TEST IT
for healthy generations

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

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TICV03025

COVID-19 Ag Test detects the antigen of SARS-CoV-2 (COVID-19) in human nasal 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 nucleocapsid (N) protein antigen of novel coronavirus in human 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 nasal swabs. The sample will be under the capillary action to move forward along the test cassette; if the sample contains new coronavirus antigen at detectable level, the antigens will bound to the antibody, which is labeled with colloidal gold, form the colored line, which means the sample is coronavirus antigen positive. If the line does not show color, it means that the sample is SARS-CoV-2 antigen negative. 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 nasal 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. Use in conjunction with the testing strategy outlined by public health authorities in your area.
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 cassette, sterile swab, sample extraction reagent tube 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 nasal swab. The samples should be used as soon as possible after they are collected (within half an hour). Samples should not be inactivated. Due to the risk of contamination, test should be performed in the appropriate biosafety laboratory protection requirements and with the use of a cabinet. Within the scope of Covid-19 pandemic measures, national guidelines and local regulatory requirements and guidelines on laboratory biosafety should be followed in all circumstances.

For nasal 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.
**If excessive mucus is detected in the person to be sampled, it should be requested to clean the excess mucus with a disposable tissue paper. In such a case, this disposable tissue paper should be thrown into the biological waste container due to the risk of infectiousness.*

TEST PROCEDURE

*** 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. Unscrew the extraction reagent tube tip (Figure 1).
4. Hold the sample extraction reagent tube at a 45 degree angle. Place the swab specimen into the extraction reagent tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab (Figure 2).
5. Squeeze the sample extraction reagent tube from over the swab head to.
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.

Figure 1

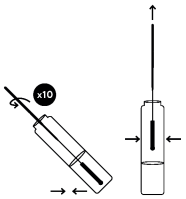


Figure 2

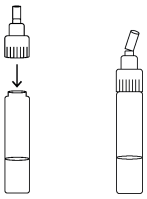


Figure 3

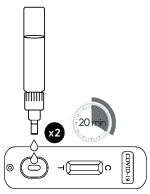
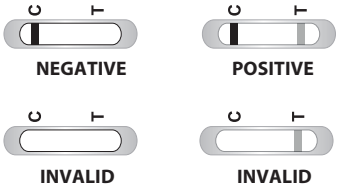


Figure 4

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 collected from both asymptomatic and symptomatic individuals/patients. RT-PCR methods were used to compare COVID-19 Ag Test and the positive samples were collected within 7 days of the onset of symptoms. The following results were obtained.

Table 1. Analysis of coincidence rate of COVID-19 Ag Test in nasal samples and RT-PCR Test from nasopharyngeal samples:

COVID-19 Ag Test	RT-PCR Test		Total
	Positive	Negative	
Positive	650	2	652
Negative	23	372	395
Total	673	374	1047

Sensitivity:
96.58% [*95% CI: 94,92% - 97,82%]

Specificity:
99.47% [95% CI: 98,08% - 99,94%]

Accuracy:
96.73% [95% CI: 95,46% - 97,72%]

**95% Confidence Interval*

Stratification of the positive specimens post onset of symptoms or suspected exposure between 1-5 days has a sensitivity of 98,02% (95% CI 96,15% to 99,14%; n=397/405).

Detection Limit:
Türklab COVID-19 Ag Rapid Test Device was confirmed to detect 21.8 TCID50/mL.

Cross-reactivity:
Specimens which tested positive with following various agents from patients were investigated with COVID-19 Ag Test. The concentration of virus samples is set to 10^6 pfu/ml or higher. The results showed no cross reactivity.

Cross Reactivity: COVID-19 Rapid AntigenTest - Virus/Bacteria/Parasite				
Human coronavirus - 229E	Human Hepatitis B Virus (HBV)	M. pneumoniae	Pseudomonas aeruginosa	Influenza A virus AH1
Human coronavirus - OC43	Pneumocystis jirovecii Recombinant	Rhinovirus	Streptococcus dysgalactiae	Influenza A virus H1N1
Human coronavirus - NL63	Staphylocuccus aureas	Enterovirus	Klebsiella quasipneumoniae	Influenza A virus AH3
MERS-coronavirus	C. pneumoniae	Escherichia Coli	Staphylococcus epidermidis	Influenza A virus
Human Metapneumovirus 3 (hMPV-3)	L. pneumophila	Bacillus thuringiensis	Rotavirus	Influenza B virus
Respiratory syncytial virus	Metapneumovirus	Klebsiella aerogenes	Adenovirus	Human Parainfluenza

Interferences:
COVID-19 Ag Test has been tested and no interference was observed in specimens containing; 10% Whole blood, 2% Mucin, 60 mg/ml Human albumin, 10 µg/ml Biotine, 5 µg/ml Tobramycin, 10 mg/ml Oseltamivir, 298 µmol/L Ascorbic acid, 3.7 mmol/L Acetylsalicylic acid, 5% Fluconazole, 12.1 µmol/L Captopril, 10% Sodium Chloride, 15% Oxymetazoline, 5% Fluticasone Propionate, 10 mg/ml Tamiflu, 100 µg/ml Amoxicillin and 10 mg/ml Mupirocin.

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CE

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