lumiraDx™ SARS-CoV-2 Flu A/B

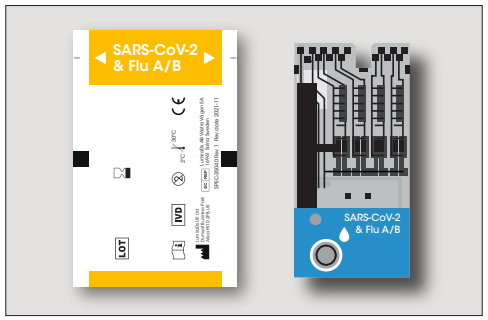
Quick Reference Instructions for processing of samples for SARS-CoV-2 & Flu A/B

For *in vitro* diagnostic use

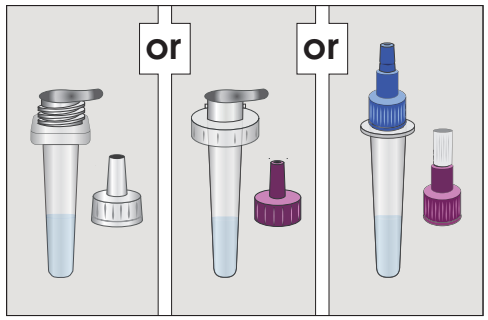
Warning and Precautions:
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at lumiradx.com/us-en/what-we-do/diagnostics/compliance-documents. 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, Flu A, or Flu B 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.

LumiraDx SARS-CoV-2 & Flu A/B Test Kit Components

Test Strip



Extraction Vial and Dropper Lids



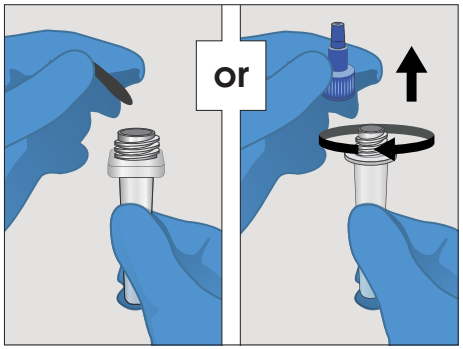
Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 & Flu A/B Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

Operate the LumiraDx Platform with the SARS-CoV-2 & Flu A/B test 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 when stored at room temperature. Extracted nasal 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 & Flu A/B Product Insert for Sample Collection, Warning and Precautions, and Limitations.

Preparing the sample

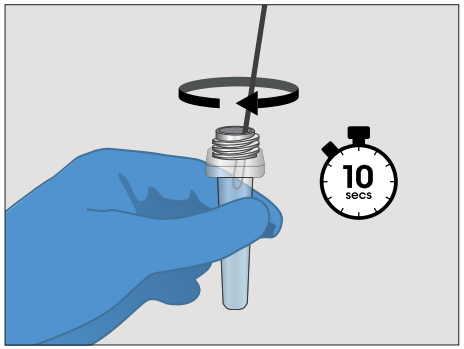
Testing is for use with nasal swab only. **Collection and Handling:** Proper sample collection and handling of swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures. .

Collect individual patient nasal swab samples before following steps 1 – 4 of Running the Test.



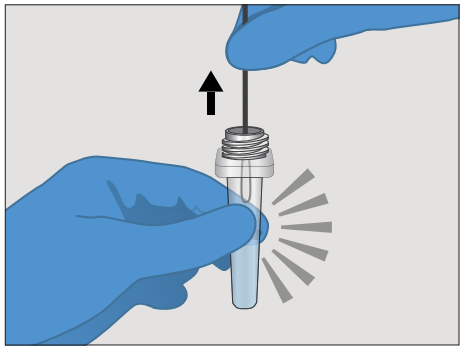
Remove seal

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



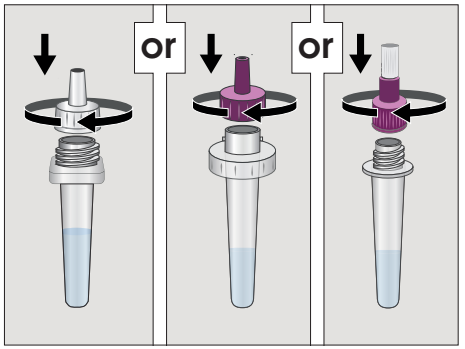
Soak Swab

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.



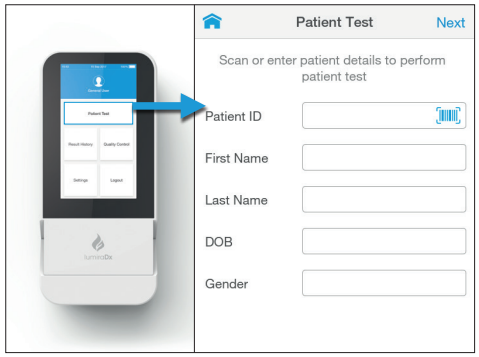
Attach Dropper Lid

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 5 hours when stored at room temperature.**

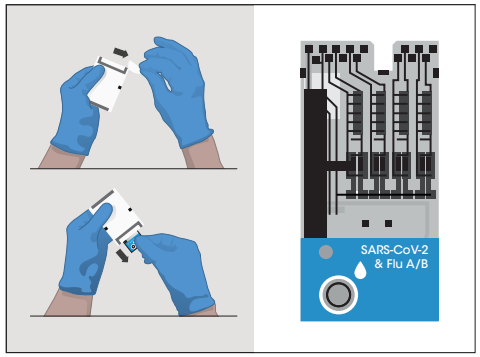
Cleaning and Disinfecting

It is recommended to disinfect the Instrument with LumiraDx approved materials if contamination is suspected and at least once per day when in use. 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. 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. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.

