PMS BLACK 7 | PMS 361 | PMS 2194

Pfizer

COVID-19
All-In-One Test Kit

Swab | Stir | Detect

The Lucira COVID-19 All-In-One Test Kit is for FDA Emergency Use Authorization (EUA) only

For Prescription 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 for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- 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

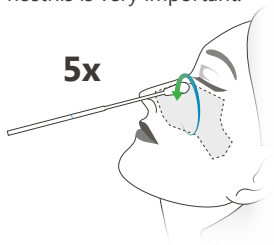
For detailed instructions for point of care use, visit:
www.lucirahealth.com/IFU

Package Insert (PI) INST014 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?
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.



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.

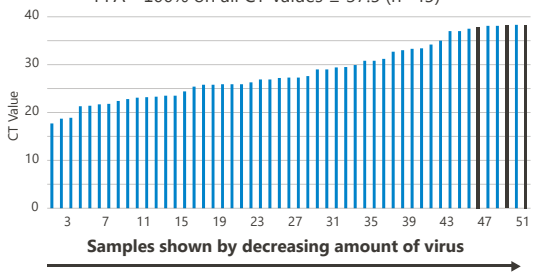
What if the display shows an invalid test result?
This means something with the test did not work properly. If your test is invalid, all the lights will be blinking when the test is done in 30 minutes. If your test shows an invalid result, please contact us at 1-888-582-4724 and we will assist you.

How accurate is this test?
The Lucira COVID-19 All-In-One 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 tests performed in clinical settings and high complexity labs.

In a Community Testing Study, where the Lucira test was compared to a FDA authorized known high sensitivity SARS-CoV-2 test, a 94% positive percent agreement (PPA) and a 98% negative percent agreement (NPA) was achieved. Excluding samples with very low levels of virus that possibly no longer reflected active infection[1], 100% positive percent agreement was achieved.

Lucira Community Testing Study
Positive Percent Agreement (PPA) Summary

PPA= 94.1% across all data (n=51)
PPA= 100% on all CT Values ≤ 37.5 (n=45)



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 COVID-19 All-In-One Test Kit positive percent agreement in the Community Testing Study. 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. 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 the clinical data, visit
www.lucirahealth.com/data

Pfizer

COVID-19
All-In-One Test Kit

Test only works if you follow each step
Open for instructions

Intended Use

The Lucira COVID-19 All-In-One 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 prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years and older who are suspected of COVID-19 by their healthcare provider. This test is also authorized for use at the Point of Care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, with self-collected anterior nasal swab samples from individuals aged 14 years and older, and in individuals aged 13 years and under when the sample is collected by a healthcare provider at the POC. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in individuals with known or suspected COVID-19.

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 SARS-CoV-2 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-19 like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their physician or healthcare provider.

The Lucira COVID-19 All-In-One Test Kit is for use under the Food and Drug Administration's Emergency Use Authorization only.

All prescribing healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Description

This Lucira COVID-19 All-In-One 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.

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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 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.

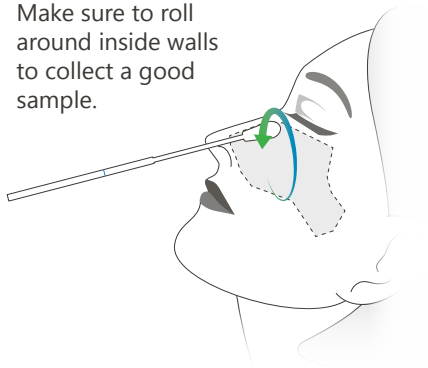
2 Swab Both Nostrils

! 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/patient 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.**

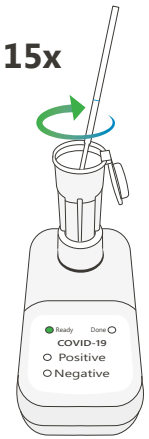
Rotate 5x in BOTH nostrils.

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

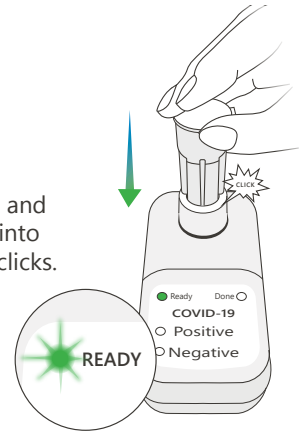


3 Stir Swab and Run Test

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.

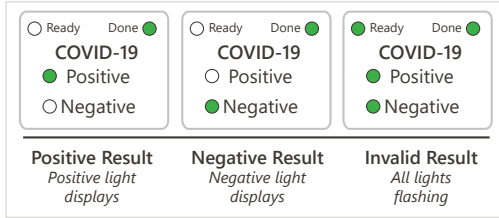
If Ready light is not blinking within 5 seconds, use palm of your hand to press down more firmly to start test.

- 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.



Please share your test result with your healthcare provider. The bottom panel of the test kit box has a photo guide that can be used to share your results.

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.