



# DxLab

## DxLab COVID-19 Test Instructions For Use (IFU)



For Use Under Emergency Use Authorization (EUA) only  
For in vitro diagnostic use  
For prescription use only

# Contents

A. Intended Use .....	3
B. Explanation of the Test .....	3
C. Principles of the Procedure .....	4
D. Materials .....	4
Materials provided .....	4
Materials required but not provided .....	4
E. Warnings and Precautions.....	5
F. Storage .....	6
G. DxHub Overview .....	6
H. DxHub Device Setup.....	7
Barcode Scanner Details .....	9
I. Quality Control .....	12
Internal Controls.....	12
External Controls .....	12
J. Test Procedure .....	13
Preparing DxHub for Testing.....	13
Section 1: Nasal Swab Collection .....	14
Section 2: Test Preparation.....	15
Section 3: Running the Test .....	16
Section 4: Test Results and Interpretation .....	19
Section 5: Viewing and Exporting Results.....	20
Section 6: Viewing QC Test Status .....	21
K. Limitations.....	22
L. Conditions of Authorization for the Laboratory .....	23
M. Performance Characteristics .....	24
Analytical Sensitivity (Limit of Detection).....	24
Analytical Reactivity (Inclusivity) .....	25
Analytical Specificity (Cross Reactivity) .....	26
Microbial Interference.....	27
Interfering Substances .....	28
Carry-Over/Cross Contamination .....	29
Sample Stability .....	29
Clinical Performance.....	30
N. Symbols.....	33
O. Contact Information .....	35

## A. Intended Use

The DxLab COVID-19 Test performed on the DxHub instrument is a rapid *in vitro* molecular diagnostic test utilizing isothermal nucleic acid amplification technology intended for the qualitative detection of RNA from SARS-CoV-2 in anterior nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider, or from individuals without symptoms or other epidemiological reasons to suspect Covid-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The DxLab COVID-19 Test is also 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The DxLab COVID-19 Test is intended for use by trained operators who are proficient in performing tests using the DxHub instrument.

The DxLab COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

## B. Explanation of the Test

The DxLab COVID-19 Test is a rapid Point-of-Care (POC) In-Vitro Diagnostic (IVD) test that detects target COVID-19 nucleic acids collected from anterior nasal samples. The DxLab COVID-19 Test consists of the DxLab COVID-19 Test Kit and requires a DxHub device (software version v2.0.5-145 or higher) to run.

For asymptomatic individuals (those without COVID-19 symptoms), the DxLab COVID-19 Test should be used as a serial test. Serial testing involves testing the same individual multiple times within a few days to increase the chances of identifying infections earlier. If an asymptomatic individual's first test results in a negative result, a second test should be completed after 24 hours but within 48 hours. If either the first or second test is positive, it is likely the individual has COVID-19 and should consult with a healthcare provider.

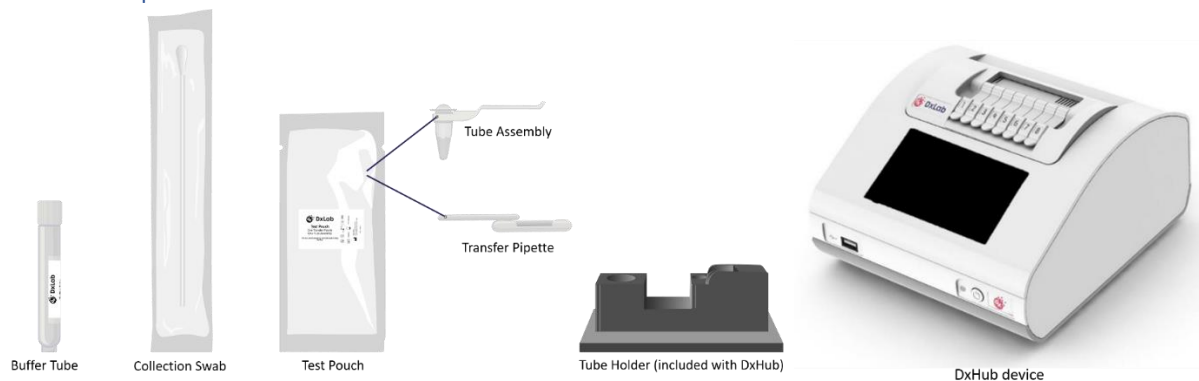
## C. Principles of the Procedure

DxLab COVID-19 Test is a real-time Reverse Transcription Loop-mediated Isothermal Amplification (RT-LAMP) test that runs on the DxHub device for the qualitative detection and diagnosis of SARS-CoV-2 from anterior nasal swab samples. The DxHub is a small tabletop device that has eight separate, individually addressable test bays with corresponding lids, allowing up to eight individual samples to be independently processed in a random-access manner for high-throughput testing at the Point of Care (POC).

The DxLab COVID-19 Test kit contains all the components required to carry out an assay for SARS-CoV-2 on the DxHub. The test kit contains a Collection Swab (for nasal specimen collection), a Buffer Tube (containing a buffer solution for sample elution and lysis), a Transfer Pipette (for transferring the eluted sample to a tube assembly), and a Tube Assembly (comprised of a reaction tube with lyophilized reagents). The reaction tube in the tube assembly contains reagents required for the multiplex detection of SARS-CoV-2 RNA and Beta-actin (ActB) RNA in a single reaction. ActB RNA serves as the internal control to check for the presence of human cellular material in the collected nasal specimen and to confirm proper assay execution, independent of the presence or absence of SARS-CoV-2 RNA in the sample. A fluorogenic DNA intercalating dye is included in the test reagents to produce a fluorescence signal upon successful reverse transcription and DNA amplification of a single region in the membrane protein (M) of the SARS-CoV-2 RNA or ActB RNA (or both). This control signal serves as a measure to ensure that the integrity of the reagents in the assay is not compromised. The presence of the SARS-CoV-2 RNA is specifically detected by using specific primers that are designed to produce fluorescence (at a different wavelength compared to the DNA intercalating dye) only when the M gene amplification occurs.

## D. Materials

### Materials provided



### Materials required but not provided

- Disposable gloves
- Biohazardous waste disposal bin
- External control swabs
- Barcode scanner

## E. Warnings and Precautions

- For in vitro diagnostic use
- For use under Emergency Use Authorization (EUA) only
- For prescription use only
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product 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 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 declaration is terminated or authorization is revoked sooner.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Follow universal precautions when handling patient samples. All patient samples should be treated as if potentially infectious. Follow standard BSL-2 guidelines when working with patient samples. Put on the appropriate personal protective equipment.
- If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.
- Control swabs, patient samples and tube assemblies should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Dispose of kit reagents and patient samples according to all local, state, and federal regulations.
- Do not use swabs or buffer other than those provided with the DxLab COVID-19 Test Kit.
- Leave test kit components in their pouch until just before use.
- Do not mix components from different lots.
- Do not use any damaged kit contents.
- Do not use scissors or sharp objects to open pouches.
- Do not use a test kit that has leaked.
- Do not use kit components after their expiration date.
- All test kit components are single-use items. Do not use with multiple specimens.
- To help obtain accurate results, follow all instructions, and regard all precautions in this IFU.
- Inadequate or inappropriate sample collection, handling, processing, and/or storage can yield inaccurate results.
- Wear clean gloves and change gloves between the handling of each specimen.
- Use only the fixed volume transfer pipette provided in the kit to transfer the patient sample from the Buffer tube into the tube assembly.
- Do not reuse transfer pipettes.
- Do not use a tube assembly that has been dropped.
- Do not shake the tube assembly.
- Do not use a tube assembly with a damaged reaction tube or barcode label.
- Do not use visually bloody or overly viscous samples.
- Once tube assembly is added and the test bay lid is closed, the test has started. Do not move the DxHub, open the lid, or unplug the DxHub until the DxHub indicates the test has completed.
- Do not attempt to open a used tube assembly.
- Do not touch the heads of the Control Swabs. Cross contamination may occur due to the high sensitivity of the test.

