

Thyroid Test Rapid TSH Cassette (Whole Blood)

Procedure Card (See back for quick start guide)



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P.N.: AT-THYROCHEK-120-A-KIT Rev.: C: CLIA WAIVED for USE in WAIVED and COMPLEX Labs

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Made in the U.S.A.

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.

Test Procedure

- 1. Remove buffer bottle from test kit.
- **2.** Remove the test cassette and pipette from the foil pouch by tearing at notch at the corner of the pouch.
- **3.** Place the cassette on a hard flat surface with the windows facing up.
- **4.** Add **one drop** of whole blood directly into the circular specimen well **S**, located in the lower portion of the cassette, with the pipette provided in the pouch. Discard the pipette into an appropriate waste container after use.
- **5.** Set timer and wait for **90 seconds** before proceeding.
- **6.** Add four full drops of the buffer into the the circular specimen well **S**, located at the bottom of the cassette.
- **7.** Set timer for **10 minutes**. Do not move the cassette during this time.
- **8.** 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 mlU/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 mlU/L.

NEGATIVE POSITIVE INVALID

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 1-888-882-7739 for CLIAwaived, Inc. Technical Services.

