2019-nCoV Ag Rapid Test Kit

(Immunochromatography)

Catalog Number:

0685C2X001 (1 Test/Kit) 0685C2X005 (5 Tests/Kit) 0685C2X025 (25 Tests/Kit)

INTENDED USE

This kit is used for the in vitro qualitative detection of 2019-nCoV antigen. It is an immunochromatography sandwich assay, and intended to detect 2019-nCoV N-protein antigen in human nasal (NS) swab specimens. This kit 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. A PCR confirmation test is necessary.
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. Confirm with a molecular assay, 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 kit uses double-antibody sandwich to legally detect the antigen of novel coronavirus (2019-nCoV) in nasal swab 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. Then 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 in the Test area (T) on the nitrocellulose membrane. 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

REF / Component	0685C2X001 (1 Test/Kit)	0685C2X005 (5 Tests/Kit)	0685C2X025 (25 Tests/Kit)
Pouch(test cassette and desiccant)	1	5	25
Swab	1	5	25
Tube with buffer	1	5	25
Instruction for use	1	1	1
Quick reference guide	NA	1	1
Workstation	NA	NA	1

Note:

1. Each individual sealed pouch contains one test cassette and one desiccant pouch (The desiccant pouch is for storage purposes only).
2. *The components in different lots of the kit cannot be mixed.*

Materials required but not provided

1. Timer

STORAGE AND STABILITY

1. Store at 2°C - 30°C.
2. Keep away from direct sunlight, moisture and heat.
3. Expiration date and lot No.: see label. Do not use expired product.
4. Do not freeze any contents of the test.
5. The test cassette should be used within 1 hour of removal from the foil pouch.

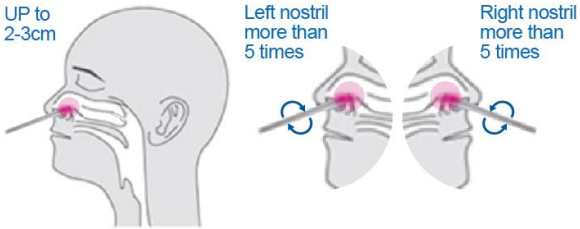
TEST PROCEDURE

Caution:

1. *Please read the instruction for use carefully before starting the test.*
2. *Familiarize yourself with the contents of the test kit in advance without opening the packaging of the components.*
3. *The test cassette should be used within 1 hour of removal from the foil pouch.*
4. *The test kit must be brought to room temperature (15°C - 30°C) before testing.*
5. *Use of gloves is recommended when conducting testing.*
6. *Do not remove the swab until ready for sample collection and do not touch the swab tip.*

Sample collection

1. Insert the entire absorbent tip of the swab (2-3 cm) into the left nostril and swipe firmly against the inside of the nostril more than 5 times in a circular motion. Take out the swab,
2. Insert the swab into the right nostril and firmly stroke the inside of the nostril more than 5 times in a circular motion. Take out the swab.



Note:

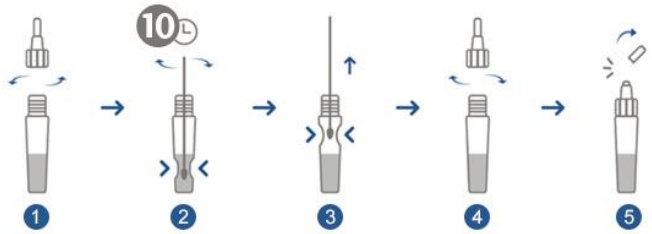
1. False negative results may occur if the swab is not properly collected.

2.The samples should be used as soon as possible after collected (within half an hour).

3. Samples should not be inactivated.

Sample processing

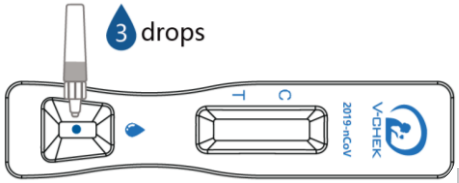
1. Open the drip cap of the buffer tube.
2. Immerse the swab tip with the sample into the buffer tube and rotate the swab tip at least 10 times in the buffer liquid while applying pressure with your fingers.
3. Remove the swab while squeezing the sides of the tube to extract the liquid with the sample from the swab.
4. Screw the drip cap tightly onto the buffer tube.
5. Break off the tip of the drip cap, the sample solution in the tube is ready for test.



Sample testing

Place the test cassette flat on the table and mark it.

1. Add 3 drops to the sample well and start the timer.
2. As the test begins to work, you will see the color move across the result window in the center of the test cassette.
3. Read the result at 15 minutes. Do not read the result after 20 minutes.



INTERPRETATION OF TEST RESULTS

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

Positive Result:

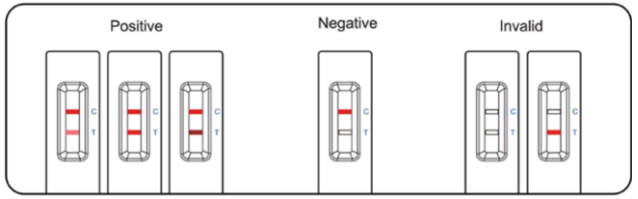
If both C and T lines are visible at 15 minutes, the test result is positive and valid.

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 having a 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
- have a PCR confirmation test performed

If the test is negative:

- Continue to comply with all applicable rules regarding contact with others 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 cannot be detected accurately in all phases of an infection
- Confirm with a molecular assay, if necessary.

If the test result is invalid:

- Possibly caused by incorrect test execution
- Repetition of the test, using a new test cassette
- If test results are still invalid, contact the distributor or the store where you bought the product, with the lot number.

LIMITATIONS

1. The result of the test should not be taken as a confirmed diagnosis. It is 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 nasal (NS) swab. The performance of this test using other specimens has not been substantiated.
3. Test performance depends on the amount of virus (antigen) in the sample. It may or may not correlate with viral culture results performed on the same sample.
4. A false 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.
5. The test kit must be brought to room temperature (15℃~30℃) before used, otherwise the results may be incorrect.
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. Reading time less than 15 minutes may lead a false negative result; Reading time more than 20 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 if nessessary.
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 2019-nCoV Ag Rapid Test Kit (Immunochromatography) was established with 505 Nasal (NS) swabs collected from symptomatic and asymptomatic patients.

2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	266	2	268
Detected Negative	11	226	237
Total	277	228	505
Sensitivity	96.03%, 95% CI (93.03,97.77)		
Specificity	99.26%, 95% CI (97.33, 99.80)		
Accuracy	97.43%, 95% CI (95.65, 98.49)		

The performance of 2019-nCoV Ag Rapid Test Kit (Immunochromatography)with positive results stratified by the comparative method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, As presented in the table below, the positive agreement of the 2019-nCoV Ag Rapid Test Kit (Immunochromatography)is higher with samples of a Ct count <25.

Positive results broken down by CT value are as below:

2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Comparative RT-PCR Method (Positive by Ct Value)	
	Positive (Ct<=25)	Positive (25<Ct)
Detected Positive	193	73
Total	195	82
Positive agreement	98.97%	89.02%

2. Limit of Detection

When the virus culture concentration was 100 $TCID_{50}$/mL and above, the positive rate was greater than or equal to 95%, so the limit of detection for 2019-nCoV Ag Rapid Test Kit (Immunochromatography) is 100 $TCID_{50}$/mL

3. Cross-reactivity

Cross-reactivity of the Kit 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	10^7 $TCID_{50}$/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 replicates of negative and positive by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.

b.Test three different lots kits including positive and negative reference materials of enterprises. The negative results and the positive results were 100%

6. Hook Effect

There was no Hook effect detected when the concentration of inactivated virus stock solution reach to 4.0×10^5 $TCID_{50}$/ml.

PRECAUTIONS

1. For in vitro diagnostic use.Do not swallow.
2. Read the instructions for use carefully before starting the test.
3. The components in different lots of the kit cannot be mixed.
4. Do not use the kit contents beyond the expiration date printed on the outside of the box.
5. Use appropriate precautions in the collection, handling, storage, and disposal of samples and used kit contents.
6. Do not reuse the test cassette, tube or swab.
7. Do not touch swab tip when handling the swab.
8. The user should never open the foil pouch of the test cassette until it is ready for immediate use
9. Do not use the kit if the pouch is punctured or not well sealed.Do not use any damaged or dropped test cassette or material.
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 cassette should not be used.
14. Keep out of the reach of children.
15. Wear safety mask or other face covering when collecting swab specimen from child or another individual
16. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling samples.
17. The sample buffer contains a salt solution (saline). If the solution contacts the skin or eye, flush with plenty of water.
18. Wash hands thoroughly after handling.
19. 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.

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

KEY TO SYMBOLS USED

	Consult Instructions For Use		Date of Manufacturer
2°C 30°C	Store at 2°C~30°C		Do Not Reuse
	Expiration Date	Σ	Tests per Kit
	Manufacturer		Keep away from Sunlight
LOT	Lot Number		Keep Dry
IVD	In Vitro Diagnostic Medical Device	REF	Catalogue Number
EC REP	Authorized Representative		

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Doc No.: DC-IN-0685C2 Ver 1.2

Rel.:2021/04/14