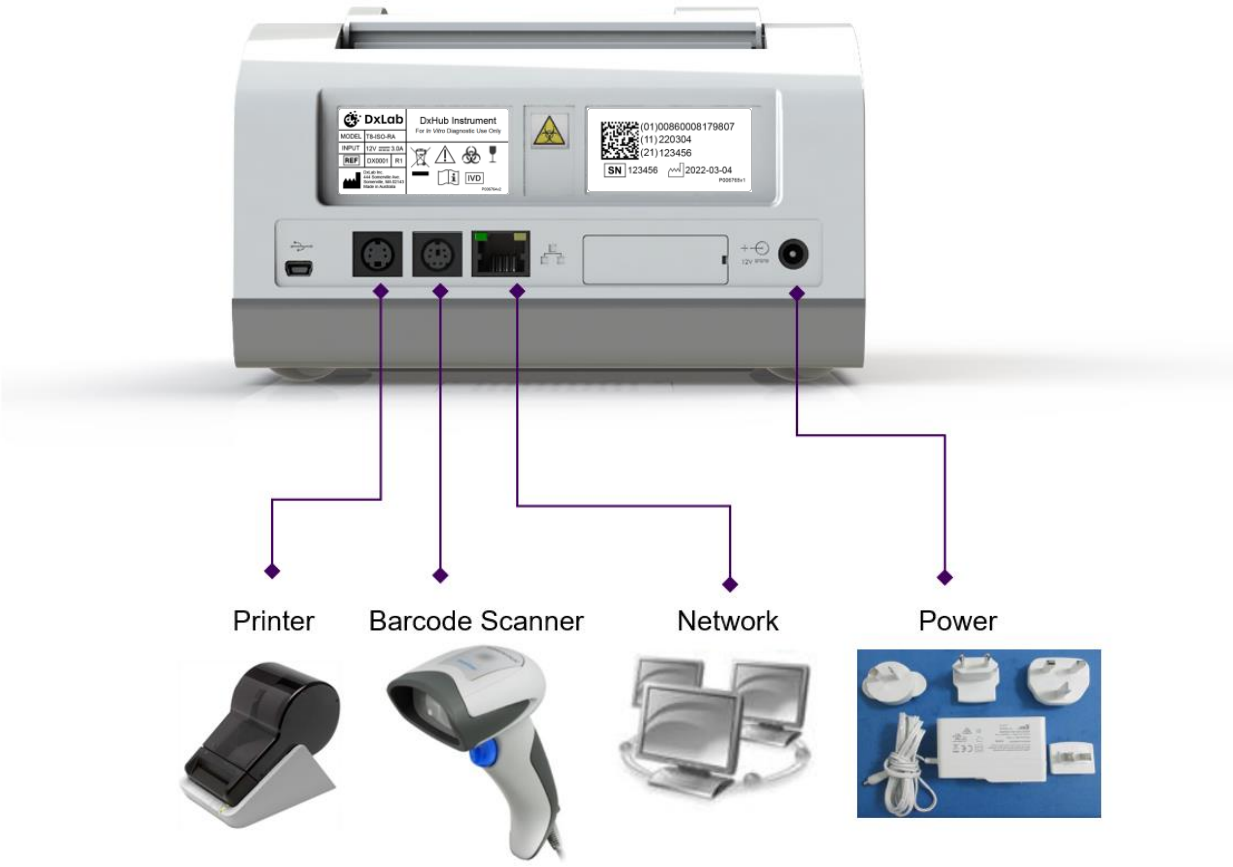
- Due to the high sensitivity of the DxLab COVID-19 Test, contamination of the work area with previous samples may cause false positive results. Clean the DxHub and surrounding surfaces regularly as described in the procedure in the DxHub user manual.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. Clean the DxHub as described in the procedure in the DxHub User Manual.
- For data transmission to the Laboratory Information System (LIS) server, only operate the DxHub instrument on wired network interfaces on trusted networks that have a properly configured firewall in place. Follow the procedures in the DxHub User Manual to configure LIS communications.
- Do not use the Sample ID or User Name fields to record the patient name or other identifiable information. The policy for entry of this data into the DxHub instrument should be decided by considering privacy requirements and regulations in your location.

## F. Storage

Store DxLab COVID-19 Test kit at room temperature (15°-30°C/59°-86°F) in a dry location. Keep the test kit components in their original packaging prior to use and avoid prolonged exposure to light. Store DxHub device at 2°-45°C/36°-113°F.

## G. DxHub Overview





## H. DxHub Device Setup



Unpack the DxHub and set up on a stable, level bench, in a clean environment.



Configure the power supply for your region. Connect the 12V power supply to the DxHub's rear port.

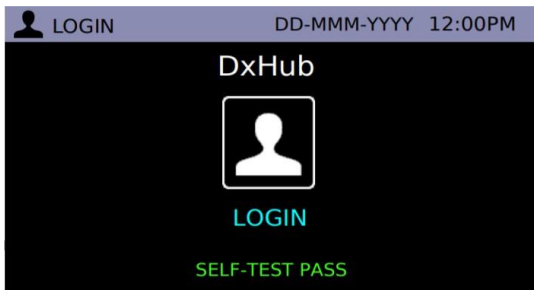


Press the power button for one second to power up and start the instrument. When desired, press and hold the power button for 3 seconds to shut down. It is recommended that the DxHub is powered down when not in use.



The loading screen will be displayed and the instrument will perform a self test.

If an error is found, refer to the DxHub user manual for further instruction.



Enter username and password.

**First-time login only:** The user will be required to login using “admin” as the default username AND password.



**First-time login only:** After first login using the default username and password, the user is prompted to change the password.

Enter a new admin password. Touch ✓ to confirm.

Touch ✗ to cancel.

Re-enter the new admin password. Touch ✓ to confirm.

Touch ✗ to cancel.



## Barcode Scanner Details

---



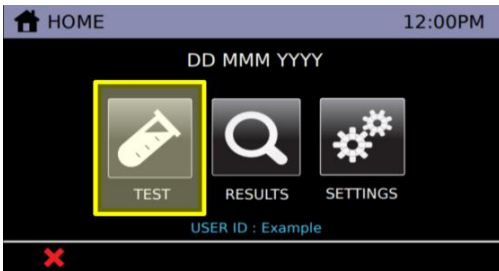
### Datalogic QuickScan Barcode Wand, QD2430

The DxHub **requires** input from a barcode scanner. The scanner is **NOT** provided with the DxLab COVID-19 test or the DxHub instrument and should be purchased separately. The barcode scanner will supply a character string that appears in the text box as if it was typed on the onscreen keyboard.

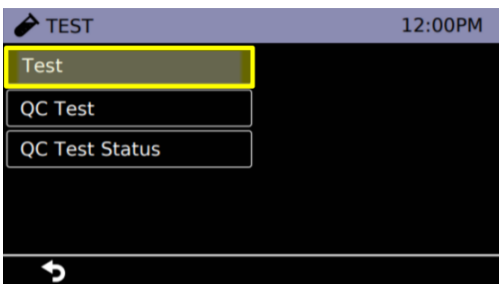
The recommended barcode scanner is Datalogic QuickScan QD2430, 2D Area Imager, KBW/USB/RS-232 Multi-Interface, 4.5-14V, Black ([QD2430-BK](#)) or Datalogic QuickScan QD2430, 2D Area Imager, KBW/USB/RS-232 Multi-Interface, 4.5-14V, White ([QD2430-WH](#)) from BarcodeFactory. The QD2430 scanner is connected to the instrument via a specific cable supplied with the DxHub. Once connected and set up, the scanner is typically operated in default mode and will read both standard barcodes and 2D,QR-type barcodes.



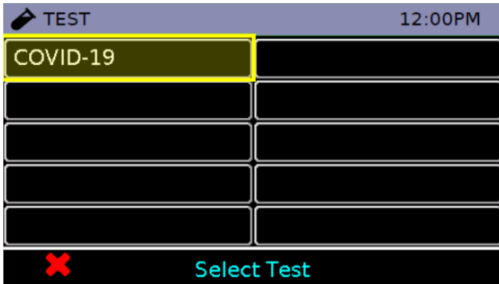
Plug the cable provided with the DxHub (**NOT** the cable included with the barcode scanner) into the bottom of the barcode scanner handle. Connect the barcode scanner cable to the DxHub's rear port.



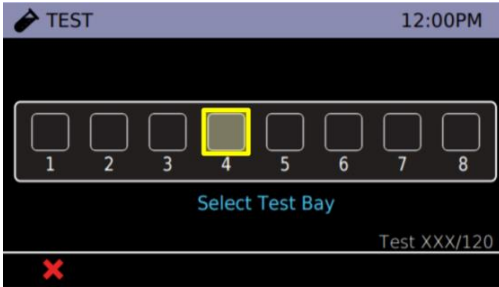
Select the "Test" icon.



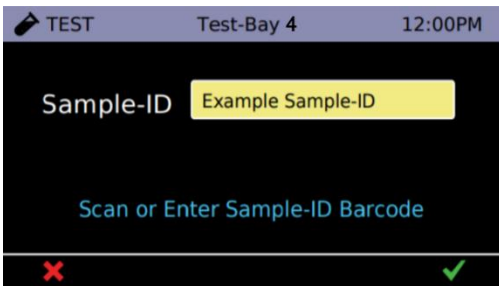
Select "Test".



Select "COVID-19" test. Please wait for the device to warm the heat block.



Select any unoccupied test bay (empty box). #4 is highlighted for demonstration purposes.



Once the Sample-ID screen has been reached, pick up the barcode scanner.



