LumiraDx™ SARS-CoV-2 Ag Test

Quick Reference Instructions

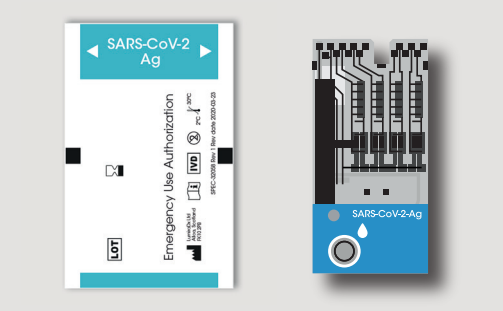
For Emergency Use Authorization Only (EUA). For *in vitro* Diagnostic Use. Rx Only.

SPEC-32757 R1 S-COM-ART-00406 R3 Date of Rev 2020/08

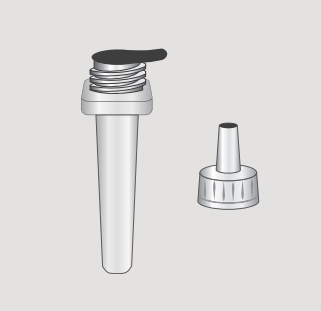
Warning and Precautions:
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at **https://lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antigen-test**. Exercise the normal precautionsrequired 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 and where any component is of animal origin, the source is certified as free from infectious or contagious material – however, should any reagent become exposed it should be treated as potentially infectious.

LumiraDx SARS-CoV-2 Ag Test Kit Components

Test Strip



Extraction Vial and Dropper Lid



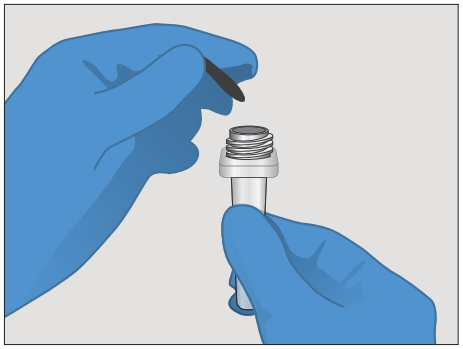
The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform. Intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within twelve days of the onset of symptoms.

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% - 90% relative humidity. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal specimens may be frozen at -80°C and used up to 5 days after freezing. Specimens 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 Specimen Collection, Warning and Precautions, and Limitations.

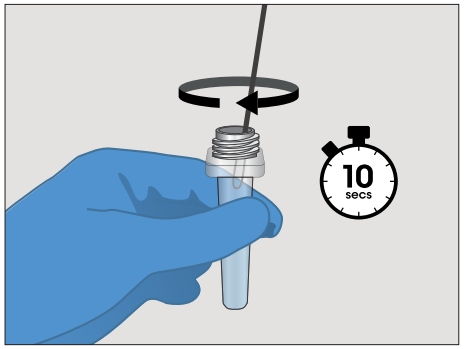
Preparing the sample

Collect a patient swab sample before following steps 1 – 4 of **Running the Test.**
Specimen Collection and Handling: Proper specimen collection and handling of nasal swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with specimen collection and handling procedures.



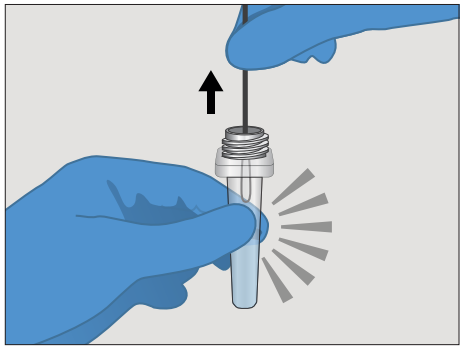
Remove seal

Remove the seal from the top of the **Extraction Vial** containing the **Extraction Buffer.**



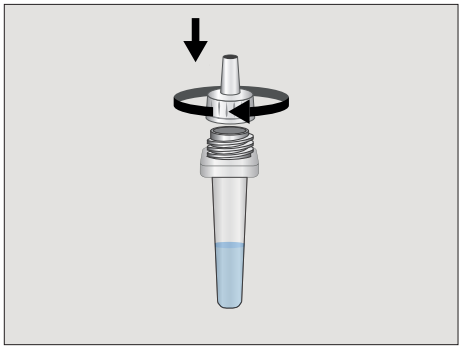
Soak Swab

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.



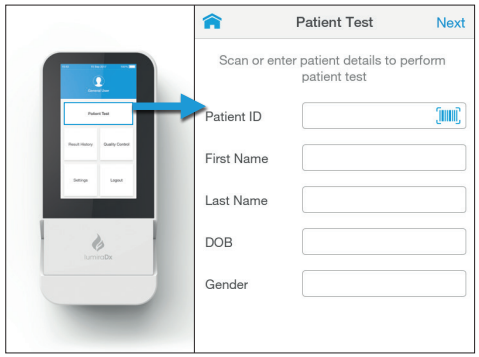
Attach Dropper Lid

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

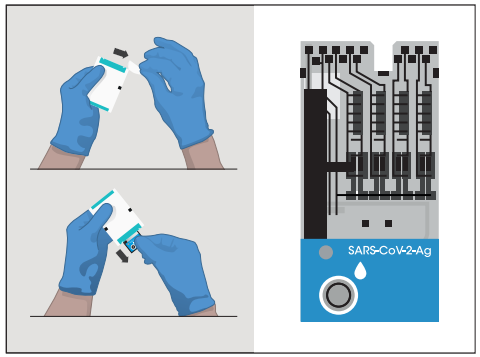
Cleaning and Disinfecting

Wipe the external surfaces of the LumiraDx Instrument with a soft, slightly damp cloth when it appears visibly dirty. Disinfect the Instrument between each patient test using LumiraDx approved wipes such as TECcare CONTROL wipes. Use the wipe until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **5 minutes** 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.**

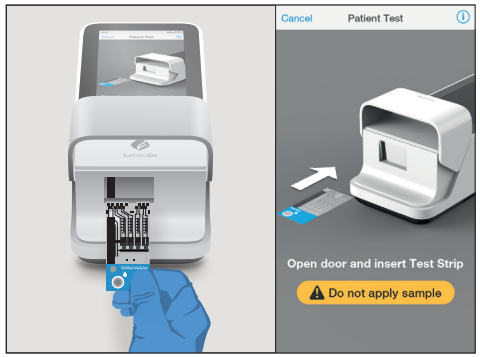
Running the Test



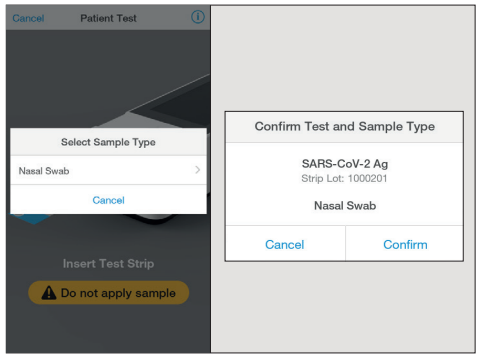
1. Select *Patient Test* from the **Instrument** *Home Screen* and enter patient details using the **Keyboard** or **Barcode Scanner**. See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner.**



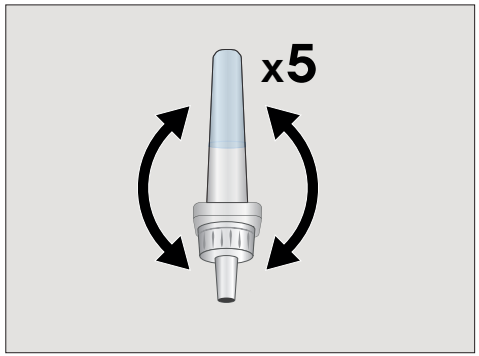
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



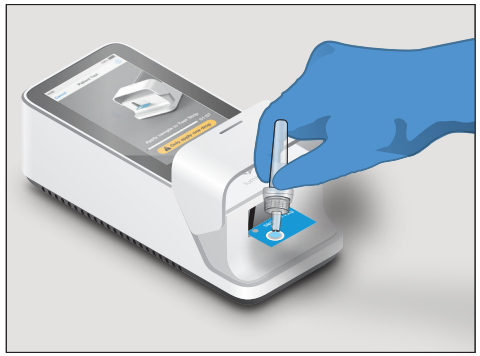
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration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



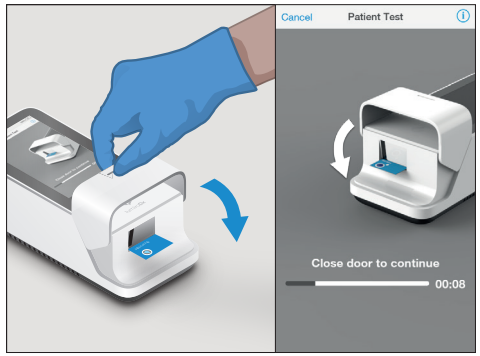
4. Select the appropriate sample type and confirm the test type.



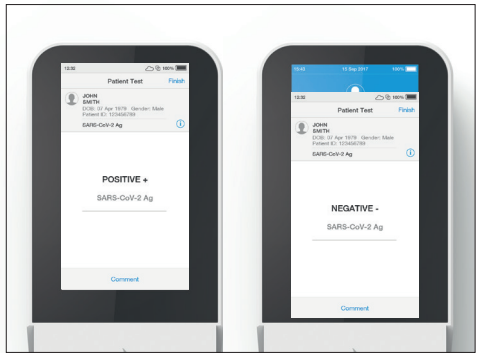
5. Gently invert the **Extraction Vial** five times just before applying the sample to the **Test Strip**.



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.

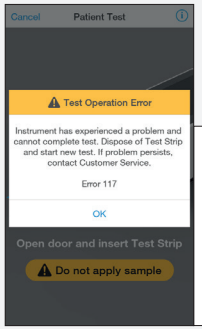


8. Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag and the right-hand image shows a negative result for SARS-CoV-2 Ag. Tap *Finish* to complete testing or tap *Comment* to leave a comment or to reject the Test, then follow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

INTERPRETATION OF RESULTS

Positive Test Results:
SARS-CoV-2 antigen present; does not rule out coinfection with other pathogens.

Negative Test Results:
Negative results are presumptive for patients with symptom onset beyond 12 days. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary for patient management.



⚠ 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.**

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test 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 test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this test 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 the virus that causes 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 authorization is terminated or revoked sooner.

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

LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK. Registration Number: 09206123

Copyright © 2020 LumiraDx UK and affiliates. All rights reserved. LumiraDx and Flame logo are protected trademarks of LumiraDx International LTD.
Full details of these and other registrations of LumiraDx can be found at lumiradx.com/IP. All other trademarks are the property of their respective owners.