No.IFU-COVID-19Ag-NST-01,Ver.A/3

CE 1434

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

For in vitro diagnostic use only.
Please read the instructions carefully before use.

HKMD No. 220120

OPERATION DEMO AND E-MANUAL

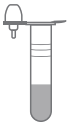
Intended use

This product is used for in vitro qualitative detection of the COVID-19(SARS-CoV-2) antigen in human nasal swab specimen. It is intended for personal use by untrained layman as a rapid test method for COVID-19(SARS-CoV-2) infection. However, please do not make a medical decision without consulting with the doctor.
It is suitable for users over 15 years old. Users under the age of 15 should be tested with assistance of adults. Both symptomatic and asymptomatic infections can be tested.

[Materials and Components]

Test Device

Instructions



Antigen Extraction Tube with 0.4ml Extraction Reagent

Collection Bag

Sterilized Swab

Timer (Materials required but not provided)

Preparation Before The Test

Blow your noses several times before taking the specimen. Clean your hands, make sure they are dry before starting the test.

Read the instructions carefully.

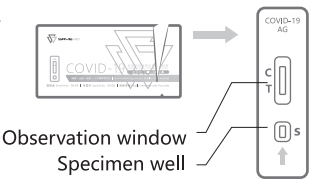
Check all parts of the test kit to make sure that all parts are complete and not damaged.

Check the Expiration Date printed on the foil pouch of the test device.

Test Procedure

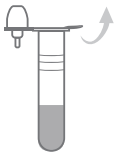
Allow test device extraction reagent and specimens to equilibrate to room temperature (15 ~ 30 ℃) prior to testing.
Please keep the temperature at 15 ~ 30 ℃ and the humidity at 20%-80% during the whole test.

1.



Open the package and take out the test device. Know the observation window and specimen well(S).It should be used within one hour.

2.

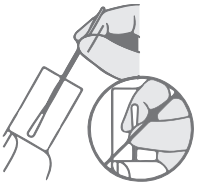


Gently peel off the aluminium foil seal.

3.

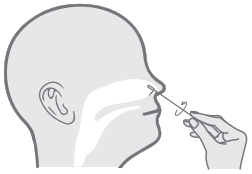
Press the pre-drilled circle, make a hole in the outer box, and then insert the bottom of the antigen extraction tube into the hole.

4.



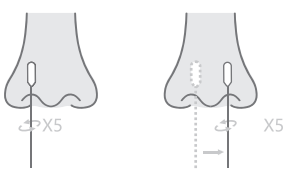
Remove the sterilized swab from the packaging.

5.



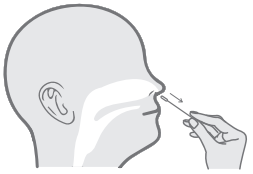
Relax your head naturally. Carefully insert the swab into your nasal cavity, the swab tip should be inserted up to 2 cm until resistance is met.

6.



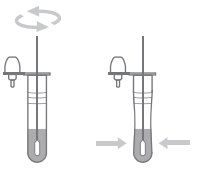
Roll the swab firmly inside the nasal cavity, making 5 complete circles. Using the same swab, repeat this process for the other nasal cavity to ensure an adequate amount of specimen is collected.

7.



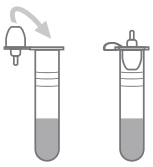
Take out the Swab from the nasal cavity.

8.



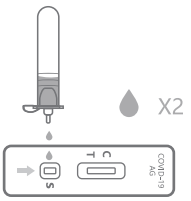
Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall 3 times to release the antigen in the swab.

9.



Press the nozzle cap firmly onto the extraction tube.

10.



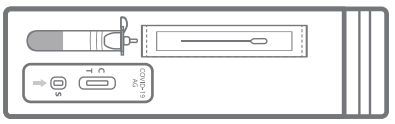
Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer.

11.

Read result at 15 minutes.

Do not read results after 30 minutes.

12.



