

# COVID-19 Antigen Control

## Package Insert

### **【INTENDED USE】**

The COVID-19 Antigen Control is designed to validate the performance of COVID-19 Antigen Rapid Test. It is intended to be used by healthcare professionals as an “External Quality Control” part of a quality control system.

### **【REAGENT】**

The **POSITIVE CONTROL** contains freeze-dried COVID-19 antigen and some Proclin300 as the preservative on the swab.

The **NEGATIVE CONTROL** contains freeze-dried 0.5% BSA-PBS with some Proclin300 as the preservative on the swab.

### **【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. Handle all specimens/controls as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Please read the entire package insert before processing the control test.

### **【STORAGE AND STABILITY】**

The control should be store at room temperature or refrigerated (2-30°C) for 24 months.

### **【PREPARATION OF THE CONTROL SOLUTION】**

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

Open the pouch of the control swab, take the control swab out from the pouch.

### **【DIRECTION FOR USE】**

**Allow the test, controls and buffer to equilibrate to room temperature (15-30°C) prior to testing.**

1. Insert the **POSITIVE CONTROL** or **NEGATIVE CONTROL** swab into the specimen Extraction tube.
2. Press against the inner wall of the tube and stir the swab for approximately 10 seconds while pressing the swab head against the inner wall of the tube to release the antigens in the extraction tube.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Discard the swab.
4. Test the extracted **POSITIVE CONTROL** or **NEGATIVE CONTROL** with the Rapid Test according to the test’s 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 COVID-19 Antigen 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 COVID-19 Antigen Rapid Test Manufactured by the company. Consult test manufacturer’s instructions when using this control.

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