Section B – Directions for running the Lucira COVID-19 Test

- **Choose a location to do this test where it can sit UNDISTURBED for 30 minutes.**
- **Please read all instructions carefully before you begin.**
- Make sure your test kit contains:
- 2 AA batteries, test unit (pouch 1), sample vial (pouch 2), swab (labeled 3), and plastic disposal bag.
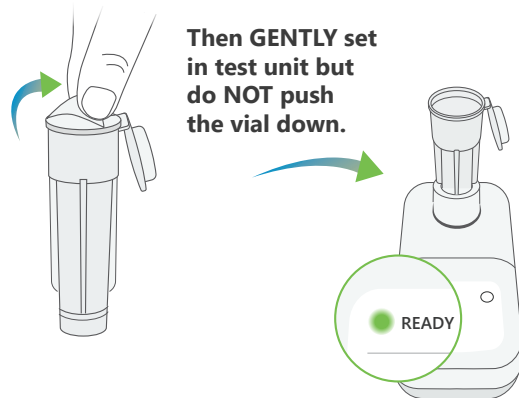- Wash and dry hands.

1. Set Up 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.

READY

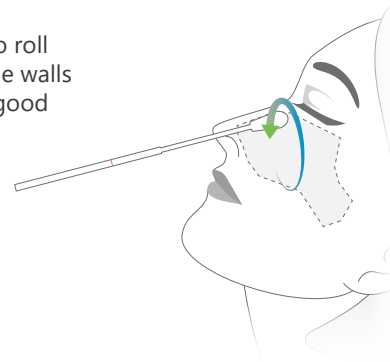- Do not open swab until ready to use.

2. Swab Both Nostrils

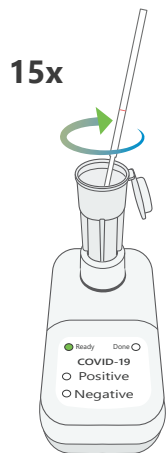⚠ **For this test to work properly, it is important you swab BOTH nostrils.**

- 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/patient 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.**

Rotate 5x in BOTH nostrils.
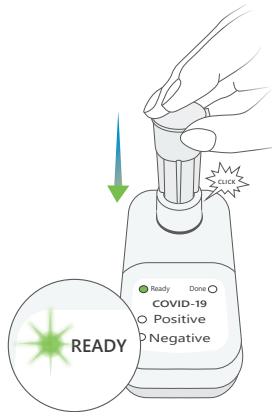
Make sure to roll around inside walls to collect a good sample.

3. Stir Swab and Run Test

15x

- Insert swab into the sample vial until it **touches the bottom.**
- Mix sample by **stirring around the sample vial 15 times.**
- Discard swab.

- Snap cap closed and press vial down into test unit until it clicks.

- Ready light will start **blinking** when test is running.

READY

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.

4. Read Result

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

Positive Result	Negative Result	Invalid Result
○ Ready Done ● COVID-19 ● Positive ○ Negative	○ Ready Done ● COVID-19 ○ Positive ● Negative	● Ready Done ● COVID-19 ● Positive ● 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.

Healthcare Providers: All Lucira COVID-19 All-In-One Test Kit results should be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Luicra's LOINC code is: 95409-9
Lucira's Device ID is: 00810055970001

For more information on reporting, please see Lucira's Healthcare Provider Guide to Reporting.

If the test is 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.
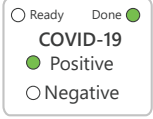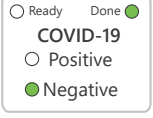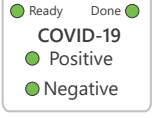
However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result with all other 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.

Section C - Test Unit Display Result

When the test is complete, the results are clearly displayed on the Test Unit.

Display	Interpretation of Results and Follow-up Actions
○ Ready Done ● **COVID-19** ● Positive ○ Negative	COVID-19 Positive SARS-CoV-2 Viral RNA detected.
○ Ready Done ● **COVID-19** ○ Positive ● Negative	COVID-19 Negative SARS-CoV-2 Viral RNA not detected.
● Ready Done ● **COVID-19** ● Positive ● Negative All LEDs flashing	Invalid Result Test should be repeated.