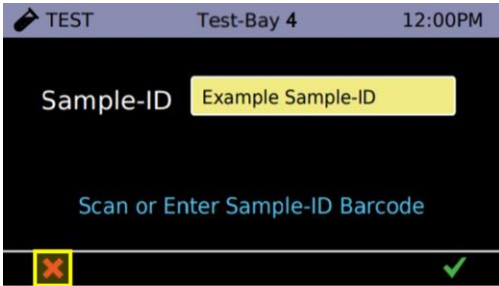
[Reset Default Settings](#)

If using Datalogic QuickScan Barcode Wand, QD2430, scan the barcode to the left first. If scanned successfully, the scanner will generate a tone on the scan and then generate a second tone moments after. If two tones are not heard, refer to the DxHub manual to troubleshoot.



[Select RS232-STD](#)

If using Datalogic QuickScan Barcode Wand, QD2430, scan the barcode to the left second. The barcode scanner is now ready for use. If scanned successfully, the scanner will generate a tone on the scan and then generate a second tone moments after. If two tones are not heard, refer to the DxHub manual to troubleshoot.



If not testing immediately, touch **X** three times to return to the logout screen.

If testing external quality control samples, touch **X** two times to return to the Home Menu, and proceed to [I. Quality Control](#).

If testing patient samples, touch **X** two times to return to the Home Menu, and proceed to [J. Test Procedure, Preparing DxHub for Testing, Step 2](#).

---

# I. Quality Control

## Internal Controls

Each DxLab COVID-19 Test includes a built-in internal control that utilizes a primer set that targets nucleic acids of the ActB gene. The internal control ensures that an adequate sample is added and the test is carried out properly through all of its stages, which include sample elution, lysis, reverse transcription, DNA amplification, and fluorescence-based detection. The internal control passes (i.e., the test result is valid) if a change in the fluorescence signal corresponding to the intercalating dye meets the threshold-based criteria. If the internal control fails to pass, the test result is invalid.

## External Controls

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable. DxLab suggests the use of commercially available positive and negative external run control swabs that have been validated with this test, Helix Elite™ Inactivated SARS-CoV-2 Whole Virus from Microbiologics® (Cat. No. HE0066NS) and Helix Elite™ Inactivated Negative Cellularity Control from Microbiologics® (Cat. No. HE0067NS).

To run external control swabs, unwrap the swab and run the swab on DxLab COVID-19 Test using the Quality Control workflow in the DxHub instrument.

DxLab recommends that external positive and negative controls be run:

- Once after each new device setup
- Once for each new lot or shipment of test kits
- Once for each new operator
- When problems are suspected or identified
- As required to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

If the External Run Control returns Invalid as the test result, repeat the control test. If repeat tests continue to return Invalid results, or if an incorrect control result is obtained (i.e., if a negative control test returns Positive or a positive control test returns Negative), do not perform patient tests or report patient results. Contact Technical Support ([support@dxlab.bio](mailto:support@dxlab.bio)) for a root cause investigation and suspend testing of patient specimens until a root cause has been identified and eliminated.

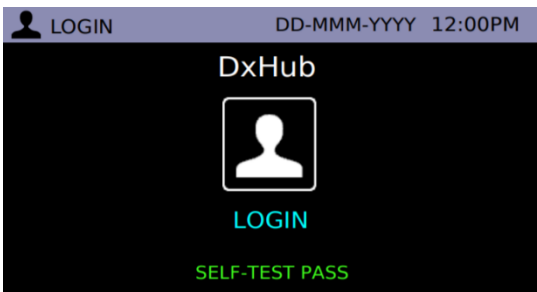
**Refer to DxLab COVID-19 Test Quality Control Instructions for detailed instructions on performing a Quality Control Test with the external run control swabs.**

**Refer to [J. Test Procedure, Section 5](#) and [Section 6](#) for instructions on viewing QC Test results and QC Test status.**

## J. Test Procedure

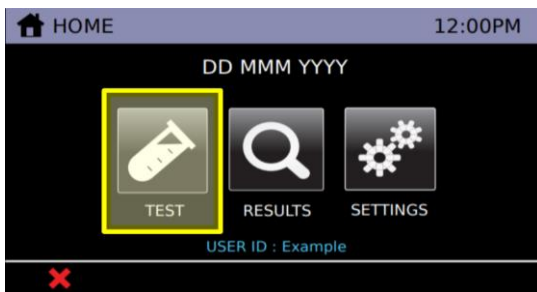
### Preparing DxHub for Testing

- Refer to [H. DxHub Device Setup](#) for instrument setup
- Refer to DxLab COVID-19 Test Quality Control Instructions for Quality Control Test Procedure
- Operate DxHub on a level surface, between 10°C to 30°C and 20% to 80% relative humidity.
- **Unless instructed, keep the test bay lids on the DxHub CLOSED.**
- **Every test should be performed with a new set of gloves.**
- **Gloves should be immediately discarded after disposing of the sample and tube assembly.**
- **Do NOT use a test kit that is wet or has leaked.**



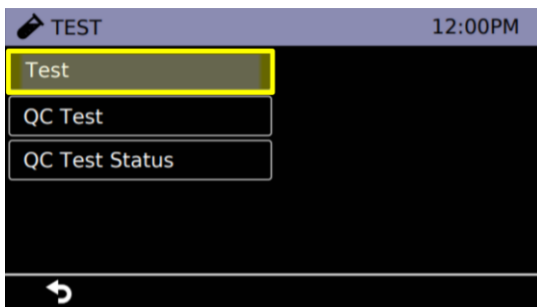
#### Step 1

- Connect 12V power supply.
- Press & hold power button.
- Login with username & password if requested.



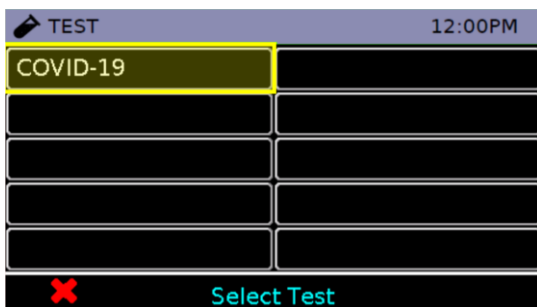
#### Step 2

- The Home Menu screen provides access to the Test, Results, and Settings functions.
- To start a test, select the “Test” icon.
- In general, touch **X** to cancel the current action/input or touch ↶ to return to the previous screen.



#### Step 3

- Select “Test”.



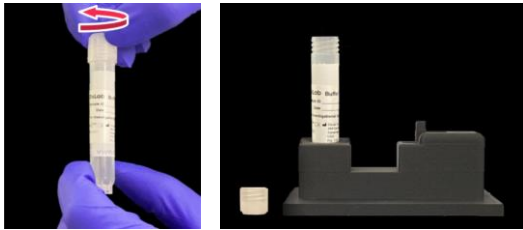
#### Step 4

- Select “COVID-19” test.
- Please wait for the device to reach 66°C.
- **Note:** Do **NOT** proceed until “Select Test Bay” is displayed on the screen.

## Section 1: Nasal Swab Collection

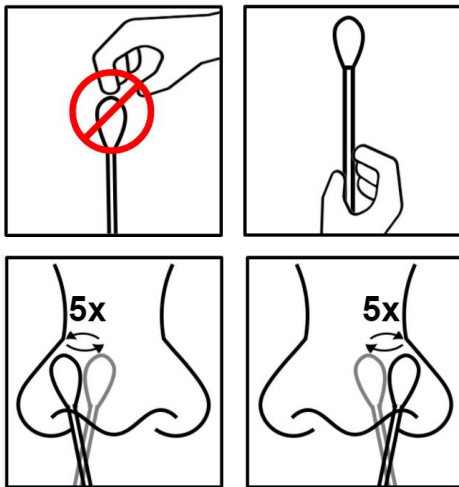
**Skip step 2 if swab sample has been pre-collected.**

**For best performance, swabs should be tested as soon as possible after collection. If immediate testing is not possible, the swab can be placed in its original packaging and kept at room temperature (15-30°C) for up to two (2) hours prior to testing. If greater than two (2) hour delay occurs, dispose of the sample. A new sample must be collected for testing.**



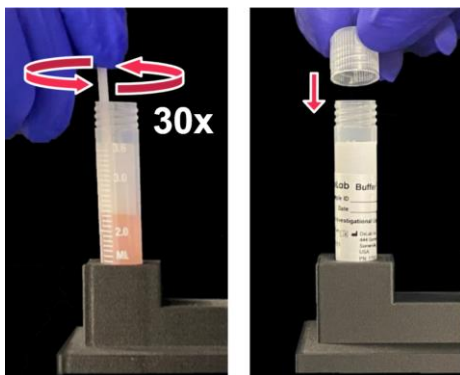
### Step 1

- Open the buffer tube. Do **NOT** dispose of the buffer tube cap.
- Place the buffer tube in the tube holder.



