2019-nCoV Ag Saliva Rapid Test Card

(Immunochromatography)

Catalogue Number:
0699C8X001 (1 Test/Kit)
0699C8X005 (5 Tests/Kit)
0699C8X020 (20 Tests/Kit)

INTENDED USE

The Test Card is a lateral flow immunoassay intended for the in vitro qualitative detection of N-protein antigen from 2019-nCoV in human saliva specimens. The Test Card can be used for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

A positive result indicates 2019-nCoV infection, Please quarantine yourself and contact a doctor. Additional testing is necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.
A negative result should be treated as presumptive. It do not rule out 2019-nCoV infection. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Contact a doctor and Confirm with a PCR test, if necessary.

For in vitro use only. Suitable for self-testing use.

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 TEST

This Test Card uses double-antibody sandwich to legally detect the antigen of novel coronavirus (2019-nCoV) in saliva samples. During detection, the gold labeled anti-2019-nCoV monoclonal antibody in the labeling pad binds to the 2019-nCoV antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, it is captured by the anti-2019-nCoV monoclonal antibody pre-coated by the Test area (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the Test area (T). If the sample does not contain 2019-nCoV antigen, a red color reaction line cannot be formed in the Test area (T). Regardless of whether the sample to be tested contains 2019-nCoV antigen, a red reaction line will always form in the quality Control area (C), if the test has been performed properly.

MATERIALS AND COMPONENTS

Materials provided with the test kits

Component \ REF	0699C8X001	0699C8X005	0699C8X020
Pouch(test card and desiccant	1	5	20
Saliva Swab	1	5	20
Instructions for use	1	1	1
Quick Reference Instructions	NA	1	1

Note:

1. Each individual sealed pouch contains one test card and one desiccant pouch (The desiccant pouch is for storage purposes only).
2. *The test strip includes: Gold conjugate (COV19-PS-Mab1-gold colloid, host animal of COV19-PS-Mab1: mouse), Test line (COV19-PS-Mab2, host animal: mouse) and Control line (Host animal: goat).*

Materials required but not provided

1. Timer

STORAGE AND STABILITY

1. Store the test card as packaged between 2-30°C.
2. Keep away from direct sunlight, moisture and heat.
3. The Test Card is stable until the expiration date printed on the outer packing. Do not use expired product.
4. Do not freeze any contents of the test.
5. The test card should be used within 1 hour of removal from the foil pouch.

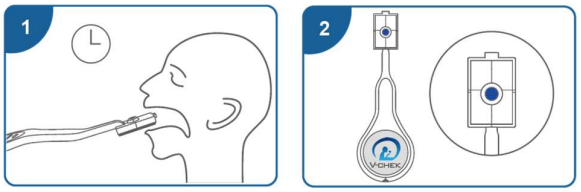
SAMPLE REQUIREMENTS

Note:

1. *Do not eat, drink or smoke prior to the test for at least 30 minutes.*
2. *When sampling, gently hold it in mouth and let saliva naturally adsorb on the sponge.*
3. *Don`t bite the sponge with teeth.*
4. *Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before mouth rinsed, eating or drinking, is recommended.*
5. *The samples should be used as soon as possible after collected.*

Sample collection:

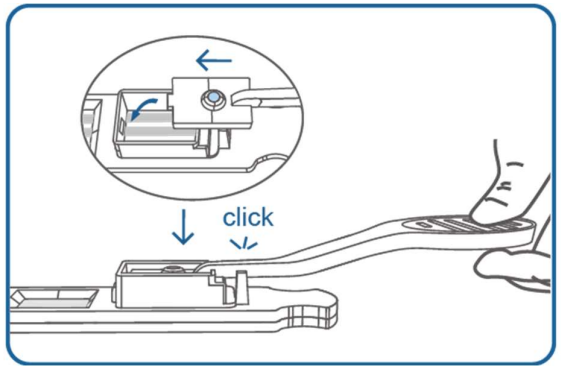
1. Insert the sponge end of the saliva swab into mouth. Actively swab the inside of the mouth and tongue to collect oral fluid.
2. Remove the saliva swab from the mouth when the sponge fill with saliva and become soft, or the indicator turns blue.



TEST PROCEDURE

Before test, please read the instructions carefully.

1. Take the Test Card to equilibrate to room temperature.
2. Unpack the aluminum foil bag, place the Test Card horizontally on the table.
3. Insert the saliva swab with collected sample into the Test Card holder and push down saliva swab. The bump at the end of the saliva swab must be into the hole of the Test Card holder.
4. As the test begins to work, the red color move across the result window in the center of the test device.
5. Wait for 10 minutes and read the results. Do not read result after 15 minutes.



INTERPRETATION OF TEST RESULTS

This product can only perform qualitative detection of 2019-nCoV antigen.

Positive Result:

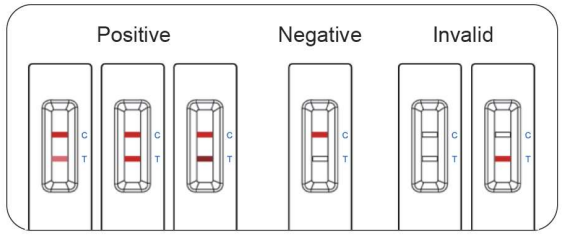
If both C and T lines are visible, the test result is positive and valid.

Negative Result:

If a colored line is visible in the control area, and no colored line appears in the test area, the result is negative and valid.

Invalid Result:

The test result is invalid if a colored line does not form in the control area. The sample must be re-tested, using a new test card.



ACTION

If the test result is positive:

- Note that you are currently suspected of COVID-19 infection
- Contact a doctor/family doctor or the local health office immediately. Any medical decision should not be made before contact a doctor.
- Comply with local self-isolation guidelines
- Do a PCR test for confirmation

If the test is negative:

- Continue to comply with all local applicable rules and protective measures
- Be aware that even if the test is negative, an infection may occur
- In case of suspicion, repeat the test after 1-2 days, as the 2019-nCoV may not be detected accurately in all phases of an infection
- Do a PCR test for confirmation, if necessary.

If the test result is invalid:

- Possibly caused by incorrect operation
- Repeat a test, using a new test cassette
- If test result is still invalid, contact the distributor or the store where you bought the product, with the lot number.

LIMITATIONS

1. The result of the test card should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2. The kit are to be used for the qualitative detection of 2019-nCoV N-protein antigens from saliva specimen.
3. Test Card 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.
4. The test card must be at room temperature (15 ~ 30°C) for 30 minutes before use, otherwise the results may be incorrect.
5. A false negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. Reading time less than 10 minutes may lead a false negative result; Reading time more than 15 minutes may lead a false positive result.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other viral or bacterial infections.
10. Negative results should be treated as presumptive and confirmed with a molecular assay.
11. Users should test specimens as quickly as possible after specimen collection.
12. If the sample volume is not enough, the test cannot be carried out successfully.

PERFORMANCE CHARACTERISTIC

1. Clinical Verification

The performance of Test Card was established with 793 saliva sample collected from symptomatic and asymptomatic patients.

Test Card	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	258	6	264
Detected Negative	22	507	529
Total	280	513	793
Sensitivity	92.14%, 95% CI (88.39, 94.75)		
Specificity	98.83%, 95% CI (97.47, 99.46)		
Accuracy	96.47%, 95% CI (94.94, 97.55)		

2. Limit of Detection

The experimental results show that for the virus culture concentration above 100 $TCID_{50}$/mL, the positive rate of detection is greater than or equal to 95%. So, the limit of detection of the Test Card is 100 $TCID_{50}$/mL.

3. Cross-reactivity

Cross-reactivity of the test card was evaluated. The results showed no cross reactivity with the following specimen.

No.	Specimen type	Conc.
1	HCoV-HKU1	10^5 $TCID_{50}$/mL
2	Staphylococcus aureus	10^6 CFU / mL
3	Streptococcus pyogenes	10^6 CFU / mL
4	Measles virus	10^5 $TCID_{50}$/mL
5	Paramyxovirus parotitis	10^5 $TCID_{50}$/mL
6	Adenovirus 3	10^5 $TCID_{50}$/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 $TCID_{50}$/mL
9	Human Metapneumovirus (hMPV)	10^5 $TCID_{50}$/mL
10	Human coronavirus OC43	10^7 $TCID_{50}$/mL
11	Human coronavirus 229E	10^7 $TCID_{50}$/mL
12	Human coronavirus NL63	$10^7$$TCID_{50}$/mL
13	MERS-Coronavirus EMC/2012	10^7 $TCID_{50}$/mL
14	Bordetella parapertussia	10^6 CFU / mL
15	Influenza B (Victoria strain)	10^5 $TCID_{50}$/mL
16	Influenza B (Y strain)	10^5 $TCID_{50}$/mL
17	Influenza A (H1N1 2009)	10^5 $TCID_{50}$/mL
18	Influenza A (H3N2)	10^5 $TCID_{50}$/mL
19	Avian influenza virus (H7N9)	10^5 $TCID_{50}$/mL
20	Avian influenza virus (H5N1)	10^5 $TCID_{50}$/mL
21	Epstein-Barr virus	10^5 $TCID_{50}$/mL
22	Enterovirus CA16	10^5 $TCID_{50}$/mL
23	Rhinovirus	10^5 $TCID_{50}$/mL
24	Respiratory syncytial virus	10^5 $TCID_{50}$/mL
25	Streptococcus pneumoniae	10^6 CFU / mL
26	Candida albicans	10^6 CFU / mL
27	Chlamydia pneumoniae	10^6 CFU / mL
28	Bordetella pertussis	10^6 CFU / mL
29	Pneumocystis jirovecii	10^6 CFU / mL
30	Mycobacterium tuberculosis	10^6 CFU / mL
31	Legionella pneumophila	10^6 CFU / mL

4. Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Interference substances	Conc.
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3μg / mL
4	Chloramphenicol	3μg / mL
5	Erythromycin	3μg / mL
6	Tobramycin	5%
7	Throat spray（Menthol）	15%
8	Mupirocin	10mg/mL
9	Throat lozenge（Menthol）	1.5mg/mL
10	Tamiflu (Oseltamivir)	5mg/mL
11	Naphthoxoline hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/mL
14	Compound Benzocain Gel	1.5mg/mL
15	Cromoglycate	15%
16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%
18	Fluticasone propionate spray	15%

5. Precision

a. Test 10 replicates of negative and positive reference controls. The negative agreement and the positive agreement were 100%.

b. Test three different lots kits including positive and negative reference controls. The negative agreement and the positive agreement were 100%.

6. Hook Effect

The Test Card was tested up to 1.6 × 10^5 $TCID_{50}$/ml of heat-inactivated 2019-nCoV strain and no high-dose effect was observed.

PRECAUTIONS

1. For in vitro diagnostic use. Do not swallow.
2. Read the instructions for use carefully before starting the test.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Use appropriate precautions in the collection, handling, storage, and disposal of samples and used test contents.
5. Do not reuse the used test card or saliva swab.
6. The user should never open the foil pouch of the test card until it is ready for immediate use.
7. Do not use the kit if the pouch is punctured or not well sealed. Do not use any damaged or dropped test card or material.
8. Do not eat, drink or smoke prior to the test for at least 30 minutes.
9. Do not bite the sponge of the saliva swab with teeth.
10. Testing should be performed in an area with adequate ventilation.
11. Inadequate or inappropriate sample collection, processing, storage and transport may yield a false positive result or a false negative result.
12. To obtain accurate results, do not use visually bloody or overly viscous samples.
13. To obtain accurate results, an opened and exposed test card should not be used.
14. Keep out of the reach of children.
15. Wear safety mask or other face covering when collecting specimen from child or another individual.
16. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling samples.
17. Wash hands thoroughly after handling.
18. Disposal of the diagnostic: all specimens and the used kit has the infectious risk. The process of disposing of the diagnostic must follow the local

infectious disposal law. Discarding the used device sealed in a plastic bag with general waste is accepted.

REFERENCES

1. Center of Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. May 22.
2. Wu F, Zhao S, Yu B, et al. A new coronavirus associated with human respiratory disease in China. Nature. 2020;579:265–9.
3. https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
4. Considerations on the use of self-tests for COVID-19 in the EU/EEA. 17 March 2021

KEY TO SYMBOLS USED

	Consult instructions for use		Date of Manufacturer
2°C 30°C	Store at 2°C~30°C		Do not reuse
	Use-by date	Σ	Contains sufficient for n tests
	Manufacturer		Keep away from Sunlight
LOT	Batch code		Keep Dry
IVD	In vitro diagnostic medical device	REF	Catalogue number
	Do not use if pouch is damaged	EC REP	Authorized representative

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