

**ThyroChek® NeoNatal**  
**TSH Whole Blood One-Step Rapid TSH Assay for**  
**Hypothyroidism Screening in Neonates**  
*for invitro diagnostic use*

**For Professional Use**

**INTENDED USE**

**ThyroChek® NeoNatal** one-step, rapid TSH assay for hypothyroidism screening in neonates is a lateral flow chromatographic immunoassay for the qualitative determination of human thyroid stimulating hormone (TSH) in whole blood.

**REAGENTS AND MATERIALS PROVIDED**

Before you start, review the contents of the kit first and read the instructions carefully.

- Test Cassette – 20 each – An absorbent membrane cassette individually wrapped in foil pouch, containing a plastic pipette for blood sample.
- Dropper Bottle – 6 mL – containing Buffer Diluent.
- Positive Control – 1 each 0.5 mL – Positive TSH serum for quality control testing of the system (See Quality Control Section).
- Negative Control – 1 each 0.5 mL– Negative TSH serum for quality control testing of the system (see Quality Control Section).

**ThyroChek® NeoNatal** Controls are prepared using human serum with purified human TSH added to achieve the desired concentration levels.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
- Alcohol wipes
- Lancets
- External Controls (optional)

**STORAGE AND STABILITY**

- The test kit may be stored at room temperature (15 – 30°C; 60 – 86°F); **do not freeze.**
- Do not use the test cassette after the date printed on the foil pouch.
- Keep away from moisture, heat, or direct sunlight.

**ThyroChek® NeoNatal** Controls are stored at 15-30° C (60-86° F) and are stable until the expiration date on the vial. After opening, the vials should be used at room temperature. The stability of TSH Controls after opening is 30 days.

**SUMMARY AND EXPLANATION OF THE 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 (TRH) and is controlled by levels of the thyroid hormones (thyroxine and triiodothyronine) at the pituitary gland and possibly the hypothalamus. Neonatal

also known as congenital hypothyroidism may be due to several etiologies: Thyroid dysgenesis, including aplasia or hypoplasia of the thyroid gland; and ectopy of the thyroid, often with hypoplasia, in which there is insufficient tissue to match the demands of the infant or growing child. Dyshormonogenesis, a serious error in thyroid hormone synthesis. There may also be end organ unresponsiveness, defects in the receptors on the thyroid or at the peripheral tissue level. Hypopituitarism (secondary hypothyroidism) due to pituitary aplasia or midline brain developmental defects. There may also be hypothalamic dysfunction (tertiary hypothyroidism).

## **WARNINGS AND PRECAUTIONS**

1. For *in vitro* diagnostic use.
2. Read instructions for use carefully before performing this test.
3. For professional use only.
4. Use with heel stick whole blood using the pipette provided.
5. 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.
6. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch.
7. Test cassettes are single use only.
8. Test buffer contains a preservative that is a poison and may be harmful if swallowed. Seek medical help if buffer is ingested.
9. The control material has been found to be non-reactive for Hepatitis-B surface antigen. However, this product should be handled as potentially infectious. The controls contain sodium azide, which may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

## **QUALITY CONTROL**

**ThyroChek® NeoNatal** contains built-in quality control features. A pink line in the Control Zone should always be seen and shows: 1) that enough volume is added, 2) that proper flow is obtained, and 3) that the antibody is reactive. If this line is missing, the test was not run correctly or failed to function correctly. The test is invalid and the test should be repeated using a new cassette. Quality control standards are available for the validation of device functionality from commercial sources.

The manufacturer recommends running Controls for each new lot. However, Controls should be run with a minimum frequency, depending on number of tests run in the laboratory. Each laboratory should establish it's own criteria based on the following parameters:

- Each new lot
- Each newly opened kit (20 tests)
- Each new shipment (even if from the same lot previously received)
- Each new operator (an individual who has 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
- Or other times as required by your laboratory's standard QC procedures.

The Positive and Negative controls included in the kit should be run according to laboratory 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 test should be re-run. If other commercial controls are preferred, it is recommended that a mid to high (positive) and a low (negative) control be run with a minimum frequency, depending on number of tests run in the laboratory. Quality control standards are available for the validation of device functionality from commercial sources, such as BioRad or call **ThyroChek** customer service (647 477 5672) for recommended controls.

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 procedure exactly. If the second test does not show lines, please contact Technical Services at 647 477 5672.

### **SPECIMEN COLLECTION AND PREPARATION**

**ThyroChek® NeoNatal** is run with one drop of fresh whole blood from a heel stick. Samples should be tested immediately after collection in the pipette. If the blood appears to be clotted in the pipette, a new, fresh blood sample should be taken.

