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?

1. Open the package and take out the test kit, swab, and 2 AA batteries.
2. Collect the sample:
   - Insert the swab 5 times around the inside walls of both nostrils. It is important to roll the swab around the inside walls as you rotate.
   - It is important to roll the swab around the inside walls of both nostrils. This 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 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.

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.

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 lab tests. Lucira’s amplification method provides a level of accuracy comparable to one of the highest sensitivity lab PCR tests.

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

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 coinfection 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 a healthcare provider. Negative results in an asymptomatic individual are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

The Lucira CHECK•IT COVID-19 Test Kit is for use only under the Food and Drug Administration’s Emergency Use Authorization.

Test results can be reported through the LUCI secure portal to relevant public health authorities in accordance with local, state and federal requirements.

Description
This Lucira CHECK•IT COVID-19 Test Kit contains everything needed to test for the novel coronavirus SARS-CoV-2: 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 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.
• 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 and Report Result
Done light will display when test is ready in 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.
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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.

For instructions in 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

Patents: www.lucirahealth.com/patents

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