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.
8. Persons must be tested for colorblindness before performing the test.

### **QUALITY CONTROL**

If you are testing under CLIA waived status, the manufacturer recommends running Controls for each new lot.

- Each new lot
- Each new shipment (even if from the same lot previously received)
- Each new operator (an individual who has not run the tests for at least two weeks)
- Monthly, as a continued check on storage conditions
- Whenever problems (storage, operator, or other) are identified
- Or other times as required by your laboratory's standard QC procedures.

The positive and negative controls available from the manufacturer 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 and Negative), patient results must **not** be reported, and the test should be re-run.

If the test does **not** show any lines in the rectangular results 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 old or non-reactive cassette may cause an invalid test, by not adding enough blood or buffer to the cassette, or not following directions. Use the Positive and Negative Controls and run the test again using a new cassette. If the second test does not show lines, please contact THYROCHEK Technical Services at 647-477- 5672.

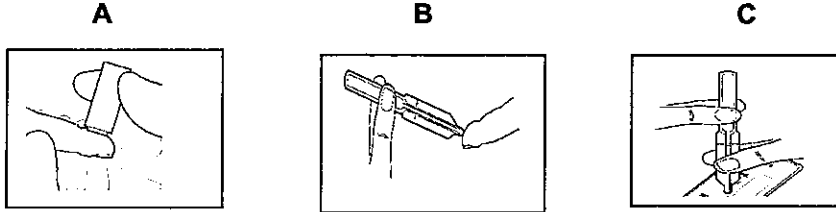
### **SPECIMEN COLLECTION AND PREPARATION**

Each THYROCHEK is run on one drop of fresh whole blood. Samples should be tested immediately after collection in 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. **One drop of whole blood** (50  $\mu$ L) is required to perform the test.
4. Stick fingertip with a lancet. Follow instructions for use. **(Picture A)**
5. Wipe away first drop of blood.

6. Rub the finger towards the tip for a second drop. **NOTE:** It is important that the second drop be used to avoid potential interference from the alcohol.
7. Hold the pipette flat and touch end of the pipette (included in the pouch) to the drop of blood. **(Picture B)**
8. Let blood fill to the line on the pipette, **(Picture C)** making sure that there are no air bubbles or empty spaces or gaps in the specimen. If air bubbles or empty spaces or gaps are present, collect another sample. The pipette will fill to the line by itself.
9. It may be necessary to rub the finger for an additional drop of blood to fill to the line.



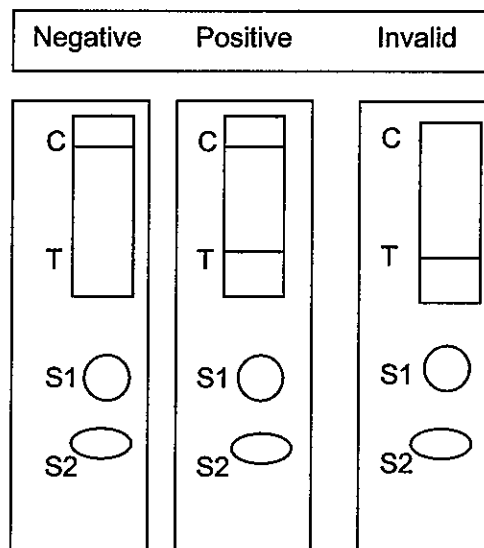
### TEST PROCEDURE

1. Remove the test cassette and pipette from the foil pouch by tearing at the notch at the corner of the pouch.
2. Place the cassette on a hard flat surface with the windows facing up.
3. Add **one drop** of whole blood directly into the circular specimen well **S1** located in the middle of the lower portion of the cassette with the pipette provided in the pouch. Discard the pipette after use into a waste container when done.
4. Set timer and wait for **90 seconds** before proceeding.
5. Add **4 drops** of the buffer into the oval buffer well **S2** located at the bottom of the cassette.
6. Set timer for **10 minutes**. Do not move the cassette during this time.
7. At the end of 10 minutes, read the line(s) in the rectangular results window of the cassette. Do not move the cassette until you have checked the lines. Do not read results after 15 minutes.

### READING TEST RESULTS

**Negative:** One pink line appears at C. There is no other pink colored line at T in the rectangular window. A negative result means that the TSH level is below the cut-off level of 5 m IU/L.

**Positive:** Two pink lines appear. One pink line appears at C, and one pink line at T in the rectangular window. A positive result means the TSH level is above the cut-off level of 5 m IU/L.



**Important:** Any pink line that is seen at T on the cassette at the 10-minute time is considered a positive result. The intensity or the width of the line does not matter.

**Invalid:** A pink line should always appear at C. If there is no pink line seen near C, the test is invalid. Do not report the result. In this case, the test should be repeated with a new cassette or call (647) 477-5672.



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