™ SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) Package Insert

REF ISIN-525H	English

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen.

For self-testing *in vitro* diagnostic use.

【PROCEDURE】

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

Remove the cover of the tube with extraction buffer and place the tube in the tube holder in the box.

Nasal swab specimen Collection

1. Remove the sterile swab from the pouch. Do not touch the soft tip of the swab.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.

Note:

This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

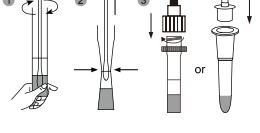
When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.

If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab so far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

3. Gently remove the swab.
4. Using the same swab, repeat step 2 in your other nostril.
5. Withdraw the swab.

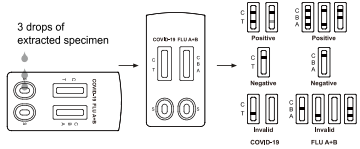
Specimen Preparation

1. Place the swab into the extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for **10-15 seconds**.
2. Remove the swab while squeezing the swab head against the inside of the extraction tube.
3. Place the swab in a plastic bag.
4. Close the cap or fit the tube tip onto the tube.



Testing

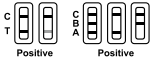
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
   Place the test cassette on a plat and level surface.
2. Invert the specimen extraction tube and add **3 drops of extracted specimen** to each **sample well**(S) of the test cassette and start the timer. Do not move the test cassette during test developing.
3. **Read the result at 10 minutes.** Do not read the result after 20 minutes.



Note: After test is completed, place all the components into plastic bag and tightly sealed, then dispose according to local regulation.

【READING THE RESULTS】

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.



POSITIVE SARS-CoV-2:* Two colored lines appear in the COVID-19 window. One colored line should be in the control region (C) and another colored line should be in the test region (T).

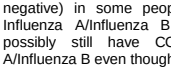
POSITIVE Influenza A:* Two colored lines appear in the FLU A+B window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).

POSITIVE Influenza B:* Two colored lines appear in the FLU A+B window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).

POSITIVE Influenza A and Influenza B:* Three colored lines appear in the FLU A+B window. One colored line should be in the control region (C) and two colored lines should be in the Influenza A region (A) and Influenza B region (B).

***NOTE:** The intensity of the color in the test line region (T/B/A) will vary based on the amount of SARS-CoV-2 and/or Influenza A+B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.

A positive results means it is very likely you have COVID-19 and/or Influenza A/Influenza B, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.



NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/B/A).

You are unlikely to have COVID-19 and/or Influenza A/Influenza B. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and/or Influenza A/Influenza B. This means you could possibly still have COVID-19 and/or Influenza A/Influenza B even though the test is negative.

In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed, migration/traveling, attending events and etc. should follow your local COVID/Influenza guidelines/requirements.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact with a COVID-19 and/or Influenza test center.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Test for children should be under the guidance of an adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Test cassette
- Package insert
- Sterile swab
- Extraction buffer
- Biosafety bag(Optional)

Materials Required But Not Provided

- Timer

【INTENDED USE】

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2, Influenza A and Influenza B virus that causes COVID-19 and/or Influenza with self-collected nasal swab specimen. The test is intended for use in symptomatic /asymptomatic individuals who are suspected of being infected with COVID-19 and/or Influenza A+B.

Results are for the detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results are indicative of the presence of SARS-CoV-2 and/or Influenza A+B. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 and/or Influenza A+B infection. Individuals who test negative and continue to experience COVID-like or flu-like symptoms should seek follow up care from their healthcare provider.

【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[1].

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[2]. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

【PRINCIPLE】

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens in human swab specimen.

【LIMITATIONS】

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 and/or Influenza A/Influenza B antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected, it is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. A negative result for Influenza A or Influenza B obtained from this kit should be confirmed by RT-PCR/culture.
6. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. A positive result for influenza A and/or B does not preclude an

underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
7. Failure to follow these procedures may alter test performance.
8. False negative results may occur if a specimen is improperly collected or handled.
9. False negative results may occur if inadequate levels of viruses are present in the specimen.

