Saliva COVID-19 Antigen Test Kit

INTENDED USE

The Saliva COVID-19 Antigen Test Kit is a lateral flow immunoassay for the qualitative detection of Nucleocapsid Protein from SARS-CoV-2 in saliva. It is intended to be used by professionals and provides a preliminary test result to aid in the diagnosis of infection with SARS-CoV-2 virus.

Any interpretation or use of this preliminary test result should based on comprehensive clinical and other laboratory information as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test.

MODEL

1 test /box，25 tests /box，30 tests /box，40 tests /box，50 tests /box，100 tests /box.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The SARS-CoV-2 virus is a new strain that has caused COVID-19 in humans. The clinical manifestations of COVID-19 are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorder may lead to death.

Based on established diagnostic practices for other respiratory infections, the nasopharyngeal swab was initially adopted as the preferred sampling technique for SARS-CoV-2. However, some studies have shown that saliva can serve as an alternative upper respiratory tract specimen type for SARS-CoV-2 detection. Saliva does not necessarily have to be obtained by a skilled healthcare provider, which increase diagnostic-associated costs. Further more, because nasopharyngeal sampling requires a swab being inserted into the back of the nares, it can cause irritation that could promote sneezing and coughing. Thus, the non-invasive collection of saliva is safer as it protects healthcare workers from being inadvertently exposed to potentially infectious droplets. In addition to being more affordable and safer.

The Saliva COVID-19 Antigen Test Kit detects the Nucleocapsid Protein of SARS-CoV-2 virus in human saliva. It can be performed within 15-20 minutes without the use of laboratory equipment.

TEST PRINCIPLCE

The Saliva COVID-19 Antigen Test Kit is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a conjugate pad containing mouse anti-nucleocapsid protein of SARS-CoV-2 monoclonal antibodies which conjugated with colloidal Gold/platinum nanoparticles. 2) a nitrocellulose membrane strip containing one test lines (T lines) and a control line (C line). The T line is pre-coated with mouse monoclonal antibodies specific for SARS-CoV-2 Nucleocapsid Protein, and the C line is pre-coated with Protein G（SPG） as internal controls of the test strip.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the test strip. The nucleocapsid protein of SARS-CoV-2 virus, if present in the specimen, will bind to the mouse anti-nucleocapsid protein antibody-gold conjugates. The immunocomplex is then captured by the pre-coated mouse anti-nucleocapsid protein monoclonal antibody, forming a black colored T line, indicating an SARS-CoV-2 virus positive test result and suggesting an infection with the virus.

Absence of T lines suggests a negative result. Each test contains an internal control (C line) which should exhibit a black colored line of the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1)Test device. The test cassette is sealed in a foil pouch each containing:
a. One cassette device
b. One desiccant
3)Plastic cup
4)Pipette droper
5)Sample tube(each contains sample processing solution)
7)Instruction of operating

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. 0.2-mL Calibrated Micropipette with pipette tips

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. To obtain accurate results, the Package Insert instructions must be followed.
2. Do not open the sealed pouch until ready to conduct the assay.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Cryopreservation kits and samples should be returned to room temperature before use, and moisture absorption should be avoided during use.
5. Do not use the components of any other type of test kit as a substitute for the components in this kit.
6. Discard and do not use any damaged Test Cassette or materials.
7. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wash hands thoroughly after performing the test.
8. before sampling, do not eat for 2 hours, and no water, no cigarettes, no alcohol, no chewing gum for 30 minutes.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
13. The testing results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 20 minute window should be considered invalid and must be repeated.
14. Do not reuse the used Test Cassette, solutions.

Transportation and Storage

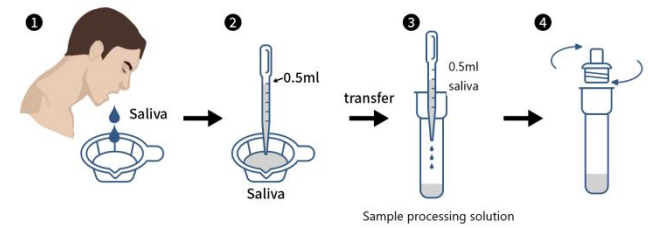
All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable until the expiration date printed on the sealed pouch. Do not freeze the kit or long expose the kit to temperatures above 30°C.

