COVID-19 And Influenza A/ influenza B virus Antigen Combined Test Cassette(Swab)

INTENDED USE

The COVID-19 And Influenza A/ influenza B virus Antigen Combined Test Cassette(Swab) is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 and influenza A/ influenza B in 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 and Influenza A/ influenza B 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.

Influenza (commonly known as ‘flu’) is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Influenza A virus are typically more prevalent than influenza B virus and are associated with most serious influenza epidemics. The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus. Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2- 23%. However, RT-PCR is expensive, complex and must be performed in specialized laboratories.

The COVID-19 And Influenza A/ influenza B virus Antigen Combined Test Cassette(Swab) detects COVID-19 and Influenza A virus/Influenza B virus in human nasopharyngeal swab sample. It can be performed within 15-20 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLCE

The COVID-19 And Influenza A/ influenza B virus Antigen Combined Test Cassette(Swab) is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) A black colored conjugate pad containing mouse anti-nucleoprotein from SARS-CoV-2 monoclonal antibodies or mouse anti-Influenza A/ influenza B monoclonal antibodies which conjugated with colloidal gold/platinum nanoparticles. 2) a nitrocellulose membrane strip containing test lines (T line or A line/B line) and a control line (C line). The C line are all pre-coated with protein G(SPG) as internal controls of the test strip.

For theCOVID-19 Test cassette: the T line is pre-coated with mouse monoclonal antibodies specific for SARS-CoV-2 nucleoprote. 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. Nucleoprotein, if present in the specimen, will bind to the labeled mouse anti-nucleoprotein antibody. The immunocomplex is then captured by the pre-coated mouse anti-nucleoprotein monoclonal antibody, forming a black colored T line, indicating an SARS-CoV-2 virus positive test result and suggesting an infection with the virus.

For the FluA/FluB test cassette:The A/B line is pre-coated with mouse monoclonal antibodies specific for inInfluenza A(A)/influenza B(B). During the test, the treated extract is added drop wise to the sample well of the test. When the test sample contains influenza A/B virus antigens , the Influenza A/B virus antigen first forms a reaction complex with the labeled antibody. Under the action of chromatography, the reaction complex moves forward along the nitrocellulose membrane and is detected by the detection area the pre-coated influenza A/B virus monoclonal antibody capture, and a black line is finally formed on the detection area(A/B line).

For each test, absence of T lines suggests a negative result. Each test contains an internal control (C line) which should exhibit a black colored line 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.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Sample Tubes
3. Lysis buffer Bottle
4. Sterile Nasopharyngeal Swabs
5. 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, unless ready to conduct the assay.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Test 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. Sample collection and handling procedures require specific training and guidance.
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. Do not pour sample from the Reagent Tube into the Test Cassette sample well.
14. 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.
15. Do not reuse the used Test Cassette, Reagent Tubes, solutions, or Control Swabs.

Transportation and Storage

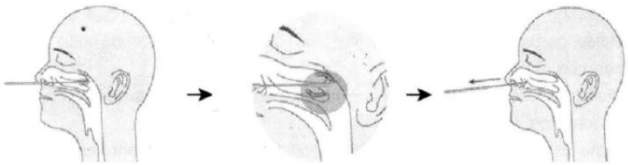
All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C.The test device is stable until the expiration date printed on the sealed pouch. Do not freeze the kit or long expose the kit to temperatures above 30°C.

This product should be shipped at room temperature.

SPECIMEN COLLECTION AND HANDLING

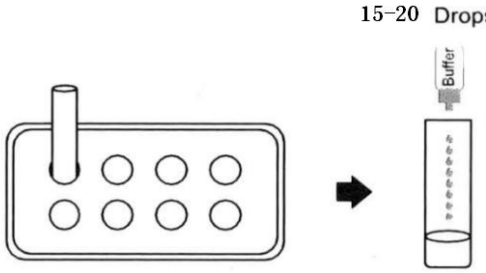
Use the nasopharyngeal swab supplied in the kit.

To collect a nasopharyngeal swab sample, carefully insert the swab (provided in the kit) into the nasopharynx 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 nasopharynx wall then remove it from the nasopharynx.

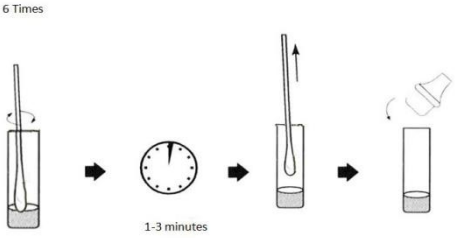


SAMPLE PREPARATION PROCEDURE

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 0.4ml-0.5ml (about15-20 drops) of the lysis buffer from the provided lysis buffer bottle to each sample tube.