#### **To collect heel-stick blood:**

1. Choose a puncture site. Do not use a previous puncture site.
2. Clean the heel site if it appears unclean.
3. If an alcohol swab is used, let the site dry before collecting blood.
4. Stick puncture site with a lancet.
5. Wipe away first drop of blood.
6. Hold the pipette flat and touch end of the pipette (included in the pouch) to the drop of blood. The pipette will fill to the line by itself.
7. It may be necessary to gently pump the heel for an additional drop of blood to fill to the line.
8. Apply digital pressure with a gauze or cotton swab to puncture site if bleeding continues after procedure.

### **TEST PROCEDURE**

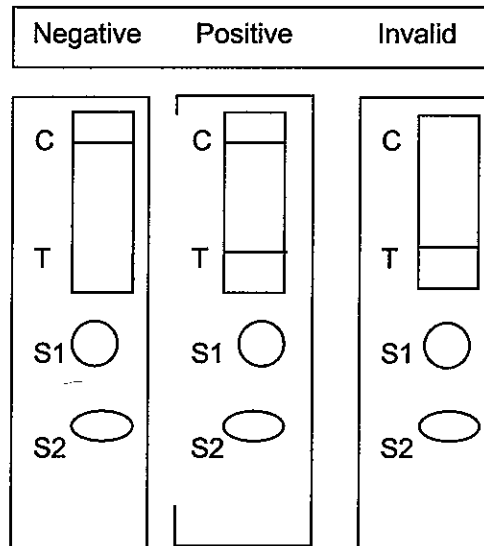
1. Remove the test cassette and pipette from the foil pouch by tearing at notch at the corner of the pouch.
2. Place the cassette on a hard flat surface with the windows facing up.
3. Add **one drop** of whole blood directly into the circular specimen **well S1** located in the middle of the lower portion of the cassette with the pipette provided in the pouch. Discard the pipette after use into a waste container when done.
4. Set timer and wait for **90 seconds** before proceeding.
5. Add **4 full drops** of the Buffer into the oval buffer **well S2** located at the bottom of the cassette.

- Set timer for **10 minutes**. Do not move the cassette during this time.
- 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.

### INTERPRETATION OF RESULTS

**Negative:** One pink line appears at C. There is no other 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 20 mIU/L.

**Positive:** Two pink lines appear. One pink line appears at C and one pink line at T in the rectangular result window. A positive result means the TSH level is above the cut-off level of 20 mIU/L.



**Invalid:** 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 647 477 65672 for **ThyroChek** technical services.

**Important:** Any pink line that is seen at T on the cassette at the 10-minute time is considered a positive result. The intensity or the width of the line does not matter.

**IMPORTANT: Do not read after 15 minutes.**

**PLEASE NOTE:** 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.

### REPORTING RESULTS

The results of this test should be reported to a physician for individual interpretation and managing the symptoms.

### LIMITATIONS OF THE TEST

- Follow the directions exactly.
- 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.
- The blood sample must be dispensed immediately after filling the pipette. If blood is clotted, collect a new sample and re-test.

4. As with all screening assays, results should be considered presumptive until confirmed. Results obtained from this kit should be used only as an adjunct to other diagnostic procedures and information available to the physician.
5. To avoid incorrect readings, do not interpret the test results after 15 minutes.
6. Check the expiration date and if the test kit is expired, do not use the test cassette(s).

**EXPECTED NORMAL VALUES**

Each laboratory must establish its own normal ranges based upon patient populations. The results provided below are based on a limited number of random normal neonatal blood specimens: neonatal hypothyroidism > 20 mIU /L TSH.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity**

The analytical sensitivity of the test is 20 mIU/L TSH

**Accuracy**

The accuracy of the test was calculated by qualitatively determining the recovery of known amounts of thyroid stimulating hormone added to patient pools. In each case, the test correctly identified the level of TSH as either over or under the cutoff value for the test.

Concentration Added (mIU/L)	Expected Result	Observed Result
0.0	-	-
2.0	-	-
10.0	-	-
20.0	+	+
25.0	+	+

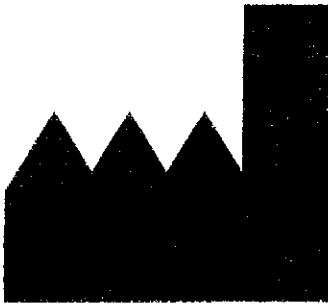
**Specificity**

Other hormones and commonly found substances were tested to show that these substances do not interfere with **ThyroChek® NeoNatal** results.

Substance	References	Concentration	TSH Negative <5 mIU/L	TSH Positive >5 mIU/L
HCG	WHO 1 <sup>st</sup> IRP	200,000 mIU/mL	Negative	Positive
FSH	WHO 2 <sup>nd</sup> IRP HMG	2,000 mIU/mL	Negative	Positive
LH	WHO 68/40	500 mIU/mL	Negative	Positive

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