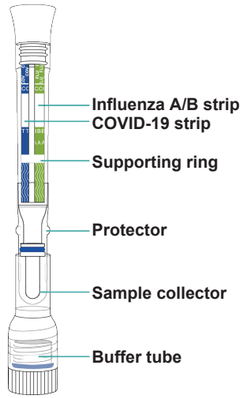
ECTEST® For Self-testing

COVID-19 & Influenza A/B Antigen Nasal Test Kit Quick Reference Instructions

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

Package Contents



Test Device

Instructions for Use

Waste bag

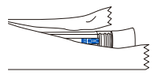
Needed but not provided:Clock

Storage and Stability

1. Store The COVID-19&Influenza A/B Antigen Nasal Test Kit at 2~30℃when not in use.
2. DO NOT FREEZE.
3. Kit contents are stable until the expiration dates marked on outer packaging and container.
4. Shelf Life: 24 months.

Before the Test

1. Remove the test device from its packing. For the best results, the assay should be performed within one hour.



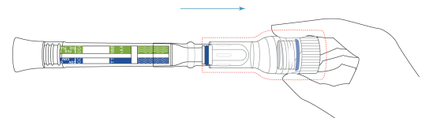
2. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

Note

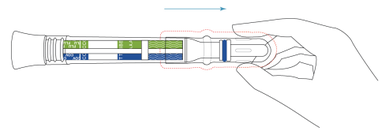
!!! Children aged between 2 and 18 years old, must be supervised or aided by an adult when carrying out the test.
!!! Do not use this test on anyone under 2 years of age.
!!! Caution should be taken when inserting the sample collector into the nasal cavity

Take Your Nasal Swab

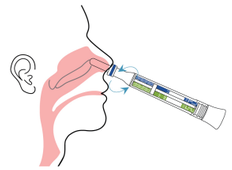
1. Take the test device out of the tube with extraction buffer.



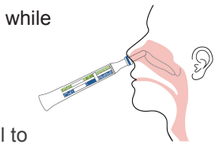
2. Remove the protector.



3. Gently insert the sample collector until resistance is met (**about 1-2 cm into the nostril**).Rotate the collector five times against the nasal wall and remove from the nostril.



4. Pull the swab out of the nose while twisting it slightly.



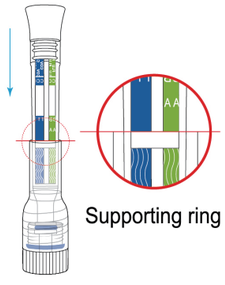
5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen be collected from both nasal cavities.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

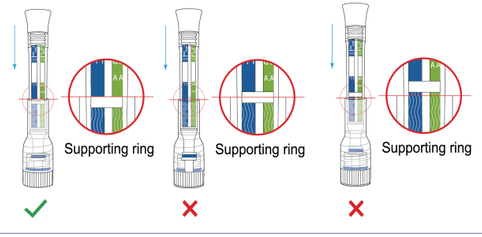
Note: With children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need to have a second person to hold the child's head while swabbing.
This may feel uncomfortable. Do not insert the collector any deeper if you feel strong resistance.

Process the Swab Sample

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reach the top of the supporting ring.



WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

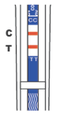


2. Read the results at 15 minutes. Do not read the results at 30 minutes.

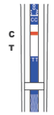
3. When the test is finished. Please follow local regulationsto dispose of the test you used.

Read and Interpret Your Results

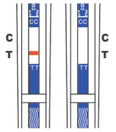
For COVID-19:



POSITIVE:
Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

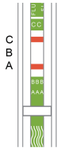


NEGATIVE:
Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

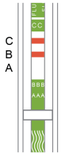


INVALID:
Control band (C) fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

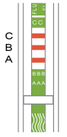
For Influenza A/B



Influenza A Positive:
One colored band appears in the control region (C), and another colored band in the A region (A).



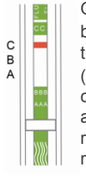
Influenza B Positive:
One colored band appears in the control region (C), and another colored band in the B region (B)



Influenza A+B Positive:
One colored band appears in the control region (C), and two other colored bands appear in both A region (A) and B region (B).

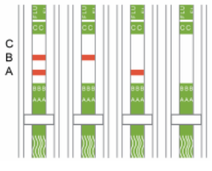
Note: Co-infection with influenza A and B is rare. A clinical specimen that generates positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.

Influenza A+B Negative:



Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (B) and test region (A)

Influenza A+B Invalid:



No colored band appears in the control region (C), whether a test band(s) is present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues.

