LumiraDx™ SARS-CoV-2 Ag Ultra Pool test

Quick Reference Instructions

For *in vitro* Diagnostic Use.

Warning and Precautions:

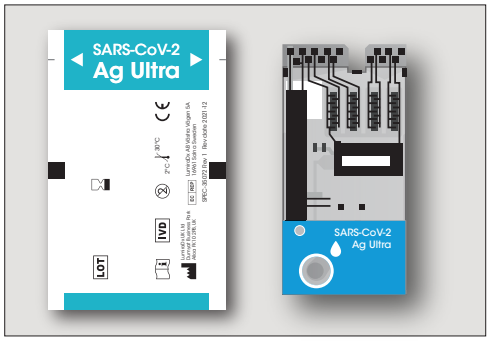
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the SARS-CoV-2 Ag Ultra product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at Lumiradx.com. Exercise the normal precautions required for handling alllaboratory 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.

The LumiraDx SARS-CoV-2 Ag Ultra Pool test is an automated 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 1 to 5 individual samples from professionally supervised & self-collected nasal swab samples or professionally collected nasal samples which are then pooled for testing. Samples should be collected from 1 to 5 individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals.

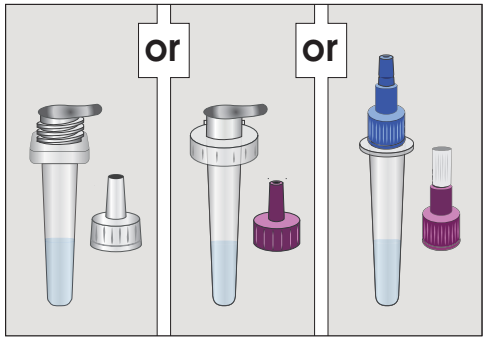
Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 Ag Ultra Pool Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert. Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F 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 swab samples may be frozen at -80°C and used up to 5 days after freezing. Samples 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 Ultra Pool Product Insert for Sample Collection, Warning and Precautions, and Limitations.

LumiraDx SARS-CoV-2 Ag Ultra Pool Test Kit Components

Test Strip



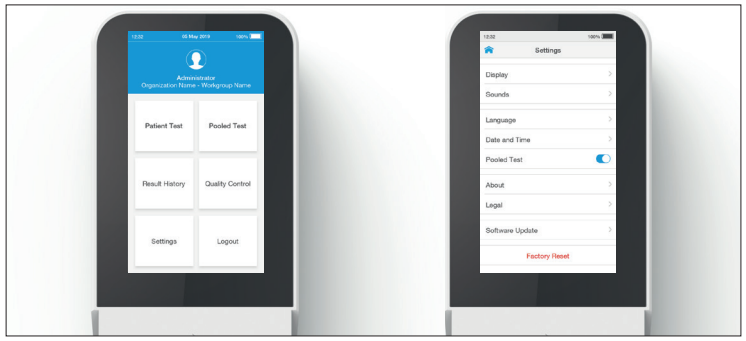
Extraction Vial and Dropper Lids



Instrument set up

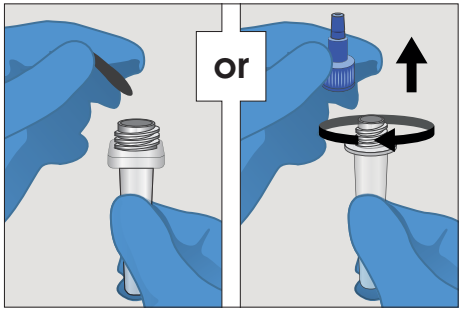
Check that 'Pooled Test' is available on Instrument home screen.

Enable 'Pooled Test' in the Instrument settings menu.



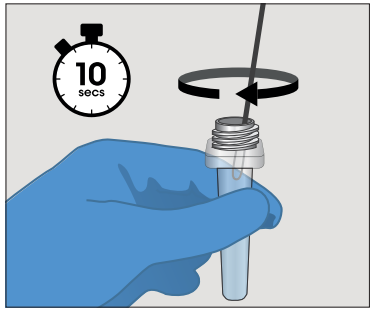
Preparing the sample

Collect 1 to 5 individual patient swab samples and place 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 sample 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 sample collection and handling procedures.



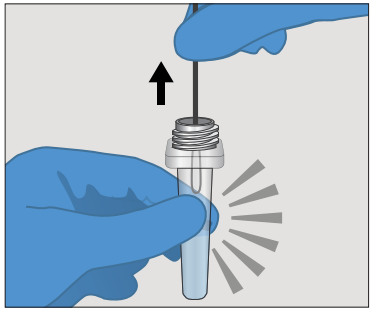
1. Remove seal

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.

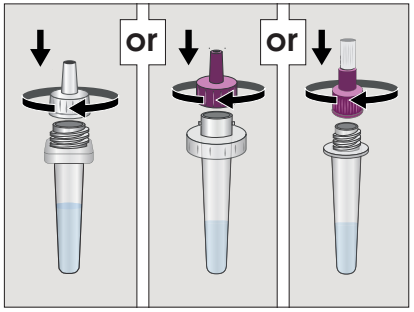


3. Squeeze Swab

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

4. Repeat steps 2-3

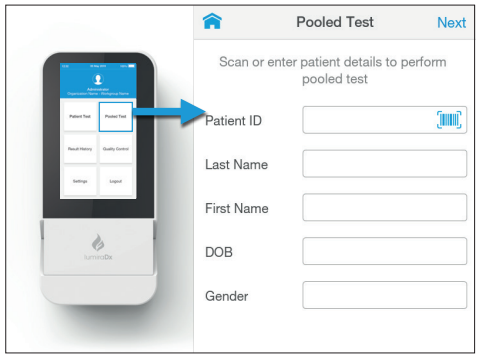
Repeat steps 2 and 3 sequentially for up to 4 more swabs into the same Extraction Buffer Vial.



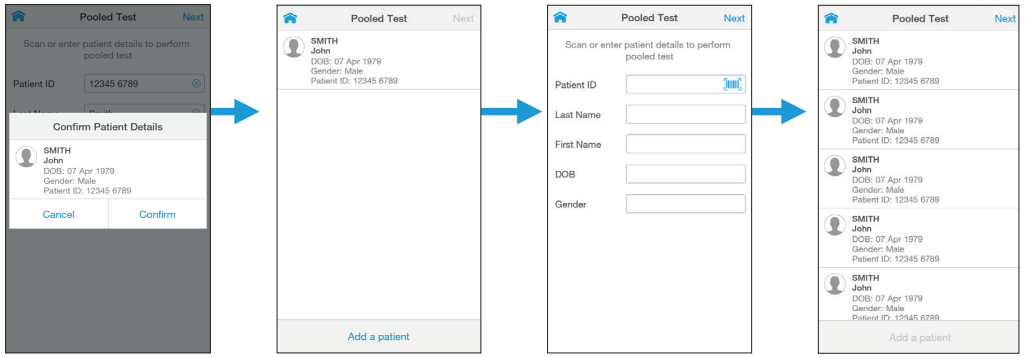
5. Attach Dropper Lid

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.**

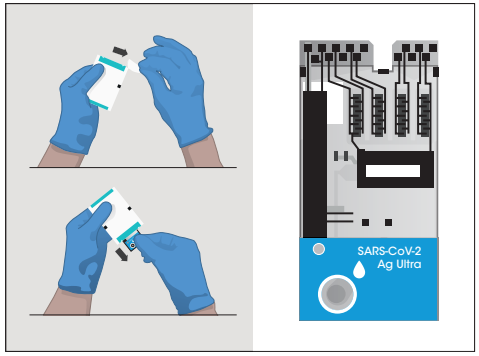
Running a Pool Test



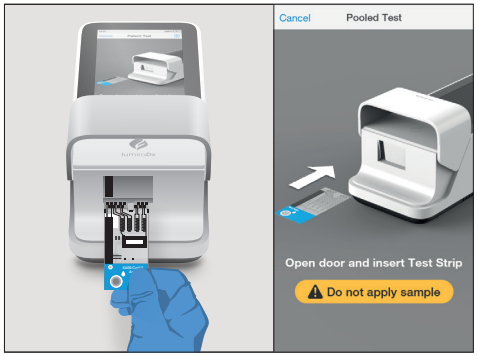
1. Select *Pooled Test* from the **Instrument** *Home Screen* and enter the first individual sample information in the Patient ID details using the **Keyboard** then press *Next*.



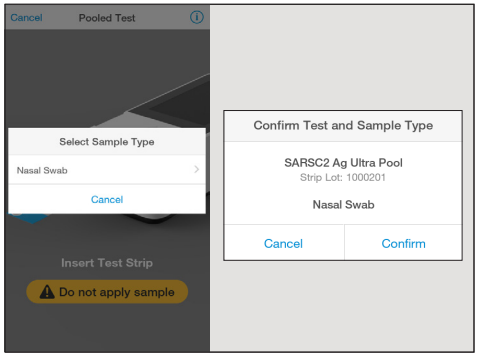
2. Confirm the first patient information. Tap *Add a patient* and enter the second individual sample information. Repeat with each individual sample of up to five individuals. Once all individual Patient IDs are added tap *Next* to continue to testing.