3. 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 1-3 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.
5. For VTM sample: When patient sample is stored in VTM tube, take 150ul VTM sample to the sample tube, add 150ul(or 5-6 drops) lysis buffer. Mixing well. Put the cap onto the sample tube and extraction for 1-3 minute. This sample is ready to use as sample.



SPECIMEN TRANSPORT AND STORAGE

Specimens should be tested as soon as possible after collection . If transport of samples with viral transport medium (VTM) is required, minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 0.5milliliter or less is best to avoid excessive dilution of the patient sample. Based on data generated with nasopharyngeal swabs in VTM or lysis buffer are stable for up to 24 hours at 2 to 8℃.

Note: When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. 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: Bring the specimen and test components to room temperature.

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

Step 3: 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) 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.

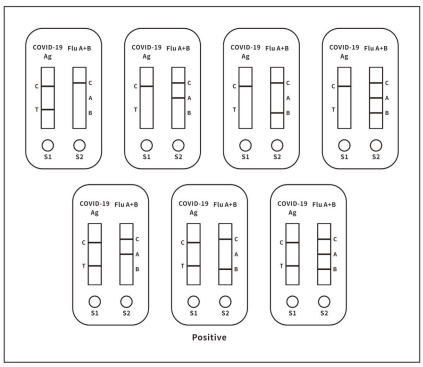
Any results interpreted outside of the 20 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local laws governing the disposal of devices.

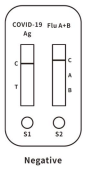
QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding sample. 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**: For each cassette, if only the C line is present, the absence of black color in test lines (T/A/B) indicates that no COVID-19/Influenza A/ influenza B are detected. The result is negative.
2. **POSITIVE RESULT:**
   For COVID-19 test cassette :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 or reactive.
   For Influenza A + Influenza B test cassette :In addition to the presence of C line, if the A line develops, the test result indicates that Influenza A virus is detected. The result is Influenza A virus positive.If the B line develops, the test result indicates that Influenza B virus is detected. The result is Influenza B 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 above. 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：L1-1,L1-2 should be COVID-19 positive; LA-1,LA-2 should be influenza A positive; LB-1,LB-2 should be influenza B positive; L1-3/LA-3/LB-3 should be Weakly positive for COVID-19/influenza A /influenza B separately ;L4 should be negative。

c.The coincidence rate of positive enterprise reference products：P1-P3 should be COVID-19 positive;P4-P11 should be influenza A positive;P12-P15 should be influenza B positive.

d.The coincidence rate of negative enterprise reference products：the result ought to be all negative。

e.Repeatability: The test results of J1,JA,JB ought to be COVID-19,influenza A,influenza B positive separately. The color should be uniform for each repeat testing .

2.Cross Reactivity

No false positive COVID-19 and Influenza A/ influenza B 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
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 throat medicine and blood) may affect the performance of the COVID-19 and Influenza A/ influenza B Antigen Rapid Test. This was studied by spiking these substances into COVID-19,Influenza A and influenza B negative and positive specimens, respectively. The results demonstrate that at the concentrations tested, the substances studied do not affect the performance of the COVID-19 and Influenza A/ influenza B Antigen Combined 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 COVID-19/Influenza A/ influenza B antigens from nasopharyngeal swab.
2. This test detects both viable (live) and non-viable, COVID-19/Influenza A/ influenza B. Test 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. 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 of COVID-19 do not differentiate between SARS-CoV, HCoV-NL63 （N protein≧50ng/ml） and SARS-CoV-2.
8. Negative test results are not intended to rule in other non-SARS-CoV-2/Influenza A/

influenza B viral or bacterial infections.

9. Negative results should be treated as presumptive and confirmed with an authorized molecular assay, if necessary, for clinical management, including infection control.
10. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
11. Users should test specimens as quickly as possible after specimen collection.
12. If the differentiation of specific strains is needed, additional testing, in consultation with local public health departments, is required.

REFERENCES

1. Guidelines for the diagnosis and treatment of corona virus disease 2019 (trial version eighth)[J]. Chin J Viral Dis,2020,10(05):321-328.
2. 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.
3. Zhang X Y, Zhang Y Y, Zhang X G, et al. Research Progress of New Coronavirus SARS-CoV-2 Detection Technology[J]. Prog. Biochem. Biophys., 2020(4):275-285.

Index of CE Symbols

Consult instructions for use	For *in vitro* diagnostic use only	Use by
Catalog #	Lot Number	Tests per kit
Store between 2-30°C	Authorized Representative	Do not reuse
Manufacturer	Date of manufacture	

Manufacturer:

Zhengzhou Fortune Bioscience Co.,Ltd .

Address:East of Wansan Road(Fangxin Industrial Zone),North Side of Shangdu Street, Zhong mu County,Zhengzhou City,Henan Province,China

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EC REP

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