Please put all used materials in the enclosed collection bag for proper disposal. The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

Interpretation of Test Results

ONE LINE
Negative Result

If there is only a control line (C) and the test line (T) is colorless, it indicates that COVID-19 (SARS-CoV-2) antigen has not been detected and the result is negative.
If the test result is negative: Continue to comply with all applicable rules regarding contacts and protective measures. Even if the test is negative, there may be an infection. In case of doubt, repeat the test after 1-2 days because the COVID-19 (SARS-CoV-2) cannot be accurately detected at all stages of infection.

TWO LINES
Positive Result

If both the control line (C) and the test line (T) appear, it indicates that COVID-19 (SARS-CoV-2) antigen has been detected and the result is positive.
If the test result is positive:
- **Currently, there is a suspected infection of COVID-19 (SARS-CoV-2).**
- **Contact your doctor or local health department immediately.**
- **Comply with the local self-isolation guidelines.**
- **Perform PCR test for confirmation.**

OTHER
Invalid Result

If the control line (C) is not observed, the test is considered to be invalid whether the test line (T) is visible or not. A new test needs to be performed using a new test device.
If the test result is invalid, it may be caused by incorrect test operation. Please repeat the test. If the test result is still invalid, please contact your doctor or COVID-19 (SARS-CoV-2) testing center.

Summary

COVID-19 (SARS-CoV-2) belong to the β genus. COVID-19 (SARS-CoV-2) is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by COVID-19 (SARS-CoV-2) 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.
Once infected with the COVID-19 (SARS-CoV-2) virus, you may be hospitalized and some complications may occur. If without prompt treatment it may even lead to death.

Test Principle

This product uses the double antibody sandwich method to detect the COVID-19 (SARS-CoV-2) N protein. When the sample contains COVID-19 (SARS-CoV-2) antigen, both the control line (C) and the test line (T) will appear, and the result will be positive. When the sample does not contain COVID-19 (SARS-CoV-2) antigen or no COVID-19 (SARS-CoV-2) antigen is detected, the test line (T) will not appear, only control line (C) will appear.

Limitations of Inspection Methods

1 . This test kit is only used for in vitro diagnosis.
2 . This test kit is only used to detect human nasal swab specimen. The results of other specimens may be wrong.
3 . This test kit is only used for qualitative detection and cannot indicate the level of COVID-19 (SARS-CoV-2) antigen in the specimen.
4 . This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.
5 . This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the COVID-19 (SARS-CoV-2) virus.
6 . This test can detect both the viable and the non-viable COVID-19 (SARS-CoV-2) virus, the accuracy of the test depends on the quality of the swab sample-false negative results may be given following poor sampling.
7 . Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.
8 . If the result of the test is negative, yet clinical symptoms persist, it is advised that you carry out additional tests using other clinical methods. A negative result at no time rules out the presence of antigens of the COVID-19 (SARS-CoV-2) virus in the sample, as they may be present but at a level inferior to the minimum detection level of the test, or if the sample has been collected incorrectly.

9 . A negative result does not rule out infection by the COVID-19 (SARS-CoV-2) virus, particularly in people who have come into contact with the virus. Follow-up tests with molecular diagnostics should be scheduled to rule out infection in these people. Persons who show symptoms of the disease but have a negative result until infection is ruled out should follow country-specific restrictions.
10 . This test is not a substitute for a medical consultation, or for the result of a biological analysis carried out in a medical analysis laboratory.
11 . Positive test results do not exclude the possibility of co-infections of other pathogens.

Warnings and Precautions

1. Read the instructions carefully before using the kit, and control the reaction time strictly. If you do not follow the instructions, you will get inaccurate results.
2. Keep away from moisture, do not open the aluminum foil bag before it is ready for testing. Do not use the test device if it is damp or the aluminum foil bag is damaged.
3. Please use it within the validity period.
4. Balance all reagents and specimens to room temperature (15-30℃) before use.
5. Do not replace the components in this kit with components in other kit.
6. Do not dilute the specimen during testing, otherwise you may get inaccurate results.
7. The kit shall be stored in accordance with the conditions specified in this Instructions strictly. Please do not store the kit under freezing conditions.
8. The test methods and results must be interpreted in accordance with this specification strictly.
9. Negative results may occur if the COVID-19 (SARS-CoV-2) antigen titer in the specimen falls below the limit of detection (LOD) of this kit.
10. The extraction reagent is individually packed, the batch number, expiration date and other information cannot be marked separately as the space is limited, but these information will be consistent with the corresponding test kit.
11. There is no reduction in sensitivity of the Antigen test against the UK variant, Brazilian variant, South African variant, Delta or the Omicron, including BA.4 and BA.5.

