No.IFU-COVID-19Ag&FLU A+B&RSV& ADV-NPO-01,Ver.A/0

CE

SARS-CoV-2 & Influenza A+B & RSV& ADV Antigen Combo Test Kit (Colloidal Gold)

REF: CFRAINPO-X

For professional use only

[Intended use]

This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigens in human nasopharyngeal (NP) swabs or oropharyngeal swabs samples.

[Summary]

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. Once infected with the SARS-CoV-2 virus, you may be hospitalized and some complications may occur. If without prompt treatment it may even lead to death.

Influenza, usually called "flu", is an acute respiratory infectious disease caused by influenza viruses. It is highly contagious and is spread mainly through coughing and sneezing. It usually breaks out in spring and winter. Divided into influenza A virus, influenza B virus and influenza C virus. Influenza A virus has strong variability, followed by influenza B virus, and influenza C virus is very stable, so influenza A virus is more serious and prevalent than influenza B virus.

Respiratory syncytial virus (RSV) is a common, and very contagious, virus that infects the respiratory tract of most children before their second birthday. Nearly half of all children become infected by RSV in their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. RSV infection can cause cold-like symptoms, including a cough and runny nose, which usually last 1 to 2 weeks. Respiratory syncytial virus spreads through the air, like after a cough or a sneeze, and through direct contact like touching. People are typically infected with RSV for the first time as an infant or toddler and nearly all children are infected before their second birthday. However, repeat infections may occur throughout life, and people of any age can be infected. Infections in healthy children and adults are generally less severe than among infants and older adults with certain medical conditions.

Although a wide variety of viral agents are capable of causing lower respiratory tract infections in children and adults, influenza A & B; respiratory syncytial virus (RSV); parainfluenza viruses 1, 2, and 3; and adenovirus are the most common. however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis and rash illness. Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids and intestines of infected hosts and shedding can occur for months or years.

The gold standard method for laboratory diagnosis is the virus isolation and culture method, while the long cycle time for cell culture identification seriously affects the timely clinical guidance of patient medication, and the method is limited in clinical application. Compared with the cell culture method, reverse transcription-polymerase chain reaction (RT-PCR) has higher sensitivity, but the cost of RT-PCR method is higher, the experiment time takes 4-6 hours, and the experiment operation is more professional , So the field application is restricted. This product uses the colloidal gold method and is suitable for the auxiliary diagnosis of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) viruses.

[Test principle]

This kit uses the double antibody-sandwich method to detect antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to the antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated antibody which was coated on the test line, a visible colored line will show up, which indicates that the antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

[Warnings and Precautions]

1. For *in vitro* diagnostic use.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
4. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use it if the aluminum foil bag is damaged or the test device is damp.
5. Please use it within the validity period.
6. Balance all reagents and specimens to room temperature (15 ~ 30 ℃) before use.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
10. The test methods and results must be interpreted in strict accordance with this specification.
11. Negative results may occur if the antigen titer in the specimen falls below the minimum detection limit of this kit.

[Materials and Components]

Materials provided

1) Sterilized Swab
2) Antigen extraction tube with Extraction Reagent
3) Test device
4) Instruction
5) Tube Rack (For 25pcs/box only)

Materials required but not provided

Timer.

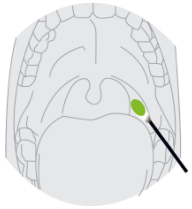
[Storage conditions & period of validity]

1. The kit should be stored at 4-30 ℃ until the expiry date printed on the sealed pouch.
2. After the foil pouch is unsealed, the test device should be used as soon as possible within one hour.
3. The test device should be kept away from direct sunlight, moisture and heat.
4. Do not freeze the test kit.

[Specimen Collection]

1. Oropharyngeal swab sample:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little hard back and forth at least 3 times.



2. Nasopharyngeal (NP) swab sample:

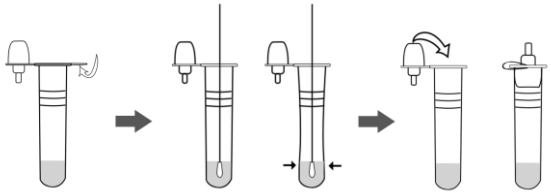
Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way.

[Sample Transport and Storage]

After Swab specimens were collected, swab can be stored in extraction reagent provided with the kit. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8℃for no more than 24 hours; Store at -70 ℃ for a long time, but avoid repeated freeze-thaw cycles.

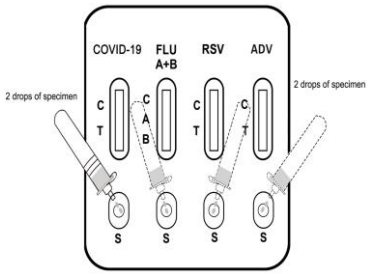
[Specimen Preparation]

1. Tear off the sealing film on the antigen extraction tube.
2. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Insert a dropper tip into the extraction tube tightly.



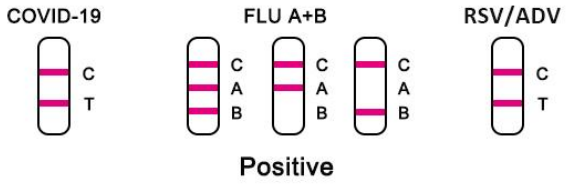
[Test Procedure]

Read the instructions carefully before use and bring test device, extraction reagent and specimens were restored to room temperature.



1. Open the package and take out the test device.
2. Hold the extraction tube vertically and add two drops of the test specimens into each specimen well (s). Start the timer.
3. Interpret the results within 15 minutes. Strong positive results can be read within 15 minutes, however, negative results must be read after 15 minutes, and the results after 30 minutes are no longer valid.

