SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method) for self-testing use IFU

CE 1434 IVD

INSTRUCTIONS FOR USE WITH ANTERIOR NASAL (FRONT NOSE) SWABS.

REF 2061702 for 20 tests / kit

REF 2061703 for 1 test / kit

Please read prior to use carefully and follow the instructions for use strictly.

【INTENDED USE】

The SARS-CoV-2 Antigen Assay Kit is a one-step *in vitro* test based on the principles of immunochromatography. It is a screening test for the rapid qualitative detection of SARS-CoV-2 antigens in anterior nasal swabs (front nose) from individuals with suspected SARS-CoV-2 infection in a fortnight's time, mostly 3 to 7 days from symptom onset. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Therefore, the SARS-CoV-2 rapid antigen test should not be used as the sole basis for the diagnosis and exclusion of SARS-CoV-2 infection. This test is for *in vitro* diagnostic use only.

【SUMMARY】

COVID-19 is an acute contagious respiratory disease caused by SARS CoV-2 infection, to which humans are highly susceptible. People infected with SARS CoV-2 antigens are the major infectious source, not excluding those with no symptoms. Based on current epidemiological studies, the incubation period is 1 to 14 days, mostly from 3 to 7 days. The most typical symptoms include fever, fatigue, dry cough, loss of smell and / or sense of taste. Some cases could come with symptoms such as nasal congestion, runny nose, detected sore throat, muscle pain and diarrhea.

【MATERIALS SUPPLIED】

Common component	For 20 tests / Kit	For 1 test / Kit
SARS-CoV-2 antigen test cassette	1 pc×20	1 pc
Biosafety bag	1 pc×20	1 pc
Extraction solution tube	400μL/pc×20	400μL/pc×1
Instructions for use	1 pc	1 pc
Bracket box	1 pc	1 pc
Siphon dropper	1 pc×20	1 pc
Disposable sampling swab	1 pc×20	1 pc

Disposable sampling swab: Class A Sterile, identification number of notified body: 0197

【MATERIALS REQUIRED BUT NOT SUPPLIED】

Timer

【IMPORTANT INFORMATION BEFORE PROCEEDING】

1. Read these instructions carefully.
2. Do not use the product after the expiration date.
3. If the pouch is damaged or the seal is broken, do not use the product.
4. Swabs, siphon droppers and test cassette etc. are disposable materials.
5. Children under the age of 14 should be supported by adults.
6. Store the test between 4°C and 30°C in the original sealed pouch.
7. The product should be used at room temperature (15°C to 30°C). If the product is stored below 15 °C, leave it at room temperature for 30 minutes before use.
8. Treat all specimens as potentially infectious.
9. Inadequate or inaccurate specimen collection, storage and transport can lead to inaccurate test results.
10. Use the swabs provided to ensure optimal performance of the test.
11. Proper sampling is the most important step in performing the test.
12. Samples should be tested as soon as possible after collection.
13. Put the drops of the test sample in the sample well (S) only.

【STORAGE AND STABILITY】

1. Unopened reagent should be stored at 4-30°C. Valid for 24 months.
2. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

【LIMITATIONS】

1. The test is for the exclusive use of the qualitative detection of SARS-CoV-2 virus antigen in anterior nasal swabs (front nose).
2. Proper sampling is critical. Failure to follow the **PROCEDURE** can lead to inaccurate test results. Improper removal, storage or freezing and thawing the sample can lead to inaccurate test results.
3. If the viral load of the sample is below the detection limit, the test may give a negative result.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be made on the basis of individual test results, but in combination with other properly evaluated clinical and laboratory tests.
5. A negative result does not rule out possibilities of other viral infections except SARS-CoV-2. For users with a history of close contact with infected population or suspected symptom, further diagnosis should be made at a professional medical facility.
6. A positive result does not exclude co-infection with other pathogens.
7. The SARS-CoV-2 Rapid Antigen Test can detect both active and inactive SARS-CoV-2 viruses. The performance of the SARS-CoV-2 rapid test is dependent on viral load and may not be correlated with other diagnostic methods performed on the same sample.
8. Users should test the samples upon collection and in any case within two hours after sampling.
9. The amount of antigens in a sample can decrease with the duration of the disease.
10. The kit has been validated with the provided swabs. The use of alternative swabs can lead to false negative results.
11. The kit has not been verified for the identification/confirmation of tissue culture isolates and should not be used in this capacity.

