CE 1434 IVD

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

For Self-testing

Ref.GF102BS

Version No: 202102

Issued Date: 2022-09-08

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test(Colloidal Gold) is an immunochromatographic test for the rapid qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human nasal swabs. It is intended to be used as a self-test during the acute phase of infection in cases of suspected COVID-19. The SARS-CoV-2 Antigen Rapid Test cannot be used as a basis for diagnosis or exclusion of SARS-CoV-2 infection. Children under 18 years of age must be supervised by adults when performing the test.

SUMMARY

COVID-19 is an acute respiratory infectious disease caused by the novel coronavirus SARS-CoV-2. Humans are generally susceptible to it. Currently, patients infected with the novel coronavirus are the main source of infection; asymptomatically infected people may also be a source of infection. Symptoms include fever, fatigue, loss of smell and/or taste, and dry cough. In some cases symptoms may include a stuffy or runny nose, sore throat, muscle aches, and diarrhea may occur.

MATERIALS PROVIDED

Component	Description	Specification			
		1 test/kit Ref.GF102BS1	5 test/kit Ref.GF102BS5	10 test/kit Ref.GF102BS10	25 test/kit Ref.GF102BS25
Test cassette	Foil ouched test device containing one reactive strip.	1	5	10	25
Sterile swab	For sample collection and transfer.	1	5	10	25
Inside page	Instructions for use.	1	1	1	1
Extraction buffer	Dissolve the sample	1	5	10	25
The certificate		1	1	1	1

of conformity					
Packages with holes	Be used as tube stand (optional).	1	1	1	1

To perform the test correctly everytime should require the Clock or timer, however we don't provide the clock or timer originally.

STORAGE AND DISPOSAL

Store at room temperature (2-30°C or 35.6-86 T).
24 months of shelf life (production date to expiration date).
The test cassettes must be stored in the sealed foil pouch before use.
Do not use after the expiration date.
Waste from used tests should be disposed according to the local regulations.

PREPARATION

Read the instructions for use carefully before performing the test. Blow your nose and then wash your hands thoroughly with soap or disinfect them with disinfectant. Keep the test cassette and components at room temperature (15°C to 30°C) before performing the test. Place all the materials supplied on a clean, dry and flat surface.

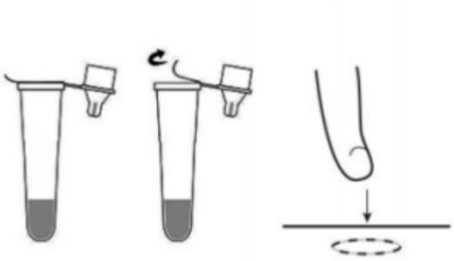
SAMPLING IN THE NOSE

Please follow the instructions on the next page step by step for sampling test.

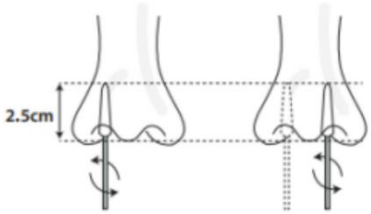
Test Procedure

1. Blow your nose. Wash or disinfect your hands. Remove the test cassette by tearing open the foil pouch and place it in front of you.

2. Tear off the seal of extraction buffer tube, Press in the perforated hole on the top of the packaging and use the hole as a tube stand.

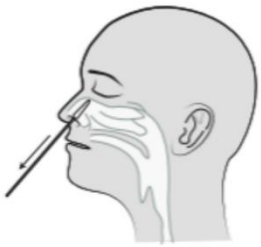


3. Remove the swab. Do not touch the sterile tip of the swab. Instead, grasp the swab by the handle. Insert the swab about 2.5 cm deep into your nostril until you feel resistance.

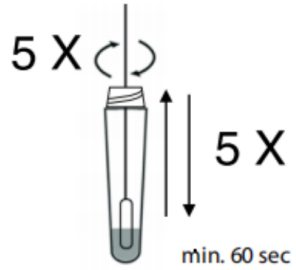


4. Collect sample from the left and right nostril with the same swab: rub the swab against the inner wall of your nose and turn it at least 5 times to make sure you collect a sufficient amount of sample. Repeat the procedures in the other nostril.

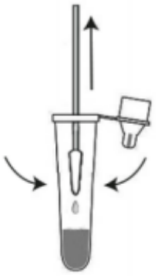
Note: Children (at least 2 years old) younger than 15 years old, and people who are unable to perform the test themselves including the elderly and the sick should be tested by another adult. To sample a child, insert the swab into of one of their nostris until you feel some resisteance (about 2 cm). Rotate the swab 5 times against the nasal wall. Remove the swab and insert the same swab into the other nostril, repeat the sampling process. Do not continue the test if the child feels any pain.



5. Dip the swab into the tube and ensure that it is thoroughly mixed with the extraction liquid by agitating it and dipping it up and down at least 5 times. Allow the swab to soak for one minute.

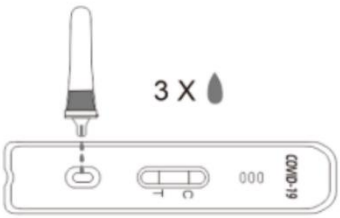


6. Slowly pull the swab out of the tube while gently squeezing the sides of the tube to keep as much liquid in the tube as possible.

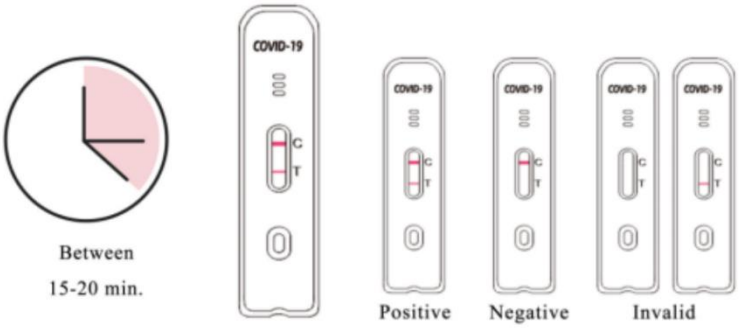


7. Place the dropper tip firmly on the extraction buffer tube and mix the liquid thoroughly.

8. Drop 3 drops into the sample well (S) on the test card.



9. Interpret the test result between 15-20 minutes. The result after 20 minutes is invalid.



INTERPRETATION OF THE TEST RESULT

Check whether a line is visible at the control line (C). The color thickness of the control line (C) is irrelevant. If it is not visible, the test was not performed correctly and a new test with a new test set must be performed.

POSITIVE TEST RESULT

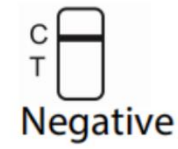
If a colored line is visible in the test line region (T) and a colored line is visible in the control line region (C), indicating positive test result. This means that SARS CoV-2 antigens are detectable in your nasal sample and indicates with high probability of COVID-19 infection.

Please stay home and call your physician or local health department. Follow local guidelines for self isolation and have a PCR confirmatory test performed.

*Note: The thickness of the line is irrelevant; any reddish line in the test line (T) should be interpreted as a positive test result. A positive test result must be confirmed by molecular diagnostics (e.g. PCR test).

NEGATIVE TEST RESULT

If only a colored line is visible in the area of the control line (C), but not at the test line (T), the test result is negative. This indicates that no or too few SARS-CoV-2 antigens are present in the nasal sample and that there is probably no infection with the SARS-CoV-2 virus.



Negative

Continue to follow applicable rules regarding contact with others and applicable protective measures. In case of suspicion, repeat the test using new test kit, as SARS-CoV-2 virus cannot be accurately detected at all stages of infection. A negative result does not rule out infection with SARS CoV-2 and should be confirmed by PCR testing if suspected.

INVALID TEST RESULT

If no line is visible in the control line (C) or only one line is visible in the test line area (T), indicating the test is not performed correctly and the result is invalid. It is important to follow the instructions for the test carefully. Please repeat the test with new sample and new test set.

Invalid

If test results remain invalid, please contact a physician or COVID-19 testing center.

PERFORMANCE DATA

For the anterior nasal swab method, 645 specimens were collected.

		Vitassay qPCR SARS-CoV-2		Total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test kit	Positive	238	0	238
	Negative	7	400	407
Total		245	400	645

Statistic	Value	95% CI
Sensitivity	97.14%	94.20% to 98.84%
Specificity	99.99%	99.08% to 100%
Total coincidence rate	98.91%	97.78% to 99.56%

DETECTION LIMIT

The limit of detection (LOD) for the SARS-CoV-2 Antigen Rapid Test is 4 x 10^2 $TCID_{50}$/mL.

