



# LUCIRA™

## COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)



SWAB



STIR



DETECT



UNFOLD

### The Lucira COVID-19 & Flu Test is for Health Canada Interim Order Authorization Only

#### For In Vitro Diagnostic (IVD) Use

- This home test kit has been authorized by Health Canada under an Interim Order Authorization.
- This home test kit has been authorized only for the testing of nasal swabs for detection of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, not for any other viruses or pathogens.

For the most up to date information on COVID-19, please visit:  
[www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html](http://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html)

For detailed instructions, visit:  
[lucirahealth.com/Canada/IFU](http://lucirahealth.com/Canada/IFU)

For Customer Support, call:  
**1-888-LUCIRA-4**  
 (1-888-582-4724)

For further information, visit:  
[lucirahealth.com](http://lucirahealth.com)

Lucira Health, Inc. 1412 62nd Street  
 Emeryville, CA 94608, United States

Package Insert (PI) INST033 Rev. B

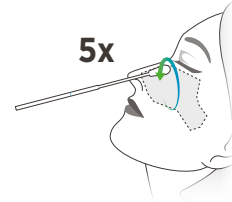
## Frequently Asked Questions

Please Read Instructions on Reverse

**Will this test hurt?** No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly.

### What tips will help me use the nasal swab correctly? How do I make sure I am getting a good sample?

It is important to roll the swab around the inside walls of both nostrils. You want the swab to be touching and rubbing around the inside walls as you rotate.



**Rotating the swab 5 times around the inside walls of both nostrils is very important for the test to work properly.**

### What are the known and potential risks and benefits of this test?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results.

Potential benefits include:

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

### What if the display shows an invalid test result?

This means something with the test did not work properly. If your test has any invalids, the Positive and Negative lights will be blinking when the test is done in 30 minutes. If your test shows an invalid result, please contact Lucira at 1-888-LUCIRA-4 (582-4724).

### What is influenza A & B?

The two most common types of influenza are influenza A & B. This test kit tests for both of these types of flu. If you test positive for either Influenza A (Flu A) or Influenza B (Flu B), you have the flu.

### How accurate is this test?

Lucira's COVID-19 & Flu Test is a Nucleic Acid Amplification Test (NAAT) *in vitro* diagnostic test that has a sensitivity, or ability to detect the SARS-CoV-2, Influenza A, and Influenza B viruses, that is comparable to some of the best PCR tests performed in clinical settings and high complexity labs. In a Remnant Sample Testing Study, the Lucira test was compared to two FDA-authorized known high sensitivity SARS-CoV-2 PCR tests and an FDA-cleared known high sensitivity Influenza A and B PCR test. For each virus, Lucira achieved 99% accuracy. Lucira achieved 98% (108/110) sensitivity, measured by positive percent agreement (PPA) for COVID-19, 100% (59/59) sensitivity for Influenza A, and 98% (40/41) sensitivity for Influenza B. Specificity, measured by Negative Percent Agreement (NPA), was 100% (296/296) for COVID-19, 99% (347/348) for Influenza A, and 99% (363/365) for Influenza B.

### Lucira COVID-19 & Flu Test Retrospective Results Summary

Virus	Sensitivity (PPA)	Specificity (NPA)	Accuracy
COVID-19	98% 108/110	100% 296/296	99% 404/406
Influenza A	100% 59/59	99% 347/348	99% 406/407
Influenza B	98% 40/41	99% 363/365	99% 403/406

For more clinical data, visit [lucirahealth.com/data](http://lucirahealth.com/data)

### Can this test detect new SARS-CoV-2 variants and Flu strains?

Lucira Health performs routine surveillance of emerging SARS-CoV-2 and Influenza strains and will continue to monitor the situation with emerging variants. A technical brief that lists COVID variants and flu strains to which the Lucira test is reactive is available at [lucirahealth.com](http://lucirahealth.com)

# LUCIRA™

## COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)

Test only works if you follow each step

Open for instructions



### Indication

The Lucira COVID-19 & Flu Test is a single use real-time RT-LAMP test kit intended for self testing at home for the simultaneous rapid qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A and Influenza B virus from self-collected nasal swab samples in individuals 14 years and older (self-collected) or individuals ≥2 years (collected by an adult) with symptoms of respiratory viral infection consistent with COVID-19, Influenza A and/or Influenza B. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

This test is also intended for use at the Point of Care (POC) for individuals with symptoms of respiratory viral infection consistent with COVID-19, Influenza A and/or Influenza B with specimens collected by trained personnel. The Lucira COVID-19 & Flu Test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, Influenza A and Influenza B, in humans, and is not intended to detect Influenza C.

The SARS-CoV-2, Influenza A or Influenza B RNA is generally detectable in nasal swab samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Influenza A or Influenza B RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Persons who test positive with the Lucira COVID-19 & Flu Test should seek follow up care with their physician, or healthcare provider, as additional testing and public health reporting may be necessary.

Negative results do not preclude infection from SARS-CoV-2, Influenza A, and/or Influenza B and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

### Description

This Lucira COVID-19 & Flu Test contains everything needed to perform one (1) Lucira COVID-19 & Flu Test: Instructions, 2 AA Batteries, 1 test unit, 1 sample vial, 1 sterile nasal swab and 1 disposal bag. For this test to work properly, it is important to read the instructions and follow each step.

## Instructions - Start Here

- Choose a location to do this test where it can sit **UNDISTURBED** for 30 minutes.
- Please read all instructions carefully before you begin.
- Do not insert batteries into test unit until ready to perform test.
- Keep test box to use for LUCI PASS.
- Make sure your test kit contains: 2 AA batteries, test unit (pouch 1), sample vial (pouch 2), swab (labeled 3), and plastic disposal bag.
- Wash and dry hands.