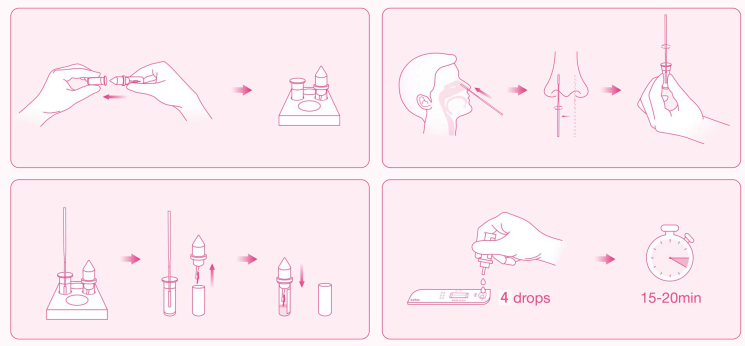
【PREPARATION】

1. Clear a dry flat surface for testing.
2. Check the contents of the test reagent.
3. Make sure that no component is missing, damaged or broken.
4. Get a timer at hand.
5. For nasal swab test, blow your nose several times before sampling.
6. Wash your hands.

【PROCEDURE】

1. Sampling for anterior nasal swab

• Pierce the extraction solution tube cover with siphon dropper's tip.



CAUTION: Keep it away from your face when you open the kit, and take care not to spill any liquid.

• Observe the swab in the sealed package and make sure to use the soft textile tip to collect sample.

• Unseal the swab packaging and take the swab out carefully.

CAUTION: Do not touch the swab tip (the soft, textile side) with hands.

• Gently insert the swab tip into one nostril. The textile tip of the swab should be up to 2 cm to 4 cm deep until resistance is met. Rotate against the mucous membrane in nostril to make sure samples are well collected.

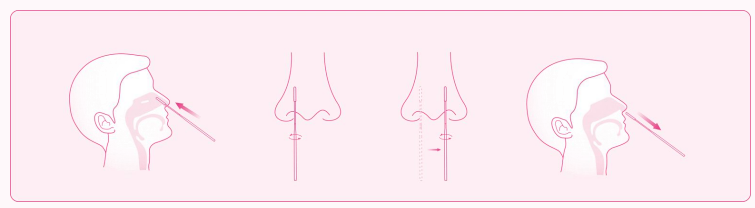
• Use the same swab and repeat **Step 2** for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

CAUTION: It may make you feel uncomfortable. Do not insert the swab deeper if you feel strong resistance or pain.

• Insert the swab with the sample into the extraction solution tube. Turn the swab 3 to 5 times. Make sure that the tube stands upright and the swab reaches the bottom of extraction tube.

• Dip the swab in extraction buffer for 1 minute and then withdraw the dissolved swab, remove and dispose.

• Remove the bottom plastic of siphon dropper, and insert the capillary side in extraction solution tube.



2. Test and read the result

• Open the foil pouch, take out the test cassette and lay it flat.

• Align the dropper with the sample hole of the test cassette, and then drop 4 drops (about 75μL) of sample vertically.

• Read the results within 15-20 minutes.

CAUTION: Once your test is complete, put all of the used test kit contents in the biosafety bag provided and dispose it in accordance with the local authorities, regulations and the disposal protocol for biological hazards.

【INTERPRETATION OF THE TEST RESULTS】

Positive:

If within 15-20 minutes two color lines - one colored line appears in the control area (C) and another colored line appears in the test area (T), the test is valid and positive, no matter how faint the colored line in the test area (T) is. A positive result does not rule out co-infection with other pathogens.

Negative:

If a colored line appears in the control area (C) within 15-20 minutes, while no colored line can be seen in the test area (T), the test is valid and negative. A negative result does not exclude a viral infection with SARS-CoV-2. For users with a history of close contact with infected population or suspected symptom, further diagnosis should be made at a professional medical facility.

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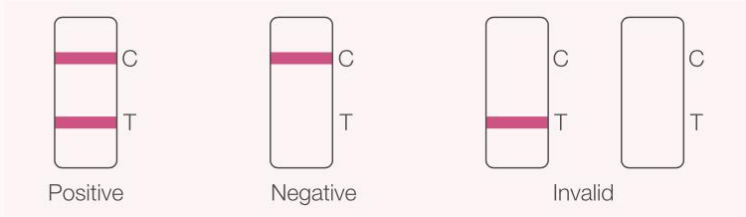
Invalid:

If no colored line appears in the control area (C) within 15-20 minutes, the test turns out invalid. Repeat the test with a new test cassette or contact the supplier if necessary.



【LIMIT OF DETECTION】

Limit of detection (LOD) studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. The LoD of SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method) was determined as 70 $TCID_{50}$/mL.

【SPECIFICITY ANALYSIS】

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the SARS-COV-2 Antigen Assay Kit.