Storage Conditions & Period of Validity

Store at 4℃~30℃, and it is valid for 24 months.
After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour (15 ~ 30℃, Humidity ≤80%).

Sample Transport and Storage

Freshly collected specimens should be processed as soon as possible. It should be no later than one hour after collection.The processed specimens could be stored at 2-8℃ for no more than 24 hours.

Quality Control

Program control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient volume of the specimen.

Performance Index

1. Limit of detection (LOD): $TCID_{50}$/ml is 80.
2. High Dose Hook Effect: When the virus concentration exceeds 1.4×10^5 $TCID_{50}$/ml, the result may be false negative.
3. Cross-reactivity: There is no cross-reactivity, including human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, MERS-coronavirus, SARS coronavirus, adenovirus 3, and parainfluenza virus type 2, Enterovirus, respiratory syncytial virus (A), parainfluenza virus type 3, parainfluenza virus type 4a, influenza A H3N2 (Wisconsin/67/05), influenza A H1N1, influenza B (VICRTORIA), Rhinovirus (HRVA30), Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bacillus pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumonia, Mycobacterium tuberculosis, Pneumocystis, Pseudomonas Bacteria, human pneumonia virus (hMPV), parainfluenza virus type 1, Staphylococcus epidermidis, Streptococcus salivarius, etc.
4. Microbial Interference Studies: There is no interference in studies on the following microorganisms or pathogens, including parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3, parainfluenza virus type 4a, adenovirus, human pneumonia virus (hMPV), A H3N2 Influenza (Wisconsin/67/05), H1N1 influenza, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, influenza B (Malaysia/2506/04), enterovirus, respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Legionella pneumoniae, Mycobacterium tuberculosis, Pneumocystis, Pseudomonas, Candida albicans, Bacillus pertussis, Mycoplasma pneumoniae, Staphylococcus epidermidis, Streptococcus salivarius, human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, MERS coronavirus, etc.
5. Endogenous Interference Studies: There is no interference in studies on the following substances, including blood, mucin, Alkalol, dexamethasone, Neilmed, benzocaine, oseltamivir, tobramycin, mupirocin, biotin, etc.

Clinical Performance

There were 520 cases overall in the study, including 110 positive samples and 410 negative samples. Statistics of nasal swab test results were as follows:

COVID-19 Rapid Antigen Test	Comparator Method (RT-PCR)		
	Positive	Negative	Total
Positive	106	1	107
Negative	4	409	413
Total	110	410	520

		95% Wilson Score CI	
		LCI	UCI
Positive Percentage Agreement (PPA)	96.4%	90.8%	98.2%
Negative Percentage Agreement (NPA)	99.8%	94.4%	99.9%
Positive Predictive Value (PPV)	99.1%	93.7%	99.8%
Negative Predictive Value (NPV)	99.0%	93.5%	99.7%

Conclusion	
Sensitivity	96.4% (95% CI: 90.8% - 98.2%)
Sensitivity: Compared with the RT-PCR Assay, among people infected with COVID-19 (SARS-CoV-2) virus, the probability of correct detection by the COVID-19 (SARS-CoV-2) Antigen Test Kit.	
Specificity	99.8% (95% CI: 94.4% - 99.9%)
Specificity: Compared with the RT-PCR Assay, among people who have not been infected with COVID-19 (SARS-CoV-2) virus, the probability of correct detection by the COVID-19 (SARS-CoV-2) Antigen Test Kit.	

CT Value	Test Result (n=110)		
	Amount of sample	Antigen positive	Percentage of sample
≤25	60	59	98.3%
25-30	30	29	96.7%
>30	20	18	90.0%

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

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