

THYROCHEK[®]

Quick Reference Instructions

A certificate of 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 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 (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.

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 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 cannot 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, a preservative that is a poison and may be harmful if swallowed. Seek medical help if buffer is swallowed.
7. Persons performing the test must be tested for colorblindness before performing the test.

QUALITY CONTROL

If you are testing under CLIA-waived status, the manufacturer recommends running controls:

- Each new lot
- Each new shipment (even if from the same lot previously received)
- Each new operator (an individual who was 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
- Other times as required by your laboratory's standard QC procedures.

A set of positive and negative ThyroChek TSH Controls may be included in this kit or can be ordered from CLIAwaived, Inc. For ordering information, please visit www.cliawaived.com.

The positive and negative controls should be run according to laboratory requirements. These controls should be run like an unknown sample. If the 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 testing should be re-run.

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 procedures exactly. If the second test does not show lines, please contact Technical Services at 1-888-882-7739.

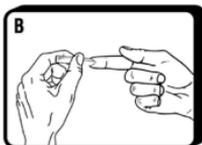
SPECIMEN COLLECTION AND PREPARATION

Each ThyroChek TSH is run on one drop 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. If the fresh whole blood is from a venous collection, use the sample immediately and discharge after use.

TO COLLECT FINGER-STICK BLOOD:



1. Rub the chosen finger toward the tip and wipe the end of the finger with an alcohol pad.

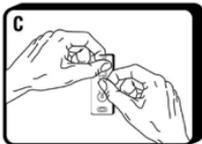


2. Let dry thoroughly. Alcohol will affect the test.

3. One drop of whole blood (50 µL) is required to perform the test.

4. Stick fingertip with lancet. Follow instructions for use.

(See Picture A.)



5. Wipe away first blood drop.

6. Rub the finger toward the tip for a second drop.

NOTE: It is important to use the second drop to avoid potential interference from the alcohol.

7. Hold the pipette flat and touch end of pipette (included in pouch) to the drop of blood. (See Picture B.)

8. Let the blood fill to the line on the pipette, making sure that there are no air bubbles, empty spaces or gaps in the specimen. If air bubbles, empty spaces or gaps are present, collect another sample. The pipette will fill to the line by itself.

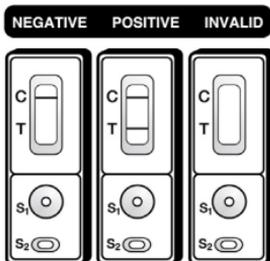
9. It may be necessary to rub the finger for an additional drop of blood to fill the line.

TEST PROCEDURE

1. Remove the test cassette and pipette from the foil pouch by tearing at 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. (See Picture C.) Discard the pipette into a waste container after use.

4. Set timer and wait for **90 seconds** before proceeding.
5. Add **four full 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 RESULT:

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

POSITIVE RESULT:

Two pink lines appear in the rectangular result window. (One pink line appears at C and one pink line appears at T.) A positive result means that the TSH level is above the cut-off level of 5 mIU/L.

IMPORTANT: In addition to the pink line by the control mark, **ANY** 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.

PLEASE NOTE: Do not read after 15 minutes.

INVALID RESULT:

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 1-858-481-5031 for ThyroChek Technical Services.

THYROCHEK®

EC REP

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