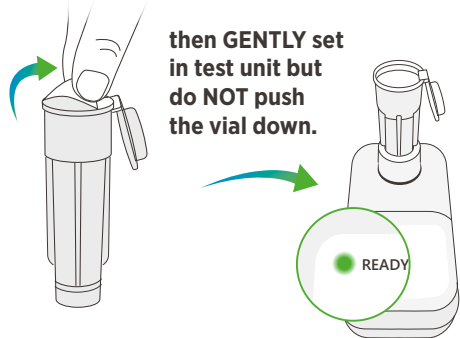
### 1 Set Up Test

- When ready to begin test, open test unit pouch 1.

Open battery door and insert batteries.

- Check that **Ready** light is on.
- Open sample vial pouch 2.

REMOVE sample vial seal



then GENTLY set in test unit but do NOT push the vial down.

Do not open swab until ready to use.

### 2 Swab Both Nostrils

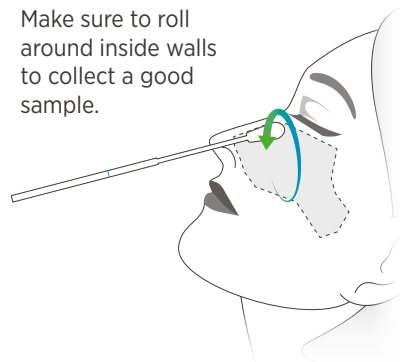


**!** For this test to work properly, it is important you swab **BOTH** nostrils.

- Remove swab and hold with handle end. Do not set swab down.
- Tilt head back and **gently insert swab tip until it is fully inside your nostril** and you meet resistance.
- Once swab tip is fully inside nostril, **roll the swab 5 times around the inside walls of your nostril. The swab should be touching the walls of the nostril as you rotate.**
- Repeat swab step in other nostril.

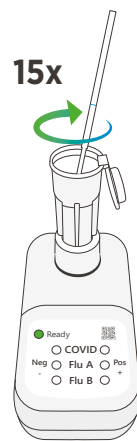
Rotate **5X** in **BOTH** nostrils.

Make sure to roll around inside walls to collect a good sample.



**!** Adults must swab children ages 2-13.

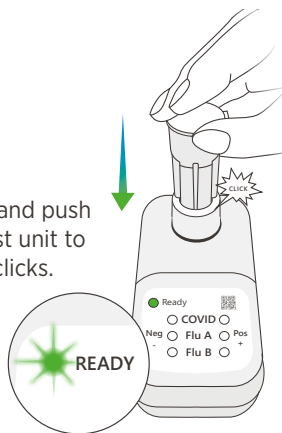
### 3 Stir Swab and Run Test



- Insert swab into the sample vial until it **touches the bottom.**
- Mix sample by **stirring around the sample vial 15 times.**
- Discard swab.

- Snap cap closed and push vial down into test unit to start test until it clicks.

- Ready light will start **blinking** when test is running.



If Ready light is not blinking within 5 seconds, use palm of your hand to push down more firmly to start test.

- Do not move test unit once the test has started running.

Wait 30 minutes.

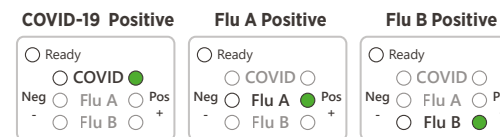
### 4 Read Result



- Ready light will continue blinking while the test is running.
- Positive results may display before the test is done running.
- Ready light will turn off and all results for COVID-19, Flu A, and Flu B will display in 30 minutes when test is done.

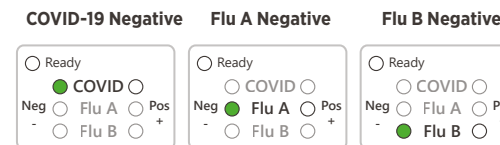
**+** POSITIVE Results

Positive results light up on the right



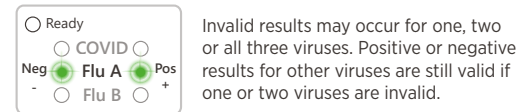
**-** NEGATIVE Results

Negative results light up on the left



INVALID Results

Positive and Negative lights flash if result is Invalid



Invalid results may occur for one, two or all three viruses. Positive or negative results for other viruses are still valid if one or two viruses are invalid.

Share your results with your healthcare provider. If you receive any invalid results, retest with a new test, consult with your healthcare provider, or contact Lucira at 1-888-LUCIRA-4. Contact Lucira if result is invalid upon retesting.

LUCI PASS is a verified digital record of this test result. To get your personal LUCI PASS, after taking this test:  
1) Use your smartphone camera app to scan the QR code on the top of the test unit OR on the sticker  
2) Tap the notification that appears on the screen to go to [lucipass.com](https://lucipass.com)  
3) Follow the easy step-by-step instructions

**+** If you test POSITIVE

It is very likely you have COVID-19 (if you tested positive for COVID-19) or flu (if you tested positive for flu A or flu B) and it is important to be under the care of a healthcare provider. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive). 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.

**-** If you test NEGATIVE

A negative result means the virus that causes COVID-19 (if you test negative for COVID-19) or flu (if you test negative for flu A & flu B) was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 or flu. This means you could possibly still have COVID-19 or flu even though the test is negative. If this is the case, your healthcare provider will consider the test result with all other aspects of your history such as symptoms and possible exposures to decide how to care for you. It is important you work with your healthcare provider to help you understand the next steps you should take.

### 5 Dispose of Test

After test is completed, remove batteries, place the test unit in plastic disposal bag and dispose of all materials in accordance with local regulations.