COVID-19 Antigen Rapid Test Cassette(Swab)
Instruction For Use

CE IVD

【Product name】

Common name:
COVID-19 Antigen Rapid Test Cassette(Swab)

【Package】

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

【Intended use】

The COVID-19 Antigen Rapid Test Cassette(Swab) is a lateral flow immunoassay for the qualitative detection of Nucleocapsid Protein from SARS-CoV-2 on nasopharyngeal (NP) swab. 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.

【Summary and explanation of the test】

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 7days.The main manifestations include fever,fatigue and dry cough.Nasal congestion,runny nose,sore throat,myalgia and diarrhea are found in a few cases.
Nasopharyngeal swab is a common sampling method for the diagnosis of respiratory infections, such as common cold, influenza, RSV etc. The COVID-19 Antigen Rapid Test Cassette(Swab) detects the Nucleocapsid Protein of SARS-CoV-2 virus in human nasopharyngeal swab sample. The result can be performed within 15-20 minutes by minimally skilled personnel without the use of laboratory equipment.

【Test principle】

The COVID-19 Antigen Rapid Test Cassette(Swab) use the lateral flow chromatographic immunoassay to detect COVID-19 antigen. 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 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
(2) Sample Tubes.
(3) Lysis buffer Bottle
(4) Nasopharyngeal Swabs
(5) sample tube holder
(6) Instruction of operating

【Materials required but not provided】

1. Clock or timer
2. Vortex
3. 0.2-mL Calibrated Micropipette with pipette tips

【Warnings and precautions】

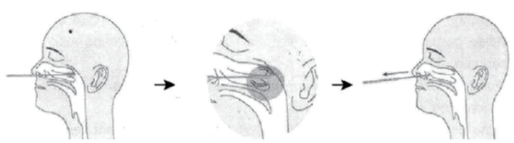
For in Vitro Diagnostic Use
1. To obtain accurate results, the Package Insert instructions must be followed.
2. Do not open the sealed pouch until ready to conduct the assay.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Cryopreservation kits and samples 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. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
12. Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided Small, Clear 100µL Fixed Volume Pipette when adding the sample to the Test Cassette.
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, Reagent Tubes, solutions, or Control Swabs.

【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. The product is valid for 24 months.Do not freeze the kit or long expose the kit to temperatures above 30°C.

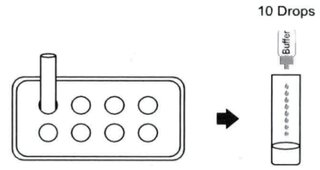
【Specimen collection and handling】

Use the nasopharyngeal swab supplied in the kit.
To collect a nasopharyngeal swab sample, carefully insert the swab (provided in the kit) into the nostrill pharynx that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinate. Rotate the swab several times against the nostrill pharynx wall then remove it from the nostrill pharynx.

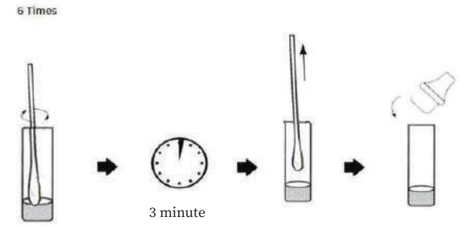


【Sample preparation procedure】

1. Insert the sample tube into the sample tube holder in package box. Make sure that the tube is standing firm and reaches the bottom of the holder.
2. Add 0.2ml-0.3ml (about10 drops) of the lysis buffer from the provided lysis buffer bottle to each sample tube.



3. After sample collection, insert the swab into the sample tube. Rotation to mix the swab with the lysis buffer at least 6 times while pressing the head against the bottom and side of the sample tube. Leave the swab in the sample tube for 3 minute. Squeeze the tube several times with fingers from outside of the tube to immerse the swab.
4. Remove the swab.Put the cap onto the sample tube. The extracted solution will be used as test sample.



【Specimen transport and storage】

Specimens should be tested as soon as possible after collection .Samples in lysis buffer are stable for up to 24 hours at 2 to 8°C.
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】

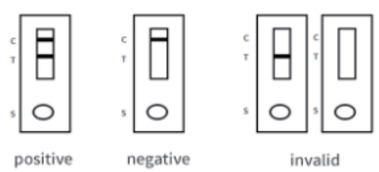
Step 1: When ready to test, open the pouch and remove device. Place the test device on a clean, flat surface.
Step 2: Add the sample(prepared above step) by putting the cap onto the sample tube. Holding the capped sample tube, and add 100µL(or 3~4 drops) of the specimen into the center of the sample well (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.NEGATIVE RESULT: If only the C line is present, the absence of black color in test lines (T) indicates that no SARS-CoV-2 are detected. The result is negative.
2.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.
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
the cross-reactivity and Microbial couldn't cause Interference When the concentration of the substance does not exceed the concentration listed in the table below:

Interference	The highest concentration	Units
HCoV-229E nucleocapsid protein	10	μg/mL
HCoV-OC43 nucleocapsid protein	10	μg/mL
HCoV-NL63 nucleocapsid protein	2.5	μg/mL
SARS-COV nucleocapsid protein	0.625	ng/mL
MERS-COV nucleocapsid protein	10	μg/mL
HCoV-HKU1 nucleocapsid protein	10	μg/mL
Adenovirus 71	10^5	$TCID_{50}$/mL
AdenovirusC1	The result of protein blast showed it have no significant similarity with nucleocapsid protein of SARS -COV-2	
Human Metapneumovirus (hMPV)	The result of protein blast showed it have no significant similarity with nucleocapsid protein of SARS -COV-2	
Parainfluenza virus 1	10^5	$TCID_{50}$/mL
Parainfluenza virus 2	10^5	$TCID_{50}$/mL
Parainfluenza virus 3	10^5	$TCID_{50}$/mL
Parainfluenza virus 4	10^5	$TCID_{50}$/mL
Influenza A Protein	10	μg/mL
Influenza B Protein	10	μg/mL
Enterovirus	10^5	$TCID_{50}$/mL
Respiratory syncytial virus	10^5	$TCID_{50}$/mL
Rhinovirus	10^5	$TCID_{50}$/mL
Haemophilus influenzae	10^6	CFU/ml
Streptococcus pneumoniae	10^6	CFU/ml
Streptococcus pyogenes	10^6	CFU/ml
Candida albicans	10^6	CFU/ml
Pooled human nasal wash – representative of normal respiratory microbial flora	/	/
Bordetella pertussis	10^6	CFU/ml
Mycoplasma pneumoniae	10^6	Copies/ml
Chlamydia pneumoniae	10^6	Copies/ml
Legionella pneumophila	10^6	CFU/ml
Staphylococcus aureus	10^6	CFU/ml
Staphylococcus epidermidis	10^6	CFU/ml
Mycobacterium tuberculosis	The result of protein blast showed it have no significant similarity with nucleocapsid protein of SARS -COV-2	
Pneumocystis jirovecii (PJP)	The result of protein blast showed it have no significant similarity with nucleocapsid protein of SARS -COV-2	

4. Interference
Common substances (such as throat medicine and blood) may affect the performance of the COVID-19 Antigen Rapid Test. This was studied by spiking these substances into SARS-CoV-2 negative and positive specimens, respectively. The results demonstrate that the substances do not affect the performance of the COVID-19 Antigen 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

5. Sensitivity and specificity
a. Day 0-7
Summary of positive and negative agreement with real patient specimen type.

Test result	PCR confirmed samples		
	Positive	Negative	Total
Positive	50	1	51
Negative	0	50	50
Positive agreement	98.04% (95% CI 89.70% to 99.65%)		
Negative agreement	100% (95% CI 92.87% to 100.00%)		

Specificity:100% Sensitivity:98.04%

b. Day 0-14
Summary of positive and negative agreement with real patient specimen type.

Test result	PCR confirmed samples		
	Positive	Negative	Total
Positive	53	2	55
Negative	0	50	50
Positive agreement	96.36% (95% CI 87.68% to 99.00%)		
Negative agreement	100% (95% CI 92.87% to 100.00%)		

Specificity:100% Sensitivity:96.36%

【Limitations Of Test】

1. The contents of this kit are to be used for the qualitative detection of SARS antigens from nasopharyngeal swab.
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 between SARS-CoV, HCoV-NL63(nucleocapsid protein≧2.5ug/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】

1. Chaolin Huang, Yeming Wang,etal. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. TheLancet.2020;VOL395:497-506.
2. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. 24 January 2020. New England Journal of Medicine.
3. Wu P, Hao X, Lau EHY, Wong JY, Leung KSM, Wu JT, et al. Real-time tentative assessment of the epidemiological characteristics of novel coronavirus infections in Wuhan, China, as at 22 January 2020. Eurosurveillance. 2020;25(3):2000044.
4. Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989;35(10):972-4.
5. Bucknall RA, King LM, Kapikian AZ, Chanock RM. Studies with human coronaviruses II. Some properties of strains 229E and OC43. Proceedings of the Society for Experimental Biology and Medicine. 1972;139(3):722-7.
6. John RKS, King A, De Jong D, Bodie-Collins M, Squires SG, Tam TW. Border screening for SARS. Emerging Infectious Diseases. 2005;11(1):6.
7. Gunaratnam PJ, Tobin S, Seale H, Marich A, McAnulty J. Airport arrivals screening during pandemic (H1N1) 2009 influenza in New South Wales, Australia. Medical Journal of Australia. 2014;200(5):290-2.
8. Shu P-Y, Chien L-J, Chang S-F, Su C-L, Kuo Y-C, Liao T-L, et al. Fever screening at airports and imported dengue. Emerging Infectious Diseases. 2005;11(3):460.
9. Huizer Y, Swaan C, Leitmeyer K, Timen A. Usefulness and applicability of infectious disease control measures in air travel: a review. Travel Medicine and Infectious Disease. 2015;13(1):19-30.
10. Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. PLoS One. 2012;7(4):e35797-e.
11. Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. The Lancet. 24 January 2020.

【Interpretation of signs】

Symbol	Used for	Symbol	Used for
IVD	In vitro diagnostic instruments	®	Trademark
	Temperature limitation		Manufacturers
	The date of production		Expiry date
LOT	Product batch number		Do not reuse
	Not use if the package is damaged		

Manufacturer:
Zhengzhou Fortune Bioscience Co.,Ltd.
Address:East of Wansan Road(Fangxin Industrial Zone),North Side of Shangdu Street, Zhongmu County,Zhengzhou City,Henan Province,China
Telephone: 86-371-55018786
Email: info@fortunebio.com

EC REP
CMC Medical Devices& Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain