A study was conducted at three geographical sites demonstrating minimal among-site variability. Suspect primary hypothyroidism. Suspect primary hypothyroidism. Suspect primary hypothyroidism. Suspect primary hypothyroidism.


Shome, B. and Parlow, A.F. "Human Follicle Stimulating Hormone (hFSH): First proposal for the amino acid sequence of the alpha subunit (hFSH alfa) and first demonstration of its identity and with the alpha subunit of human luteinizing hormone (hLH) ," Endocrinology, 95 (1974) 336-342.


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5. Shome, B. and parlow, A.F. "Human Follicle Stimulating Hormone (hFSH): First proposal for the amino acid sequence of the alpha subunit (hFSH alfa) and first demonstration of its identity and with the alpha subunit of human luteinizing hormone (hLH)," Endocrinology, 95 (1974): 336-342.


8. Shome, B. and parlow, A.F. "Human Follicle Stimulating Hormone (hFSH): First proposal for the amino acid sequence of the alpha subunit (hFSH alfa) and first demonstration of its identity and with the alpha subunit of human luteinizing hormone (hLH) ," Endocrinology, 95 (1974) 336-342.


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

QUALITY CONTROL

The CTTRTC contains built-in quality control 
features. A pink line in the Control Zone should 
avways 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 
fails 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 lot new
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 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 not be run in an unknown 
condition. If the controls do not give expected results 
(positive or negative), patient results must not be 
reported, and the testing should be re-run.

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.

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 CTTRTC, please call 
1-888-481-5031. Monday – Friday 8 a.m. to 
5 p.m. Pacific Standard Time (PST).

SPECIMEN COLLECTION AND 
PREPARATION

1. Draw venous whole blood sample into syringe 
and the NACB guidelines for 
thyroid testing.
2. Do not use test cassettes if foil 
pouches are
8. Test results cannot be used to determine
2. Running the test at temperatures below or 
above room temperature (15°- 30°C, 60°- 
86°F) may affect the results. Make sure the 
buffer and cassette are at room temperature 
before running the test.
3. The blood sample must be dispensed 
immEDIATELY after filling the pipette. If the 
blood is clotted, collect a new sample and re-test.
4. TSH elevations have been reported concomitant 
to hypothyroidism in patients with neoplasia of 
the pituitary.
5. As with all screening assays, results should be 
considered presumptive until confirmed. Results 
based on these tests should be used only as a 
comparison to other diagnostic procedures and 
information available to the physician.
6. To avoid incorrect readings, do not interpret 
the results after 15 minutes.
7. Check the expiration date. If the test kit is 
expired, do not use the test cassette.

TEST PROCEDURE

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

POSITIVE RESULT:
Two pink lines appear in the rectangular result window. (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 area, there is a small pink line in the assay area. This is normal and does not affect the 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 Technical Services.

REPORTING RESULTS
Test results should be reported to a physician for individual interpretation and symptom management.

DISCARD USED MATERIALS
After the test is completed, discard all used materials in the appropriate waste container.

LIMITATIONS OF THE TEST
1. Follow the directions exactly.
2. Running the test at temperatures below or 
above room temperature (15°- 30°C, 60°- 
86°F) may affect the results. Make sure the 
buffer and cassette are at room temperature 
before running the test.
3. The blood sample must be dispensed 
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