The Lucira COVID-19 All-In-One 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 prescription home use with self-collected nasal swab samples in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider. This test is also authorized for use at the Point of Care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, for 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 are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed. 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. The Lucira COVID-19 All-In-One Test Kit is for use under the Food and Drug Administration’s Emergency Use Authorization only.

Description
This Lucira COVID-19 All-In-One Test Kit contains everything needed to perform one (1) Lucira COVID-19 test:
- 1 Sample Vial
- 1 Sterile Nasal Swab
- 1 Disposal Bag
For this test to work properly, it is important to read the instructions and follow each step.

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

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.
   - 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.
   - 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.
   - Do not open swab until ready to use.

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.

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 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.

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

   If you test POSITIVE
   - 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.

   If you test NEGATIVE
   - Positive Result Positive light displays
   - Negative Result Negative light displays
   - Invalid Result All lights flashing

   Please share your test result with your healthcare provider. The bottom panel of the test kit box has a photo guide that can be used to share your results.