

QUICK REFERENCE INSTRUCTIONS

THYROCHEK[®] TSH Cassette

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.

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.

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

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.

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 judgement 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 > 5mIU/L is not seen as 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 appropriate biohazard container.
2. Do not use test cassettes if foil pouches are open or defective.
3. Do not use the buffer or cassette after the expiration date printed on the outside label of the 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 and controls contains sodium azide as a preservative that is a poison and may be harmful if swallowed. Seek medical help if either is swallowed.
7. 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.

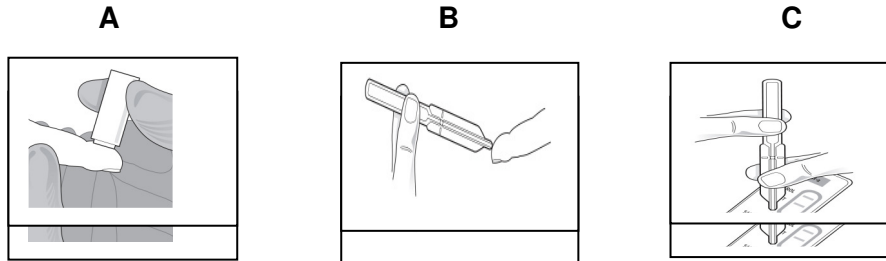
If the test does **not** show any lines in the rectangular results window or a smudged or partial line, the test cassette should be discarded. Do **not** report the results. Run the test again with a new cassette and follow the procedure exactly. An old or non-reactive cassette may cause an invalid test, 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 toward the tip and wipe the end of the finger with an alcohol pad.
2. Let it dry thoroughly as alcohol will affect the test.
3. Stick the fingertip with a lancet. (See a. Below) Follow instructions for use in package insert.
4. Wipe away the first drop of blood.

5. Rub the finger towards the tip for a second drop.
 6. Hold the pipette flat, parallel to the drop of blood and touch end of pipette included in the pouch to the drop of blood. (See b. Below) Follow instructions for use in package insert.
 7. Let blood fill to the line on the pipette.(See c. Below) The pipette will fill to the line by itself.
1. It may be necessary to rub the finger for an additional drop of blood to fill to the line.



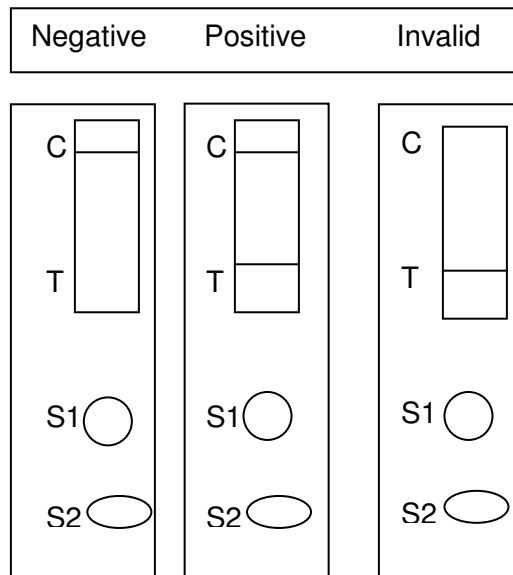
TEST PROCEDURE

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 318-227-4994.

To Order Contact:

American Screening Corporation

6658 Youree Dr Ste 180 PMB 404

Shreveport, LA 71105

Ph: 318-227-4994 * Fax:318-227-4996

Toll Free: 1-866-526-2873

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