

## Quick Reference Instructions

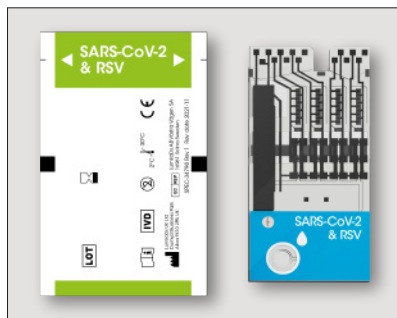
For *in vitro* diagnostic use

### Warning and Precautions:

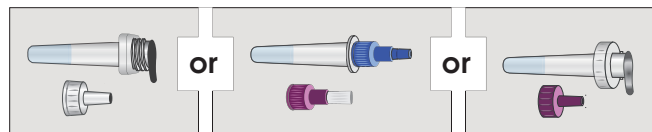
All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at [lumiradx.com](http://lumiradx.com). Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 & RSV 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 & RSV Test Kit Components

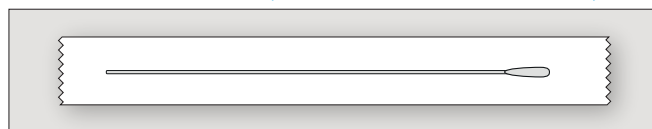
### Test Strip



### Extraction Vial and Dropper Lids



### Nasal Collection Swabs (only available with certain kits)



The LumiraDx SARS-CoV-2 & RSV test is an automated rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform for near-patient testing, intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2 nucleocapsid protein antigen and respiratory syncytial virus (RSV) viral antigens in direct nasal swab specimens from individuals suspected of a viral respiratory infection consistent with COVID-19 by a healthcare provider. The LumiraDx SARS-CoV-2 & RSV test is intended for use as an aid in the differential diagnosis of SARS-CoV-2 and RSV in humans.

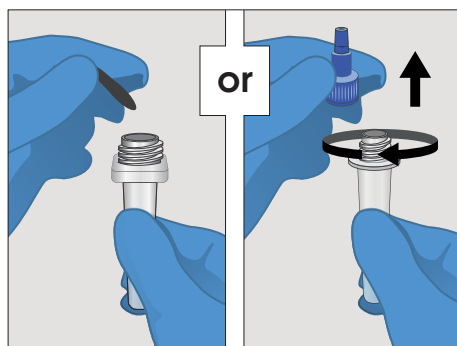
Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 & RSV Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

Operate the LumiraDx Platform with the SARS-CoV-2 & RSV 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 component beyond its expiration date.** Refer to the LumiraDx SARS-CoV-2 & RSV Product Insert for Sample Collection, Warnings and Precautions, and Limitations.

## Preparing the sample

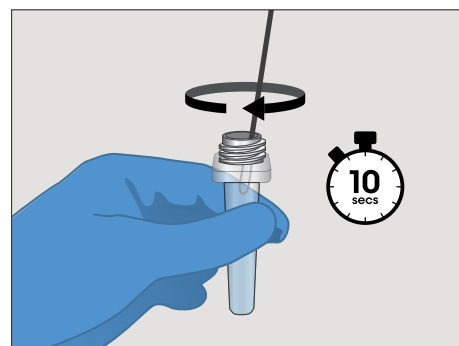
Collect a patient swab sample before following steps 1 - 4 of **Running the Test**. Testing is for use with nasal swab only.

**Sample 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.



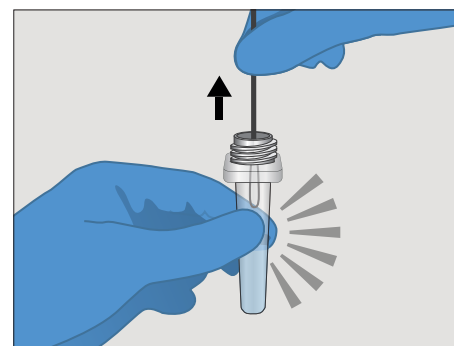
### Remove seal

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



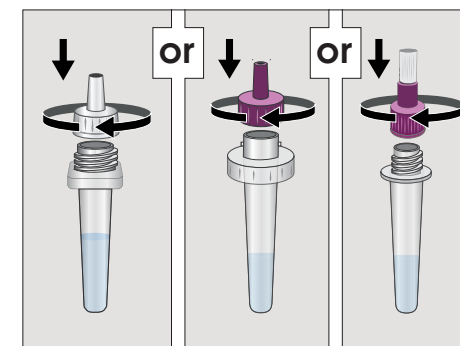
### Soak Swab

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.



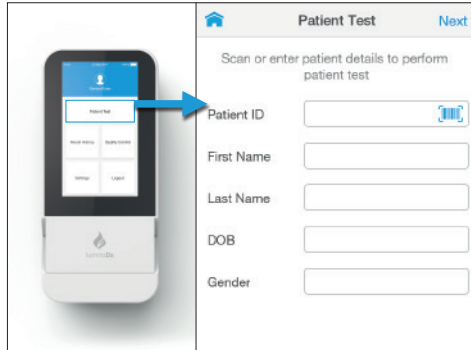
### Attach Dropper Lid

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 5 hours when stored at room temperature.

