COVID-19 All-In-One Test Kit

Swab
Stir
Detect

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

How do I make sure I am getting a good sample?
• Making sure you are touching the inside walls of both 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.

Potential risks include:
• 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.

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).

What tips will help me use the nasal swab correctly?
• 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?

How accurate is this test?
Lucira’s 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, Lucira achieved a 94% positive percent agreement (PPA) and a 98% negative percent agreement (NPA). Excluding samples with very low levels of virus that possibly no longer reflected active infection, Lucira achieved 100% positive percent agreement.

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)

For more information about Lucira’s clinical data, visit www.lucirahealth.com/data

Samples shown by decreasing amount of virus

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 Scala B., Clinical Infectious Diseases, September 2020

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For prescription use with self-collected nasal swab samples in individuals aged 14 and older, and in individuals aged 13 and under when the specimen 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.

Positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should 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.

For use under the Food and Drug Administration’s Emergency Use Authorization (EUA) only.

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

1 Set Up Your Test

- Remove test unit from 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.

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.

4 Read Result

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

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.

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

If Ready light does not display within 5 seconds, check that Ready light is on and batteries are inserted.

If test result is not displayed after 1 minute, check that batteries are inserted and replace with new batteries.

If test result is not displayed after 5 minutes, repeat test.