NOTE:
(1)The intensity of the color in the test area (T) can vary. However, any shade in the test area should be considered positive. Note that this is a qualitative test only and the virus concentration in the sample cannot be determined.
(2)A positive test result means that the virus that causes COVID-19 and/or Influenza was detected in your sample and it is very likely you have COVID-19 and/or Influenza and are contagious. Please contact your medical practitioner immediately and adhere to the local guidelines regarding self-isolation. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms. Do not take any decision of medical relevance without first consulting your medical practitioner.
(3)A negative test result indicates that antigens from the virus that causes COVID-19 and/or Influenza were not detected from the specimen. A negative result does not rule out COVID-19 and/or Influenza. This means that there is a higher chance this test will give you a negative result when you have COVID-19 and/or Influenza. If you test negative and continue to experience COVID-19 and/or Influenza like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your medical practitioner.

Intended Use

The COVID-19&Influenza A/B Antigen Nasal Test Kit is an in vitro immunoassay. The assay is for the direct and qualitative detection of viral nucleocapsid proteins of SARS-CoV-2, Influenza A virus, and Influenza B virus from nasal secretions. The test is for self-testing use. Children aged between 2 and 18 years old, must be supervised or aided by an adult when carrying out the test. Negative results do not preclude these viral infections. Testing results should not be the sole basis for treatment or other management decisions.
This test is intended for asymptomatic and people who with symptoms of COVID-19 within the first 7 days of symptom onset.
In individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19, more false positive results may occur. Testing of individuals without symptoms should be limited to contacts of confirmed or probable cases or to other epidemiological reasons to suspect a COVID-19 infection and should be followed by additional confirmatory testing with a molecular test.
Testing results should never be seen separated but always in the clinical context (e.g., patient history, symptoms, and other available clinical information). This is clearly stated under “Limitations” section and also in the “Intended Use” section in the package insert.

Warnings and Precautions

• Caution should be taken when inserting the sample collector into the nasal cavity.
• Do not use kit or components beyond the expiration date.
• Do not puncture the membrane in the extraction tube before testing.
• Read the instructions for use before use. The instructions for use must be read carefully and followed.
• Do not use this test on anyone under 2 years of age.
• The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film or the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
• If samples and test components are not brought to room temperature before the test, the test sensitivity may be reduced. Incorrect or unsuitable sampling and storage can lead to false negative test results.
• Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
• Keep out of the reach of children. Small test components can pose a choking hazard.
• Use only the supplied test components. Do not replace the buffer with any other liquid.
• Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
• Use a separate test for each person.
• If you have a nose piercing, dab the other nostril. If pierced on both sides, remove the piercing on one side before wiping it off.

Principle

The COVID-19 & Influenza A/B Antigen Nasal Test Kit detects SARS-CoV-2 viral nucleocapsid proteins and Influenza A&B virus through visual interpretation of color development on the internal strip. Anti-SARS-CoV-2 mAb and Influenza A&B antibodies are immobilized at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 mAb and Influenza A&B antibodies conjugated to colored particles are immobilized on the conjugated pad.
During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer.As the specimen migrates along the strip by capillary action and then interacts with reagents on the sample pad, the target antigens will bind to anti-SARS-CoV-2 mAb or Influenza A&B antibodies on the conjugatepad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb or InfluenzaA&B antibodies immobilized at the test region. Excess colored particles will be captured at the control regionof the NC membrane.
The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral and Influenza A&B antigens, while its absence indicates a negative result. A colored band at the control regionserves as a procedural control, generally indicating that a proper volume of specimen has been added andmembrane wicking is working.

Limitations

1. The test is suitable for personal use and may only be used for the qualitative detection of the SARS-CoV-2 viral nucleocapsid proteins and Influenza A&B virus.
2. As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
3. Failure to follow the TEST PROCEDURE and INTERPRETATION OF RESULTS may negatively affect and / or falsify the test result.
4. Negative results do not completely rule out an infection with SARS-CoV-2 viral and Influenza A&B virus.

Quality Control

Internal Procedural Controls
The COVID-19&Influenza A/B Antigen Nasal Test Kit has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the “C” region is present before reading the result.