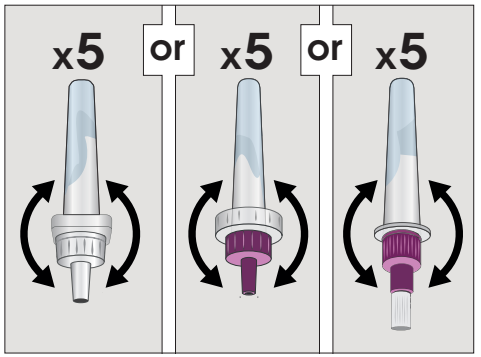
3. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



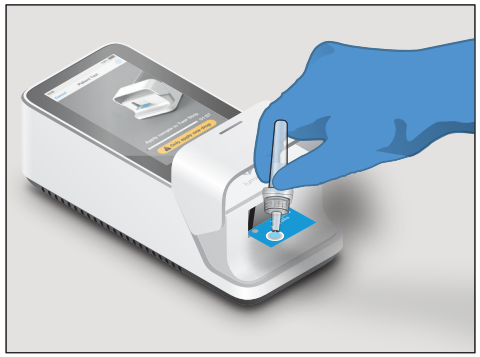
4. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration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



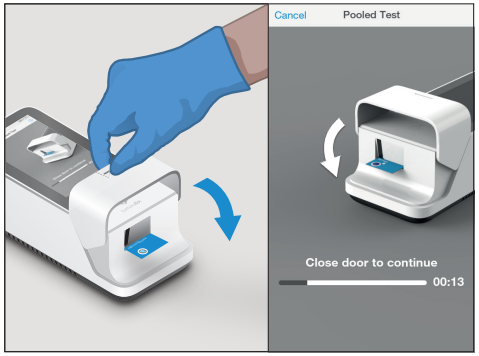
5. Select the appropriate sample type and confirm.



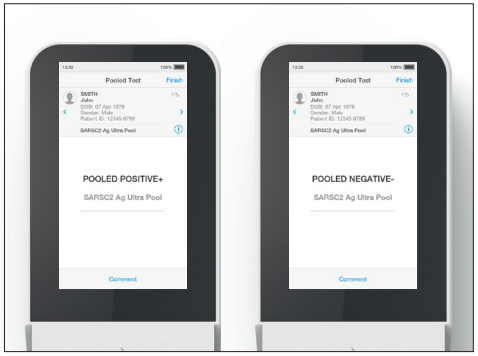
6. Gently invert the **Extraction Vial** 5 times just before applying the sample to the **Test Strip**.



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**.



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

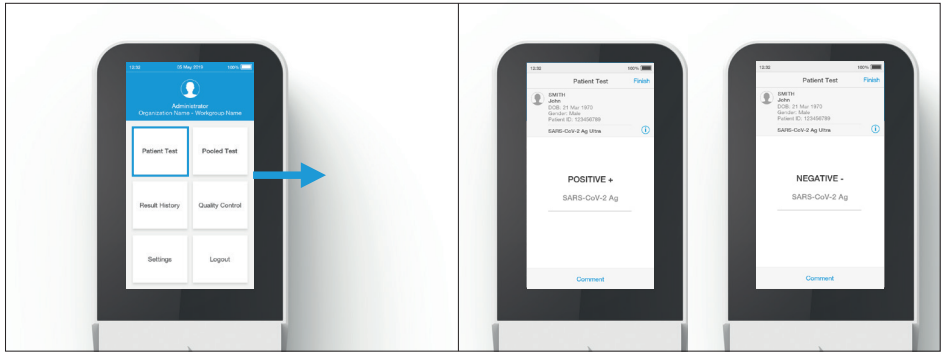


9. Results are displayed within 5 minutes of applying the sample. The left-hand image here shows an Ultra pooled positive result for SARS-CoV-2 Ag and the right-hand image shows a pooled negative result for SARS-CoV-2 Ag.

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.

Running an individual patient test

To run a test on an individual patient sample select '*Patient Test*' on the Instrument home screen before following steps 1-9 described in 'Running a Pool Test'.



Interpretation of results

Positive Test Results

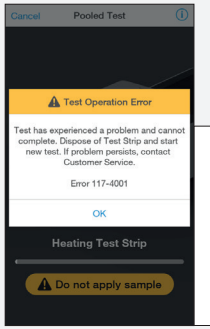
A positive pool means that one or more of the individuals tested in that pool may be positive for SARS-CoV-2 antigen. Individuals should be recalled for testing with individual sample collection or seek follow up care with their physician or healthcare provider for additional testing.

Negative Test Results

Negative results from pooled sample testing require no further testing of individuals within the pool and each constituent sample is reported as negative. If the individual's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for individual sample management, then the individual should be considered for individual testing.

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 within 5 hours of preparation when stored at room temperature, 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.

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 Ultra Pool Test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via **lumiradx.com** or **customerservices@lumiradx.com**

Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ag Ultra Pool 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.

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