ADVIN BIOTECH

Check 3 COVID-19/Flu A&B 3-in-1 Rapid Test

Instructions for Use

For Investigational Use Only

For Over the Counter Use

For *in vitro* diagnostic use

Intended Use

Check 3 COVID-19/Flu A&B 3-in-1 Rapid Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen in anterior nasal swab samples from the SARS-CoV-2 virus, Influenza A, Influenza B, that causes COVID-19, Influenza A, Influenza B from individuals with symptoms of respiratory tract infections. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals aged two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of SARS-CoV-2, influenza A virus and influenza B virus protein antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs 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 do not rule out bacterial infection or co- infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with Check 3 COVID-19/Flu A&B 3-in-1 Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results

should be considered in the context of an individual's recent exposure, history, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, Influenza A and Influenza B infection. Individuals who test negative and continue to test negative and continue to experience SARS-CoV-2 and/or Influenza-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 and/or Influenza infection and should seek follow-up care with their physician or healthcare provider.

Summary

COVID-19 and influenza are acute and highly contagious viral infections of the respiratory tract. The causative agents of the diseases are immunologically diverse, single-strand RNA viruses known as SARS-CoV-2 viruses and influenza viruses, respectively. There are three types of influenza viruses: A, B and C. Type A viruses are the most prevalent and are associated with more serious disease whereas Type B infection is generally milder. Type C virus has never been associated with a large epidemic of human disease.

A patient can be infected with a single virus or co-infected with SARS-CoV-2 and one or more types of influenza viruses. These viral infections occur more often during the respiratory illness season (in the U.S. this includes the fall and winter seasons) and the symptoms generally appear 3 to 7 days after the infection. Transmission for all of these viruses occurs through coughing and sneezing of aerosolized droplets from infected people, who may be either symptomatic or asymptomatic. For symptomatic patients, the main symptoms include fever, fatigue, dry cough, and loss of taste and smell. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are also associated symptoms.

Rapid diagnosis of SARS-CoV-2 and influenza A & B viral infection will help healthcare professionals treat patients and control these diseases more effectively.

Principle

The Check 3 COVID-19/Flu A&B 3-in-1 Rapid Test is a rapid, qualitative lateral flow immunochromatographic assay test for the detection of nucleocapsid (N) protein from SARS-CoV-2, and nucleoprotein (NP) from Influenza A, Influenza B in anterior nasal swab specimens. Antibodies specific to the N/NP proteins of SARS-CoV-2, Influenza A and Influenza B are separately coated on the test line regions of the test cassette, to which the extracted specimen reacts during testing. The mixture migrates up the membrane to react with the antibodies to the N/NP proteins of SARS-CoV-2, Influenza A and/or Influenza B on the membrane and generate one or two or three colored lines in the test regions. The presence of this colored line in either or both or three of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

Warning, Precautions and Safety Information

1. Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate test results.

2. Symptomatic individuals who test negative on the initial test should be tested again in 48 hours to confirm if the initial result is accurate.
3. An anterior nasal swab sample can be self-collected by individuals aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
4. Do not use on anyone under 2 years of age.
5. Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
6. This test may only be used in symptomatic individuals.
7. Do not use if any of the test kit contents or packaging is damaged or open.
8. Test components are single-use. Do not re-use the test strip, buffer liquid, or swab.
9. If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
10. Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
11. If uncertain how to proceed, contact Technical Assistance at 1-888-925-2788
12. Do not touch swab tip when handling the swab.
13. Do not open the test contents until ready for use, if the test cassette is open for an hour or longer, false test results may occur.
14. Testing should be performed in an area with good lighting.
15. Do not use kit after its expiration date.
16. Keep testing kit and kit components away from children and pets before and after use. Do not ingest any kit components. The extraction buffer solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.

If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222

Chemical Name	GHS Code for each Ingredient	Concentrations
Proclin 300	Causes skin irritation (H315) Causes eye irritation (H320)	0.02%

Storage and Stability

- Store the test kit between 36-86 °F (2-30 °C) in a place outside of direct sunlight. Kit contents are stable in the unopened box until the expiration date printed on the kit box.
- Reagents and devices must be used at room temperature (59-86 °F / 15-30 °C).
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. Use beyond one hour may not produce accurate results.
- The expiration date is on the package.
- Do not freeze any of the test kit components.