## Cleaning and Disinfecting

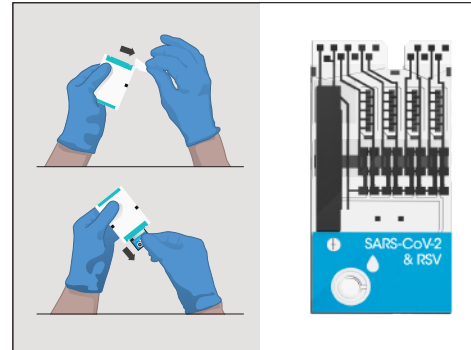
It is recommended to disinfect the Instrument with LumiraDx approved materials if contamination is suspected and at least once per day when in use. Details of LumiraDx approved disinfectant materials can be found at [LumiraDx.com](http://LumiraDx.com). Use the material until the surface of the Instrument 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

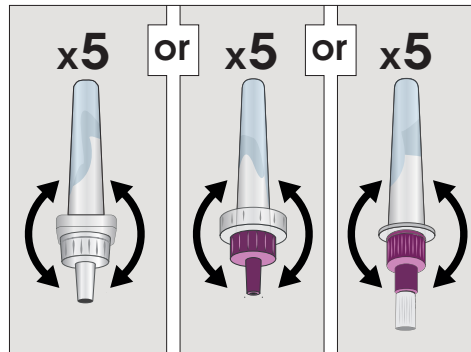


1. Select **Patient Test** from the **Instrument Home Screen** and enter the unique patient identifier information in the Patient ID details using the **Keyboard or Barcode Scanner**.

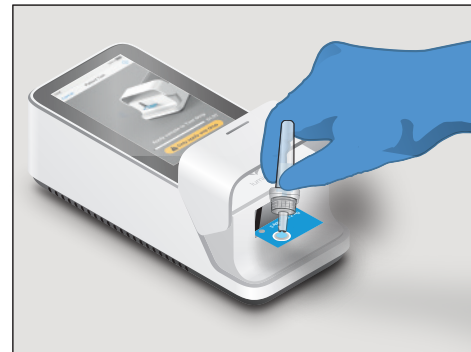
See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner**.



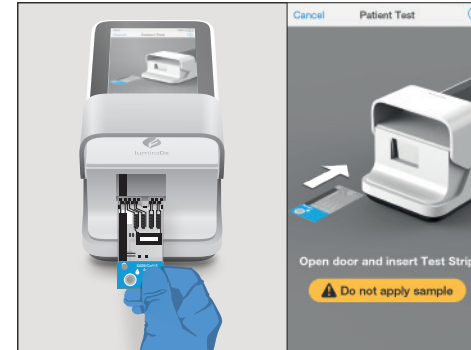
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not touch the Test Strip Sample Application Area. Do not bend the Test Strip or touch any part other than the blue portion.**



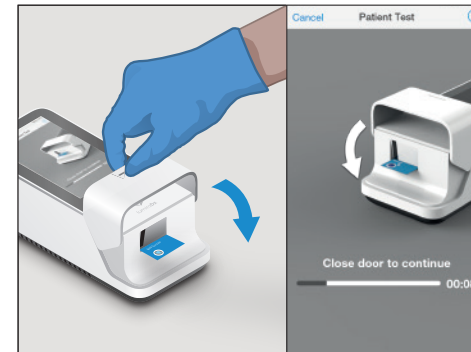
5. Gently invert the **Extraction Vial** five times before applying the sample to the **Test Strip**.



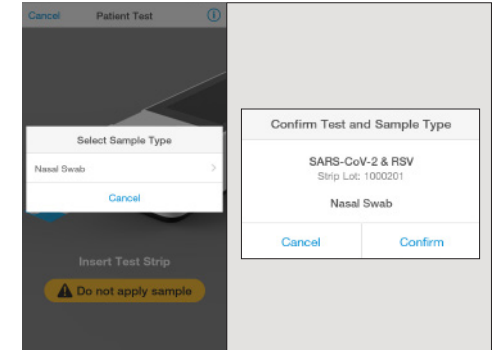
6. Apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument**.



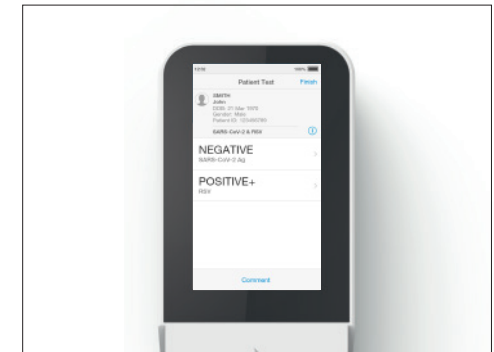
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the left and line up with the black line on the **Instrument**. **Do not apply the sample until prompted.** Install the Lot Calibration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



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



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



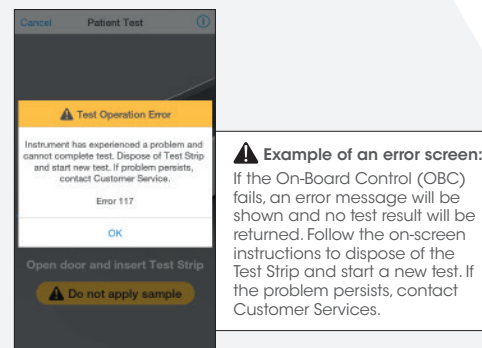
8. Results are displayed within 12 minutes of applying the sample. Tap **Finish** to complete testing or tap **Comment** to leave a comment or to reject the Test, then follow prompts to return to the **Home Screen**. All test results must be read using the LumiraDx Instrument.

## INTERPRETATION OF RESULTS

**Positive results** indicate the presence of viral antigens from infective virus, but clinical correlation with individual's history and other diagnostic information is necessary to confirm infection status.

**Negative results** do not rule out SARS-CoV-2 or RSV virus infections and should not be used as the sole basis for treatment or other patient management decisions.

**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.



**! 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.

## Quality Controls

To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 & RSV test strips, you must use LumiraDx SARS-CoV-2 & RSV Quality Control Pack which is 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 & RSV test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services via [lumiradx.com](http://lumiradx.com) or [customerservices@lumiradx.com](mailto:customerservices@lumiradx.com)



### Manufacturer Information

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