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Persons performing the test must be tested for colorblindness before performing the test.

QUALITY CONTROL
The Thyrocheck contains built-in quality control features. A pink line in the Control Zone should always be seen. It shows: (1) that enough volume is added and (2) that proper flow is obtained. If this line is missing, the test was not run correctly or it failed to function correctly. The test is invalid, and testing should be repeated using a new cassette. 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 conditions)
• 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 procedure.

A set of positive and negative CLIAwaived, Inc. TSH Controls is available 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 on an uninterrupted basis. 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. For any other concerns regarding Thyrocheck, please call 1-888-461-5031, Monday – Friday, from 8 a.m. to 5 p.m. Pacific Standard Time (PST).

SPECIMEN COLLECTION AND PREPARATION

1. Draw venous whole blood sample into syringe or vacuum collection tube containing heparin as an anticoagulant.
2. Clot the blood sample and let it stand at room temperature for one hour before running the test.
3. Set timer and wait for 90 seconds before proceeding.
4. Add four full drops of the buffer into the Specimen well S located at the bottom of the cassette. The buffer provided is a poison and may be harmful if swallowed. Seek medical help if buffer is swallowed.
5. Perform the test as described below.
6. Discard the pipette and buffer container.

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 Specimen well S, located at the bottom of the cassette, with the pipette provided. (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 Specimen well S located at the bottom of the cassette.
6. Set timer for 10 minutes. Do not move the cassette during this time.
7. Make sure that the line is visible. If the blood appears to be clotted in the pipette, a new, fresh blood sample should be taken. If the fresh blood is from a veinous collection, use the sample immediately and discard after use.

Each Thyrocheck is run with fresh whole blood. Samples should be tested immediately after collection if the blood appears to be clotted in the pipette. If the blood appears to be clotted in the pipette, a new, fresh blood sample should be taken. If the fresh blood is from a veinous collection, use the sample immediately and discard 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 fingerlip with lancet. Follow instructions for use. (See Picture A.)
5. Wipe away first drop of blood.
6. Rub the finger tip toward 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 to the line by itself. If the control line is missing, the test was not run correctly or it failed to function correctly. The test is invalid, and testing should be repeated using a new cassette.
8. 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.
9. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch. Each CTTRTC is run with fresh whole blood.
10. If you are testing under CLIA-waived status, the manufacturer recommends running controls:

I. Each new operator (an individual who was not run the tests for at least two conditions)
II. Monthly, as a continued check on storage conditions
III. Whenever problems (storage, operator or other) are identified
IV. Other times as required by your laboratory’s standard QC procedure.
V. Each new lot
VI. Each new shipment (even if from the same lot previously received)
VII. Each new operator (an individual who was not run the tests for at least two conditions)
VIII. Whenever problems (storage, operator or other) are identified
IX. Other times as required by your laboratory’s standard QC procedure.

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