### Step 2

- Remove the collection swab from its pouch.
- **Note:** Do **NOT** touch the swab tip. Only hold the swab by its handle.
- Insert the swab tip fully into one nostril until resistance is met.
- Using moderate pressure, rub the swab against the inside wall of the nostril. Make 5 big circles for 10 seconds.
- Using the same swab, repeat the swabbing step for the other nostril.
- **After collection, do NOT let the swab tip touch anything.**

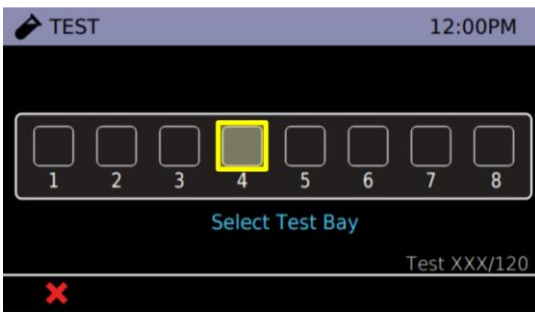


### Step 3

- Insert the swab tip into the buffer tube.
- Swirl the swab along the tube wall **30 times**. Keep the swab tip in contact with the bottom of tube.
- Dispose of the used swab in a biohazard bin.
- Screw on the buffer tube cap.
- **Note:** Colored liquid used for demonstration purposes only.

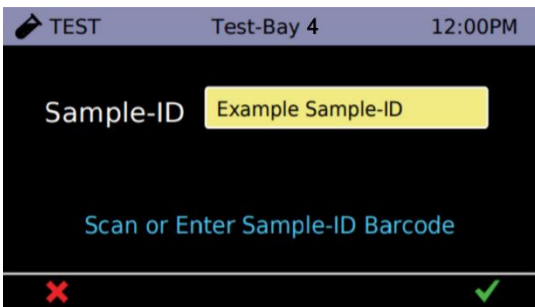
## Section 2: Test Preparation

**Proceed to testing the sample immediately after collection**




### Step 1

- The main test screen is shown on the DxHub touchscreen.
- Select any unoccupied test bay (empty box). #4 is highlighted for demonstration purposes.



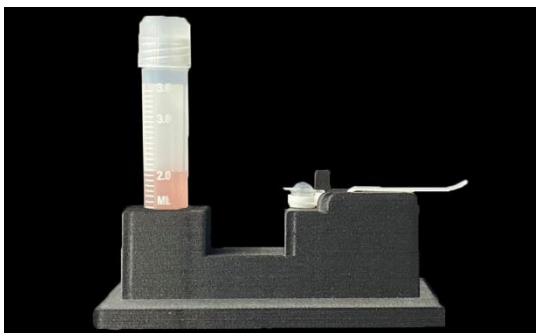
### Step 2

- Enter Sample ID by touching the yellow box next to “Sample ID” or scanning a barcode.
- Touch  to continue.
- **Note:** Please refer to [H. DxHub Device Setup, Barcode Scanner Details](#) for recommended scanner and setup.
- **Note:** Do **NOT** use the Sample ID field to record the patient name or other identifiable information.



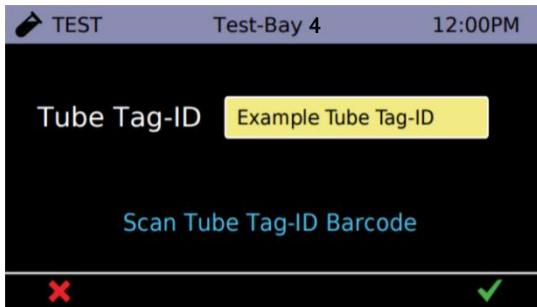
### Step 3

- Remove **ONLY** tube assembly from test pouch.
- **Note:** Do **NOT** remove transfer pipette from test pouch.
- **Note:** Do **NOT** touch the tube portion of the tube assembly.
- Proceed to the next step **IMMEDIATELY**.




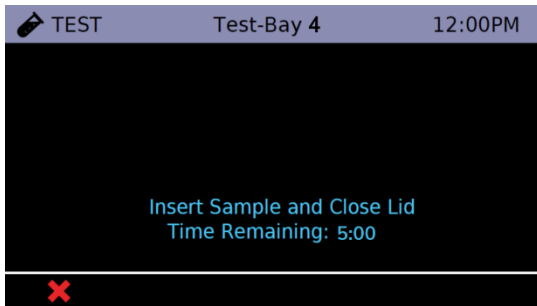
### Step 4

- Place the tube assembly in the tube holder.
- **Note:** Do **NOT** use a tube assembly that has been dropped.
- Proceed to the next step **IMMEDIATELY**.



#### Step 5

- Scan the Tube Tag ID barcode. The Tube Tag ID barcode is located on the tube assembly.
- Touch  to continue.
- **Note:** Please refer to [H. DxHub Device Setup, Barcode Scanner Details](#) for recommended scanner and setup.

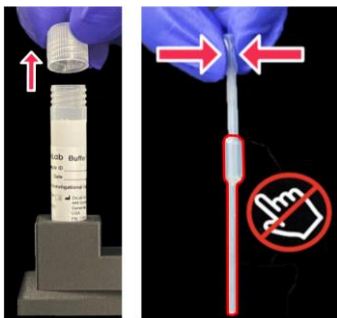


#### Step 6

- You have 5 minutes to complete up to Section 3, step 8.
- **Note:** If the timer expires and the DxHub times out, discard the buffer tube and the tube assembly. Return to Section 1.

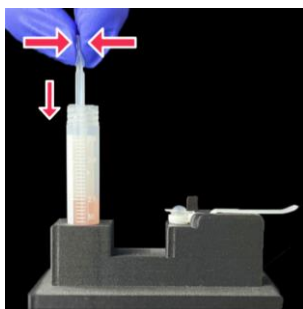
### Section 3: Running the Test

- **When handling the transfer pipette, touch ONLY the top bulb.**
- **If lower bulb or shaft of the transfer pipette is touched, dispose of all test materials (transfer pipette, buffer tube, and tube assembly) and restart the testing procedure with a new kit.**



#### Step 1

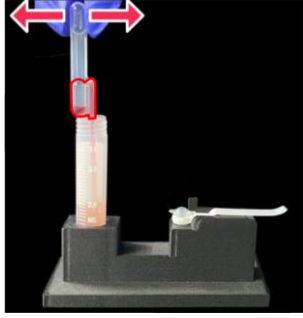
- Open the buffer tube.
- Remove the transfer pipette from test pouch.
- Squeeze the **top bulb** until it is fully flat.



#### Step 2

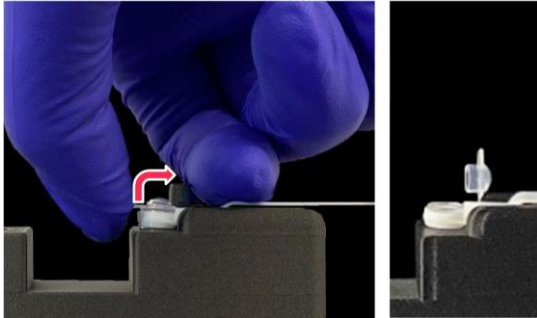
- **While keeping the bulb squeezed**, insert the transfer pipette tip into the buffer tube until it touches the bottom of the tube.





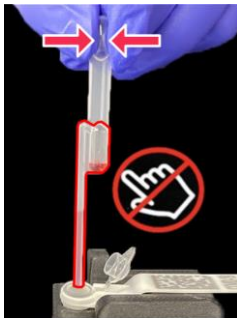
### Step 3

- Keep the tip fully under liquid and release the upper bulb to **fill the entire shaft** with liquid.
- **Note:** There should be some liquid in the lower bulb.
- **Note:** Do **NOT** invert transfer pipette.



### Step 4

- Carefully flip open the cap of the tube assembly.
- **Note:** Once cap is open, sample must be added **IMMEDIATELY** (within 1 minute).



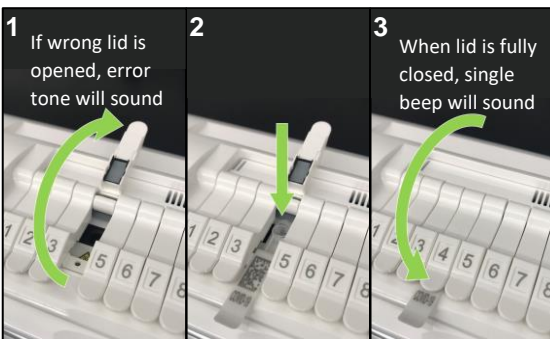
### Step 5

- Keep the transfer pipette tip level with the tube rim.
- Squeeze top bulb of transfer pipette to dispense liquid.
- **Note:** Some liquid will remain in the lower bulb.
- **Note:** Do **NOT** release top bulb.
- Dispose of the transfer pipette in a biohazard bin.



