

LUCIRA® by Pfizer

COVID-19 & Flu Home Test

Nucleic Acid Amplification Test (NAAT)

For Individuals with signs and symptoms of Respiratory Tract Infection including COVID-19



SWAB



STIR



DETECT

The Lucira by Pfizer COVID-19 & Flu Home Test 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 detection and differentiation of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, 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

Detailed instructions for (IFU) may be obtained at no additional cost at:

www.lucirahealth.com/IFU

or by calling Pfizer at 1-888-LUCIRA-4 (582-4724)

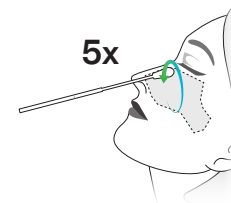
Package Insert (PI) INST094 Rev. D

Frequently Asked Questions

Please Read Instructions On Reverse

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 the 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.

What if the display shows an invalid test result?

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

What is Influenza A & B?

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

While seasonal influenza viruses are detected year-round in the United States, flu viruses typically circulate during the fall and winter during what's known as the flu season.

How accurate is this test?

The Lucira by Pfizer COVID-19 & Flu Home Test was compared to an FDA-authorized known high sensitivity SARS-CoV-2 PCR test and an FDA-cleared known high sensitivity Influenza A and B PCR test. Please refer to the IFU at www.lucirahealth.com/IFU for complete data.

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

Pfizer 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 SARS-CoV-2 variants and flu strains to which the Lucira test is reactive is available at lucirahealth.com

LUCIRA® by Pfizer

COVID-19 & Flu Home Test

Nucleic Acid Amplification Test (NAAT)
Test only works if you follow each step.

Open for instructions.



Intended Use

The Lucira by Pfizer COVID-19 & Flu Home Test is a single use (disposable) home test kit intended for simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral nucleic acid. This test is authorized for non-prescription home use with anterior nasal swab samples from individuals 14 years or older (self-collected) or individuals 2 years or older (collected by an adult) with signs and symptoms consistent with a respiratory tract infection, including COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

The Lucira by Pfizer COVID-19 & Flu Home Test is intended for use in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in clinical specimens and is not intended to detect influenza C. SARS-CoV-2, influenza A, and influenza B viral nucleic acid is generally detectable in anterior nasal swab samples during the acute phase of infection.

Positive results indicate the presence of viral nucleic acid, 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 pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Lucira by Pfizer COVID-19 & Flu Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results for SARS-CoV-2 and influenza B are presumptive, meaning that they should be confirmed, if necessary for patient management, with an authorized or cleared molecular test performed in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests.

Negative results do not rule out SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other management decisions, including infection control decisions. Negative results should be considered in the context of current prevalence of infection, an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with respiratory infection.

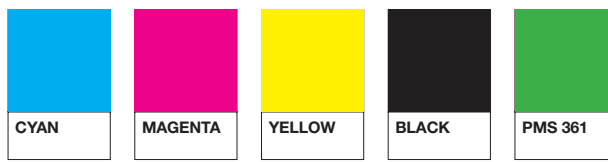
Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have a respiratory infection and should seek follow up care with their healthcare provider.

Individuals should report all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All 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.

The Lucira by Pfizer COVID-19 & Flu Home Test is authorized for non-prescription self-use by individuals aged 14 years or older and/or, as applicable, for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The Lucira by Pfizer COVID-19 & Flu Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Description

This Lucira by Pfizer COVID-19 & Flu Home Test contains everything needed to perform one (1) Lucira by Pfizer COVID-19 & Flu Home 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

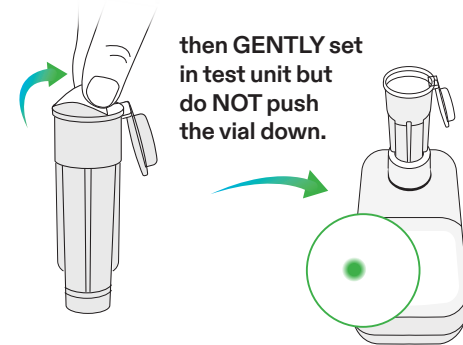
- Choose a location to do this test where it can sit **UNDISTURBED** for 30 minutes.
- Please read all instructions carefully before you begin.
- Do not insert batteries into test unit until ready to perform test.
- Keep test box to use for Lucira Connect.
- Make sure your test kit contains: 2 AA batteries, 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.

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



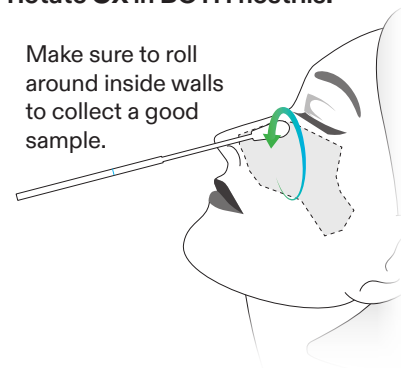
! For this test to work properly, it is important to swab **BOTH** nostrils.

- 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.
 - o For adults - insert less than one inch.
 - o For younger children - insert less than 1/2 inch

- 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.

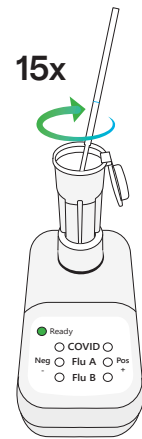
Rotate 5X in BOTH nostrils.

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



! Adults must swab children 2 years or older.

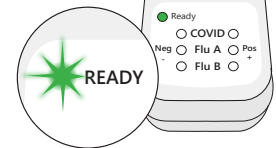
3 Stir Swab and Run Test



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

- Immediately 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.

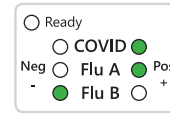
⌚ Wait 30 minutes.

4 Read Result



- Ready light will continue blinking while the test is running.
- Positive results may display before the test is done running.
- Results may be positive for more than one virus.
- 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.

Example Result: Positive for COVID-19 & Flu A; Negative for Flu B. You must wait until the Ready light has stopped blinking, indicating the test is complete, to interpret results.



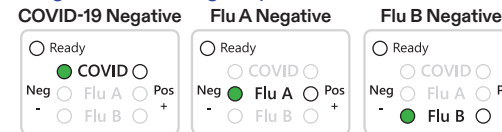
POSITIVE Results

Positive results light up on the right



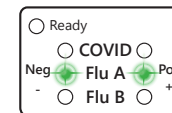
NEGATIVE Results

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. If an invalid result is observed for any of the viruses the entire test is considered invalid. Retest with a new test and use the retest results as final.

If you receive any invalid results, retest or contact Pfizer at 1-888-LUCIRA-4 to obtain a free replacement test.

Lucira Connect is a website that helps you:

- Create a shareable digital record of your test result

Use your smartphone camera to scan the QR code on the top of the test unit or on the sticker on the back of the box to begin at luciraconnect.com

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If you test **POSITIVE**
It is very likely you have COVID-19 (if the test result is positive for COVID-19) or flu (if the test result is 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.

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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.

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If the test is **INVALID**
An invalid result means something with the test did not work properly. If the test result is invalid, the positive and negative lights on the device will be blinking/flashing. If your test shows an invalid result, retest or contact Pfizer at 1-888-LUCIRA-4 to obtain a free replacement test.

5 Dispose of Test Kit

After use remove the batteries, place the test unit in plastic disposal bag and dispose all test kit materials in trash. Do not allow the test unit to come into contact or be disposed of with bleach, as harmful gases could be emitted as a result.