GOLDSITE

EN **SARS-CoV-2 Antigen Kit (Colloidal Gold)**
(for self-testing)

Intended Use

This SARS-CoV-2 Antigen Kit (Colloidal Gold) is a single use, in vitro visually read rapid immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid (N) antigen in human nasal swab specimens.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but correlation with patient history and other diagnostic information is necessary to determine the infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.
The SARS-CoV-2 Antigen Kit (Colloidal Gold) is intended to be used manually by lay users (self-testing) in a private setting to aid in the rapid diagnosis of SARS-CoV-2 infections. Children (at least 2 years old) younger than 15 years old should be tested by an adult. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

Summary and Explanation

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.

Principle of the Procedure

The kit employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2.
To begin the test, a self-collected nasal swab sample is inserted into the Extraction Tube. The pre-filled solution in the tube interacts with the sample and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The extracted sample is then added to the sample well of the Test Cartridge.
If the extracted sample contains SARS-CoV-2 antigens, a pink-to-red line will appear on the test line region (T) and a red line will appear on the procedural control line region (C). Absence of the test line (T) indicates SARS-CoV-2 antigens are not detected, suggesting SARS-CoV-2 is not present, or is present at very low levels.

Materials Required But Not Provided

1. Timer
2. Hand soap and water or hand sanitizer
3. Household waste container

Materials Provided

			
REF Catalog number	Test Cartridge	Sampling Swab	Extraction Tube	Instructions for Use
CG123001	1	1	1	1
CG123003	3	3	3	1
CG123005	5	5	5	1
CG123007	7	7	7	1
CG123025	25	25	25	1

Warnings and Precautions

- For in vitro diagnostic use.
- Read the instructions fully before starting the test. To obtain accurate results, the instructions must be followed.
- If the package has been damaged, the label cannot be seen clearly or if the cartridge has expired, do not use the cartridge.
- Do not open the foil pouch of the Test Cartridge until ready for use.
- Do not eat the desiccant.
- Do not reused the cartridges, tubes or swabs.
- Do not interchange or mix components from different kit lots.
- Do not touch swab tip when handling the swab.
- Inadequate or inappropriate specimen collection, may yield false negative test results.
- Dispose of kit components and samples in household trash.
- Use of gloves during sampling and testing is recommended.

Storage and Stability

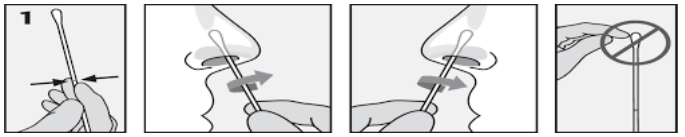
Store the kits at 2 – 30° C in a dry place and avoid direct sunlight. Do not freeze any of the kit components. Keep the kits out of reach of children. The unopened cartridges are stable until the expiry date printed on the labels. Once the foil pouch of the test cartridge is opened, the test should be started within 30 minutes.

Test Procedure

Note: Before starting the test, wash your hands with soap and water or use hand sanitizer. Make sure they are dry before starting.

1. **Allow the kit to equilibrate to room temperature (15 – 30℃) before testing**. Open the kit and identify kit components and instructions.

2. **Collecting the nasal swab sample**. Open swab package at stick end. Take swab out. While gently rotating, insert the swab into one nostril. The swab tip should be inserted up to 2 cm (1/2 to 3/4 of an inch) from the edge of the nostril. Rotate the swab 5 times against the nasal wall. Remove and repeat the sampling process using the same swab for the other nostril.
Note: Do not touch swab tip when handling the swab.
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. 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.

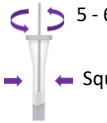


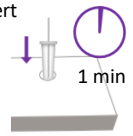
Note: Inadequate or inappropriate sample collection may yield false negative results.

3. Remove the Dropper Lid from the purple pre-filled Extraction Tube .Place and soak the swab into the tube.

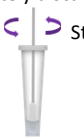
Remove the Dropper Lid  Place and soak the swab into the tube 

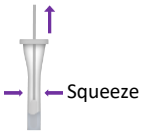
4. Rotate the swab 5 – 6 times while squeezing the sides of the tube. Insert the tube into the hole indicated on the kit box. Make sure the tube is standing upright and reaches the bottom. Leave the swab in the Extraction Tube for 1 minute.

Rotate the swab 5 – 6 times while squeezing 

Insert the tube to the hole on the kit box. Leave the swab for 1 minute. 

5. Stir to mix the contents well. Remove the swab while squeezing the sides of the tube. Immediately discard the swab into the garbage.

Stir to mix the contents well 

Remove the swab while squeezing the sides of the tube 

6. Attach and tighten the Dropper Lid to the top of the Extraction Tube. Mix the contents thoroughly (by inverting the tube several times).

Attach and tighten the Dropper Lid  Invert gently several times 

7. Open the foil pouch of the Test Cartridge. Place the cartridge on a clean, flat and dry surface. Label the cartridge with patient ID number. Remove the cap on top of the Dropper Lid, invert the extraction tube, and then add two drops (around 70 uL) of the well-mixed sample into the sample well of the cartridge.

