# INSTRUCTION FOR USE
## COVID-19 Ag Test
For the antigen of novel coronavirus
detection in human throat swabs or nasal swabs

*in vitro* diagnostic test

Only for professional *in vitro* diagnostic use

**Product Code: TCV03**

COVID-19 Ag Test detects the antigen of SARS-CoV-2 (COVID-19) in human throat swabs, nasal swabs or nasopharyngeal swabs.

### BACKGROUND INFORMATION

The novel coronaviruses belong to the β 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.

### INTENDED USE

COVID-19 Ag Test is used for in vitro qualitative detection of the antigen of novel coronavirus in human throat swabs or nasal swabs.

### REAGENTS

This test included 2019- nCoV antibody, anti chicken IgY polyclonal antibody, chicken IgY and colloidal gold conjugate.

### METHOD

COVID-19 Ag Test is a rapid, qualitative, immunochromatographic assay for the detection of 2019-nCoV antigen in human throat swabs or nasal swabs. The sample will be under the capillary action to move forward along the test cassette, if the sample contains new crown of antigenat detectable level, the antigens will with colloidal gold labeling will be coronavirus monoclonal antigen, the immune complex will be membrane fixed will be coronavirus monoclonal antibody capture, form the colored line, display will be coronavirus antigen positive; If the line does not show color, the negative result will be displayed. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

### PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wear disposable gloves while performing the test.
6. The test device and swabs should be discarded in a proper biohazard container after testing.
7. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
8. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample transportation and storage or freezing and thawing of the sample will affect the test results.
9. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
10. This reagent can only qualitatively detect 2019-nCoV antigens in human nasopharyngeal swab, oropharyngeal swab. It cannot determine the certain amount of antigen content in the samples.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
11. It is optimum when eluting swabs with the extraction reagent in the test kits. Using other reagent may result in wrong results.
12. In the early stage of infection, the test result may be negative because the low 2019- nCoV antigen level or antigen has not yet appeared in the sample.
13. A negative result does not exclude the possibility of SARS-CoV-2 (COVID-19) infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
14. Sensitivity maybe decrease if the sample did not test directly after they are collected . Please test the sample as soon as possible.
15. Cross reactions maybe exist due to the N protein in SARS has a high homology with the SARS-CoV-2.
16. Analysis the possibility of false negative results:
a) Inappropriate sample collection, using other non-matching reagent with the test kits, the time between sample transfer and test is too long (more than half an hour), the volume of reagent added when eluted the swab are too much, wrong application of test protocols for elution operation, low virus titer in the sample, these may all lead to false negative results.
b) Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
17. Analysis the possibility of false positive results:
a) Inappropriate sample collection, using other non-matching reagent with the test kits, wrong application of test protocols for elution operation, these may all lead to false positive results.
b) Cross-contamination of samples may lead to false positive results.
18. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of coronavirus.

### STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used within maximum 1 hour after the foil is opened.
**Kit components:** Test cassettes, sterile swab, sample extraction tube, extraction tube tips, extraction reagent (R), work station and instructions for use.
**Additional materials required but not provided:** Timer, pipette.
**Additional materials recommended but not provided:** Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

### SAMPLE COLLECTION AND PREPARATION

The test can be performed using human nasopharyngeal swabs, throat swabs and nose swab. The samples should be used as soon as possible after they are collected (within half an hour). Samples should not be inactivated.

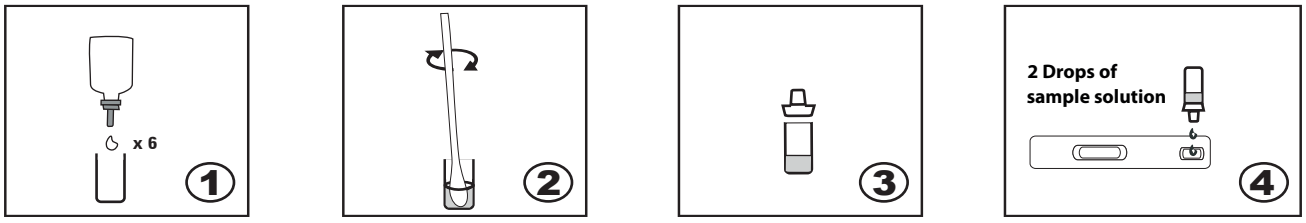
**For throat swab:** Have the patient's head slightly tilted back, mouth open, and "ah" sound, exposing both sides of the pharyngeal tonsils. Use a hand swab to gently wipe the pharyngeal tonsils on both sides of the patient for at least 3 times, and then wipe them on the posterior pharyngeal wall for at least 3 times. Place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.
**For nose swab:** Allow the patient's head to relax naturally, and slowly rotate the swab against the nostril wall into the nostril of the patient to the nasal palate, and then slowly rotate it out while wiping. Wipe the other nostril with the same swab, using the same method; place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.
**For nasopharyngeal swabs:** Place the nasal swab into the sampling tube where the pharyngeal swab has been collected. In this way, there is a pharyngeal swab and a nasal swab in a sampling tube, so-called nasopharyngeal swab tube. Place the swab specimen in the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

**TEST PROCEDURE**

*** Do not use samples taken for use in PCR testing and applied in VTM solution.**

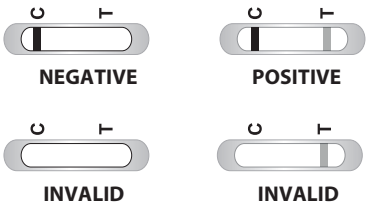
**** The samples should be used as soon as possible after they are collected (within half an hour). Samples should not be inactivated.**

1. Bring the tests, reagents and samples to room temperature.
2. Open the pouch and take out the test cassette.
3. Place the test tube to the work station. The extraction reagent (R) is pressed vertically downward to allow the solution to drip freely into the extraction tube without touching the edge of the tube. Add 6 drops of extraction reagent to the extraction tube (Figure 1).
4. Put the swab specimen into the extraction tube (Figure 2).
5. Rotate the swab for more than 5 times (about 10 seconds), and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab .
6. Place the extraction tube tip tightly on top of the test tube (Figure 3).
7. Put two drops into the sample well of the test cassette, and start the timer (Figure 4).
8. Results should be read at 20 minutes as shown below. Results forming after 30 minutes should be regarded as invalid.




**INTERPRETATION OF RESULTS**

**Negative :** Only one colored line is visible in "C" area.
**Positive:** One colored line should be in "C" area and a colored line appears in "T" area.
**NOTE:** Low concentration of the virus antigens in the sample may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
**Invalid :** No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.




**QUALITY CONTROL**

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

**PERFORMANCE EVALUATION**

COVID-19 Ag Test has been evaluated using clinical samples. PCR methods are used to compare COVID-19 Ag Test and following results are obtained.

| COVID-19 Ag Test | PCR Test | | Total |
|---|---|---|---|
| | Positive | Negative | |
| Positive | 74 | 2 | 76 |
| Negative | 6 | 238 | 244 |
| Total | 80 | 240 | 320 |

Analysis of coincidence rate of COVID-19 Ag Test and PCR Test in nasal samples:

**Sensitivity:**

74/ (74+6) × 100% = 92.5%

**Specificity:**

238 / (2+238) × 100% = 99.16%

**Accuracy:**

(74+238) / (74+6+2+238) × 100% = 97.7%

**REFERENCES**

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CE

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date