



## Test Content

### INTENDED USE

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (NS) swab from individuals who are suspected of COVID-19 by their healthcare provider.

The SARS-CoV-2 Antigen Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

This product is suitable for self-test only. People with visual impairment need to use it with the help of others.

### GENERAL INFORMATION

The novel coronaviruses belong to the  $\beta$ genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.

### REAGENTS AND MATERIALS PROVIDED

Specifica tion Component	1 test/ kit	1 test/ kit	1 test/ kit	6 tests/ kit	20 tests/ kit	20 tests/ kit	20 tests/ kit
Test Cassette	1	1	1	6	20	20	20
Dropper	/	/	1	6	/	/	20
sample tube with extraction	1×0.5 mL	1×0.5 mL	/	/	20×0. 5 mL	20×0. 5 mL	/



reagent							
Nasal Swab	1	/	/	/	20	/	/
Instruction for use	1	1	1	1	1	1	1

#### Materials needed but not provided

Timer or watch.

#### PECIMEN COLLECTION AND PREPARATION

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

Nasal swab:

To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.

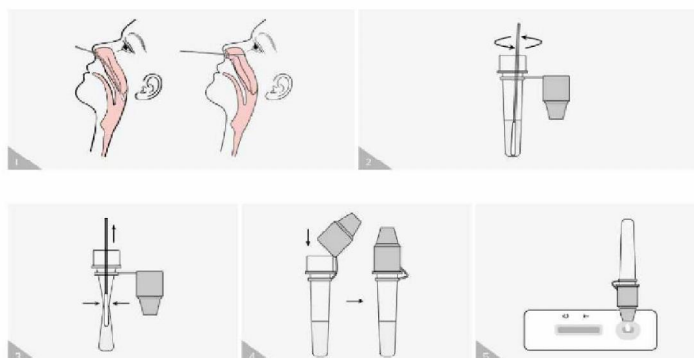
#### TEST PROCEDURE

Please read the instructions for use carefully before testing, and complete the test in strict accordance with the directions of the manual, otherwise reliable results cannot be guaranteed.

- Open the aluminum foil bag, put the test cassette on a clean, horizontal bench.
- Bring the samples to room temperature prior to assay in case of the samples were stored at 2-8°C.

#### Swab Test Procedure (Nasal Swab):

1. Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.
2. Press the sample tube to release the antigen in the swab and take out the swab. Dispose of the used swab in a biohazard waste following the local government regulations.
3. Install the dropper cap onto the sample tube, add two drops of the extraction sample into the sample well and start the timer.



Read the results within 15 minutes, and the results after 15 minutes are invalid.