[Interpretation of test results]



Positive result:

1) For COVID-19:

If both the control line (C) and the test line (T) appear, it indicates that SARS-CoV-2 antigen has been detected and the result is positive.

2) For Flu A+B:

· If the quality control line C and the test line A&B all appear, indicating that influenza A&B antigens have been detected and the result is positive.

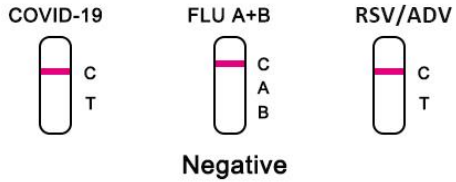
· If both the quality control line C and the test line A appear, indicating that influenza A antigen has been detected and the result is positive.

· If both the quality control line C and the test line B appear, indicating that influenza B antigen has been detected and the result is positive.

3) For RSV or ADV:

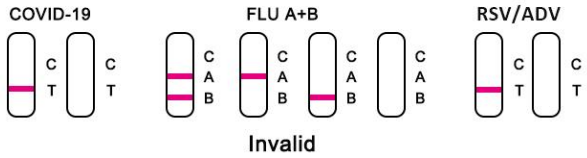
If both the control line (C) and the test line (T) appear, it indicates that RSV or ADV antigen has been detected and the result is positive.

Note: The red line in the test line (T) can show different shades of color. However, even a very weak ribbon should be judged as a positive result during the specified observation period, regardless of the color of the ribbon.



Negative result:

If only quality control line C, test line T or test line A or test line B are colorless, it means that no antigen of corresponding pathogen is detected, and the result is negative.



Invalid result:

If the quality control line C is not observed, it will be invalid regardless of whether there is detection line T or detection line A or detection line B, and the test shall be conducted again.

[Quality Control]

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

[Limitations of inspection methods]

1. This product is used for quantitative testing only and cannot indicate the level of antigen in the specimen.
2. This test kit is only used to detect human nasopharyngeal (NP) swabs or oropharyngeal swab extracts. The results of other specimens may be wrong.
3. This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor’s diagnosis shall prevail.
4. Diagnosis and treatment can not only rely on this test result. Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

[Performance index]

1. Physical characters

1.1 Appearance: The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without waggle. The extraction reagent should be free of foreign matter.

1.2 Size: the size of the inner strip should not be less than 2.5mm.

1.3 Liquid migration speed should not be less than 10mm/min.

2. Limit of detection (LOD)

2.1 For COVID-19: 80 $TCID_{50}$/ml

2.2 For Flu A: the positive quality control diluted 10^5-fold

For Flu B: the positive quality control diluted 10^3-fold

2.3 For RSV: 10 ng/ml

2.4 For ADV: 1 ng/ml

3.Cross reaction:

3.1 For COVID-19:

Do not cross react with Adenovirus 3, Parainfluenza virus Type 2, Human coronavirus NL63, MERS, coronavirus(Pseudovirus,, part of ORFlab+N gene), Human coronavirus 229E, Human coronavirus OC43, Human Coronavirus HKU1, SARS-COV-2Pseudovirus (N full-length gene), Enterovirus, Respiratory syncytial virus(A), Parainfluenza virus Type 3, Parainfluenza virus Type 4a, Influenza A H3N2 (Wisconsin/67/05), Influenza A H1N1, Influenza B, (VICRTORIA), Rhinovirus(HRVA30), Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Human Metapneumovirus (hMPV), Parainfluenza virus Type 1, Staphylococcus Epidermidis, Streptococcus Salivarius, etc.

3.2 For Flu A+B:

- Influenza A virus and influenza B virus do not cross each other
- Do not cross react with influenza C virus, parainfluenza virus, adenovirus, respiratory syncytial virus, herpes simplex virus, mumps virus, rhinovirus, respiratory chlamydia, mycoplasma, tuberculosis, bacillus pertussis, candida albicans, diphtheria, influenza Haemophilus, Legionella pneumophila, Mycobacterium tuberculosis, Staphylococcus aureus, gastrointestinal virus 71, coronavirus, etc.

3.3 For Flu RSV and ADV:

Do not cross react with SARS-CoV-2, Influenza A, Influenza B, etc.

4.Interfering substances

4.1 For COVID-19:

There is have no interference with test results, such as Parainfluenza virus Type 1, Parainfluenza virus Type 2, Parainfluenza virus Type 3, Parainfluenza virus Type 4a, Adenovirus (e.g. C1 Ad. 71), Human Metapneumovirus (hMPV), Influenza A H3N2(Wisconsin/67/05), Influenza A H1N1, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Influenza B (Malaysia/2506/04), Enterovirus, Respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Candida albicans, Pooled human nasal wash, Bordetella pertussis, Mycoplasma pneumoniae, Staphylococcus Epidermidis, Streptococcus Salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS coronavirus, etc.

4.2 For Flu A+B, RSV and ADV:

Common interfering substances in the sample, such as blood, mucin, pus, etc., have no effect on the test results

[Instruction of Symbols]

CE	CE mark		Consult instructions for use
LOT	Batch number		Do not re-use
IVD	*In vitro* diagnostic medical device	30℃ 2℃	Storage temperature
	Date of manufacture		Manufacturer
Σ	Contains sufficient for <n> tests		Keep dry
	Use before the date		Do not use if package is damaged and consult instructions for use
	Keep away from sunlight	EC REP	Authorized Representative in European Community

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,High-Tech Development Zone,230088 Hefei, Anhui,China

EC REP
MedUnion S.L.
Carrer de Tapioles, 33, 2- 1,
08004 - Barcelona
Cataluña, Spain