EN
No.IFU-CFRA-NST-01,Ver.A/5

CE 3018

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

For in vitro diagnostic use only. For self-testing.
Please read the instruction carefully before use.

Operational Use Video

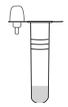
[Intended use]

This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigen in human nasal swab specimens. It is a non-automated rapid test method for infection. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing may be necessary. Users under the age of 15 should complete the test with supervision of an adult. Both symptomatic and asymptomatic infections can be tested.

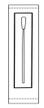
[Materials and Components]

Test Device


Instruction


Antigen Extraction Tube with Extraction Reagent

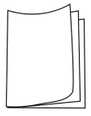

Collection Bag


Sterilized Swab


Timer (Materials required but not provided)

[Preparation before the test]


Blow your noses several times before taking the specimen. Clean your hands, make sure they are dry before starting the test.


Read the instructions Carefully.

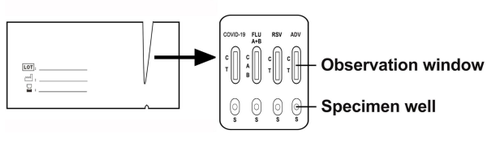

Check all parts of the test kit to make sure that all parts are complete and not damaged.


Check the Expiration Date printed on the foil pouch of the test device.

[Test Procedure]

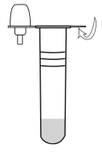
Allow test device extraction reagent and specimens to equilibrate to room temperature (15～30 ℃） prior to testing.
Please keep the temperature at 15～30 ℃ and the humidity at 20%-80% during the whole test.

1.

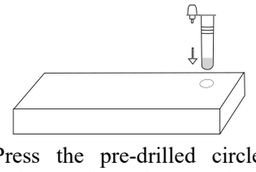


Open the package and take out the test device. Know the observation window and specimen well(S). It should be used within one hour.

2.


Gently peel off the aluminium foil seal.

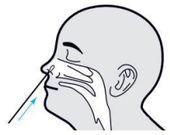
3.


Press the pre-drilled circle, make a hole in the outer box, and then insert the bottom of the antigen extraction tube into the hole.

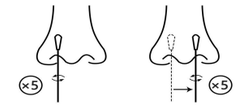
4.


Remove the sterilized swab from the packaging.

5.

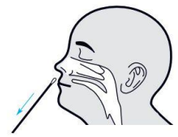

Relax your head naturally. Carefully insert the swab into the your nostril, the swab tip should be inserted up to 2 cm until resistance is met.

6.

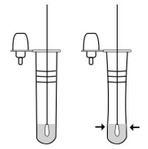


Roll the swab firmly around the inside of the nostril, making 5 complete circles. Using the same swab, repeat this process for the other nostril to ensure an adequate amount of specimen is collected.

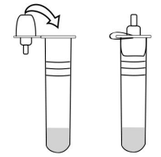
7.


Withdraw the swab from the nasal cavity.

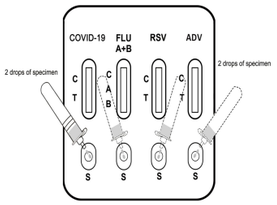
8.


Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall 3 times to release the antigen in the swab.

9.


Press the nozzle cap firmly onto the extraction tube.

10.



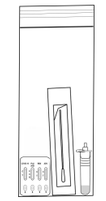
Hold the Antigen extraction tube vertically and add two drops of the test specimens into each specimen well(S).

11.


15 min

Read result at 15 minutes.
Do not read results after 30 minutes.

12.


Please put all used materials in the enclosed collection bag for proper disposal. The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

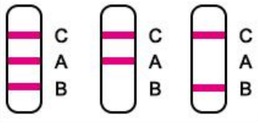
[Interpretation of test results]

Positive result:

COVID-19/RSV/ADV

For COVID-19/RSV/ADV:
If both the control line (C) and the test line (T) appear, it indicates that SARS-CoV-2/RSV/ADV antigen has been detected and the result is positive.

FLU A+B



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.

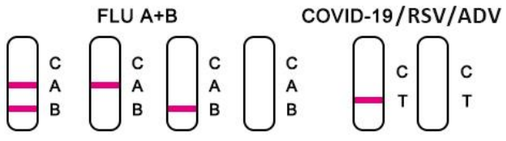
Note: The test line (T) could show different shades of color. However, even a very weak test line should be judged as a positive result during the specified observation period, regardless of the color of the test line.

Negative result:

FLU A+B COVID-19/RSV/ADV

If only quality control line C appear, 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 test line T or test line A or test line B, and the test shall be conducted again.

[Summary]

COVID-19

The novel corona viruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel corona virus 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.

Influenza

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)

Respiratory syncytial virus is a common, and very contagious, virus that infects the respiratory tract of most children before their second birthday. 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.

Adenovirus (ADV)

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 rapid self test method and is suitable for the auxiliary diagnosis of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus.

[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 you need to do the test again.

[Limitations of inspection methods]

1. This product is used for qualitative testing only and cannot indicate the level of antigen in the specimen.
2. This test kit is only used to detect human nasal swab specimens. The results of other specimens may be wrong.
3. Negative results may occur if the antigen titre in the specimen falls below the minimum detection limit of this kit.
4. 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.
5. 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.
6. The accuracy of the test depends on the quality of the swab sample, false negative results may be given following poor sampling.
7. Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.
8. If the result of the test is negative, yet clinical symptoms persist, it is advised that you carry out additional tests using other clinical methods. A negative result at no time rules out the presence of antigens of the virus in the sample, as they may be present but at a level inferior to the minimum detection level of the test, or if the sample has been collected incorrectly.
9. This test is not a substitute for a medical consultation, or for the result of a biological analysis carried out in a medical analysis laboratory.

[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 may get inaccurate results.
3. Guard against moisture, do not open the aluminum foil bag before it is ready for testing. Do not use it if the aluminum foil bag or label of sterilized swab is damaged or the test device is damp.
4. Please use it within the validity period.
5. Balance all reagents and specimens to room temperature (15 ~ 30 ℃) before use.
6. Do not replace the components in this kit with components from other kits.
7. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this Instruction. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this specification.
10. The extraction reagent is individually packed, the batch number, expiration date and other information cannot be marked separately as the space is limited, but this information will be consistent with the corresponding test kit.
11. Any serious incident occurring during the use of the equipment should be reported to the manufacturer and to the competent authorities of the Member State in which the user and/or the patient is based.

[Storage conditions & period of validity]

1. The kit should be stored at 2-30 ℃ 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.

[Sample Transport and Storage]

Freshly collected specimens should be processed as soon as possible. It should be no later than one hour after collection. The processed specimens could be stored at 2-8℃ for no more than 24 hours.

[Quality Control]

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

[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 (50 mM Tris + 150 mM NaCl + 0.1% $C_{12}H_{25}SO_4Na$ + Tween 20) 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: It should not be less than 10mm/min.

2. Limit of detection (LOD)

Type		**LoD**
COVID-19		80 $TCID_{50}$/ml
Influenza A	Liao Ning/1183/2007 (H1N1)	2.2×10^3 $TCID_{50}$/mL
Influenza A	A/Victoria/3/75	1.16×10^2 $TCID_{50}$/mL
Influenza A	A/HongKong/8/68	2.58×10^4 $TCID_{50}$/mL
Influenza B	Jiang Xi/32/2000	2.9×10^2 $TCID_{50}$/mL
Influenza B	B/1704	6.8×10^2 $TCID_{50}$/mL
RSV		10 ng/ml
ADV		10 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-2, Pseudovirus (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 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.

5. Clinical performance

5.1. For COVID-19:

A total of 420 samples were collected in this study, of which 220 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference RT-PCR analysis							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	96.82%	93.58%	98.45%
	POS	213	0	213	NPA	＞99.9%	98.12%	100%
	NEG	7	200	207	Total compliance rate			98.33%
	TOTAL	220	200	420				

Specificity:＞99.9%; Sensitivity: 96.82%; Accuracy: 98.33%

5.2. For Flu A:

A total of 305 samples were collected in this study, of which 105 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.47%	100%
	POS	105	0	105	NPA	＞99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			＞99.9%
	TOTAL	105	200	305				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.3. For Flu B:

A total of 305 samples were collected in this study, of which 100 were positive and 205 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.30%	100%
	POS	100	0	100	NPA	＞99.9%	98.16%	100%
	NEG	0	205	205	Total compliance rate			＞99.9%
	TOTAL	100	205	305				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.4. For RSV:

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.30%	100%
	POS	100	0	100	NPA	＞99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			＞99.9%
	TOTAL	100	200	300				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.5. For ADV:

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	99.00%	94.55%	99.82%
	POS	99	0	99	NPA	＞99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.67%
	TOTAL	100	200	300				

Specificity: ＞99.9%; Sensitivity: 99.00%; Accuracy: 99.67%

[Index of Symbols]

IVD	In vitro diagnostic *medical device*		Do not re-use		Keep away from sunlight
	Use-by date		Consult instructions for use or consult electronic instructions for use		Date of manufacture
	Caution		Manufacturer		Do not use if package is damaged and consult instructions for use
30℃ 2℃	Temperature limit	LOT	Batch code	Σ	Contains sufficient for <*n*> tests
EC REP	Authorized representative in the European Community/ European Union		Keep dry	CE 3018	CE Mark

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2 pieces per box	CFRA1ST-2
3 pieces per box	CFRA1ST-3
5 pieces per box	CFRA1ST-5
10 pieces per box	CFRA1ST-10
15 pieces per box	CFRA1ST-15
20 pieces per box	CFRA1ST-20
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