No.IFU-COVIDAg-01,Ver.A/2

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

REF SL030101

Spec:1pc/box,10pcs/box,25pcs/box.
For professional use only
[Intended use]
This product is used for in vitro qualitative detection of the antigen of SARS-CoV-2 in human nasopharyngeal (NP) swabs or oropharyngeal swabs.
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.

[Test principle]
This kit uses the double antibody-sandwich method to detect SARS-CoV-2 antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to the SARS-CoV-2 antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated antibody against the SARS-CoV-2 which was coated on the test line, a visible colored line will show up, which indicates that the SARS-CoV-2 antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

[Warnings and Precautions]
1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
2. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
3. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use it if the aluminum foil bag is damaged or the test device is damp.
4. Please use it within the validity period.
5. Balance all reagents and specimens to room temperature (15 ~ 30 ℃) before use.
6. Do not replace the components in this kit with components in other kits.
7. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this specification.
10. Negative results may occur if the SARS-CoV-2 antigen titer in the specimen falls below the minimum detection limit of this kit.
11.If the extraction reagent is individual packing and one piece per test device, the batch number, expiration date and other information cannot be marked separately due to the space is limited, but those information will be consistent with the corresponding test kit.

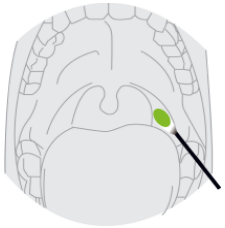
[Materials and Components]
Materials provided
1) Sterilized Swab
2) Antigen extraction tube
3) Extraction Reagent
4) Test device
5) Instruction
6) Workstation(Except for single package)

Materials required but not provided
Timer.

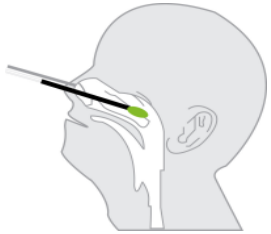
[Storage conditions & period of validity]

1. Store at 4℃~30℃, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour.

[Specimen Collection]
1. Oropharyngeal Swab Sample:
Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and gently wipe both sides of the patient's pharyngeal tonsils back and forth at least three times.

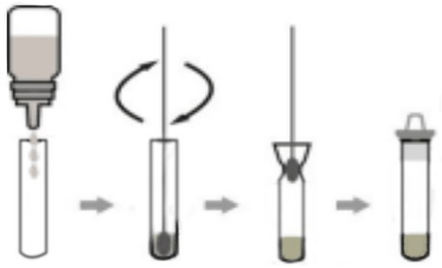


2. Nasopharyngeal Swab Sample:
Let the patient's head relax naturally, carefully insert the swab in the patient's nostril. Swab over the surface of the posterior nasopharynx and rotate the swab several times.Use the same swab, take specimens from the other nostril in the same way.

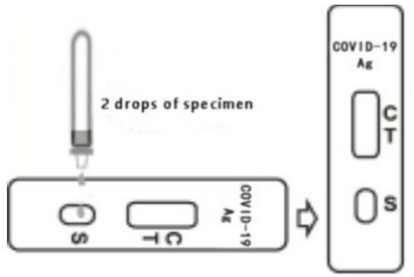


[Sample Transport and Storage]
After Swab specimens were collected, swab can be stored in extraction reagent provided with the kit. Also can be stored by immersing the swab head in a tube containing 2 to 3 mL of virus preservation solution (or isotonic saline solution, tissue culture solution, or phosphate buffer).
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8℃for no more than 24 hours; Store at -70 ℃for a long time, but avoid repeated freeze-thaw cycles.

[Specimen Preparation]
1. Take out the extraction tube, add 8 drops (about 0.3 mL) of the extraction reagent into the extraction tube, and put it on the workstation.
2. Put the swab specimen into 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.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Insert a dropper tip into the extraction tube tightly.



[Test Procedure]
Read the instructions carefully before use and allow test device, extraction reagent and specimens to equilibrate to room temperature prior to testing.
1. Open the package and take out the test device.
2. Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer.
3. Interpret the results within 20 minutes. Strong positive results can be reported within 20 minutes, however, negative results must be read after 20 minutes, and the results after 30 minutes are no longer valid.



[Interpretation of test results]
Negative result: if there is only a quality control line C, the detection line T is colorless, indicating that SARS-CoV-2 antigen has not been detected and the result is negative.
Positive result: if both the quality control line C and the detection line T appear, indicating that SARS-CoV-2 antigen has been detected and the result is positive.
Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line T (as shown in the figure below), and the test shall be conducted again.

Positive Negative Invalid

[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 specimen volume. The kit does not provide control standards.

[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 nasopharyngeal or oropharyngeal swab extracts. The results of other specimens may be wrong.
3.This test kit is only used for qualitative detection and cannot indicate the level of 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.

[Performance index]

1. Physical characters

1.1 Appearance: The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without waggle. The extraction reagent should be clear and free of foreign matter.
1.2 Size: the size of the inner strip should not be less than 2.5mm.
1.3 Liquid migration speed should not be less than 10mm/min.

2. **Minimum detection limit:** The minimum test limit reference products S1 should be negative, S2 and S3 should be positive.

NOTE:S1:Extraction Reagent for Antigen;S2:0.1ng/ml of recombinant antigen S3:1ng/ml of recombinant antigen

3. **Negative compliance rate:** 5 pieces of negative reference products of the test company shall be all negative, with a negative compliance rate of 100%.
4. **Positive compliance rate:** 5 pieces of positive reference products, each reference test one times and shall be all positive, with a positive compliance rate of 100%.
5. **Repeatability:** Test 1 piece of the enterprise positive reference, test it 10 times, the color should be consistent and all positive.

[Limit of detection, LOD]

Using the 320 $TCID_{50}$/mL concentration, the LOD was further refined using a 2-fold dilution series (four dilutions in total) of the gamma-irradiated SARS-CoV-2 virus made in pooled negative human nasal matrix. These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was treated as the tentative LOD for the DeepBlue SARS-CoV-2 Ag Test. This $TCID_{50}$/mL was still 320.

[High Dose Hook Effect]

The serial increased concentrations of SARS-CoV-2 samples were tested with the COVID-19 (Sars-CoV-2) Antigen Test Kit (Colloidal gold) manufactured by the DeepBlue. No impact on test performance or hook effect at high concentrations was observed up to 1.4 x 10^5 $TCID_{50}$/mL of SARS-CoV-2 with the DeepBlue SARS- CoV-2 Ag Test.

Test Dilution	Concentration ($TCID_{50}$/mL)	Mean Signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4 x 10^5	86220

[Clinical Performance]

The overall study scale was 520 cases, 110 positive samples and 410 negative samples.

Statistics of test results of nasopharyngeal (NP) swab samples:

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
DEEP BLUE SARS-CoV-2 Ag Test	POS	106	1	107	PPA	99.4%	94.4%	99.9%
	NEG	4	409	413	PPV	99.1%	93.7%	99.8%
	TOTAL	110	410	520	NPV	99.0%	93.5%	99.7%

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement (Specificity)
PPV - Positive Predictive Value
NPV - Negative Predictive Value
CI - Confidence Interval
LCI - Lower Confidence Interval
UCI - Upper Confidence Interval

[Index of CE Symbols]

IVD	The product is used in vitro		Please don't reuse it
	Expire date		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the package		Manufacturer
4℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
EC REP	European union authorization representative		Keep dry
	Avoid over exposure to the sun		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
CE	CE Mark	Σ	Contains sufficient for <n> tests

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,High-Tech Development Zone,230088 Hefei, Anhui,China

EC REP
Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich,Germany