Materials Provided

- 1 Test Cassette
- 1 Sterile Nasal Swab
- 1 Extraction Buffer Tube
- 1 Disposal Bag
- 1 Quick Reference Instructions (QRI)

Materials Required But Not Provided

- A timer: required to determine the time to read the test results after addition of the extracted specimen to the test device
- Personal protective equipment: Disposable masks and gloves if swabbing others

Preparing for the Test

NOTE:

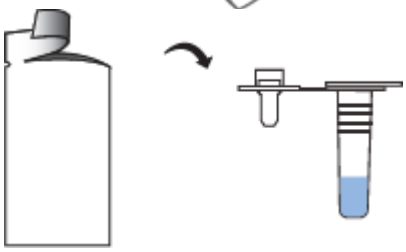
- Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Allow the test device and reagents to come to room temperature (59-86°F / 15-30°C) prior to testing.

1. **Check the expiration date on the test printed on the outer box. For** information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit: http://www.fda.gov/covid-tests.

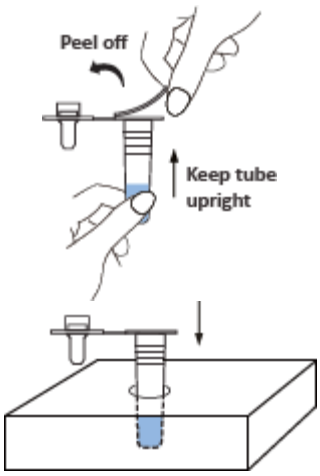
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly.

3. Clean the tabletop on which the test will be performed.

4.
   a. Remove the extraction buffer tube from the foil pouch.



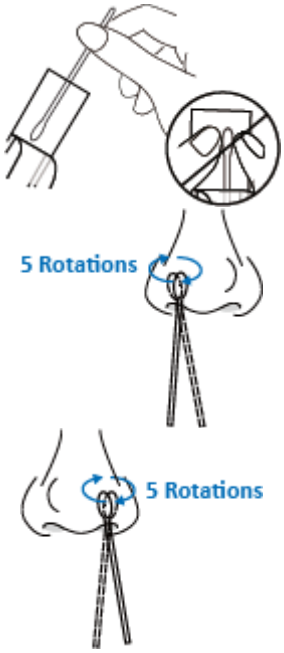
b. Peel off the aluminum foil on the extraction buffer tube.



c. Place the extraction buffer tube in the tube holder on the kit box.

Sample Collection

5. Remove the nasal swab from the pouch. DO NOT touch the swab tip.



6. Gently insert the swab no more than 3/4 inch (1.5 cm) into the nostril. Rotate against the walls of the nostril at least 5 times for 15 seconds against the nostril wall.

7. Repeat step #6 in your second nostril using the same swab.

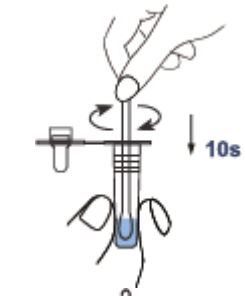
⚠ **DO NOT insert the swab any deeper if you feel any resistance.**

NOTE: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

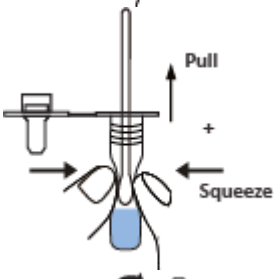
Running the Test

8. Place the swab into the liquid inside the tube. Rotate the swab head against the tube at least 5 times for 10 seconds.

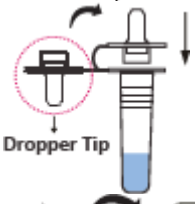
⚠ **Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.**



9. Remove the swab while squeezing the sides of the tube to remove excess liquid. Dispose of the swab in the Disposal bag provided.

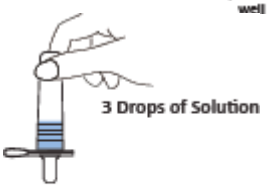


10. Firmly press the dropper tip on the extraction buffer tube.



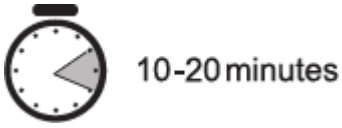
11. Remove the cassette from its packaging and place it on a clean flat surface. Find the Result Window and Specimen Well on the cassette.

12. Add 3 drops of solution into the sample well.



⚠ **Sample must be applied to the test cassette within one (1) hour of completing step 8.**

13. Set timer for 10 minutes. Do not move or lift the test cassette. Read the test results at 10 minutes.

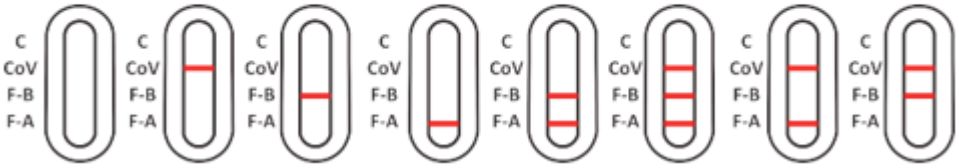


⚠ **Do not interpret results before 10 minutes or after 20 minutes. Inaccurate test interpretations may occur.**

