CYAN | MAGENTA | YELLOW | BLACK | PMS 361

UNFOLD

LUCIRA™ by Pfizer

COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)

SWAB STIR DETECT

The Lucira by Pfizer COVID-19 & Flu Test is for FDA Emergency Use Authorization (EUA) only

For Prescription Use Only
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 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 point of care use (IFU) may be obtained at no additional cost at:

www.lucirahealth.com/IFU

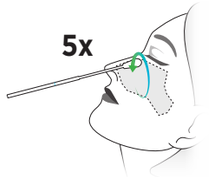
or by calling Pfizer at 1-888-LUCIRA-4 (582-4724)

Package Insert (PI) INST037 Rev. C

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.

How accurate is this test?
The Lucira by Pfizer COVID-19 & Flu 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 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 Test is a single use (disposable) RT-LAMP test kit intended for the simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in anterior nasal swab specimens collected from individuals (2 years of age or older) who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and Influenza can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Lucira by Pfizer COVID-19 & Flu Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in clinical specimens and is not intended to detect Influenza C virus. SARS-CoV-2, Influenza A, and Influenza B viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Influenza A, and/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 pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results for SARS-CoV-2, and Influenza B are presumptive and should be confirmed with an alternative molecular FDA-cleared or authorized assay, if necessary for patient management. Negative results do not preclude SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Lucira by Pfizer COVID-19 & Flu Test is intended for use by operators who have received specific training in the use of the Lucira by Pfizer COVID-19 & Flu Test. The Lucira by Pfizer COVID-19 & Flu Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Description

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

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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.**
- **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

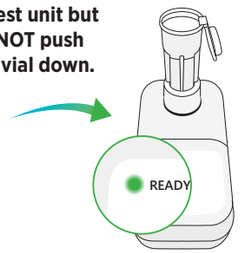
- When ready to begin test, open test unit pouch 1.

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.



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

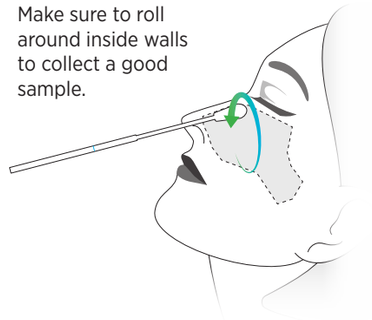
2 Swab Both Nostrils

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

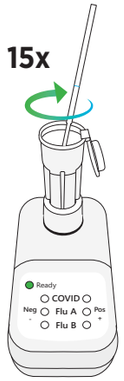
- Remove swab and hold with handle end. Do not set swab down.
- Tilt head back and **gently insert swab tip until it is fully inside the individual's nostril** and you meet resistance.
- Once swab tip is fully inside nostril, **roll the swab 5 times around the inside walls of the nostril. The swab should 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



- 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.

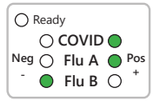
- Do not move test unit once the test has started running.

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. Do not report results until the Ready light has stopped blinking, indicating the test is complete.



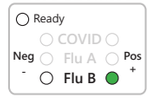
POSITIVE Results

Positive results light up on the right

COVID-19 Positive

Flu A Positive

Flu B Positive



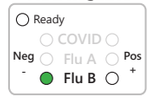
NEGATIVE Results

Negative results light up on the left

COVID-19 Negative

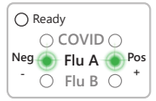
Flu A Negative

Flu B Negative



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.

If you receive any invalid results, retest with a new test or contact Pfizer at 1-888-LUCIRA-4 (582-4724). Contact Pfizer if result is invalid upon retesting.

LUCI PASS is a verified digital record of this test result. After taking this test, the individual can make a LUCI PASS for personal use if you invite them to:
1) Use their smartphone camera app to scan the QR code on the top of the test unit OR on the box sticker
2) Tap the notification that appears on the screen to go to **lucipass.com**
3) Follow the easy step-by-step instructions

If the test is POSITIVE

It is very likely the test individual has 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).

If the test is NEGATIVE

Negative test results for COVID-19, flu A and flu B are presumptive and should be confirmed using an alternative molecular diagnostic test, if clinically inidcated. A negative result means the virus that causes COVID-19 (if the test result is negative for COVID-19) or flu (if the test result is negative for flu A & flu B) was not found in the 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 the tested individual could possibly still have COVID-19 or flu even though the test is negative. If this is the case, the test result with all other aspects of the individual's history such as symptoms and possible exposures should be used to decide care.

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. 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.

External Run Controls (ERCs) are not required to use this test. ERCs may be tested, regularly or when new tests are received, in order to train new operators, or to conform with local regulations, accrediting groups, or the lab's standard Quality Control produces. Reference the complete IFU for more information.