Pathogens	Concentration	Pathogens	Concentration
Measles virus	1.0 x 10^5 $TCID_{50}$/mL	Influenza A H1N1 virus	1.0 x 10^5 $TCID_{50}$/mL
Mumps virus	1.0 x 10^5 $TCID_{50}$/mL	Influenza A H3N2 virus	1.0 x 10^5 $TCID_{50}$/mL
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	Avian influenza virus H7N9	1.0 x 10^5 $TCID_{50}$/mL
Mycoplasma pneumoniae	1.0 x 10^6 U/mL	Avian influenza virus H5N1	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza 2	1.0 x 10^5 $TCID_{50}$/mL	Epstein-Barr virus	1.0 x 10^5 $TCID_{50}$/mL
Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL
Human Coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	Rhinovirus	1.0 x 10^5 PFU/mL
Human Coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	Staphylococcus aureus strains	1.0 x 10^6 CFU/mL
Human Coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
Influenza B Yamagata	1.0 x 10^5 $TCID_{50}$/mL	Bordetella pertussis	1.0 x 10^6 CFU/mL
Influenza B Victoria	1.0 x 10^5 $TCID_{50}$/mL	MERS-CoV	1.0 x 10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type A	1.0 x 10^6 PFU/mL	Respiratory syncytial virus Type B	1.0 x 10^6 PFU/mL

【QUALITY CONTROL】

The control line is used to monitor the process. The control line appears when the test was performed correctly and proved valid.

【FREQUENTLY ASKED QUESTIONS (FAQ)】

1) How does the recognition work?

The N protein of the SARS-CoV-2 virus reacts with the strip-shaped coating of the test line and leads if there is a color change, for example a red line appears. If the sample does not contain virus proteins or antigens, there is therefore no red test line (T).

2) When should / can I test myself?

You can test yourself to see if you have symptoms or not. Studies show that previous tests within the first 4 days of sickness typically mean a higher viral load, the easier it is to recognize. Since the test result is a snapshot that is valid at this point in time, the tests should be repeated as recommended by local authorities.

3) What can influence my test result? What should I watch out for?

Make sure you blow your nose thoroughly before taking a sample, make sure to visibly remove sample material (nasal secretions). Or do not drink, eat or smoke 30 minutes before sampling, it is recommended to gargle 30 minutes in advance. Perform the test immediately after collecting the sample. Follow the instructions for use exactly.

Apply the drops of extraction solution only to the sample well (S). Too many or too few drops of extraction solution can result in an invalid or incorrect test result.

4) The test strip is clearly discolored or smeared? Why is that?

Please note that the test cassette should not be used with more than 5 drops of sample, as the liquid absorption of the test strip is of course limited. If the control line does not appear or the test strip is badly messed up or discolored making it illegible, repeat the test please according to the instructions.

5) I did the test, but I don't see a control line (C). What should I do?

Your test result is invalid. Note the answer to question 4 and repeat the test accordingly the instructions for use.

6) I am unsure about reading the result. What should I do?

For the result to be positive, there must be 2 straight horizontal lines the full width of the cassette be clearly visible. If you are still not sure about the results, contact us to the nearest healthcare facility as recommended by your local authorities.

7) My result is positive. What should I do?

If your result is positive, and test cassette one colored line appears in the control area (C) and a colored line appears in the test area (T). You should call the nearest medical facility, and you, anyone who lives with you, and anyone in your support bubble, must self-isolate in accordance with current national and local guidance. Your test result may be double-checked, and the authority or institution explains the next steps accordingly.

8) My result is negative. What should I do?

If the test cassette only clearly shows the control line, it may mean you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, Migraines, loss of the sense of smell or taste, etc.), please consult your family doctor or the nearest healthcare facility as recommended by your local authorities. If not sure, please repeat the test.

NOTE: This test result is not intended for any travel endorsements and/or public events participation.

【CLINICAL EVALUATION】

Commercially available CE marked Real-Time PCR test was used as the reference RT-PCT Assay. A total of 524 samples were included in this study. The following results were obtained:

Zybio	PCR		
	Positive	Negative	Total
Positive	95*	4	99
Negative	12**	413	425
Total	107	417	524

Note:

* It includes 7 samples with CT value higher than 31.

** It includes 10 samples with CT value higher than 31.

Specificity = 413/417 = 99.041%, 95%CI: (97.562%-99.738%)
Accuracy = 508/524 = 96.947%, 95%CI: (95.089%-98.245%)
Overall sensitivity = 95/107 = 88.785%, 95%CI: (81.229%-94.069%)
Sensitivity with CT≤31: 88/90=97.78%, 95%CI: (92.20%-99.73%)

【REFERENCES】

1. Zhou P, Yang X L, Wang X G, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature, 2020, 579(7798): 270-273.

2. Wu F, Zhao S, Yu B, et al. A new coronavirus associated with human respiratory disease in China. Nature, 2020, 579(7798): 265-269.

3. Li G, Fan Y, Lai Y, et al. Coronavirus infections and immune responses. Journal of medical virology, 2020, 92(4): 424-432.

【LABEL INTERPRETION】

Symbol	Title and Description	Symbol	Title and Description
IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
EC REP	Authorized Representative in the European Community		Manufacturer
REF	Catalog Number		Temperature Limit
CE 1434	CE Mark with identification number of notified body		Do not re-use
Σ	Contains sufficient for <n> tests		Date of manufacture

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