

**LUCIRA**<sup>™</sup>  
HEALTH

## CHECK✓IT COVID-19 Test Kit



Swab



Stir



Detect

The Lucira CHECK✓IT COVID-19 Test Kit 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, 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:  
[www.lucirahealth.com/Canada/IFU](http://www.lucirahealth.com/Canada/IFU)

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Emeryville, California 94608, United States

Package Insert (PI) INST018 Rev. B

## Frequently Asked Questions

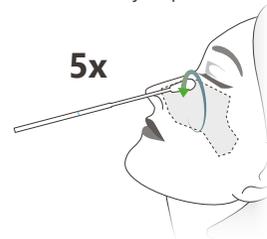
Please Read Instructions On Reverse

### 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?

Collecting a good sample requires rolling or rubbing the swab around the inside walls of both nostrils. Making sure you are touching the inside walls of the nostrils is very important.



5x

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 (see Read Results section).

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.

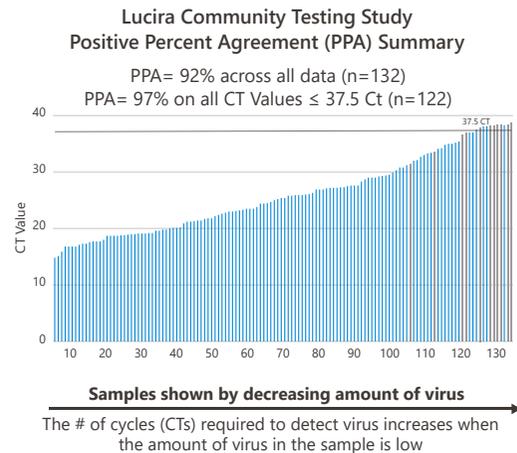
You have the option to refuse this test. However, your doctor has prescribed this test because they believe it could help with your care.

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

This means something with the test did not work properly. If your test is invalid, all the lights will be blinking when the test is done in 30 minutes. If your test shows an invalid result, please contact us at 1-888-582-4724 and we will assist you.

### How accurate is this test?

In two Community Testing Studies which included 404 individuals with and without COVID-19 symptoms, the Lucira test achieved 98% (267/272) negative percent agreement (NPA) when compared to a FDA authorized known high sensitivity SARS-CoV-2 PCR test. Positive percent agreement (PPA) among symptomatic individuals was 94% and 90% in asymptomatic. Total PPA was 92% (121/132) across all samples and included 10 samples with very low levels of virus >37.5 Ct as shown below.



The above graph shows the Lucira CHECK✓IT COVID-19 Test Kit positive percent agreement in Lucira's two Community Testing Studies. BLUE bars represent samples where the Lucira positive test result matched the comparison test result. GREY bars represent the Lucira test results that were negative and did not match the comparison test positive result. Nearly all of the GREY bars occurred in samples where there were very low levels of virus detected by the comparison test.

1. La Scola B., *Clinical Infectious Diseases*, September 2020

For more information about Lucira's clinical data, visit [www.lucirahealth.com/data](http://www.lucirahealth.com/data)



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## CHECK✓IT COVID-19 Test Kit

Test only works if you follow each step  
Open for instructions

### Indication

The Lucira CHECK✓IT COVID-19 Test Kit is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for over-the-counter (OTC) use with self-collected nasal swab samples in individuals 14 years and older (self-collected) or individuals ≥2 years (collected by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. This test is similar to a PCR test in that it utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA.

Positive results are indicative of the presence of SARS-CoV-2. It is important for individuals who test positive to 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 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

### Description

This Lucira CHECK✓IT COVID-19 Test Kit contains everything needed to perform one (1) Lucira COVID-19 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.**
- 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 Your 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

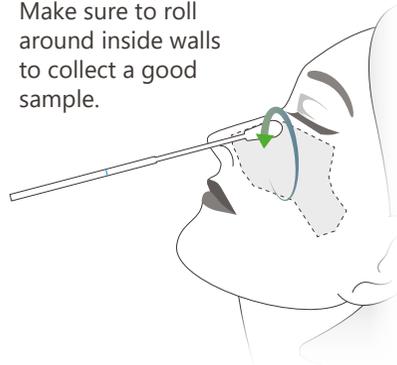


**!** For this test to work properly, it is important you swab **BOTH** nostrils.

- 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.



### 3 Stir Swab and Run Test



15x

- 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 press vial down into test unit 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 press down more firmly to start test.**

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

- ⌚ Wait 30 minutes.

### 4 Read Result



Test will be ready in 30 minutes.  
Done light will display when test is finished.

Ready	Done	COVID-19
<input type="radio"/>	<input checked="" type="radio"/>	Positive
<input checked="" type="radio"/>	<input type="radio"/>	Negative

Ready	Done	COVID-19
<input checked="" type="radio"/>	<input checked="" type="radio"/>	Positive
<input type="radio"/>	<input checked="" type="radio"/>	Negative

Ready	Done	COVID-19
<input type="radio"/>	<input type="radio"/>	All lights flashing

If you receive an Invalid result, please contact us at 1-888-582-4724 and we will assist you.

#### + If you test POSITIVE

It is very likely you have COVID-19 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 was not found in your sample. If you took this test while you have symptoms, a negative test result usually means that your current illness was not caused by COVID-19.

However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 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 Kit

After test is completed, place the test unit in plastic disposal bag and dispose all test kit materials in trash.