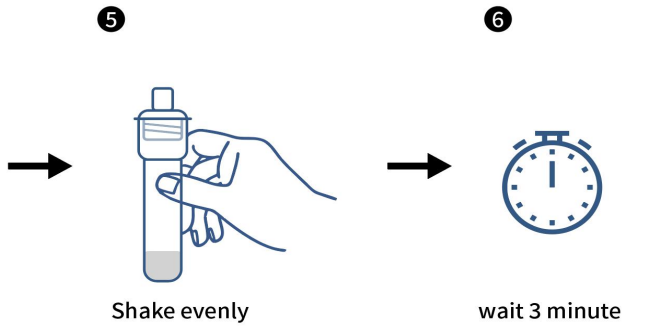
SPECIMEN COLLECTION AND HANDLING

1.Put your tongue on your upper jaw and bow your head to let saliva secrete naturally into a disposable plastic cup.

2.Remove the aluminum foil cover from the sample tube. Use a new dropper to transfer 0.5ml of saliva from the plastic cup to the sample tube (which contained sample processing solution).

3.Put the cap onto the sample tube. Shake evenly, and keep the saliva still in the tube for 3minute.This sample is ready to use as sample for test.



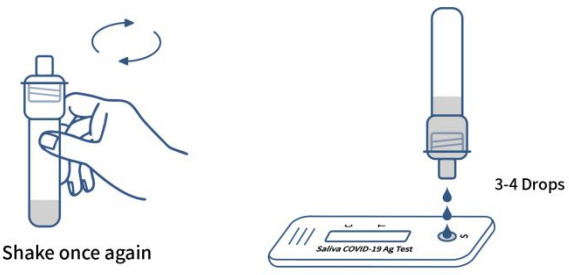


SPECIMEN TRANSPORT AND STORAGE

Specimens should be tested as soon as possible after collection .Samples in sample processing solution are stable for up to 24 hours at 2 to 8℃.

Note: Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

ASSAY PROCEDURE



Step 1: Before testing,bring the sample and kit to room temperature.

Step 2: When ready to test, open the pouch and remove device. Place the test device on a clean, flat surface.

Step 3: Shake the tube again before performing the assay., and add 100μL(or 3-4 drops)

from sample bottle into the center of each sample wells (S well) making sure that there are no air bubbles.

Step 4: Set up a timer.

Step 5: Read the result at 15-20 minutes.

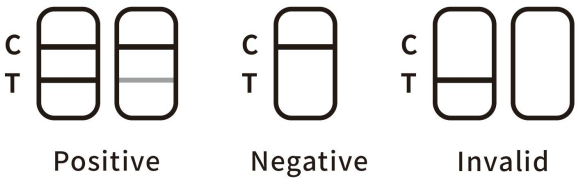
Any results interpreted outside of the 20 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local laws governing the disposal of devices.

QUALITY CONTROL

This test contains a built-in control feature, the C line. The C line develops after adding specimen and sample diluent. If there is no visible C line, review the whole procedure and repeat the test using a new device.

INTERPRETATION OF ASSAY RESULT

1. **POSITIVE RESULT:**
   In addition to the presence of C line, if the T line develops, the test result indicates that SARS-CoV-2 virus is detected. The result is SARS-CoV-2 virus positive.
   Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.
2. **NEGATIVE RESULT**: If only the C line is present, the absence of black color in test lines (T) indicates that no SAES-CoV-2 are detected. The result is negative.
3. **INVALID:** If no C line develops, the assay is invalid regardless of black color in the test lines as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1.The inspection of enterprise reference products shall meet the following requirements：

a.The liquid migration speed should not be less than 10mm/min(n=3).

b.Minimum detection limit：L1,L2 should be positive，L3 could be Weakly positive；L4 should be negative。

c.The coincidence rate of positive enterprise reference products：（+/+）5/5。

d.The coincidence rate of negative enterprise reference products：（-/-）10/10。

e.Repeatability:The test results J were all positive with uniform color.