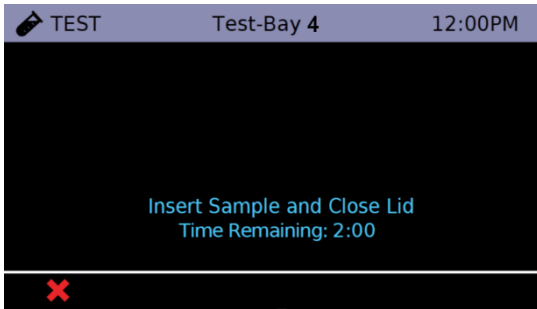
### Step 6

- **COMPLETELY** close the cap of tube assembly (as shown in green circle).
- **Note:** Do **NOT** shake or tilt the tube assembly.
- Close the buffer tube.



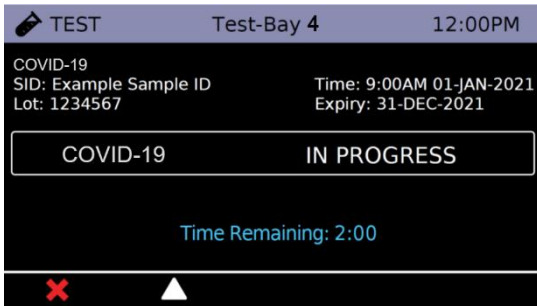
### Step 7

- Open lid of test bay that was selected in [J. Test Procedure, Section 2: Test Preparation step 1](#) (1), insert tube assembly into test bay (2), and firmly close test bay lid (3).
- The selected test bay is displayed at the top of the screen.
- **Note:** Do **NOT** keep the test bay lid open for more than 10 seconds.



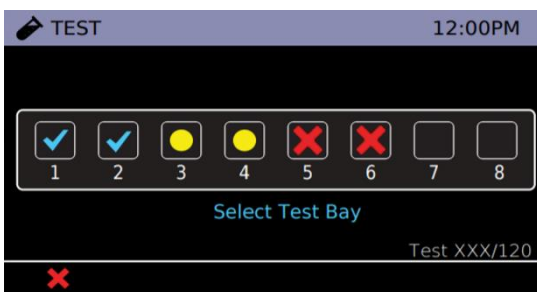
#### Step 8

- The test will automatically start once the lid is shut.
- **Note:** Do **NOT** open the lid of the test bay while the test is running.







#### Step 9

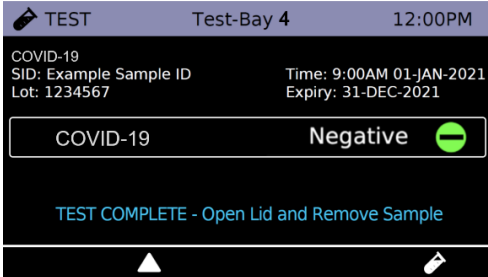
- The test will complete in ~25 minutes. Two beeps will sound when a test is complete.
- **Note:** Do **NOT** turn off or unplug the DxHub while a test is in progress.
- Touch the  $\Delta$  icon to return to the main test screen.
- From the main test screen, you can view the result of a completed test, view the progress of a test in progress, or start a new test.














#### Step 10

-  Test complete: touch to view test outcome. See Section 4 for possible results and interpretation.
-  Test in progress: touch to view progress.
-  Test cancelled: touch to view and clear test bay.
-  Ready for another sample: touch to start a new test, repeating [J. Test Procedure, Sections 1-3](#).  
**Note:** Put on **NEW** clean gloves when performing a new test.

## Section 4: Test Results and Interpretation



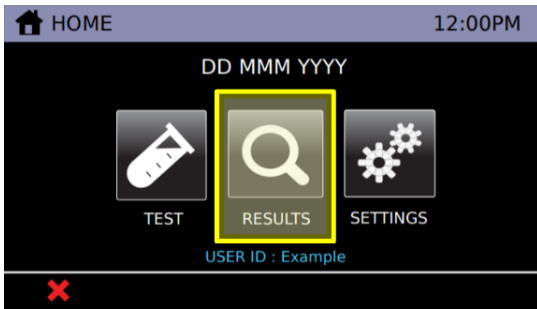
- Possible test outcomes are: Negative , Positive , Invalid , or Error 
- Open the test bay lid and dispose of the tube assembly in a biohazard bin. Close the test bay lid **IMMEDIATELY** after removing the tube assembly.
- **Note:** Do **NOT** keep the test bay lid open for more than 10 seconds.
- **Note:** Do **NOT** open the cap of the tube assembly.
- Dispose of used buffer tube and gloves in a biohazard bin. Ensure all test materials are closed before disposal.
- Touch the  icon to begin a new test in the same test bay, repeating [J. Test Procedure: Sections 1-3](#). Alternatively, touch  to return to the main test screen.

<p><b>POSITIVE</b> </p>	<p><b>Positive test for SARS-CoV-2</b> (SARS-CoV-2 RNA detected); Report results to HCP, patient, and applicable Public Health Authorities</p>
<p><b>NEGATIVE</b> </p>	<p><b>Negative test for SARS-CoV-2*</b> (SARS-CoV-2 RNA not detected); Report results to HCP, patient, and applicable Public Health Authorities</p>
<p><b>INVALID</b> </p>	<p><b>Test result is invalid, repeat test with new sample and new DxLab COVID-19 Test Kit</b> If repeat tests continue to return Invalid results, suspend testing of patient specimens. Contact DxLab Inc. Technical Support (support@dxcab.bio) for a root cause investigation.</p>
<p><b>ERROR XX</b> </p>	<p><b>Device error</b> Refer to error code in DxHub User Manual. “XX” next to “ERROR” represents the error code.</p>
<p><b>CANCELED</b> </p>	<p><b>Test canceled</b> Clear test bay of the DxHub device and begin new test</p>

\* Note: A negative result is presumptive and confirmation with a second molecular assay, if necessary for patient management, may be performed.

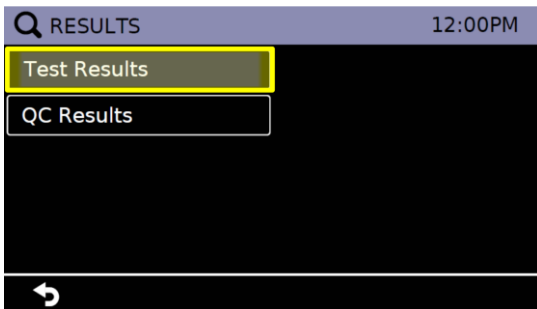
\* Note: For serial testing programs, additional confirmatory testing is required when a negative result is obtained for the first sample. This second sample must be collected and tested at least 24 hours after your first test and within the next 48 hours. Additional testing may also be necessary if the individual was exposed to someone who tested positive for SARS-CoV-2 (the virus that can cause COVID-19), or in communities with high numbers of positive cases (high prevalence of infection).

## Section 5: Viewing and Exporting Results



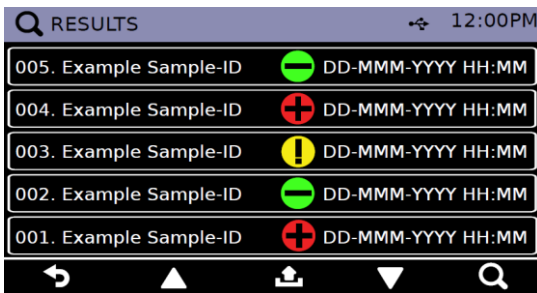
### Step 1

- Return to the Home Menu.
- Select the “Results” icon.





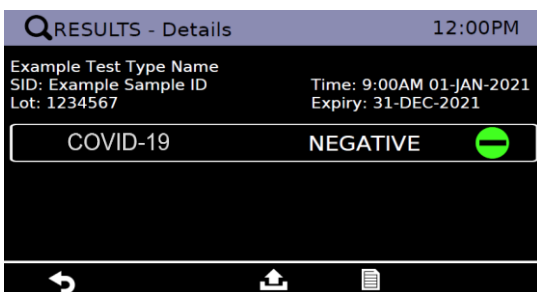
### Step 2

- Select “Test Results” to view patient sample test results.





### Step 3

- A list of results is displayed.
- Insert a USB drive and touch the  icon to export all saved results. If in admin mode, the device will provide the option to delete all results following a successful export.
- Touch the  icon to search for a test result by Sample ID or text string. Refer to the DxHub User Manual for more details.

