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.

How accurate is this test? Lucira’s 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 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 10 samples with very low levels of virus >37.5 Ct as shown below.

Lucira Community Testing Study
Positive Percent Agreement (PPA) Summary

Possible incorrect test results.
Possible discomfort during sample collection.
Potential risks 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.
- 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 test results that were negative and did not match the comparison test result positive. Nearly all of the GREY bars occurred in samples where there were very low levels of virus that possibly no longer reflected active infection' that were detected by the comparison test.

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

For Over-The-Counter (OTC) Use
For In Vitro Diagnostic (IVD) Use
• This OTC test kit has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
• This OTC test kit 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 OTC test kit 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-F1 Rev. C
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 box to use 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 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

2 Swab Both Nostrils
• For this test to work properly, it is important you swab 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.

4 Read and Report Result
• Snap cap closed and push vial down into test unit to start test until it clicks.
• Ready light will start blinking when test is running.
• Do not move test unit once the test has started running.
• Wait 30 minutes.

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.

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

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.

Adults must swab children ages 2-13.
What is PCR quality molecular accuracy? Lucira is a molecular test that amplifies the virus’s genetic material while the test is running just like PCR tests. Lucira’s amplification method provides a level of accuracy comparable to one of the highest sensitivity PCR tests.

To receive a verified test result, Lucira has developed LUCI, a secure test result reporting portal. You will use the QR code at left to register your test result. To get started, see Read Results section in enclosed instructions.

The Lucira Check It COVID-19 test kit 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 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Para instrucciones en español: www.lucirahealth.com/espanol

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

Patients: www.lucirahealth.com/patients