

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

For self-testing.

For in vitro diagnostic use only.

Please read the instruction carefully before use.

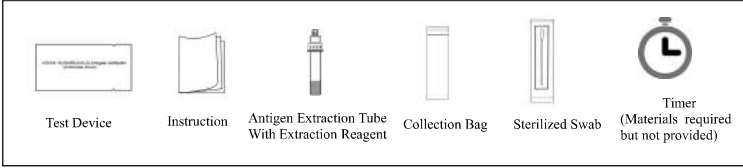


Operation Video

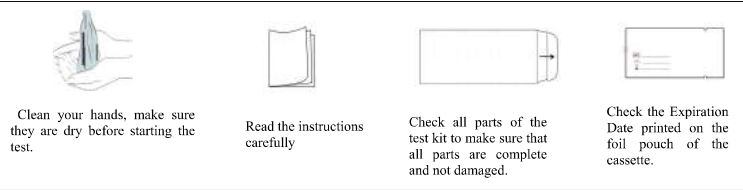
[Intended use]

This product is used for in vitro qualitative detection of the SARS-CoV-2 antigen in human saliva specimen. This product is intended for home self-testing as a rapid test for novel coronavirus infection. Both symptomatic and asymptomatic infections can be tested. The final diagnosis should be made by medical staff based on laboratory results and symptom analysis. This product is suitable for users over 10 years old. Users under 10 years old are advised to complete the self-test under the guidance and assistance of appropriate family members.

[Materials and Components]

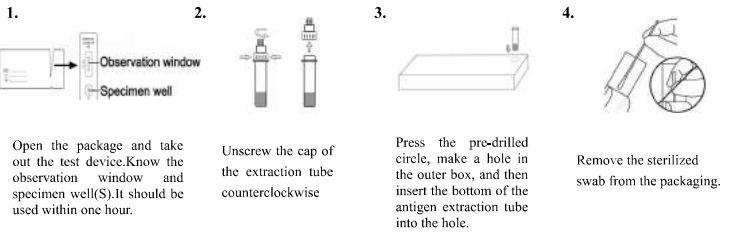


[Preparation before the test]



[Test Procedure]

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



[Summary]

The novel coronavirus belongs 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. Diarrhea is a very common symptom in children and young people.

Once infected with the SARS-CoV-2 virus, you may be hospitalized and some serious 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 SARS-CoV-2 N protein. When the sample contains the coronavirus antigen, both the test line (C) and the control line (T) will appear, and the result will be positive. When the sample does not contain the coronavirus antigen or no coronavirus antigen is detected, the test line (T) will not appear, only control line (C) will appear.

[Limitations of inspection methods]

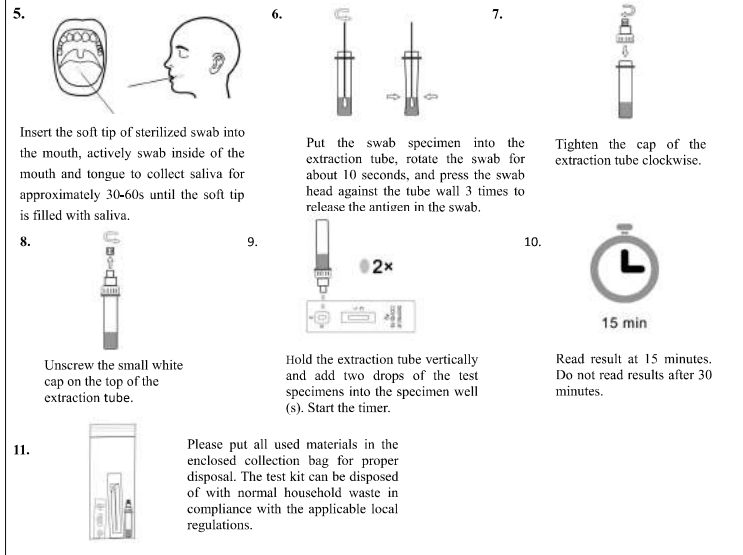
- This test kit is only used for in vitro diagnosis.
- This test kit is only used to detect human saliva. The results of other specimens may be wrong.
- This test kit is only used for qualitative detection and cannot indicate the level of SARS-CoV-2 antigen in the specimen.
- This test kit is only a 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.
- This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2 virus.
- This test can detect both the viable and the non-viable 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.
- Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.
- 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 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.
- A negative result does not rule out infection by the 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.
- 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.
- Positive test results do not exclude the possibility of co-infections of other pathogens.

