LUCIRA™ CHECK✓IT

COVID-19 Test Kit

Swab   **Stir**   **Detect**

The Lucira CHECK✓IT COVID-19 Test Kit is for FDA Emergency Use Authorization (EUA) only

For Over-The-Counter (OTC) Use
For In Vitro Diagnostic (IVD) Use

• This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
• This product 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.
• The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
• For more information on EUAs go here:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

For detailed instructions for point of care use, visit:

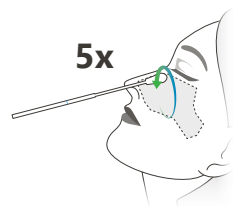**www.lucirahealth.com/IFU**

Package Insert (PI) INST017 Rev. D

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.

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.

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 that 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.
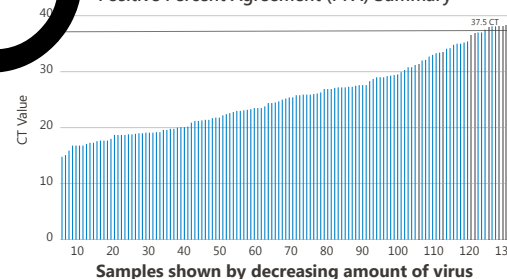
What is PCR quality molecular accuracy?
Lucira CHECK✓IT COVID-19 Test Kit is a molecular test that amplifies the virus's genetic material while the test is running just like PCR lab tests. The amplification method provides a level of accuracy comparable to one of the highest sensitivity lab PCR tests.

How accurate is this test?
The Lucira CHECK✓IT COVID-19 Test Kit is a molecular in vitro diagnostic test that has an analytical sensitivity, or ability to detect the SARS-CoV-2 virus, that is comparable to some of the best molecular PCR tests performed in clinical settings and high complexity labs.

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 9 samples with very low levels of virus >37.5 Ct as shown below.

Lucira Community Testing Study
Positive Percent Agreement (PPA) Summary

The # of cycles (CTs) required to detect virus increases when the amount of virus in the sample is low

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 that possibly no longer reflected active infection[1] that were detected by the comparison test.

1. La Scola B., *Clinical Infectious Diseases,* September 2020
For more clinical data, visit www.lucirahealth.com/data

LUCIRA™ CHECK✓IT
COVID-19 Test Kit

Test only works if you follow each step

Open for instructions

Intended Use
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 for nonprescription home use with self-collected anterior nasal swab samples from individuals aged 14 years and older (self-collected) or individuals 2 years or older (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 viral RNA. SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab samples during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past medical 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 should self-isolate and seek additional care from their healthcare provider.

Negative results are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection should seek follow up care from their physician or healthcare provider.

The Lucira CHECK✓IT COVID-19 Test Kit is for use only under the Food and Drug Administration's Emergency Use Authorization.

Test results can be reported through the LUCI secure web portal, to relevant public health authorities in accordance with local, state and federal requirements.

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.**
- **Do not discard box so it can be used for LUCI reporting.**
- Make sure your test kit contains: 2 AA batteries, test unit (pouch 1), sample vial (pouch 2), swab (labeled 3), and plastic disposal bag.
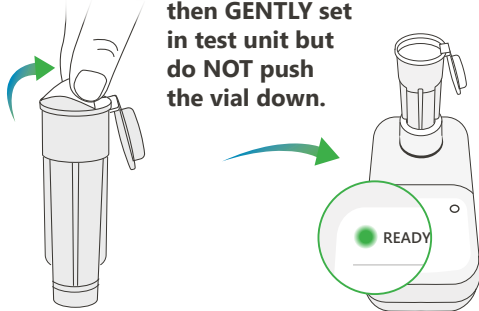- Wash and dry hands.

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.

READY

Note: Keep vial away from children. Avoid contact with eyes and skin. If contact occurs, rinse with water. If irritation persists, seek medical attention.

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

15x

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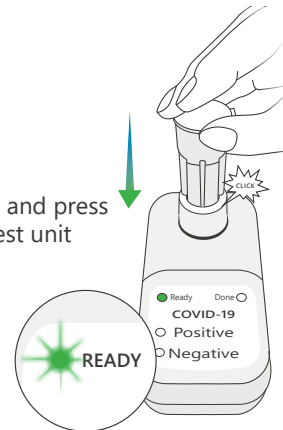- Mix sample by **stirring around the sample vial 15 times.**
- Discard swab.

- Snap cap closed and press vial down into test unit until it clicks.
- Ready light will start **blinking** when test is running.

CLICK

READY

COVID-19
Positive
Negative

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 and Report Result

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

Ready ○ Done ●	Ready ○ Done ●	Ready ● Done ●
COVID-19	**COVID-19**	**COVID-19**
● Positive	○ Positive	● Positive
○ Negative	● Negative	● Negative
Positive Result *Positive light displays*	**Negative Result** *Negative light displays*	**Invalid Result** *All lights flashing*

Next, please use Pfizer's secure LUCI portal (Lucira Connect) to receive a verified test result on your phone and transmit your result to public health agencies. To get started, go to **luciraconnect.com** from your smartphone.

⊕ 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. 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.

CYAN | MAGENTA | YELLOW | BLACK | LUCIRA LIGHT BLUE | LUCIRA BLUE | PMS 360

REVOKED

OPEN THIS END
Please read instructions
Por favor de leer las instrucciones

LUCIRA™

1 Single-use
molecular test kit

Read instructions
before using

LUCIRA™ CHECK✓IT

COVID-19

SWAB
STIR
DETECT

PCR quality molecular accuracy in 30 minutes or less

1 Single-use
molecular test kit

Read instructions
before using

SWAB
STIR
DETECT

LUCIRA™ CHECK✓IT

COVID-19

PCR quality molecular accuracy
in 30 minutes or less

1 Single-use
molecular test kit

Read instructions
before using

SWAB
STIR
DETECT

PCR quality molecular accuracy in 30 minutes or less

LUCIRA™

CHECK✓IT

COVID-19

OPEN OTHER
END

59°F — 86°F

PACK038 Rev. A

Keep this box. Your unique test kit number is stickered above.

Use this photo guide if
sharing your results with a
healthcare provider. After
test is finished, place test
unit here and take photo that
includes your test result
alongside sticker with your
unique test kit number.

O Ready   Done O
COVID-19
O Positive
O Negative

What is PCR quality molecular accuracy? Lucira CHECK IT COVID-19
Test Kit is a molecular test that detects the virus's genetic material
while the test is running just like PCR. This amplified genetic material
provides a level of accuracy comparable to one of the highest
sensitivity PCR tests, with results in just 30 minutes or less.

To receive a verified quality molecular method
test result reporting portal will use the QR code at ... register
your test result. To get started, see Read ... enclosed
instructions.

The Lucira Check It COVID-19 test kit has not been ... approved or
authorized ... The emergency use of this product is only authorized for the ... of
circumstances ... detection ... COVID-19 under Section ... duration of the declaration ...
and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless ... is terminated or
authorization is revoked sooner.

**This kit contains everything you need to run
this test:** instructions, 2 AA batteries, 1 test
unit, sample vial, nasal swab and disposal bag.

For use under Emergency Use Authorization
(EUA) only

For In Vitro Diagnostic Use

8 10055 97004 9