Matrix	LOD Concentration $TCID_{50}$/mL	Number of Positive/ Total	%Detected
A viral sample inactivated by gamma irradiation	4 x $10^2$$TCID_{50}$/mL	20/20	100%

Cross Reactivity and Microbial Interference

The cross-reactivity with the following microorganisms was examined. Samples that tested positive for the following microorganisms were negative when tested with the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold). The microbial interference study evaluated whether microorganisms possibly contained in clinical samples interfere with the detection capability of the kit which may lead to false negative results. Each microorganism was tested in the presence of a fabricated SARS-CoV-2 positive sample. No cross-reactivity or interference with the microorganisms listed in the table below was found.

No.	Microorganism	Final Test Concentration
1	SARS-Cov recombinant protein	2.5 mg/mL
2	MERS-Cov recombinant protein	2.07 mg/mL
3	Adenovirus(Type 1)	1.0×10^7 pfu/mL
4	Adenovirus(Type 3)	1.0×10^7 pfu/mL
5	Coronavirus(229E)	1.0×10^7 pfu/mL
6	Coronavirus(HKU1)	1.0×10^7 pfu/mL
7	Coronavirus(NL63)	1.0×10^7 pfu/mL
8	Coronavirus(OC43)	1.0×10^7 pfu/mL
9	Influenza A Seasonal H1N1	1.0×10^7 pfu/mL
10	Influenza B Yamagata	1.0×10^7 pfu/mL
11	Legionella pneumonila	1.0×10^7 pfu/mL
12	MERS	1.0×10^7 pfu/mL
13	Mycobacterium tuberculosis	1.0×10^7 pfu/mL
14	Mycoplasma pneumoniae	1.0×10^7 pfu/mL
15	Parainfluenza virus (Type 1)	1.0×10^7 pfu/mL
16	Respiratory syncytial virus	1.0×10^7 pfu/mL
17	Rhinovirus（Group A）	1.0×10^7 pfu/mL
18	Rhinovirus（Group B）	1.0×10^7 pfu/mL

Interference

The following interfering substances have no impact on SARS-CoV-2 Antigen Rapid Test (Colloidal Gold).

No.	Interfering Substance	Final Test Concentration
1	Mucin	0.54%
2	Menthol	1.4 mg/mL
3	Whole Blood	5%
4	Triamcinolone acetonide	1 ng/mL

5	Tobramycin	5 µg/mL
6	Levofloxacin	1.5 µg/mL
7	Mupirocin	12 mg/mL
8	Oxymetazoline	9%v/v
9	Nasal Spary	16%v/v
10	Dexamethasone	0.5 µg/mL

HOOK EFFECT

No high dose hook effect was observed when tested with up to a concentration of 1.3×10^6 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

WARNINGS AND IMPORTANT INFORMATION

1. The test is designed for external use outside human body only. Please do not ingest. Avoid skin and eye contact with the buffer liquid.
2. Failure to follow the instructions may affect the test result. The final diagnosis should be confirmed by a physician.
3. Keep it out of reach of children.
4. Persons with reduced vision or mobility should ask for assistance.
5. Do not use the test if test components are damaged.
6. Use only the materials supplied with this test. Do not reuse the test or test components.
7. The test should be performed immediately, latest one hour after opening the foil pouch (at 20-30°C, humidity<60%).

Swabs: CE 0197 / TÜV Rheinland
Manufacturer of the swabs: Dalian Rongbang Medical Healthy Devices Co.,Ltd.
Maoyingzi Hamlet, Dalianwan Town, Ganjingzi District, Dalian, 116113, China.

FURTHER PRODUCT INFORMATION

Manufacturer: Shenzhen Lvshiyuan Biotechnology Co., Ltd
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EU Authorized Representative: Obelis s.a.
Bd General Wahis 53, 1030 Brussels Belgium

Explanation Of Labels

IVD	In Vitro Diagnostic Use
LOT	Batch Number
	Do not reuse
	Keep Dry
	Do not use if package is damaged

	Instruction for Use
	Expiry Date
2° 30°	Store between 2～30°C
	Manufacturer

CE	CE Mark
	Manufacturing Date
	Keep away from Sunlight
EC REP	EU Authorized Representative