Performance

Analytical Sensitivity:

Item		LOD
Influenza A	H1N1	4.3×10^{4} $TCID_{50}$/ml
	H3N2	1.0×10^{4} $TCID_{50}$/ml
Influenza B	Yamagata	2.5×10^{5} $TCID_{50}$/ml
	Victoria	2.2×10^{5} $TCID_{50}$/ml
SARS-CoV-2		$1\times10^{2.4}$ $TCID_{50}$/mL

Clinical Evaluation:
Two samples were collected from each participants (total 450), one is the nasal secretion for Rapid Test, and the other one is the nasopharyngeal swab for comparison with RT-PCR. For COVID-19, 140 positive samples and 310 negativesamples, for Influenza A, 73 positive samples and 377 negative samples, for Influenza B, 54 positive samples and 396 negative samples. These samples were tested with both RT-PCR and COVID-19 & Influenza A/B Antigen Nasal Test Kit. The obtained sensitivity and specificity results are summarized in following tables:

Result / Type	Antigen positive/PCR positive	Antigen Negative/PCR Negative	Relative Sensitivity	Relative Specificity	Total Agreement
COVID-19	135 out of 140	309 out of 310	96.4% (91.9%-98.5%)	99.7% (98.2%-99.9%)	98.7% (97.1%-99.4%)
Influenza A	70 out of 73	375 out of 377	95.9% (88.6%-98.6%)	99.5% (98.1%-99.9%)	98.9% (97.4%-99.5%)
Influenza B	51 out of 54	395 out of 396	94.4% (84.9%-98.1%)	99.7% (98.6%-100.0%)	99.1% (97.7%-99.7%)
*95% Confidence Interval					

Hook Effect:

COVID-19	The highest concentration of inactivated SARS-CoV-2 stock available ($1\times10^{6.4}$ $TCID_{50}$/mL) was tested, no hook effect occurred on the COVID-19 detection.
Influenza A	The highest concentration of inactivated Influenza A (H1N1) (2.0×10^{6} $TCID_{50}$/mL) and Influenza A (H3N2) (8.6×10^{6} TCID50/mL) were tested, no hook effect occurred on the FLU A detection.
Influenza B	The highest concentration of inactivated nfluenza B Victoria lineage (4.4×10^{6} $TCID_{50}$/mL) and Influenza B Yamagata lineage (5.0×10^{6} TCID50/mL) were tested, no hook effect occurred on the FLU B detection.

Cross Reactivity and Interfering

Cross Reactivity:
Cross reactivity with the following organisms has been studied. The following organisms were found negative when tested with the COVID-19&Influenza A/B Antigen Nasal Test Kit.

HCoV-229E	*Bordetellapara pertussis*	Adenovirus 1
HCoV-OC43	*Bordetella pertussis*	Adenovirus 2
HCoV-NL63	*Candida albicans*	Adenovirus 3
MERS-coronavirus	*Chlamydia pneumoniae*	Adenovirus 4
Human metapneumovirus	*Group C Streptococcus*	Adenovirus 5
Norovirus	*Haemophilus influenzae*	Adenovirus 7
Parainfluenza virus 1	*Legionella pneumophila*	Adenovirus 55
Parainfluenza virus 2	*Mycoplasma pneumoniae*	Epstein-Barr virus
Parainfluenza virus 3	*Mycobacterium tuberculosis*	Enterovirus EV70
Parainfluenza virus 4	*Staphylococcus aureus*	Enterovirus EV71
Respiratory syncytial virus A	*Staphylococcus epidermidis*	Enterovirus A16
Respiratory syncytial virus B	*Streptococcus agalactiae*	Enterovirus A24
Rhinovirus A30	*Streptococcus pneumoniae*	Enterovirus B1
Rhinovirus B52	*Streptococcus pyogenes*	Echovirus 6
HKU1		

Note:
1) **For FLU A detection:** FLU A detection has no across reactivity with influenza B and SARS-CoV-2.
2) **For FLU B detection:** FLU B detection has no across reactivity with influenza A and SARS-CoV-2.
3) **For COVID-19 detection:** COVID-19 test has across reactivity with SARS-CoV.

Interfering Substances:
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of The COVID-19&Influenza A/B Antigen Nasal Test Kit.

Substance		
3 OTC nasal sprays	Dextromethorphan	Oxymetazoline
3 OTC mouthwashes	Diphenhydramine	Phenylephrine
3 OTC throat drops	Doxylamine succinate	Phenylpropanolamine
4-acetamidophenol	Flunisolide	Zanamivir
Acetylsalicylic acid	Guaiacol glyceryl ether	Adamantanamine
Albuterol	Mucin	Oseltamivir phosphate
Chlorpheniramine	Whole blood	Tobramycin
Dexamethasone	Mupirocin	Triamcinolone

Literature References

1.Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2.Ithete, N. L. et al. Close relative of human Middle East respiratory syn¬drome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

Glossary of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		Do not use if package is damaged
EC REP	Authorized representative in the European Community		
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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