[Warnings and Precautions]

- 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.
- Do not eat, drink, chew gum, smoke or vape for at least 30 minutes before collecting saliva. False negative results can occur if the saliva is not collected properly.
- 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.
- Please use it within the validity period.
- Do not replace the components in this kit with components in other kits.
- Do not dilute the specimen when testing, otherwise you may get inaccurate results.
- The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
- The test methods and results must be interpreted in strict accordance with this specification.
- Negative results may occur if the SARS-CoV-2 antigen tier in the specimen falls below the minimum detection limit of this kit.
- 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.
- There is no reduction in sensitivity in the DeepBlue Antigen test against the UK variant, Brazilian variant or the South African variant.
- Do not swallow the extraction reagent. If accidentally touch the human skin, eyes or mucous membranes, please rinse with water immediately. If discomfort occurs, please consult a doctor.

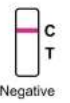
[Storage conditions & period of validity]

- Store at 4°C~30°C, and it is valid for 24 months.



[Interpretation of test results]

Negative result:



Negative

If there is only a control line (C) and the test line (T) is colorless, it indicates that 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 coronavirus cannot be accurately detected at all stages of infection, and there is a possibility of false negatives for negative results.

Positive result:



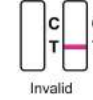
Positive

If both the control line (C) and the test line (T) appear, it indicates that 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.**
- **Contact your doctor or local health department immediately.**
- **Comply with local regulations, self-isolate and report according to local regulations.**
- **Perform PCR test for confirmation.**

Invalid result:



Invalid

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 testing center.

- After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour (15 ~ 30°C, Humidity \leq 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.

[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]

- Limit of detection (LOD):** TCID₅₀/mL is 80. This means that if the virus concentration in the body does not exceed this limit, the test result will be negative.
- High Dose Hook Effect:** When the virus concentration exceeds 1.4×10^7 TCID₅₀/mL, the result may be false negative.
- 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 (VICTORIA), Rhinovirus (HRVA30), Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bacillus pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumoniae, Mycobacterium tuberculosis, Pneumocystis, Pseudomonas Bacteria, human pneumonia virus (hMPV), parainfluenza virus type 1, Staphylococcus epidermidis, Streptococcus salivarius, etc.
- 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.
- Endogenous Interference Studies:** There is no interference in studies on the following substances, including blood, mucin, Alkaloid, dexamethasone, Neilmid, benzocaine, oseltamivir, tobramycin, mupirocin, biotin, etc.

[Clinical Performance]

The overall study scale was 600 cases, 150 positive samples and 450 negative samples.

Statistics of test results of saliva samples:

	Reference RT-PCR Assay				95% Wilson Score CI			
	POS	NEG	TOTAL	PPA	98.7%	92.33%	99.07%	
DEEP BLUE SARS-CoV-2 Ag Test	148	0	148	NPA	>99.9%	98.17%	100%	
	2	450	452	PPV	>99.9%	98.17%	100%	
	150	450	600	NPV	99.6%	92.76%	99.31%	

Sensitivity: 98.7% (95% CI: 92.33% - 99.07%)







Specificity: >99.9% (95% CI: 98.17% - 100%)

Sensitivity: Compared with the RT-PCR Assay, among people infected with SARS-CoV-2 virus, the probability of correct detection by the DeepBlue SARS-CoV-2 Ag Test Kit.

Specificity: Compared with the RT-PCR Assay, among people who have not been infected with SARS-CoV-2 virus, the probability of correct detection by the DeepBlue SARS-CoV-2 Ag Test Kit.

[Index of Symbols]

	The product is used in vitro		Do not re-use		Avoid excessive exposure to the sun
	Expire date		Please read the instruction for use carefully before using		Date of manufacture
	Warning, please refer to the instructions in the package		Manufacturer		Don't use the product when the package is damaged

	Temperature range of product storage		Batch number		Contain sufficient quantity for <n> tests
	European union authorization representative		Keep dry		CE Mark



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