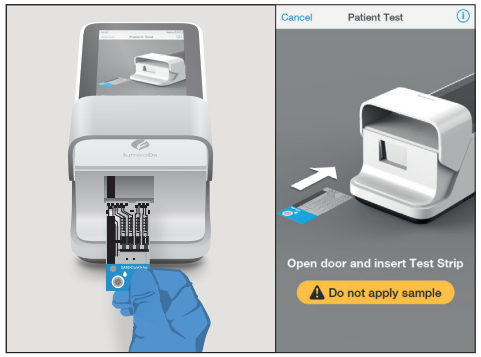
Running the Test



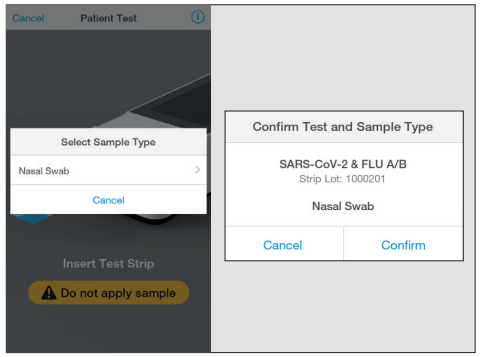
1. Select *Patient Test* from the **Instrument** *Home Screen* and enter the unique patient identifier information in the Patient ID details using the **Keyboard**.



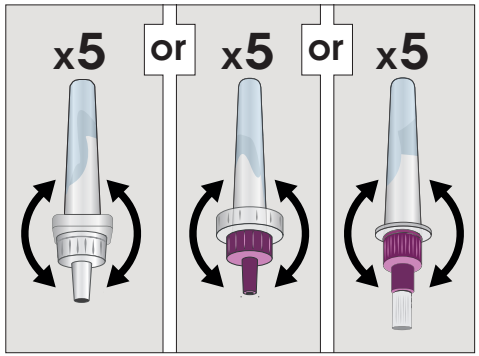
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not touch the Test Strip Sample Application Area. Do not bend the Test Strip or touch any part other than the blue portion.**



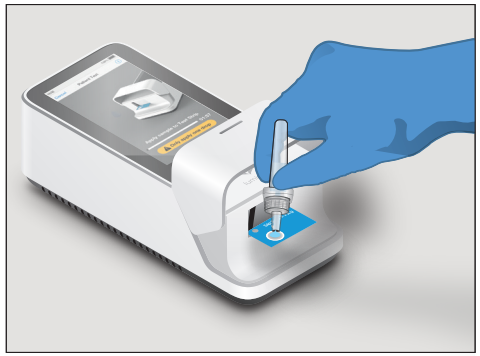
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration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



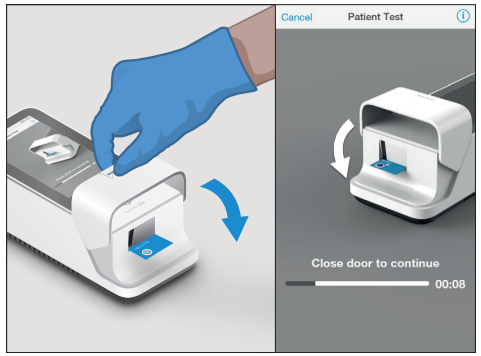
4. Confirm the test type.



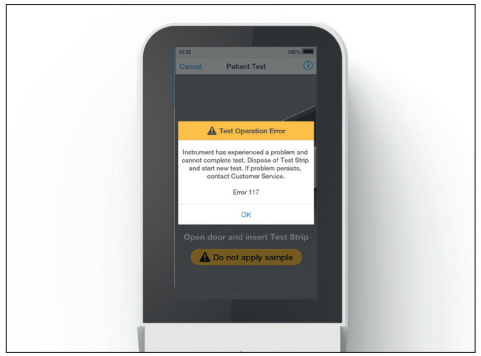
5. Gently invert the **Extraction Vial** five times just before applying the sample to the **Test Strip.**



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.



⚠ **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 LumiraDx Customer Services.

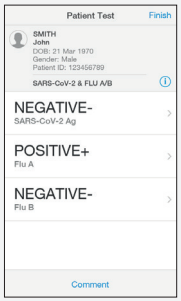
Interpretation of Results

Results are displayed within 12 minutes of applying the sample. 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.

Negative

Positive SARS-CoV-2

Positive Flu A



Positive Flu B

Invalid results

If an issue occurs, a message will be displayed on the Instrument touch screen and a result will not be displayed. 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 & Flu A/B test strips, you must use LumiraDx SARS-CoV-2 & Flu A/B Quality Controls which are available separately. If the 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.

Customer Services

If the **LumiraDx SARS-CoV-2 & Flu A/B test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via Lumiradx.com or customerservices@lumiradx.com

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