Interpretation of Results

- **Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.**
- Look for lines next to ‘C' (Control), ‘F-B'(Flu B), ‘F-A'(Flu A) and ‘CoV'(COVID).
- Look closely! Any faint line is still a line.
- If uncertain how to proceed, contact Advin Biotech at support@advinbio.com or 1-888-925-2788 (Monday-Friday 9:00 a.m. to 5:00 p.m. PST).
- This test uses an internal procedural control that is needed to generate a valid result for your test. If a colored line appears in the control line regions (C) in the test window, this confirms that membrane wicking has occurred and the test reagents are functional. A test result is valid when the strip has a visible control line.

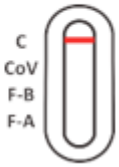
Invalid



Check to see if a pink line is visible at the control line ‘C’ in the result window. If a line is not visible at ‘C’, even if any other line is visible in the results window, the results are considered invalid.

If you do not see a C line, DO NOT CONTINUE reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials.

Negative (-)

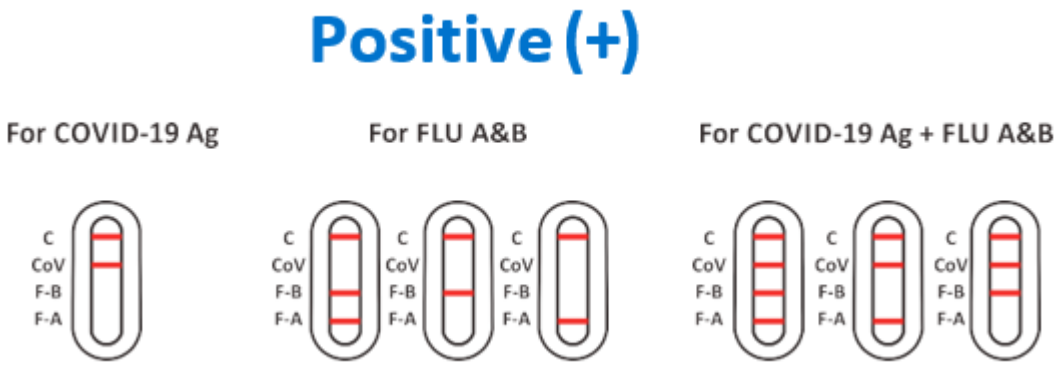


If a control ‘C’ line is visible and you do not see a line at ‘F-A’, ‘F-B’ or ‘CoV’, it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

If respiratory symptoms persist, you seek follow-up care with healthcare provider.

A negative test result means that COVID-19, Flu A, and/or Flu B viruses were not detected in the sample. A negative result is presumptive because despite a negative result you may still have COVID-19, Flu A,

and/or Flu B infection. This is because the amount of virus in your sample may be too low for the test to detect it, which is called a 'false negative result'. False negative results can occur if you read your test result before the 10 minutes have passed or when your sample has only a low amount of virus in it. A low amount of virus can occur if you take your sample at a time when your symptoms just started appearing, or when you already started to feel better at the end of your infection. If you tested negative and continue to experience COVID-19, Flu A, and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider who will determine the best course of action. Your health care provider can also determine if confirmation of your test result with a molecular assay is necessary.



If the control line at "C" is visible and any other line or multiple lines on 'F-A', 'F-B' and/or 'CoV' are visible, the test is positive for that virus.

NOTE: Any pink to red test line, no matter how faint, should be considered a positive result when the control line is also present.

Consult your healthcare provider to discuss your positive test result. Self-isolate at home per CDC recommendations to stop spreading virus to others.

A positive test result means that anyone, or multiple, of the viruses detectable by this test were also detected in your sample. It is very likely that you have the respective COVID-19 or influenza infection(s) and are contagious. You should self-isolate following local guidelines. Please contact your physician or healthcare provider to discuss your tests results and follow-up care. In rare instances, individuals may also have co-infections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of your disease. There is a very small chance that this test can give you a positive result that is incorrect (a false positive).

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between Month YYYY and Month YYYY. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of viruses and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual as compared to a molecular test, especially in samples with low viral load.
- All negative results SARS-CoV-2 or influenza are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19 or influenza but both this test and molecular test are negative, you may not have COVID-19 or influenza. You should follow up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 or the flu have been found in the sample and you are likely to have respiratory infection with COVID-19 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.

Symbol Index

	Manufacturer		Date of manufacture
	Use-by date		Batch code
	Catalogue number		Keep away from sunlight
	Keep dry		Temperature limit
	Do not reuse		Consult instructions for use
	In vitro diagnostic medical device		Contains sufficient for <n> tests