FDA Emergency Use Authorization (EUA) only

IT COVID-19 Test Kit is for

• The emergency use of this OTC test kit is only authorized for the testing of individuals with and without COVID-19 symptoms, the Lucira test achieved 98% (267/272) negative percent agreement (NPA) when compared to a FDA authorized known 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 viral load of >37.5 Ct as shown below.

For detailed instructions for point of care use, visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

For more clinical data, visit www.lucirahealth.com/data

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 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. Nearly all of the GREY bars occurred in samples where there were very low levels of virus that possibly no longer reflected active infection1 that were detected by the comparison test.

1. La Scola B. Clinical Infectious Diseases, September 2020

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

Swab
Stir
Detect

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

The Lucira CHECK IT COVID-19 Test Kit is for FDA Emergency Use Authorization (EUA) only

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

Package Insert (PI) INST017 Rev. 4

What is 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.
- The # of cycles (CTs) required to detect virus increases when the amount of virus in the sample is low.

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 known 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 of >37.5 Ct as shown below.

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

For more clinical data, visit www.lucirahealth.com/data

The Lucira CHECK IT COVID-19 Test Kit is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for nonprescription over-the-counter (OTC) use with self-collected nasal swab samples in individuals 14 years and older (self-collected) or individuals ≥2 years (collected by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. This test is similar to a PCR test in that it utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA. 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 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.

The Lucira CHECK IT COVID-19 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.
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.

When ready to begin test, open test unit pouch 1. 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. Insert swab into the sample vial until it touches the bottom. Mix sample by stirring around the sample vial 15 times. Discard swab.

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.

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

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.

After test is completed, place the test unit in plastic disposal bag and dispose all test kit materials in trash.