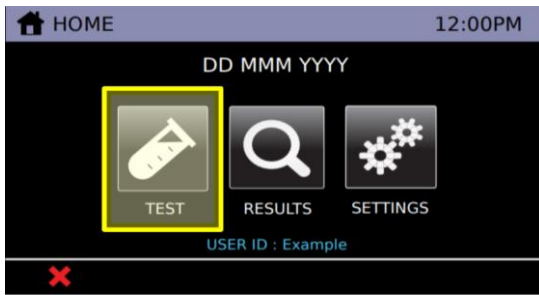


### Step 4

- Select a test from the list to view information about time, Sample ID, Tube Assembly ID, and test result.
- Insert a USB drive and touch the  icon to export the selected result.
- Connect a printer to the printer port at the back of the DxHub and touch the  icon to print the selected result. Refer to the DxHub user manual for recommended printer and setup.

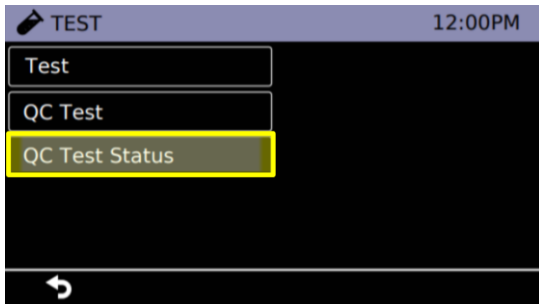
**Note:** The same procedure can be followed to view and export quality control test results by selecting “QC Results” in step 2.

## Section 6: Viewing QC Test Status



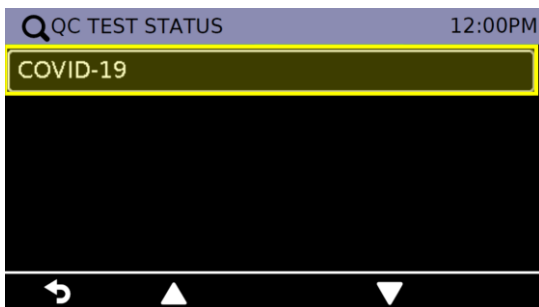
### Step 1

- Return to the Home Menu
- Select the “Test” icon



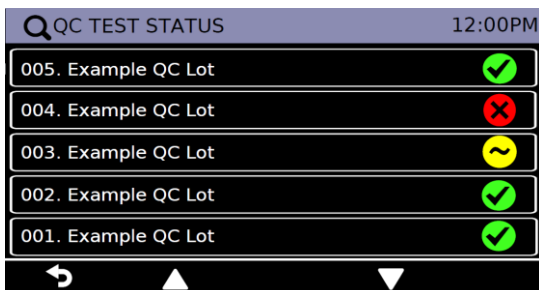
### Step 2

- Select “QC Test.”



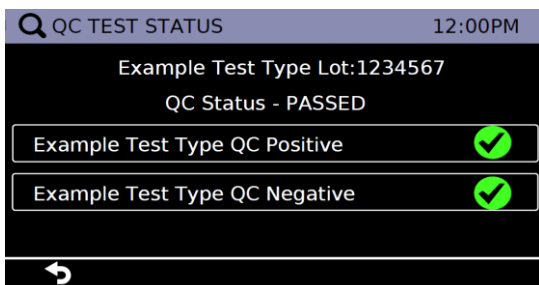
### Step 3

- Select “COVID-19.”



### Step 4

- The possible QC Test Statuses are:
  - Passed – Both QC Positive and QC Negative have a passed status for a specific lot.
  - Failed – Either QC Positive and/or QC Negative have a failed status for a specific lot.
  - Not Run – Either QC Positive and/or QC Negative have not been run and neither have a failed status for a specific lot.
- Select a QC lot to see more details on its status.



### Step 5

- The status of the QC Positive and QC Negative test for the specific lot are displayed.

## K. Limitations

- The performance of the DxLab COVID-19 test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The effect of interfering substances has only been evaluated for those listed in this labeling. Potential interference has not been evaluated for substances other than those described in the Interfering Substances section below. Interference by substances other than those described in the Interfering Substances section below could lead to erroneous results.
- False negative results may occur if a specimen is improperly collected, transported, or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.
- Exposing the test sample or test kit components to Method All-Purpose Cleaner may cause false negative results.
- As with any molecular test, mutations within the target regions of the DxLab COVID-19 test could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.
- The DxLab COVID-19 test is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.

## L. Conditions of Authorization for the Laboratory

The DxLab COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

However, to assist clinical laboratories using the DxLab COVID-19 Test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- A. Authorized laboratories<sup>1</sup> using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and DxLab Inc. ([support@dxlab.bio](mailto:support@dxlab.bio) or [www.dxlab.bio](http://www.dxlab.bio)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- G. DxLab Inc., authorized distributor(s) and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

---

<sup>1</sup> The letter of authorization refers to “authorized laboratories” as “laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. The DxLab COVID-19 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.”

## M. Performance Characteristics

### Analytical Sensitivity (Limit of Detection)

A Limit of Detection (LoD) study was completed to establish the lowest number of viral copies per swab that could be detected by the DxLab COVID-19 Test at least 95% of the time. The study was run using swab samples that were prepared by serially diluting gamma-irradiated SARS-CoV-2 virus of a known concentration in the clinical nasal swab matrix and then pipetting 50 µL of the virus dilution onto a fresh, unused nasal swab.

Using Lot 1 of the DxLab COVID-19 Test kits, preliminary range finding was performed by testing 3 different target concentrations, with 3-6 replicates at each target concentration. The lowest concentration at which all the replicates were positive was 3,000 copies/swab, which was treated as the tentative LoD.

#### LoD Range Finding Results

Viral Load (copies/swab)	Test Kit Lot	Positive/Replicates	% Positive
1500	Lot 1	5/6	83.3%
3000	Lot 1	3/3	100%
6000	Lot 1	3/3	100%

To confirm the LoD, 20 additional swab samples at 3,000 copies/swab were tested using Lot 1 of the test kits, which yielded 19/20 positives (95%). Using Lot 2 test kits, testing 10 replicates at 3,000 copies/swab yielded 8/10 positives (80%), and testing 20 replicates at 4,000 copies/swab yielded 20/20 positives (100%). The LoD of the DxLab COVID-19 Test is thus 4,000 copies/swab, the highest LoD across two lots (per CLSI EP17-A2).

#### LoD Confirmation Results

Viral Load (copies/swab)	Test Kit Lot	Positive/Replicates	% Positive
3000	Lot 1	19/20	95%
3000	Lot 2	8/10	80%
4000	Lot 2	20/20	100%



## Analytical Reactivity (Inclusivity)

Analytical reactivity of DxLab COVID-19 Test was evaluated by in silico analysis of the test's 6 primers in relation to the US nucleotide sequences available from the NCBI database as of May 11, 2022. The initial alignment was done using BLAST alignment of each of six primers individually against the entire dataset.

From the in silico analysis, mismatches of 4 base-pairs were observed at a frequency lower than 0.0003%, mismatches of 3 base-pairs were observed at a frequency lower than 0.0049%, and mismatches of 2 base-pairs were observed at a frequency lower than 0.0693% for all six primers used in the DxLab COVID-19 Test (there were no mismatches of more than 4 base pairs). Of those variant sequences, a majority of the identified mismatches were based on failures of the sequencing algorithm to identify the nucleotide at the affected positions (i.e., the sequence position was denominated with 'N'; all of the 3 base-pair and 4 base-pair mismatches had all of the nucleotides at the affected positions denominated with 'N'; about 85% of the 2 base-pair mismatches had all of the nucleotides at the affected positions denominated with 'N').

Mismatches of a single base-pair did not exceed a prevalence of 0.7350% for all but one of the six primers (for the forward internal primer, one of the single base-pair mismatches had a prevalence of 7.3789% in the full US database, 44.0055% in the past 90 days, and 93.6946% in the past 30 days; this variant sequence belongs to the omicron subvariant BA.2). The potential impact of this single base-pair mismatch was evaluated by calculating the predicted melting temperature (T<sub>m</sub>) of the oligonucleotide sequence with and without the single-point mutation using the nearest-neighbor two-state model, with ion and primer concentrations which are reflective of the conditions of the test as inputs to the model. The expected change in T<sub>m</sub> due to the single-point mutation did not result in a decrease in T<sub>m</sub> to below the reaction temperature of the DxLab COVID-19 Test. It is thus expected that this single base-pair mismatch would not impact the primer's ability to bind the target in the LAMP amplification.

### **Ongoing Variant Monitoring Plan:**

DxLab plans to monitor new and emerging SARS-COV-2 viral mutations on a 30-day rolling period as new sequences are added to NCBI. In the event that a new variant of concern is declared by the WHO, DxLab will isolate these sequences from other NCBI data and analyze them separately.

