

# TSH Control

## Package Insert

### 【INTENDED USE】

The TSH Control is a powder which contains **POSITIVE CONTROL** that used as the “External Quality Control” for Rapid Test.

The TSH Control is a liquid which contains **NEGATIVE CONTROL** that used as the “External Quality Control” for Rapid Test.

### 【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 specimens and kits are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
4. The used test should be discarded according to local regulations.
5. Humidity and temperature can adversely affect results.

### 【STORAGE AND STABILITY】

The positive and negative control could be stored at room temperature or refrigerated (2-30°C) for 24 months. If the positive powder was dissolved, keep storing the positive control solution at 2-8°C for 1 day.

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

### 【PREPARATION OF THE CONTROL SOLUTION】

Open the cap of the positive control tube, add 0.5ml water or 1xPBS 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, then open the cap of **POSITIVE CONTROL** or **NEGATIVE CONTROL** tube.  
Hold the dropper vertically and 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 results at 10 minutes.
- 4 The results should be **POSITIVE** or **NEGATIVE** at the reading time.

Number: R1006000  
Effective date: