2019-nCoV Ag Saliva Rapid Test Card

(Immunochromatography)

Catalog Number: 0589C4X001 0589C4X005 0589C4X010 0589C4X015 0589C4X020

INTENDED USE

The Test Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from 2019-nCoV in saliva specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset. Results are given for the identification of 2019-nCoV nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, and do not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. 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, and confirmed with a molecular assay, if necessary, for patient management.

The Test Card is intended for use by trained clinical medical personnel specifically instructed and trained on in-vitro diagnostic procedures.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible to infection. Currently, people 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 and more typically, 3 to 7 days. The main manifestations include fever, fatigue, loss of sense of smell and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in some cases.

PRINCIPLE OF THE TEST

This Card uses a double-antibody sandwich to detect the antigen presence 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. The reaction complex moves along the nitrocellulose membrane under the action of chromatography. It is then captured by the anti-2019-nCoV monoclonal antibody pre-coated in the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain 2019-nCoV antigen, a red color reaction line cannot be formed in the T zone. 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).

MATERIALS AND COMPONENTS

Materials provided with the test kits

Specifications / Ingredients	0589C4X001	0589C4X05	0589C4X010	0589C4X015	0589C4X020
Test Card	1	5	10	15	20
Saliva Swab	1	5	10	15	20
Instructions for use	1	1	1	1	1
Quick Reference Instructions	NA	1	1	1	1

Note: *The components in different batches of the kit cannot be mixed.*

Materials required but not provided

1. Timer

STORAGE AND STABILITY

1. Store the test card as packaged between 2-30°C.
2. The Test Card is stable until the expiration date printed on the outer packing. The product will expire after 24 months.
3. Do not use beyond the expiration date.
4. Do not freeze any contents of the test
5. The test card must remain in the sealed pouch until use.

SAMPLE REQUIREMENTS

1. Insert the sponge end of the saliva swab into mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for around 90 seconds without compressing the sponge. It may take longer at times.
2. Remove the saliva swab from the mouth when the sponge becomes fully saturated and the inductor turns blue.
3. Do not eat or drink for 2 hours before the test.
4. The samples should be used as soon as possible after being collected.
5. Samples should not be inactivated.

NOTE:

****When sampling, gently hold the collector in the mouth and let saliva naturally adsorb to the sponge.***

****Don't press the sponge with tongue and don`t bite the sponge with teeth or compress it in any way.***

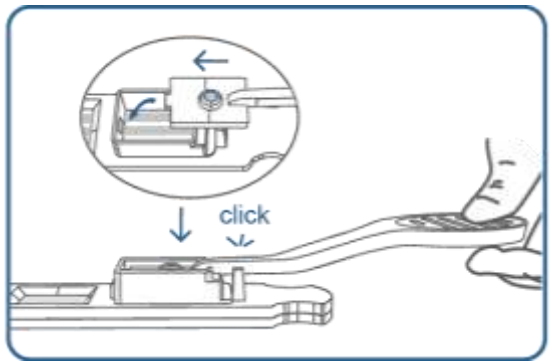
****Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before brushing, eating or drinking is recommended.***

TEST PROCEDURE

Before test, please read the instructions carefully.

1. Allow the test card to equilibrate to room temperature.
2. Open the aluminum foil bag, place the test card horizontally on the table .

3. Insert the saliva swab 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, a purple color will move across the result window in the center of the test device.
5. Wait for 15 minutes and read the results. Ignore all results after 20 minutes.



INTERPRETATION OF TEST RESULTS

This product can only perform qualitative analysis.

Positive Result:

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

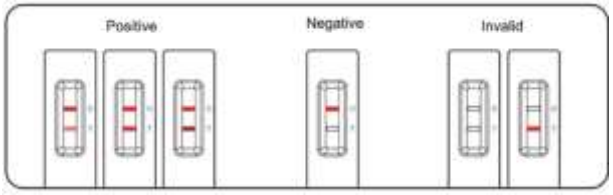
Note: *Specimens containing very low levels of target antigens may develop two colored lines over 15 minutes.*

Negative Result:

If test area (T line) has no color and the control area displays a colored line, the result is negative and valid

Invalid Result:

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



LIMITATIONS

1. The result of the test card should not be taken as a confirmed diagnosis and are for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information, and further clinical data and observation.

2. The 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.

3. The test card must be equilibrated to room temperature (18℃~26℃) before use, otherwise results may be incorrect.

4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.

5. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

6. A reaction time of less than 15 minutes may lead to a false negative result; A reaction time of more than 15 minutes may lead a false positive result.

7. Positive test results do not rule out co-infections with other pathogens.

8. Negative test results are not intended to rule in other viral or bacterial infections.

9. Negative results should be treated as presumptive and confirmed with a molecular assay.

10. Clinical performance was evaluated with fresh samples.

11. Users should test specimens as quickly as possible after specimen collection.

PERFORMANCE CHARACTERISTIC

1. Clinical Verification

The performance of Test Card was established with 243 samples collected from symptomatic patients, with symptoms onset within 7 days of infection.

2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)	Comparative RT-PCR Test Reslt		
	Positive (+)	Negative (-)	Total
Detected Positive	110	2	112
Detected Negative	5	126	131
Total	115	128	243
Sensitivity	95.65%, 95% CI (90.22,98.13)		
Specificity	98.44%, 95% CI (94.48, 99.57).		
Accuracy	97.12%, 95% CI (94.17,98.60)		

The performance of the Test Card 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 with the positive agreement of the Test Card higher with samples of a Ct count <25.

2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)	Comparative RT-PCR Method (Positive by Ct Value)	
	Positive (Ct<=25)	Positive (Ct>25)
Detected Positive	91	19
Total	92	23
Positive agreement	98.91%	82.60%

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%. For the virus culture concentration of 50 $TCID_{50}$/mL and below, the positive rate of detection is lower than 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 specimens.

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	10^5 $TCID_{50}$/mL
11	Human coronavirus 229E	10^5 $TCID_{50}$/mL
12	Human coronavirus NL63	10^4 $TCID_{50}$/mL
13	MERS-Coronavirus EMC/2012	10^4 $TCID_{50}$/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 are not interfered with the substances at the following concentrations:

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

1. Tested against 10 replicates of negative and positive results by using the reference materials of other enterprises. The negative agreement and the positive agreement were 100%.
2. Test three different lots including positive and negative reference materials of other enterprises. The negative results and the positive results 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.
2. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used test contents.
3. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
4. Do not reuse the used Test Card or saliva swab.
5. Do not open the foil pouch of the Test Card exposing it to the ambient environment until the Test Card is ready for immediate use.
6. Discard and do not use a damaged or dropped Test Card or material.
7. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
8. Sample collection and handling procedures require specific training and guidance.
9. To obtain accurate results, do not use visually bloody or overly viscous samples.
10. To obtain accurate results, an opened and exposed Test Card should not be used.
11. Testing should be performed in an area with adequate ventilation.
12. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this test.
13. Wash hands thoroughly after handling.

KEY TO SYMBOLS USED

COMPONENT	Materials Included	CASSETTE	Test Card
IFU	Instructions for Use	SWAB	Saliva Swab
	Consult Instructions For Use		Date of Manufacturer
	Store at 2°C~30°C		Do Not Reuse

	Expiration	REF	Catalogue Number	Date
	Manufacturer		Keep away from Sunlight	
LOT	Lot Number	Σ	Tests per Kit	
	Keep Dry	IVD	In Vitro Diagnostic Medical Device	

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