Thus far, mutations and variants of significance have not had (and is not expected to have) any significant impact on the accuracy of the DxLab COVID-19 Test. This is primarily due to the fact that the test targets a well-conserved region of the M gene, which has not been as susceptible to mutations as other regions (e.g., the S gene). DxLab will continue to monitor emerging viral mutations as described, and perform additional mitigation measures as needed, should any mutation that may impact the DxLab COVID-19 Test's performance has >1% frequency on the 30-day rolling window.

## Analytical Specificity (Cross Reactivity)

The analytical specificity of DxLab COVID-19 Test was first estimated by performing an in silico analysis of the test's six primers against high priority organisms. The analysis was conducted by mapping the individual primer sequences to the microbial organism's genome sequences downloaded from the NCBI database. Primers that generated an E-value <0.05 were considered a positive hit (i.e., sequence alignment reported).

BLAST alignments showed that *Bordetella pertussis* has 90% homology with LoopB primer of the DxLab COVID-19 Test, but this is not expected to impact the detectability of SARS-CoV-2 as only one of the six primers exhibited high rate of homology, and we do not expect a single primer to lead to an exponential amplification that will result in a detectable signal. Moreover, the loop primers are not used to bind the target sequence, so any potential adverse effects on target detection is further minimized. *Candida albicans* also displayed 66% homology with the F3 primer. With a <80% homology and just being a single primer, this is similarly not expected to lead to exponential amplification. Finally, SARS-CoV-1 showed sequence homology to more than one primer at the >80% sequence homology level (95% for F3, 72% for FIP\_F1c, 87% for FIP\_F2, 94% for BIP\_B2, 86% for LoopF). The cross-reactivity with and interference by SARS-CoV-1 were checked by performing wet testing, as described in this section and in the following [Microbial Interference](#) section.

To confirm analytical specificity of DxLab COVID-19 Test, wet testing was performed with high priority organisms. Each of the organisms being tested was diluted 10-fold in negative clinical nasal swab matrix. A swab sample, which was created by pipetting 50 µL of the dilution onto a fresh, unused nasal swab, was tested using the DxLab COVID-19 Test. None of the organisms showed cross-reactivity at the concentrations tested. The results are summarized below.

### Cross-reactivity Wet Testing Results

Organism Tested	Source	Concentration Tested	# Pos / # Tested	Cross Reactive
Adenovirus 1	Zeptomatrix	3.09x10 <sup>7</sup> TCID50/ml	0/3	No
Human Metapneumovirus (hMPV)	Zeptomatrix	3.8x10 <sup>5</sup> TCID50/mL	0/3	No
Parainfluenza virus 1	Zeptomatrix	1.26x10 <sup>5</sup> TCID50/ml	0/3	No
Parainfluenza virus 2	Zeptomatrix	1.51x10 <sup>5</sup> TCID50/ml	0/3	No
Parainfluenza virus 3	Zeptomatrix	3.39x10 <sup>6</sup> TCID50/ml	0/3	No
Parainfluenza virus 4a	Zeptomatrix	1.41x10 <sup>4</sup> TCID50/ml	0/3	No
Influenza A	Zeptomatrix	4.17x10 <sup>4</sup> TCID50/ml	0/3	No
Influenza B	Zeptomatrix	4.68x10 <sup>3</sup> TCID50/ml	0/3	No
Enterovirus 68 (e.g., EV68)	Zeptomatrix	1.51x10 <sup>5</sup> TCID50/ml	0/3	No
Enterovirus 71	Zeptomatrix	4.17x10 <sup>4</sup> TCID50/ml	0/3	No
RSV A	Zeptomatrix	1.05x10 <sup>5</sup> TCID50/mL	0/3	No
RSV B	Zeptomatrix	1.55x10 <sup>3</sup> TCID50/mL	0/3	No
Rhinovirus type 1A	Zeptomatrix	1.41x10 <sup>4</sup> TCID50/mL	0/3	No
<i>Pneumocystis jirovecii</i> (PJP)	Zeptomatrix	6.34x10 <sup>7</sup> cfu/mL	0/3	No
Human coronavirus OC43	Zeptomatrix	5.01x10 <sup>4</sup> TCID50/mL	0/3	No
Human coronavirus NL63	Zeptomatrix	1.70x10 <sup>4</sup> TCID50/mL	0/3	No

MERS-coronavirus	Zeptomatrix	4.17x10 <sup>4</sup> TCID50/mL	0/3	No
SARS-coronavirus	Zeptomatrix	10 fold dilution of 27.62 Ct*	0/3	No
<i>Candida albicans</i>	ATCC	2.09x10 <sup>7</sup> cfu/ml	0/3	No
<i>Pseudomonas aeruginosa</i>	ATCC	6.64x10 <sup>6</sup> cfu/ml	0/3	No
<i>Staphylococcus epidermidis</i>	ATCC	9.0x10 <sup>7</sup> cfu/ml	0/3	No
<i>Streptococcus salivarius</i>	ATCC	1.2x10 <sup>7</sup> cfu/mL	0/3	No
Human coronavirus 229E	Zeptomatrix	1.26x10 <sup>5</sup> TCID50/mL	0/3	No
<i>Haemophilus influenzae</i>	ATCC	5.1x10 <sup>7</sup> cfu/mL	0/3	No
<i>Legionella pneumophila</i>	ATCC	2.4x10 <sup>7</sup> cfu/mL	0/3	No
<i>Streptococcus pyogenes</i>	ATCC	1.2x10 <sup>8</sup> cfu/mL	0/3	No
<i>Bordetella pertussis</i>	ATCC	1.95x10 <sup>8</sup> cfu/mL	0/3	No
<i>Mycoplasma pneumoniae</i>	ATCC	4.4x10 <sup>6</sup> cfu/mL	0/3	No
<i>Mycobacterium tuberculosis</i>	ATCC	4.3x10 <sup>4</sup> genome copies/μL	0/3	No
<i>Streptococcus pneumoniae</i>	ATCC	4.1x10 <sup>4</sup> genome copies/μL	0/3	No
<i>Chlamydomphila pneumoniae</i>	Zeptomatrix	2.11x10 <sup>7</sup> IFU/mL	0/3	No
Human coronavirus HKU1	ATCC	5.5x10 <sup>4</sup> genome copies/μL	0/3	No

\*This material was not quantified but instead characterized by the vendor by Ct value in an RT-PCR test.

### Microbial Interference

A microbial interference study was performed for SARS-coronavirus because it displayed >80% homology with more than one primer used in the DxLab COVID-19 Test. SARS-coronavirus was diluted 10-fold in negative clinical nasal swab matrix and ~2.25x LoD SARS-CoV-2 was then spiked onto a swab. SARS-coronavirus did not interfere with the detection of SARS-CoV-2 at the concentration tested. The results are summarized below.

### Microbial Interference Testing Results

Organism Tested	Source	Concentration Tested	# Pos / # Tested	Interfering
SARS-coronavirus	Zeptomatrix	10-fold dilution of 27.62 Ct*	3/3	No

\*This material was not quantified but instead characterized by the vendor by Ct value in an RT-PCR test.

## Interfering Substances

The DxLab COVID-19 Test was tested with three positive and three negative replicates for potentially interfering substances. Each substance was diluted to the concentration shown below in negative clinical nasal swab matrix. For positive replicates, SARS-CoV-2 was spiked in at ~2.25x LoD. A swab sample was then created and tested using the DxLab COVID-19 Test. None of the substances tested showed interference at the concentrations shown below.

### Interfering Substance Testing Results

Substance	Concentration Tested	# Neg / # Neg expected	# Pos / # Pos expected
Negative clinical nasal swab matrix	N/A	3/3	3/3
Afrin Nasal Spray	15% v/v	3/3	3/3
Whole blood	2.5% v/v	3/3	3/3
Chloraseptic Max	5% v/v	3/3	3/3
Flonase Allergy Relief	2.5% v/v	3/3	3/3
Method All-Purpose Cleaner <sup>†</sup>	2.5% v/v	3/3	0/3
	0.75% v/v	3/3	3/3
Mupirocin	5 mg/mL	3/3*	3/3
NeoSynephrine Cold and Sinus Extra Strength Spray	2.5% v/v	3/3*	3/3
Zanamivir	250µg/mL	3/3*	3/3
Ayr Saline Nasal Mist	2.5% v/v	3/3*	3/3
Zicam Extreme Congestion Relief	2.5% v/v	3/3	3/3
Oseltamivir Phosphate	10µg/mL	3/3	3/3
Tobramycin	5µg/mL	3/3*	3/3
Robitussin	5% v/v	3/3	3/3
Cepacol Lozenges	3mg/mL	3/3	3/3
Mucin: bovine submaxillary gland, type I-S	2.5mg/mL	3/3	3/3
Nicotine	0.03mg/ml	3/3	3/3

\* One replicate was repeated with a new sample and new DxLab COVID-19 test kit due to an initial invalid result.