2.Cross Reactivity

No false positive COVID-19 Antigen test results were observed on specimens from the following disease states or specific conditions, respectively:

Interference	The highest concentration	Result
HCoV-OC43 nucleocapsid protein	10ug/ml	Negative
HCoV-229E nucleocapsid protein	10ug/ml	Negative
HCoV-NL63 nucleocapsid protein	50ng/ml	Negative
HCoV-HKU1 nucleocapsid protein	10ug/ml	Negative
SARS-COV nucleocapsid protein	15.7pg/ml	Negative
MERS-COV nucleocapsid protein	10ug/ml	Negative
Adenovirus	10^5 pfu/ml	Negative
Human Metapneumovirus (hMPV)	10^5 pfu/ml	Negative
Parainfluenza virus 1-4	10^5 pfu/ml	Negative
Influenza A & B	10^5 pfu/ml	Negative
Enterovirus	10^5 pfu/ml	Negative
Respiratory syncytial virus	10^5 pfu/ml	Negative
Rhinovirus	10^5 pfu/ml	Negative
Haemophilus influenzae	10^5 pfu/ml	Negative
Streptococcus pneumoniae	10^6 cfu/ml	Negative
Streptococcus pyogenes	10^6 cfu/ml	Negative
Candida albicans	10^6 cfu/ml	Negative
Pooled human nasal wash – representative of normal respiratory microbial flora	/	Negative
Bordetella pertussis	10^6 cfu/ml	Negative
Mycoplasma pneumoniae	10^6 cfu/ml	Negative
Chlamydia pneumoniae	10^6 cfu/ml	Negative
Legionella pneumophila	10^6 cfu/ml	Negative
Staphylococcus aureus	10^6 cfu/ml	Negative
Staphylococcus epidermidis	10^6 cfu/ml	Negative
Mycobacterium tuberculosis	10^6 cfu/ml	Negative
Pneumocystis jirovecii (PJP)	10^6 cfu/ml	Negative

3.Interference

Common substances (such as medicine and blood) may affect the performance of the COVID-19 antigen saliva rapid test. This was studied by spiking these substances into SARS-CoV-2 negative and positive specimens, respectively. The results demonstrate that at the concentrations tested, the substances do not affect the performance of the COVID-19 antigen saliva rapid test.

List of potentially interfering substances and concentrations tested:

1.Whole Blood	4%	8.Zicam	5%v/v
2.Mucin	0.5%	9.Alkalol	1:10 dilution
3.Menthol/Benzocaine	1.5mg/ml	10.Sore Throat Phenol Spray	15%v/v
4.Naso GEL(NeilMed)	5%v/v	11.Tobramycin	4ug/mL
5.Phenylephrine	15%v/v	12.Mupirocin	10mg/mL
6.Oxymetazoline	15%v/v	13.Fluticasone Propionate	5%v/v
7.Cromolyn	15%v/v	14.Oseltamivir Phosphate	5mg/ml

LIMITATIONS OF TEST

1. The contents of this kit are to be used for the qualitative detection of SARS antigens in saliva.
2. This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample.
3. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
4. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not differentiate among SARS-CoV, HCoV-NL63(nucleocapsid protein≧50ng/ml) and SARS-CoV-2.
8. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
9. Negative results, if necessary, for clinical management, including infection control.
10. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
11. The test results of this kit are for clinical reference only and should not be used as the sole basis for clinical diagnosis. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses.

REFERENCES

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3. Han M Y , Xie T A , Li J X , et al. Evaluation of Lateral-Flow Assay for Rapid Detection of Influenza Virus[J]. BioMed Research International, 2020, 2020(1):3969868.
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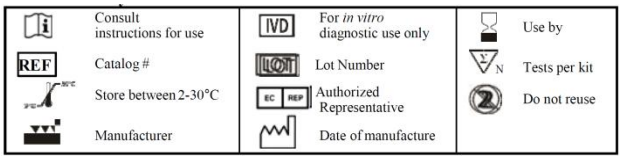
Index of CE Symbols



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EC REP

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