ADVIN BIOTECH

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

## Quick Reference Guide

For *in vitro* diagnostic use
For over-the counter (OTC)use
For use with anterior nasal swab specimens

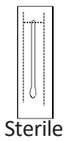
Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. Refer to the Instruction for Use (IFU) for more complete information at advinbio.com

## KIT CONTENTS


Test Cassette


Extraction Buffer Tube


Disposal Bag


Sterile Nasal Swab


Quick Reference Guide


Timer (Required but not provided)

## SPECIMEN COLLECTION

An anterior nasal saw sample can be self-collected by individuals ages 14 years or older. Children 2-13 years should be tested by an adult.

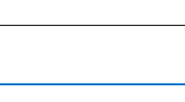
## PREPARING FOR THE TEST

**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 of 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.

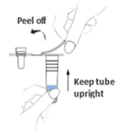
**3**

Clean the tabletop on which the test will be performed.

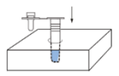
**4**

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

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



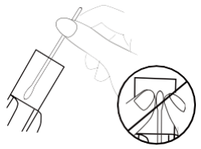

c) Place the extraction buffer tube in the tube holder on the kit box.



## SAMPLE PREPARATION

**5**

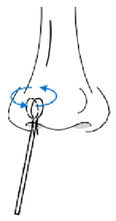
Remove nasal swab from its packaging. DO NOT touch the swab tip.



**6**

Gently insert swab no more than ¾ 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.

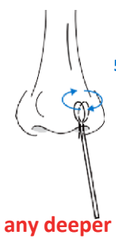
5 Rotations



**7**

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

5 Rotations



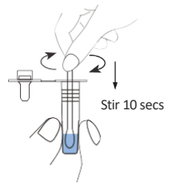
⚠ **DO NOT insert the swab any deeper if you feel any resistance.**

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

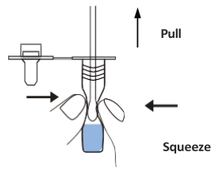



⚠ **Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.**

**9**

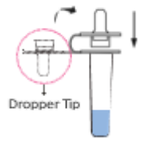
Remove the swab while squeezing the sides of the tube to remove excess liquid.

Dispose of the swab in the Disposal bag provided.



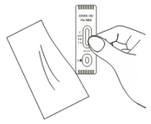

**10**

Firmly press the dropper tip on the extraction buffer tube.

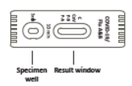



**11**

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 circular sample well.


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

**13**

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

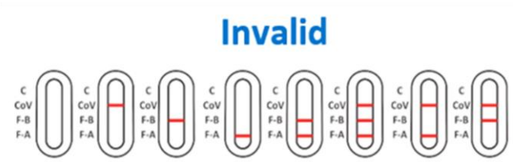

⚠ **Do not read results before 10 minutes or after 20 minutes. Inaccurate test interpretations may occur.**

## RESULT INTERPRETATION

Look for lines next to "C" (control), 'F-A', 'F-B' and 'CoV'
**C= Control line**
**F-A = Flu A Test Line**
**F-B = Flu B Test Line**
**CoV = COVID-19 Test Line**

A colored line should always appear at the **'C'** position, this is control line and signals that the test is working properly.

### Invalid Results




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 is 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 (-) Results


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.
**To increase the chance that the negative result for COVID-19, Flu A or Flu B is accurate, you should test again in 48 hours after the first day of testing.**
If respiratory symptoms persist, you seek follow-up care with healthcare provider.

### Positive (+) Results


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

## 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 nucleoprotein 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.

### *How to Use This Test*

If you test result is negative but continue to have symptoms you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 or the flu have been found in your sample and you likely have COVID-19 or influenza infection.

### *Warning, Precautions and Safety Information*

- Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate test results.
- Symptomatic individuals who test negative on the initial test should be tested again in 48 hours to confirm if the initial result is accurate.
- 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.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- This test may only be used in symptomatic individuals.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use the test cassette, buffer liquid, or swab.
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- 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.
- If uncertain how to proceed, contact Technical Assistance at 1-888-925-2788
- Do not touch swab tip when handling the swab.
- 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.
- Testing should be performed in an area with good lighting.
- Do not use kit after its expiration date.
- 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 | Concentration |
|---|---|---|
| ProClin 300 | Causes skin irritation (H315)<br>• Causes eye irritation (H320) | 0.02% |

- For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

### *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 likely 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.

### *Frequently Asked Questions (FAQ)*

**Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?**

A: Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and flu to the family of the tested individual and others in your community.

**Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?**

A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the Check 3 COVID-19/Flu A&B 3-in-1 Rapid Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give a false negative result when you have COVID-19 or the flu than a molecular test would.

**Q: WHAT IF I HAVE A POSITIVE TEST RESULT?**

A: A positive result means that it is very likely you have COVID-19 or influenza because proteins from the virus that causes COVID-19 or the flu are found in your sample you should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

**Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?**

A: A negative test result only indicates that antigens from the virus that causes COVID-19 or influenza were not detected in your sample. However, it does not rule out the possibility of SARS-CoV-2 or influenza infection, since antigen tests are not as sensitive as molecular tests. You may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

**Q: HOW ACCURATE IS THIS TEST?**

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 or flu when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at: advinbio.com

**Q: WHAT DOES AN INVALID TEST RESULT MEAN?**

A: An invalid result means something with the test did not work properly. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

**IMPORTANT: Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider**.

**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
| | Consult Instructions for Use | Σ | Tests per kit | 2 | Do not reuse |
| IVD | For in vitro diagnostic use only | | Use by | **REF** | Catalog # |
| 2°C 30°C | Store between 2-30°C | LOT | Lot Number | | |

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