<sup>†</sup> Method All-Purpose Cleaner displayed interference at the initial testing concentration of 2.5% v/v for positive replicates. Additional dilutions were tested, and 0.75% was determined to be the concentration at which there was no interference. One negative replicate at 0.75% was repeated with a new sample and new DxLab COVID-19 test kit due to an initial invalid result.

### Carry-Over/Cross Contamination

In order to determine the risk of amplicon carry-over contamination during the use of the DxLab COVID-19 Test with the DxHub instrument, an experiment mimicking the worst-case scenario was designed, in which the same instrument was used to run 3 sets of tests in immediate succession. For each of the 3 runs, all 8 test bays on the DxHub instrument were used to test alternating SARS-CoV-2 negative samples and high positive SARS-CoV-2 samples ( $\sim 3.7 \times 10^5$  copies/swab), and between each run, alternating negative and positive samples were tested in the same test bay, as shown in the table below. No carryover contamination was observed.

#### Carry-Over/Cross-Contamination Results

	Test Bay 1	Test Bay 2	Test Bay 3	Test Bay 4	Test Bay 5	Test Bay 6	Test Bay 7	Test Bay 8
Run 1	NEG	POS	NEG	POS	NEG	POS	NEG	POS
Run 2	POS	NEG	POS	NEG	POS	NEG	POS	NEG
Run 3	NEG	POS	NEG	POS	NEG	POS	NEG	POS
Results	Pass (3/3)	Pass (3/3)	Pass (3/3)	Pass (3/3)	Pass (3/3)	Pass (3/3)	Pass (3/3)	Pass (3/3)

### Sample Stability

Since the DxLab COVID-19 Test is intended for testing a sample immediately after obtaining the sample, sample stability testing was performed on contrived swab samples that were stored for 2 hours at room temperature before testing. 10 positive ( $\sim 3 \times \text{LoD}$ ) and 10 negative swab samples were created, and each swab sample was placed in its original packaging. After storing for 2 hours at room temperature, each of the swab samples was tested using the DxLab COVID-19 Test. All of the swab samples produced the expected results, as summarized below.

#### Sample Stability Testing Results

Swab Sample	# Correctly Called / # Tested	Stable for 2 Hours
Negative	10/10	Yes
Positive	10/10	Yes

## Clinical Performance

DxLab conducted an IRB-approved clinical study in two phases at one emergency department and two community drive-through COVID-19 testing sites. Ten healthcare professionals who had no laboratory training were recruited as test operators at the clinical sites. In the first phase, patients with signs and symptoms of COVID-19 infection were enrolled, and in the second phase, the study was expanded to include “all comers” with or without signs and symptoms of COVID-19 infection. Individuals of age 18 or older were included in the study. The standard of care specimen was collected before the candidate and the comparator assays, so as not to compromise the medical care of the patient. The order of anterior nasal swab collection for the comparator test and DxLab COVID-19 test was randomized to reduce the potential for bias due to an unequal distribution of viral materials.

### Evaluation of Samples from Individuals with Signs and Symptoms of COVID-19 Infection

A total of 156 subjects were enrolled and tested with the DxLab COVID-19 Test, of which 8 were excluded from the analysis of performance, either due to an invalid result with the DxLab COVID-19 Test (3 samples) or issues with the comparator sample handling or shipping (5 samples). Relative to the EUA-authorized comparator test, the DxLab COVID-19 Test demonstrated 86.8% (46/53) positive percent agreement (PPA) and 100% (95/95) negative percent agreement (NPA).

Symptomatic Individuals		High Sensitivity Molecular FDA-Authorized Test		
		Positive	Negative	Total
DxLab COVID-19 Test	Positive	46	0	46
	Negative	7*	95	102
	Total	53	95	148
PPA	86.8% (95% CI = 75.2-93.5%)			
NPA	100% (95% CI = 96.1-100%)			

\* 5 of the 7 discordant results were presumptive positives from the comparator assay. All of these presumptive positive results returned a negative result for SARS-CoV-2 (Target 1) but a positive result for pan-Sarbecovirus (Target 2) for the comparator assay, and their Ct values for Target 2 were all higher than the mean Ct of the comparator assay’s LoD for Target 2 (36.4). The remaining 2 discordant results returned a positive result for both Target 1 and Target 2, but their Ct values for Target 1 were both higher than the mean Ct of the comparator assay’s LoD for Target 1 (32.7), and their Ct values for Target 2 were both within 1.9 Ct of the mean Ct of the comparator assay’s LoD for Target 2 (36.4).

### Evaluation of Samples from Individuals without Signs or Symptoms of COVID-19 Infection

A total of 344 asymptomatic subjects were enrolled and tested with the DxLab COVID-19 Test, of which 13 were excluded from the analysis of performance, either due to an invalid result with the DxLab COVID-19 Test (11 samples) or issues with the comparator sample handling or shipping (2 samples). Of 331 evaluable asymptomatic subjects, 315 were enrolled prospectively that generated 15 SARS-CoV-2 comparator positive results. Enrichment approach was utilized to obtain additional SAR-CoV-2 comparator positives from asymptomatic subjects. Relative to the EUA-authorized comparator test, overall, the DxLab COVID-19 Test demonstrated 90% (18/20) PPA and 98.4% (306/311) NPA. The two false negative results with the DxLab COVID-19 Test were from patient samples that were considered “low positive” as determined by the comparator.

Asymptomatic Individuals		High Sensitivity Molecular FDA-Authorized Test					
		All-Comer Study <sup>1</sup>			Enrichment Study <sup>2</sup>		
		Positive	Negative	Total	Positive	Negative	Total
DxLab COVID-19 Test	Positive	13	4	17	5	1	6
	Negative	2*	296	298	0	10	10
	Total	15	300	315	5	11	16
PPA		86.7% (95% CI = 62.1-96.3%)			100% (95% CI = 56.6-100%)		
NPA		98.7% (95% CI = 96.6-99.5%)			90.9% (95% CI = 62.3-98.4%)		
Combined PPA: 90% (95% CI = 69.9-97.2%)							
Combined NPA: 98.4% (95% CI = 96.3-99.3%)							

<sup>1</sup> Prospective enrollment

<sup>2</sup> Enrollment of consecutive subjects of known positive SARS-CoV-2 status, and number of known negatives were matched.

\* The 2 subjects with discordant results returned Ct values with the comparator that were within 0.4 Ct of the mean at the assay's LoD (37.6) and were considered “low positives”.

### Performance Around Limit of Detection

To demonstrate the performance of DxLab COVID-19 Test around the limit of detection (LoD) when conducted by minimally trained operators, low positive (~2xLoD) and negative swab samples were tested at the point-of-care testing sites (i.e., the emergency department and community drive-through COVID-19 testing sites) by the same test operators running the prospective clinical studies described above. 3 positive and 3 negative swab samples were presented to each test operator in a blinded fashion. The results are summarized below.

#### Near LoD Testing Results

	Operator										% Agreement
	1	2	3	4	5	6	7	8	9	10	
<b>Positive (2xLoD)</b>	3/3*	3/3	3/3*	3/3	3/3	3/3	3/3*	3/3	3/3	3/3	100% (95% CI = 88.6-100%)
<b>Negative</b>	3/3	3/3	3/3	3/3	3/3 <sup>†</sup>	3/3	3/3	3/3	3/3	3/3	100% (95% CI = 88.6-100%)

\* One replicate was repeated with a new sample and new DxLab COVID-19 test kit due to an initial invalid result.

<sup>†</sup> Two replicates were repeated with a new sample and new DxLab COVID-19 test kit due to an initial invalid result.



## N. Symbols



DxLab Logo



WEEE Directive Compliance: Waste Electrical and Electronic Equipment Directive Compliance



Biological Risk: Potential contamination with biological substances that pose a threat to the health



Caution



DxLab Reference Number



In Vitro Diagnostic Medical Device



Fragile, handle with care.



Refer to Instructions For Use or DxHub User Manual



Instrument Serial Number

**QC PASS**

QC Pass: indicates that the instrument has passed the Quality Control procedures as part of production

WARRANTY VOID IF  
REMOVED

Tamper Evident Warranty: indicates that removal of the label will void the instruments warranty.



Manufacturer



USB Port











Network Port



DC Power connector, for connection with supplied external AC/DC power pack, 12V DC.

---

	Power Button
	Hot Surface
	Do not use if package is damaged
	Do not re-use
	Storage Temperature Range
	Use-by Date
	Batch Code
	Date of Manufacture
<b>R Only</b>	Prescription Only

---

## O. Contact Information

support@dxlab.bio

DxLab Inc.

444 Somerville Ave.

Somerville, MA 02143