



Diagnostic Automation/Cortez Diagnostics, Inc.

I M M U N O D I A G N O S T I C S

Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab)

REF 176689

PIC ID176689VV86

IVD See External Label 20 Tests

Influenza A & B plus COVID-19 Antigen Combo RapiCard™

Principle	Chromatographic Immunoassay
Detection	Qualitative
Sensitivity	COVID-19: 96.99%, Influenza A: 95.77%, Influenza B: 94.12%
Specificity	COVID-19: 99.59%, Influenza A: 99.59%, Influenza B: 99.41%

PRODUCT FEATURES

- ✓ High Sensitivity and Specificity
- ✓ Built in Internal Controls
- ✓ Simplified Workflow, Non-invasive, and Safe
- ✓ Rapid and Faster Results

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.

INTENDED USE

The Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (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.

SIGNIFICANCE AND 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 cases¹.

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 virus². 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.

ASSAY PRINCIPLE

The Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of COVID-19 virus nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens in human swab specimen.

MATERIALS AND COMPONENTS

Materials provided with the test kit

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

Materials required but not provided

- Timer

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.

Diagnostic Automation/Cortez Diagnostics, Inc.

21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax: 818-591-8383

Email: onestep@rapidtest.com Website: www.rapidtest.com



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- **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. Use it within one hour after unpacking. The shelf life of the test is 24 months.

ASSAY 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.

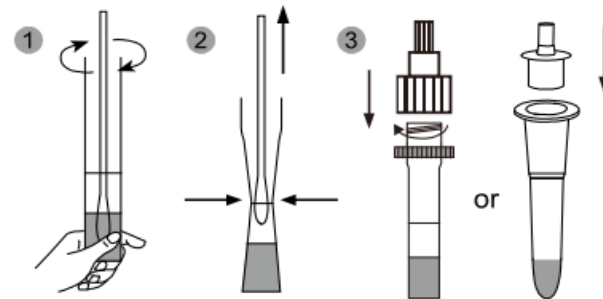


Note: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain. When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended. If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab so 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.

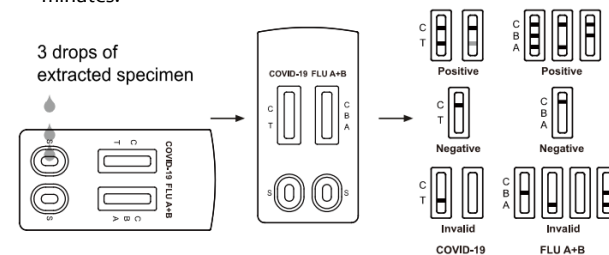
Specimen Preparation

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 flat 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.

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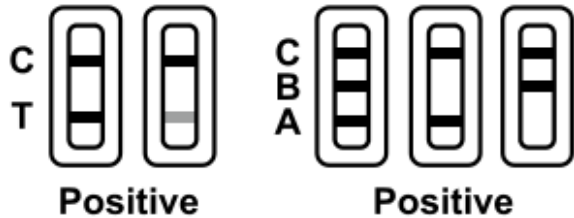


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I M M U N O D I A G N O S T I C S

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 COVID-19 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.

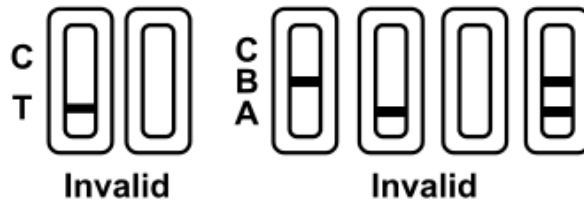
A positive results means it is very likely you have COVID-19 and/or Influenza A/Influenza B, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health 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.

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (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 COVID-19 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.
10. The kit was tested with the enclosed swabs. Using other swabs can give false negative results.
11. 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.

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PERFORMANCE CHARACTERISTICS

Clinical Performance

The Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

COVID-19 Test:

Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab)		RT-PCR (nasopharyngeal swab)		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	161	2	163
	Negative	5	482	487
Total		166	484	650
Diagnostic sensitivity		96.99% (95% CI: 93.11% – 99.01%)		
Diagnostic specificity		99.59% (95% CI: 98.52% – 99.95%)		
Total Accuracy		98.92% (95% CI: 97.79% – 99.57%)		

Influenza A+B Test:

Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab)		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen	Positive	68	2	70
	Negative	3	485	488
Total		71	487	558
Diagnostic sensitivity		95.77% (95% CI: 88.14% – 99.12%)		
Diagnostic specificity		99.59% (95% CI: 98.52% – 99.95%)		
Total Accuracy		99.10% (95% CI: 97.92% – 99.71%)		

Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab)		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen	Positive	48	3	51
	Negative	3	504	507
Total		51	507	558
Diagnostic sensitivity		94.12% (95% CI: 83.76% – 98.77%)		
Diagnostic specificity		99.41% (95% CI: 98.28% – 99.88%)		
Total Accuracy		98.92% (95% CI: 97.67% – 99.60%)		

“Diagnostic sensitivity” means the ability of a device to identify the presence of a target marker associated with a particular disease or condition.

“Diagnostic specificity” means the ability of a device to recognise the absence of a target marker associated with a particular disease or condition.

“Total Accuracy” means the ability of a device to identify the presence and recognise the absence of a target marker associated with a particular disease or condition.

Specificity Testing with Various Viral Strains

The Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab) was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed:

COVID-19 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 x 10 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 ⁵ TCID ₅₀ /mL
Human Rhinovirus 2	2.81 x 10 ⁴ TCID ₅₀ /mL

Description	Test Level
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 x 10 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

TCID₅₀ = 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 Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (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 ⁸ org/mL
Moraxella catarrhalis	1.0x10 ⁸ org/mL

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IMMUNODIAGNOSTICS

Neisseria lactamica	1.0x10 ⁸ org/mL
Neisseria subflava	1.0x10 ⁸ org/mL
Pseudomonas aeruginosa	1.0x10 ⁸ org/mL
Staphylococcus aureus subsp. aureus	1.0x10 ⁸ org/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 INFORMATION

1. How does the Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab) 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 Onestep Influenza A & B plus COVID-19

Antigen Combo RapiCard™ InstaTest (Nasal Swab) 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.

7. Is this test also valid for the SARS-CoV-2 viruses with novel mutations on the spike protein?

This test is designated to detect the nucleocapsid protein (NP) of SARS-CoV-2 virus. Epitope of capture antibody and detection antibody used in SARS-CoV-2 Antigen Rapid Test is not in the

mutation area. Thus, this test also valid for the SARS-CoV-2 viruses with novel mutations on the spike protein.

REFERENCES

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. Infect. Med. 19(3): 109-111.

MANUFACTURER AND BRAND DETAILS

	
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Date Adopted	2026-06-16
Brand Name	AccuDiag™
REF 176689	Onestep Influenza A & B plus COVID-19 Antigen Combo RapiCard™ InstaTest (Nasal Swab)
PIC	ID176689VV86
Revision Date: 2026-01-23	

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