Remove the white cap  Add two drops into sample well 


12 min

8. Leave the sample-loaded cartridge at room temperature for 12 minutes. Do not handle or move the cartridge during this time.

9. After the 12-minute incubation, read the results. Do not interpret the results after 15 minutes (from addition of the sample).

Interpretation of Results

Positive Result:
Two lines will appear.
One pink-to-red line on the test line region (T) and one red line on the control line region (C).
Note: Look very closely! The test line (T) can be very faint. Any pink/red visible T line should be considered positive.

Negative Result:
A single line appear on the control line region (C).

Invad Result:
No red line appears on the control line region (C).
Note: Insufficient sample volume, incorrect operating procedure are the most likely reasons for control line failure. If the test result is invalid, a new swab should be collected, and the test should be performed again with a new kit. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Limitations

- The test is only for qualitative detection of the SARS-CoV-2 antigen in nasal swab samples.
- This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure, Interpretation of Results may adversely affect test performance and/or invalidate the test results.
- False negative results may occur if a sample is improperly collected or handled.
- Positive test results do not rule out co-infections with other pathogens.
- A negative result does not exclude SARS-CoV-2 infection. Negative results should be treated as presumptive and may need to be confirmed by a molecular assay.
- False negative results are more likely after eight days of symptoms.

Performance

Clinical Performance
The clinical performance of SARS-CoV-2 Antigen Kit (Colloidal Gold) (for self-testing) was determined by testing samples from 267 persons suspected of COVID-19. The samples were collected within 7 days post onset of symptoms or suspected exposure. For each individual, two swabs were collected. The first one was self-sampled nasal swab and was self-tested directly with SARS-CoV-2 Antigen Kit (Colloidal Gold) (for self-testing) at the site. The second was a healthcare-collected nasopharyngeal swab which was placed in virus transport medium, shipped to laboratory, and determined to be positive or negative using an NMPA (National Medical Products Administration, China) approved RT-PCR method, i.e., the comparator method.

		RT-PCR Test Results		
		Positive	Negative	Total
SARS-CoV-2 Antigen Kit (Colloidal Gold)	Positive	110	1	111
	Negative	9	147	156
	Total	119	148	267

Clinical sensitivity: 92.44% (95% CI: 86.13 – 96.48%)
Clinical specificity: 99.32% (95% CI: 96.29 – 99.98%)
Overall percent agreement: 96.25% (95% CI: 93.22 – 98.19%)

Lmit of Detection (LoD)
SARS-CoV-2 Antigen Kit (Colloidal Gold) was confirmed to detect 2.5 ng/mL of SARS-CoV-2 nucleocapsid protein antigen.

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 Kit (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 triplicate in the presence of a fabricated SARS-CoV-2 positive sample (concentration: 3 × LOD). No cross-reactivity or interference with the microorganisms listed in the table below was found.

No.	Microorganism	Final Test Concentration
1	HCoV-OC43	2×10^6 $TCID_{50}$/mL
2	HCoV-229E	2×10^6 $TCID_{50}$/mL
3	HCoV-NL63	2×10^6 $TCID_{50}$/mL
4	RSV	2×10^5 $TCID_{50}$/mL
5	Rotavirus	2×10^6 $TCID_{50}$/mL
6	MERS	1×10^6 $TCID_{50}$/mL
7	Adenovirus	2×10^6 $TCID_{50}$/mL
8	Norovirus	2×10^6 $TCID_{50}$/mL
9	Mycoplasma pneumonia	$1,5\times10^6$ cfu/mL
10	Influenza A Virus (H1N1)	2×10^7 $TCID_{50}$/mL
11	Influenza B virus (Yamagata)	2×10^7 $TCID_{50}$/mL

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

No.	Interfering substance	Final Test Concentration
1	Phenylephrine	15% v/v
2	Oxymetazoline	15% v/v
3	Chloride de Sodium	5 mg/mL
4	Beclomethasone	5 ng/mL
5	Dexamethasone	0.5 μg/mL
6	Flunisolide	0.5 μg/mL
7	Triamcinolone acetonide	1 ng/mL
8	Budesonide	2.5 ng/mL
9	Mometasone	1 ng/mL
10	Fluticasone	2 ng/mL

Hook Effect
There is no hook effect at 600 μg/mL of SARS-CoV-2 nucleocapsid protein antigen.

Frequently Asked Questions

1. Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

2. What are the known and potential risks and benefits of this test?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results.

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

3. What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the SARS-CoV-2 Antigen Kit (Colloidal Gold) you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

4. What does it mean if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.
It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay.
If you test negative and continue to experience COVID- 19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

5. What is the difference between an antigen and molecular test?
An antigen test, such as the SARS-CoV-2 Antigen Kit (Colloidal Gold), detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home.

Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized representative in the European Community
IVD	In vitro diagnostic medical device		Use-by date		Do not reuse
	Temperature limit 2 - 30℃	LOT	Lot number	REF	Catalog number
	Avoid sunshine		Manufacture		Date of manufacture

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