【PERFORMANCE CHARACTERISTICS】

Clinical performance

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR (nasopharyngeal swab)		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	161	2	163
	Negative	5	482	487
Total		166	484	650
Relative Sensitivity		96.99% (95%CI: 93.11%~99.01%)		
Relative Specificity		99.59% (95%CI: 98.52%~99.95%)		
Accuracy		98.92% (95%CI: 97.79%~99.57%)		

Influenza A+B Test :

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Relative Sensitivity		95.77% （95%CI: 88.14%~99.12%）		
Relative Specificity		99.59% （95%CI: 98.52%~99.95%）		
Accuracy		99.10% (95%CI: 97.92%~99.71%)		

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Relative Sensitivity		94.12% （95%CI: 83.76%~98.77%）		
Relative Specificity		99.41% （95%CI: 98.28%~99.88%）		
Accuracy		98.92% (95%CI: 97.67%~99.60%)		

Specificity Testing with Various Viral Strains

The SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed:

SARS-CoV-2 Test:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/mL
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/mL
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1 x 10^6 $TCID_{50}$/mL
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/mL
MERS COV Florida	1.17 x10^4 $TCID_{50}$/mL
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/mL
Influenza A H3N2	1 x 10^5 $TCID_{50}$/mL
Influenza B	3.16 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/mL
Measles	1.58 x 10^4 $TCID_{50}$/mL
Mumps	1.58 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/mL
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/mL
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/mL

Influenza A+B Test:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/mL
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/mL
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1 x 10^6 $TCID_{50}$/mL
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/mL
MERS COV Florida	1.17 x10^4 $TCID_{50}$/mL
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/mL
Measles	1.58 x 10^4 $TCID_{50}$/mL
Mumps	1.58 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/mL
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/mL
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/mL

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Cross-reactivity

The following organisms were negative when tested with the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)

Arcanobacterium	1.0x10^8 org/mL
Candida albicans	1.0x10^8 org/mL
Corynebacterium	1.0x10^8 org/mL
Escherichia coli	1.0x10^8org/mL
Moraxella catarrhalis	1.0x10^8 org/mL
Neisseria lactamica	1.0x10^8 org/mL
Neisseria subflava	1.0x10^8 org/mL
Pseudomonas aeruginosa	1.0x10^8 org/mL
Staphylococcus aureus subspaureus	1.0x10^8org/mL
Staphylococcus epidermidis	1.0x10^8 org/mL
Streptococcus pneumoniae	1.0x10^8 org/mL
Streptococcus pyogenes	1.0x10^8 org/mL
Streptococcus salivarius	1.0x10^8 org/mL
Streptococcus sp group F	1.0x10^8 org/mL

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Substance	Concentration	Substance	Concentration
Whole Blood	20 μL/mL	Oxymetazoline	0.6 mg/mL
Mucin	50 μg/mL	Phenylephrine	12 mg/mL
Budesonide Nasal Spray	200 μL/mL	Rebetol	4.5 μg/mL
Dexamethasone	0.8 mg/mL	Relenza	282 ng/mL
Flunisolide	6.8 ng/mL	Tamiflu	1.1 μg/mL
Mupirocin	12 mg/mL	Tobramycin	2.43 mg/mL

【EXTRA INFORMATIONS】

1. How does the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test work?

The test is for the qualitative detection of SARS-CoV-2 and/or Influenza A/Influenza B antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 and/or Influenza A/Influenza B antigens present in the specimen.

2. When should the test be used?

SARS-CoV-2 and/or Influenza A/Influenza B antigen can be detected in acute respiratory tract infection, it is recommended to run the test when you are suspected of being infected with COVID-19 and/or Influenza A/Influenza B.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected.

Nevertheless, the result can be incorrect if inadequate sampling volume or the SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test gets wet before test performing, or if the number of extraction specimen drops are less than 3 or more than 4.

Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the color intensity of the test line is.

5. What do I have to do if the result is negative?

A negative result means that you are negative or that the viral load is too low to be recognized by the test. However, it is possible for this test to give a negative result that is

incorrect (a false negative) in some people with COVID-19 and/or Influenza A/Influenza B. This means you could possibly still have COVID-19 and/or Influenza A/Influenza B even though the test is negative.

In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection. Distance and hygiene rules must still be observed.

Even with a negative test result, distance and hygiene rules must be observed, migration/traveling, attending events and etc. should follow your local COVID/Influenza guidelines/requirements.

6. What do I have to do if the result is positive?

A positive result means the presence of SARS-CoV-2 /Influenza A/Influenza B antigens. A positive results means it is very likely you have COVID-19 and/or /Influenza. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner / doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

【BIBLIOGRAPHY】

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.
2. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.

【INDEX OF SYMBOLS】

IVD	For *in vitro* diagnostic use only	2°C 30°C	Store between 2-30°C
	Tests per kit		Use by
	Do not use if package is damaged	EC REP	Authorized Representative
	Keep dry		Consult Instructions For Use
LOT	Lot Number		Do not reuse
REF	Catalog #		Manufacturer

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

CE 1434

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Statement: Information about manufacturer of sterile swab is placed on the packaging.

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