LumiraDx™ SARS-CoV-2 Ag Test

Quick Reference Instructions

For Emergency Use Authorization (EUA) Only. For *in vitro* Diagnostic Use. Rx Only.

SPEC-32757 R10 S-COM-ART-00406 R12 Date of Rev 2023-03

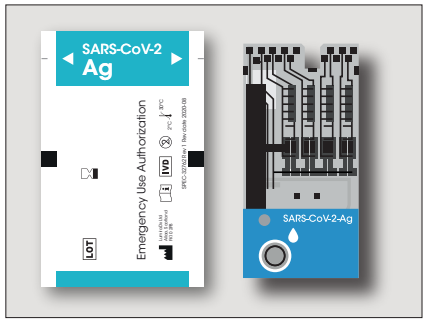
Warning and Precautions:

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. All kit components can be discarded as biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at **https://lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antigen-test**. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts however, should any reagent become exposed it should be treated as potentially infectious. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. If the patient has had symptoms longer than 12 days, consider testing at least three times over five days with at least 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.**

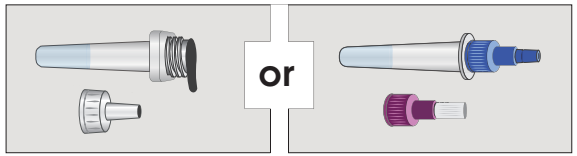
In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins 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 diagnostic tests 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.

LumiraDx SARS-CoV-2 Ag Test Kit Components

Test Strip

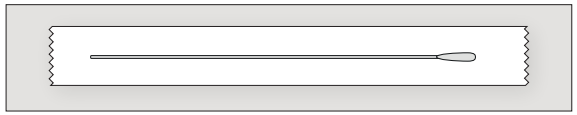


Extraction Vial and Dropper Lids



Nasal Collection Swabs

Available with product codes L016000609024, L016000609048



The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigens from SARS-CoV-2 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 Ag Test Strip Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

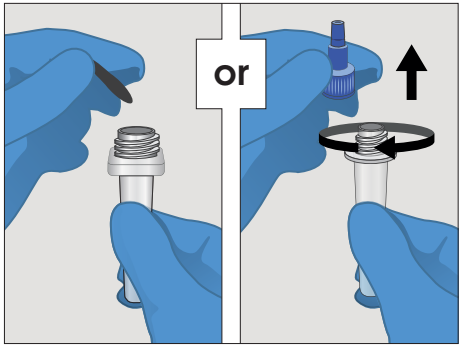
Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal or nasopharyngeal samples may be frozen at -80°C and used up to 5 days after freezing. Samples and extraction buffer must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. **Do not use any test components beyond its expiration date.** Refer to the LumiraDx SARS-CoV-2 Ag Test Strip Product Insert for Sample Collection, Warning and Precautions, and Limitations.

Preparing the sample

Collect a patient swab sample before following steps 1 – 4 of **Running the Test.**

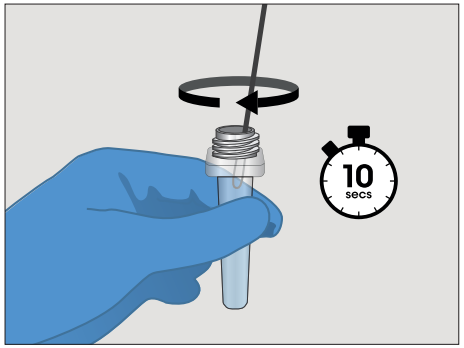
Sample Collection and Handling: Proper sample collection and handling of anterior nasal and nasopharyngeal swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures.

Storage and Stability: Store the Test Strips at room temperature – between 2˚C and 30˚C (36˚F and 86˚F). When stored correctly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. The dates printed on the Test foil pouch and the Test Strip carton will always be the same.



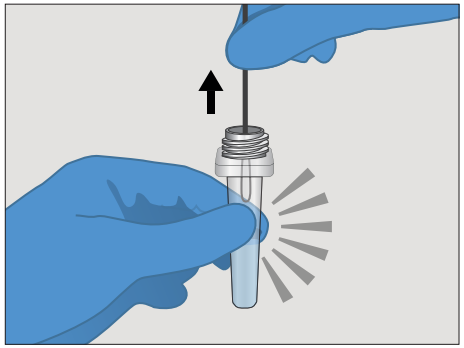
Remove seal

Remove the seal or blue screw cap from the top of the **Extraction Vial** containing the **Extraction Buffer.**



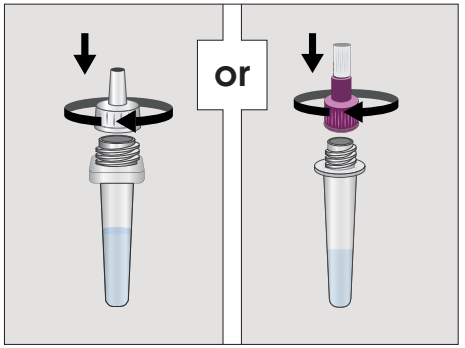
Soak Swab

Place and soak the **Patient Swab** in the **Extraction Buffer** for 10 seconds then stir well by rotating the swab against the side of the vial 5 times.



Squeeze Swab

Remove the **Patient Swab** while squeezing the **Extraction Vial** to remove the liquid from the swab. Discard the swab in biohazard waste.



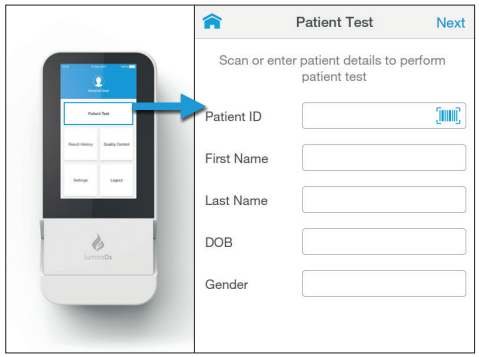
Attach Dropper Lid

Firmly attach the clear or purple **Dropper Lid** to the top of the **Extraction Vial. The extracted sample must be used (see Step 5 and 6 below) within 5h of preparation when stored at room temperature.**

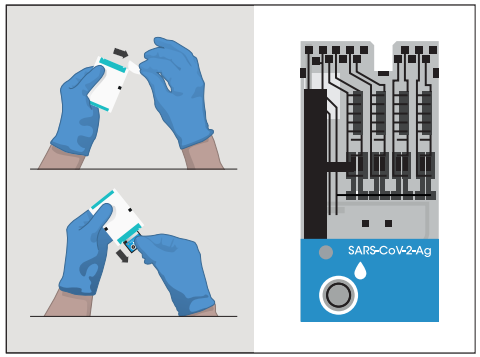
Cleaning and Disinfecting

Wipe the external surfaces of the LumiraDx Instrument with a soft, slightly damp cloth when it appears visibly dirty. Disinfect the Instrument after each patient test or if contamination is suspected and at least once per day when in use using LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at LumiraDx.com. Use the material until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **1 minute** and let air dry. **Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.**

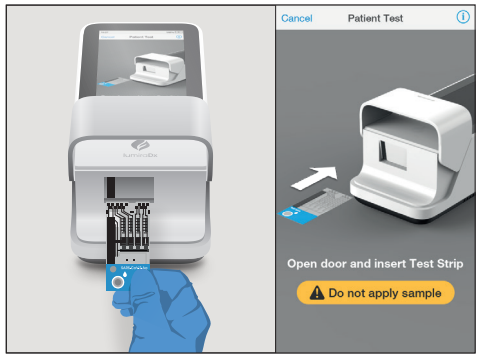
Running the Test



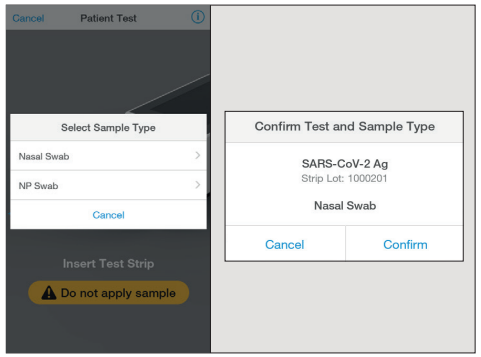
1. Select *Patient Test* from the **Instrument** *Home Screen* and enter patient details using the **Keyboard** or **Barcode Scanner**. See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner.**



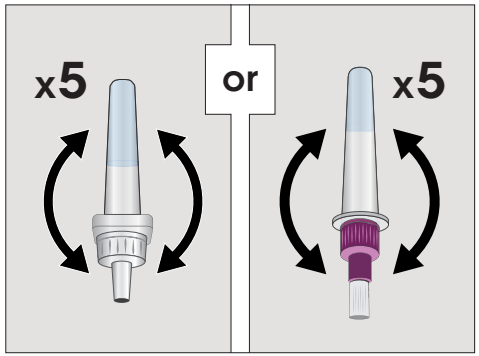
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



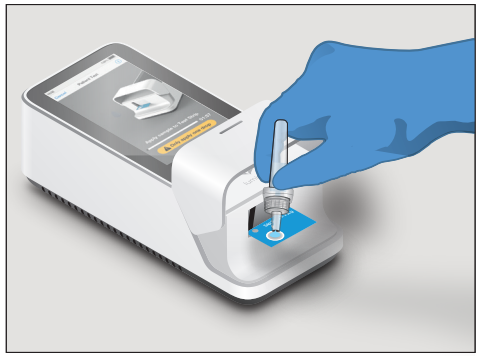
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration file if using a new **Test Strip Lot** for the first time. See section 2.8 of the **Platform User Manual.**



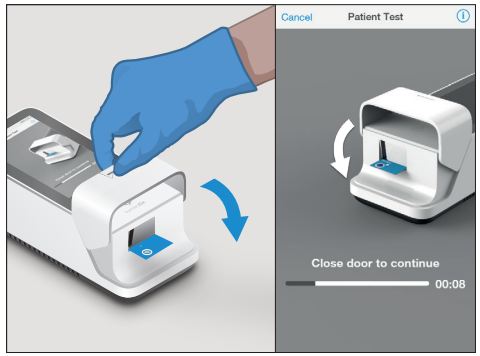
4. Select the appropriate sample type and confirm the test type.



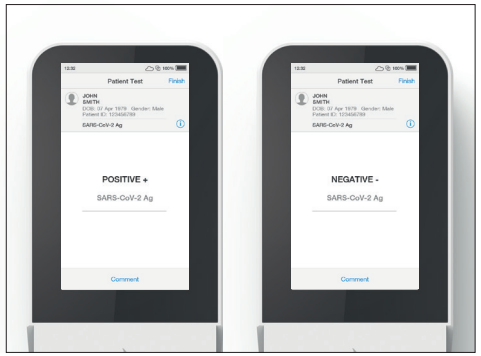
5. Gently invert the **Extraction Vial** five times just before applying the sample to the **Test Strip**.



6. Apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument.**



7. Close the door when prompted to continue the test.



8. Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag and the right-hand image shows a negative result for SARS-CoV-2 Ag. Tap *Finish* to complete testing or tap *Comment* to leave a comment or to reject the Test, then follow prompts to return to the *Home Screen*. All test results must be read using the LumiraDx Instrument.

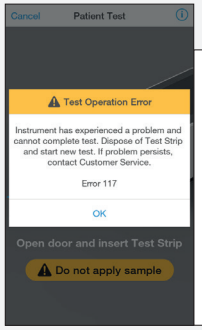
INTERPRETATION OF RESULTS

COVID-19 Positive (+)
Repeat testing does not need to be performed if patients have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the LumiraDx SARS-CoV-2 Ag test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.



Example of an error screen:
If the On Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.

Invalid Results:
If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ag Test Strips, you must use the LumiraDx SARS-CoV-2 Ag Quality Control Pack which are available separately. If the LumiraDx Antigen Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact LumiraDx Customer Services on telephone number **1-888-586-4721.**

Customer Service

If the **LumiraDx SARS-CoV-2 Ag Test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services **1-888-586-4721** or **customerservices.us@lumiradx.com**

Manufacturer Information

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Company Number: 09206123

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