TSH Control
Package Insert

【INTENDED USE】

The TSH Control is designed to monitor and validate the performance of TSH Rapid Test. It is intended to be used by healthcare professionals as an “External Quality Control” part of a quality control system.

【SUMMARY AND EXPLANATION】

The **POSITIVE CONTROL** contains freeze-dried powder of TSH antigen. The **NEGATIVE CONTROL** contains no detectable TSH antigen.

【REAGENT】

The **POSITIVE CONTROL** contains freeze-dried powder of TSH positive and some Proclin 300 as the preservative.

The **NEGATIVE CONTROL** contains TSH negative and some Proclin 300 as the preservative.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the tests are handled.
3. Handle all specimens/controls as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens/controls.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens /controls are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can affect results.
7. Please read the entire package insert before processing the control test.

【STORAGE AND STABILITY】

Unopened:

The controls are stable until the expiration date when stored at 2 to 30°C.

Opened:

Undissolved: The controls are stable for 1 week at 2 to 30°C.

Dissolved: The dissolved controls are stable for 1 day at 2 to 8°C.

Notice: Do not repeat freezing and thawing, the best result will be obtained if the control was performed immediately after opened.

【PREPARATION OF THE CONTROL SOLUTION】

Allow the test, controls to reach room temperature (15-30°C) prior to testing.

Open the cap of the POSITIVE CONTROL tube, add 0.5ml water or 1×PBS into the tube, then close the cap and mix the solution well.

The NEGATIVE CONTROL can be used directly.

【DIRECTION FOR USE】

Allow the test, control to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface, and then open the cap of POSITIVE CONTROL or NEGATIVE CONTROL tube.
   Use a pipette or a dropper to transfer **3 drops of POSITIVE CONTROL or NEGATIVE CONTROL** (approximately 75μL) to the specimen well of test cassette and start the timer.
3. Wait for the colored line(s) to appear. Read test results at the designated read time specified in the package insert.

【EXPECTED RESULTS】

The POSITIVE CONTROL must test positive on the test, the NEGATIVE CONTROL must test negative on the test.

An invalid result indicates either the assay was not performed correctly or the reagents were not working properly. If an invalid result occurs, re-test the control sample using a new test unit. If the problem persists, please contact with local distributor.

【LIMITATIONS】

1. The POSITIVE CONTROL and NEGATIVE CONTROL in the TSH Control Set are qualitative reagents and are not to be used as quantitative calibrators.
2. This control can only be used to validate the performance of TSH Rapid Test Manufactured provided. Consult test manufacturer’s instructions when using this control.

Number:
Effective date: