

LumiraDx™ SARS-CoV-2 Ag Surveillance Test

Quick Reference Instructions

For surveillance purposes only - not for use in diagnostic procedures

S-COM-ART-01479 R1 SPEC-34435 R1 Rev date - 2021/07

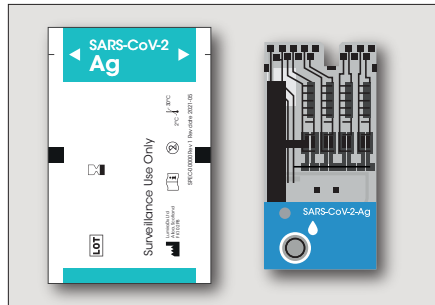
Warning and Precautions:

All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the SARS-CoV-2 Ag Surveillance Test product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at www.lumiradx.com/uk-en/what-we-do/diagnostics/compliance-documents. Exercise the normal precautions required for handling all reagents. Proper safety techniques should be followed at all times when working with specimens that may contain SARS-CoV-2. Specimen swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established 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.

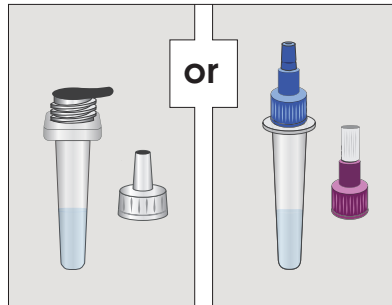
The LumiraDx SARS-CoV-2 Ag Surveillance Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in individual de-identified specimens from professionally supervised & self-collected nasal swab specimens or from 2-5 professionally collected de-identified nasal or nasopharyngeal swab specimens which are then pooled for testing. The Test aids in the surveillance of SARS-CoV-2 in populations by detecting SARS-CoV-2 antigen. Study the **LumiraDx Platform User Manual, LumiraDx Platform User Manual Addendum for Surveillance Use and LumiraDx SARS-CoV-2 Ag Surveillance Test 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% - 85% relative humidity. The extracted specimen must be used within 5 hours of preparation when stored at room temperature. Specimens and extraction buffer vials 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 Surveillance Test Strip Product Insert for Specimen Collection, Warnings and Precautions, and Limitations.

LumiraDx SARS-CoV-2 Ag Surveillance Test Kit Components

Test Strip



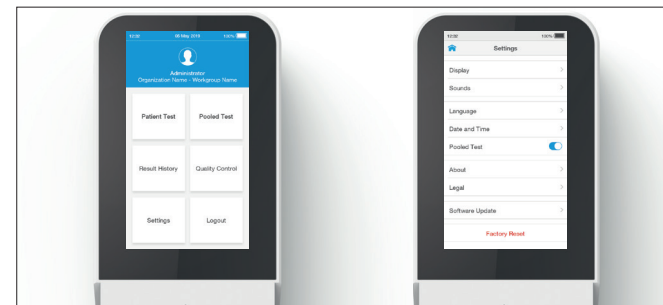
Extraction Vial and Dropper Lids



Instrument set up

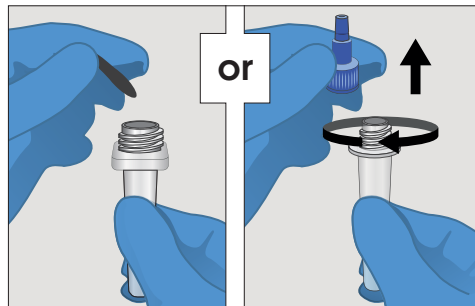
Check that 'Pooled Test' is available on Instrument home screen.

Enable 'Pooled Test' in the Instrument settings menu.



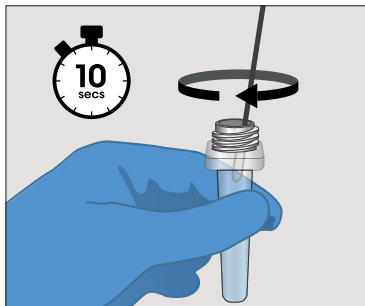
Preparing the Specimen

Collect up to 5 individual swab specimens (either all nasal swabs or all nasopharyngeal swabs) and place directly into the extraction buffer vial (see steps 1-4 below) or in dry tubes before following steps 1 - 4 of **Running the Test**. The swabs must be processed in the extraction vial within 1 hour of collection. **Collection and Handling:** Proper specimen collection and handling of 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 specimen collection and handling procedures.



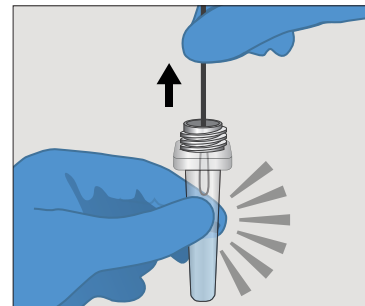
1. Remove seal

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



2. 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.



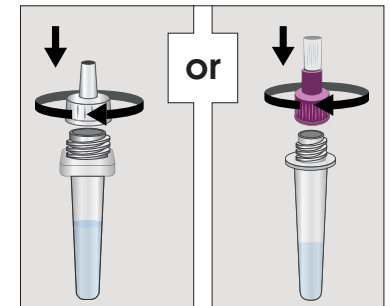
3. Squeeze Swab

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



4. Sequentially Repeat Steps 2-3

If testing only one specimen go directly to step 5. If testing pooled specimens repeat steps 2 and 3 sequentially with up to 4 more swabs in the same Extraction Buffer Vial.



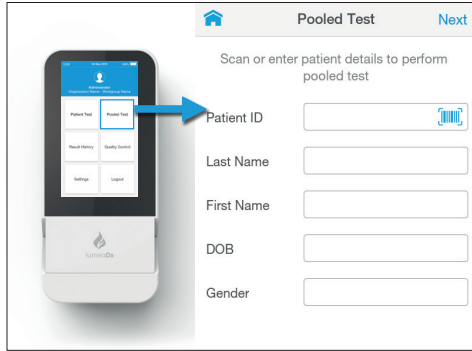
5. Attach Dropper Lid

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 5 hours of preparation when stored at room temperature.

Continued >

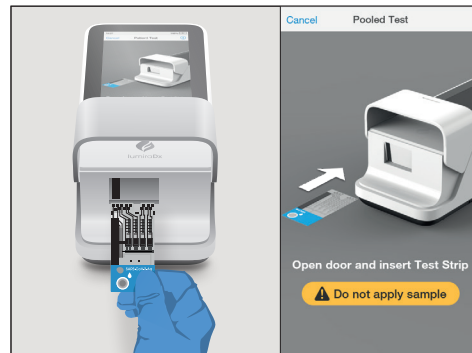
Continued >

Running a Surveillance Test

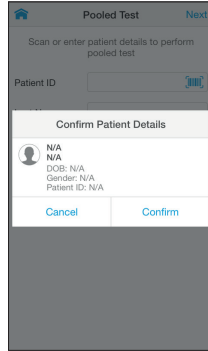


1a. If testing between 2-5 specimens, select *Pooled Test* from the Instrument Home Screen. The Instrument allows de-identified specimen information to be entered. Tap *Next* to continue.

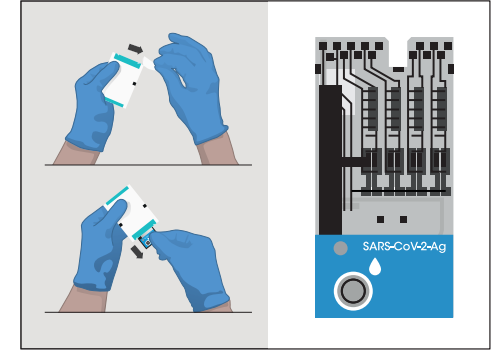
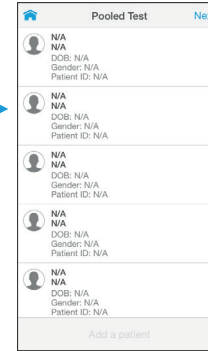
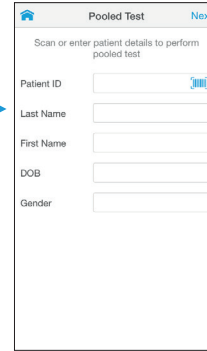
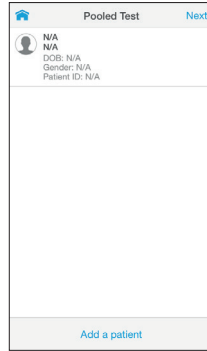
1b. If testing a single specimen, select *Patient Test* from the Instrument Home Screen. The Instrument allows de-identified specimen information to be entered. Tap *Next* to begin the test.



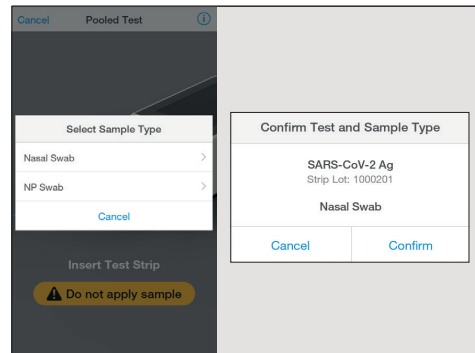
4. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument**. **Do not apply the sample until prompted.** Install the Lot Calibration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



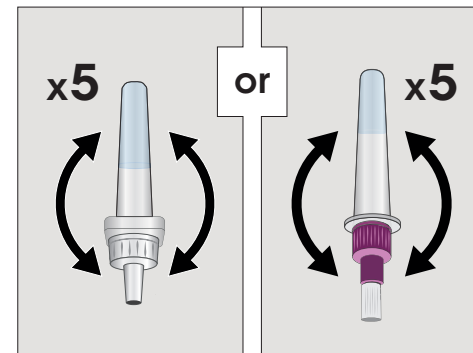
2. Confirm the first specimen's information. If needed, enter de-identified specimen information for the additional specimens and repeat for up to five specimens. Once all specimen IDs are added, tap *Next* to continue to testing.



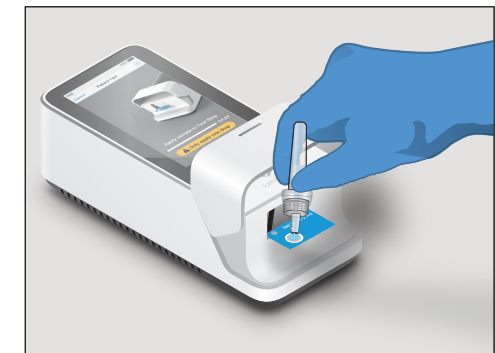
3. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



5. Select the appropriate sample type and confirm.



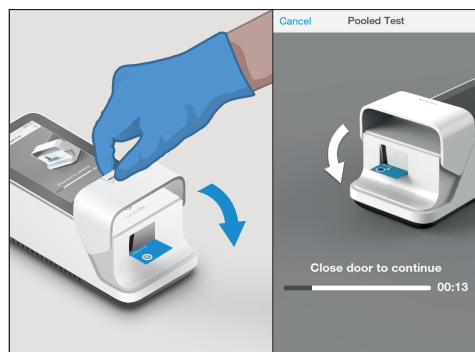
6. Gently invert the **Extraction Vial** 5 times just before applying the sample to the **Test Strip**.



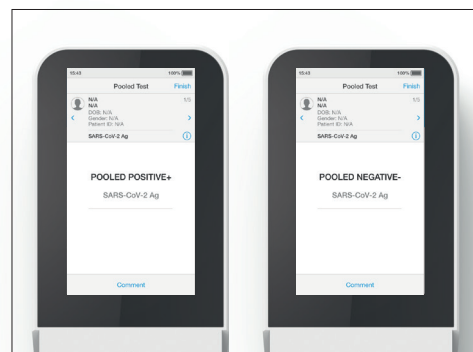
7. Squeeze the **Extraction Vial** to apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument**.

Continued >

Continued >

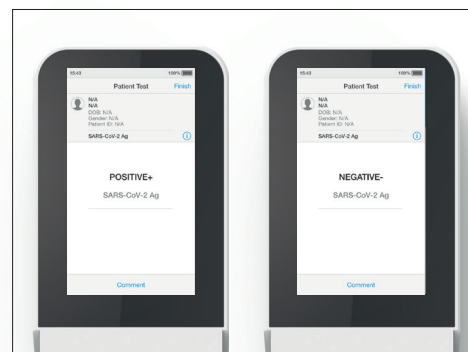


8. Close the door when prompted to continue the test.



9a. Pooled specimen results

Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a pooled positive result for SARS-CoV-2 Ag Surveillance Test and the right-hand image shows a pooled negative result for SARS-CoV-2 Ag Surveillance Test.



9b. Single specimen results

Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag Surveillance Test and the right-hand image shows a negative result for SARS-CoV-2 Ag Surveillance Test.

10.

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 Pooled Specimen test results

Positive

A positive pool means that one or more of the specimens in that pool may contain SARS-CoV-2 antigen. Further individual specimen testing may be completed if required for surveillance purposes.

Negative

Negative results from a pool mean all specimens were negative for SARS-CoV-2.

Interpretation of Individual Specimen test results

Positive

A positive result means that the specimen may contain SARS-CoV-2 antigen.

Negative

Negative results mean the specimen does not contain SARS-CoV-2 antigen.


Cleaning and disinfecting

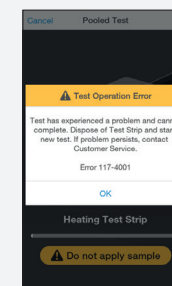
Cleaning and disinfection of the Instrument should follow and be performed according to established site protocols and schedules. To clean the Instrument wipe the external surfaces with a soft, slightly damp cloth when it appears visibly dirty. It is recommended to clean and disinfect the Instrument if contamination is suspected and at least once per day when in use with LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute. Excessive liquid may damage the Instrument. Prior to cleaning, it is necessary to manually squeeze any excess liquid from cleaning wipes or cloth. The wipe or cloth should be slightly damp, but not dripping wet prior to cleaning and/or disinfecting. **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.**

Customer Service

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

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. In the case of an error occurring, the extracted sample(s) in the Extraction Vial can be tested again, but the swabs cannot be used again.



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.

The LumiraDx SARS-CoV-2 Ag Surveillance Test has not been cleared, approved, or authorized by FDA under an emergency use authorization (EUA). This test should be used for surveillance purposes (i.e., to inform population or community-level decision-making) only. FDA does not regulate surveillance tests.

Manufacturer Information

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

Copyright © 2021 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.