A correlation study was performed using 240 elevated TSH and normal TSH blood specimens assayed with the ThyroCheck test and a commercially available 2nd or 3rd generation TSH assay kit. The reference range for serum TSH concentration in normal subjects averaged 0.5 to 5.0 mIU/L (Daniel, 1976). The TSH levels in normal subjects varied based upon the subject’s age and sex. The TSH normal values for men were higher than for women by a factor of 2 to 3. The TSH values in normal subjects are also dependent on the time of day and the subject’s physical condition. The interassay and intraassay coefficients of variation were 10% to 15% at a concentration of 0.2 to 10 mIU/L. At cutoff level of 5 mlU/L +/- < 10% = 96.9% or higher. The sensitivity of the test was 100% from different lots. The specificity of the test was 100%. At cutoff level >5 mlU/mL TSH Positive. Other hormones and commonly found substances were tested to show that these substances do not interfere with TSH determination.

**BIBLIOGRAPHY**


**INTERVENTED USE**

The ThyroCheck whole blood, rapid TSH assay is a visual, non-instrumented, qualitative, solid-phase, lateral flow, two-site immunochromatographic assay for identifying capillary or venous blood samples that contain TSH >5 microIU/mL. The test is intended for use as an in-vitro diagnostic device by medical professionals to screen for primary hypothyroidism. It is not intended for use as a screening method for neonatal hypothyroidism.

**REAGENTS AND MATERIALS PROVIDED**

Before you start, review the contents of the kit and read the instructions carefully. The Test Cassette (20 each)–An absorbent membrane cassette individually wrapped in foil pouch, containing a plastic pledget for blood sample. The waivered test cassette after the date printed on the foil pouch. Keep away from moisture, heat or direct sunlight. The thyroid stimulating hormone (TSH), or thyrotropin, is the primary regulator of the functional state of the thyroid gland. Its production and release is stimulated by the hypothalamic thyrotropin-releasing hormone (TSH-RH) and is controlled by levels of the thyroid hormones (thyroxine and triiodothyronine) at the pituitary gland and possibly by other hormones. A positive TSH value and direct determination of serum TSH levels are considered in cases of primary hypothyroidism. The diagnosis of hypothyroidism is made by finding a low total or free T4 level. The TSH level is confirmed by a raised TSH level. Mild primary hypothyroidism may be more difficult to diagnose by just measuring the level of both T3 and free T4, because the reference and free T4 value can sometimes be within the normal range. In these cases, TSH assays are useful for diagnosis since the levels of TSH are raised in hypothyroidism, levels of T3 and T4 are raised and TSH level is reduced.

**SUMMARY AND EXPLANATION OF TEST**

Thyroid stimulating hormone (TSH), or thyrotropin, is the primary regulator of the functional state of the thyroid gland. Its production and release is stimulated by the hypothalamic thyrotropin-releasing hormone (TSH-RH) and is controlled by levels of the thyroid hormones (thyroxine and triiodothyronine) at the pituitary gland and possibly by other hormones. A positive TSH value and direct determination of serum TSH levels are considered in cases of primary hypothyroidism. The diagnosis of hypothyroidism is made by finding a low total or free T4 level. The TSH level is confirmed by a raised TSH level. Mild primary hypothyroidism may be more difficult to diagnose by just measuring the level of both T3 and free T4, because the reference and free T4 value can sometimes be within the normal range. In these cases, TSH assays are useful for diagnosis since the levels of TSH are raised in hypothyroidism, levels of T3 and T4 are raised and TSH level is reduced.

**STORAGE AND STABILITY**

The test kit may be stored at room temperature (15-30°C, 60-80°F). Do not freeze. The Buffer Diluent (which may be received at room temperature) should be stored refrigerated (36-46 °F, as labeled) when not in use. Do not use the test cassette after the date printed on the foil pouch. Keep away from moisture, heat or direct sunlight.

**REQUIRED MATERIALS NOT PROVIDED**

- Timer
- Gloves
- Alcohol wipes
- Gloves
- Priced and negative controls (1 serl)
There is no single level of serum TSH at which clinical action is always either indicated or contraindicated. The higher the TSH, the more compelling is the rationale for treatment. It is important to consider the individual clinical context (e.g., pregnancy, elderly, renal insufficiency, use of antibiotics).”


For further information, please refer to the American Thyroid Association at www.thyroid.org and the NACB guidelines for thyroid testing available at www.nacb.org.

WARNINGS AND PRECAUTIONS

CLINICAL:
1. For in vitro diagnostic use.
2. A positive test must be confirmed using a qualitative 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 or other conditions such as central hypothyroidism, TSH-secreting tumors or thyroid hormone resistance.
7. A negative result does not rule out hypothyroidism as TSH is >5 mIU/L is not seen in secondary or tertiary hyperthyroidism.
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.

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

SPECIMEN COLLECTION AND PREPARATION

Each ThyroChek TSH test 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. It is the test and quality control must 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
• 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 can be ordered from CLIAwaxed.com. For ordering information, please visit www.cliawaxed.com.

The positive and negative controls should be run according to the CLIA requirements. These 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 run in compliance with those regulations. Each laboratory or testing site using the ThyroChek must have a CLIA Certificate of Waiver. Call your state health department for an application form.

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 lines (in the rectangular result window) in the test cassette. Do not move the cassette until you have checked the lines. Do not read results after 15 minutes.

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 is visible to the pink line by the control mark, ANY line that is seen near test C and the TSH level is above the cut-off level of 5 mUL.

If no line is visible to the pink line by the control mark, ANY line that is seen near the Test C mark of the test at the 10-minute time is considered a positive test. 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 visible 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, all discarded materials are to be handled as a biological waste container.

LIMITATIONS OF THE TEST

Follow these exceptions exactly:
2. Running the test at temperatures below or above room temperature (15°- 30°C, 60°- 86°F) will affect the results. Make sure the buffer and cassette are at room temperature before running the test.
3. The blood sample must be dispersed immediately after filling the pipette. If blood is clotted, collect a new sample and re-test.
4. TSH elevations have been reported concomitant to hyperthyroidism in patients with neoplasia of the pituitary.

As with all screening assays, results should be considered presumptive until confirmed. Results obtained from this kit should be used in conjunction with the companion 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.

To COLLECT HEPARINIZED VENOUS BLOOD:
.Use within 5 minutes
1. Draw venous whole blood sample into syringe or a vacuum collection tube containing heparin as an anticoagulant.
2. Remove tube cap and touch end of pipette (included in pouch) to the drop of blood. (See Picture B.)
3. 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.
4. It may be necessary to rub the finger for an additional drop of blood to fill the line.

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 result.
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 drop of blood.
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.