

### Intended Use

The(2019-nCoV) New coronavirus Antigen Test is used for the qualitative detection of novel coronavirus(COVID-19) antigen in human throat swab and nasal swab samples,only for in vitro liagnostic use.

The novel coronaviruses belong to the B genus. COVID-19 is an acute respi-ratory 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 dliarrhea are found in a few cases.

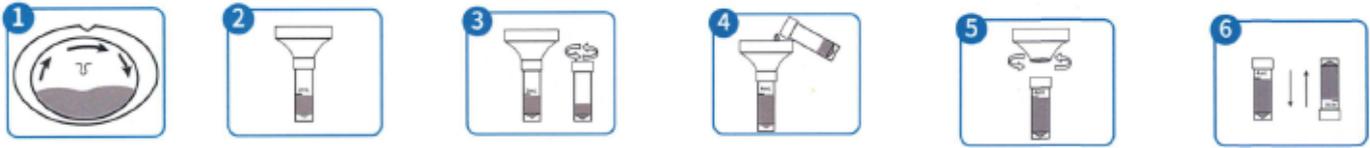
Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

### Test Principle

This kit is based on the principle of highly specific antibody-antigen reaction and colloidal gold labeling immunochromatographic analysis technology.

# Test Procedure

## Saliva Sample collection



### User Guide:

1. 30 minutes before sampling, wash out any debris in the mouth with drinking water.
2. Spit into funnel until saliva volume reaches 2mL.
3. Unscrew the funnel from the collection tube.
4. Slowly pour the saliva preservation liquid into the collection funnel.
5. Unscrew the collection tube from the collection funnel.
6. Screw the transport tube containing saliva specimen and turn it upside down 5 times.



## COVID-19 Antigen Detection operations:

- a) Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.
- b) Add 2 drops (about 60ul) of the saliva specimen to the sample well of the test cassette.
- c) Observe the results showed within 10-15 minutes, and the results showed after 15 minutes have no clinical significance.

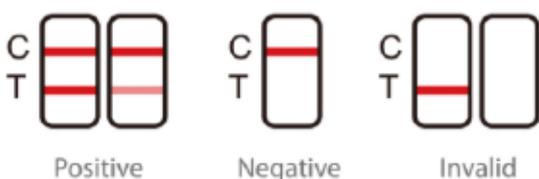


## Interpretation of Result

Negative: Only a red line appears in the quality control area(C), and no line appears in the test area(T).

Positive: Two red lines appear. One is in the test area(T) and the other is in the quality control area(C).

Invalid: No red line displays in the quality control area(C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged. Repeat the test with a new kit. If the problem persists, stop using this lot number immediately



Note: Invalid samples should be treated as infectious pollutants, and samples should be collected again.

## Product Photos

---

### ***Viral Transport Medium Tube (Saliva sample collector)***

#### Package included

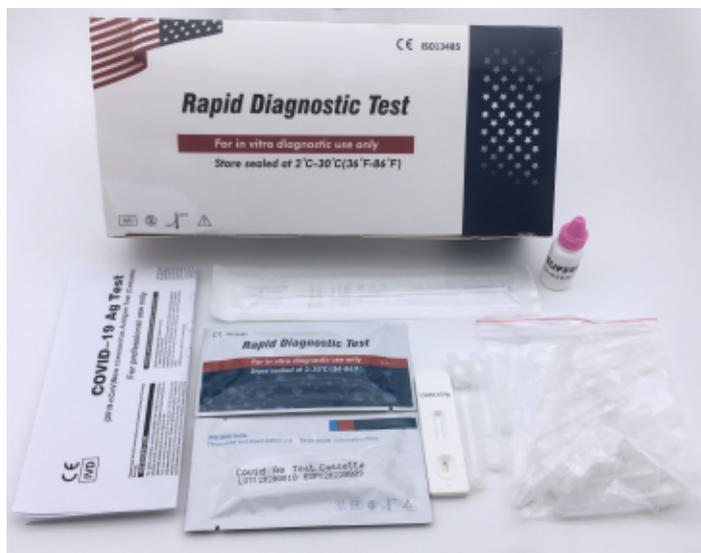
- 1x Funnel
- 1x 10mL Saliva collection tube
- 1x 5mL Preservation solution tube(with 2.0 mL preservation solution)
- 1x Saliva collecting tube cap
- 1x User Guide
- 1x Sample bag



### ***COVID-19 antigen Test (Colloidal Gold)***

#### Package included

- 25x Test cassette
- 2x Extraction buffer(6.5ml/bottle)
- 25x Extraction tube
- 25xDropper tip
- 25x Sample collection Swab
- 1x User guide



---

SINGUWAY BIOTECH INC.  
Tel/Fax: +86 0755 - 23704711  
E-mail: sales@singuway.com  
Web: www.singuway.com

