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

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.

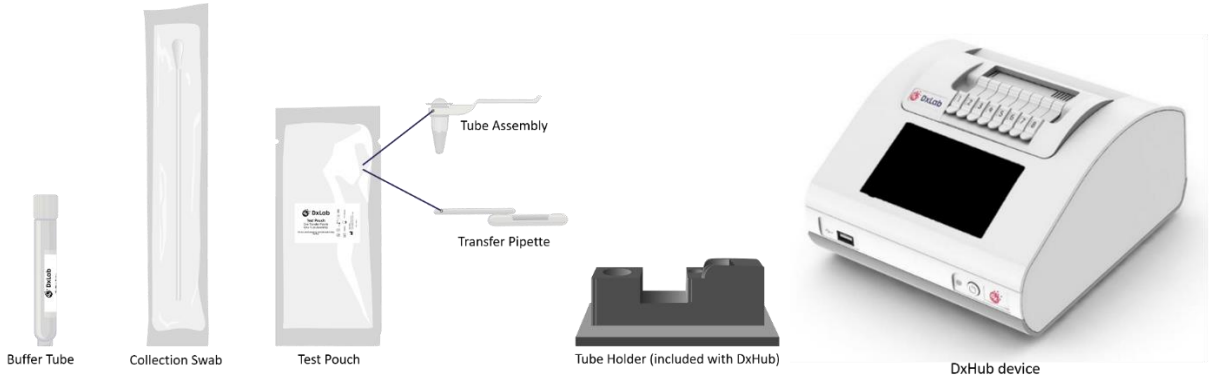
C. Principles of the Procedure

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

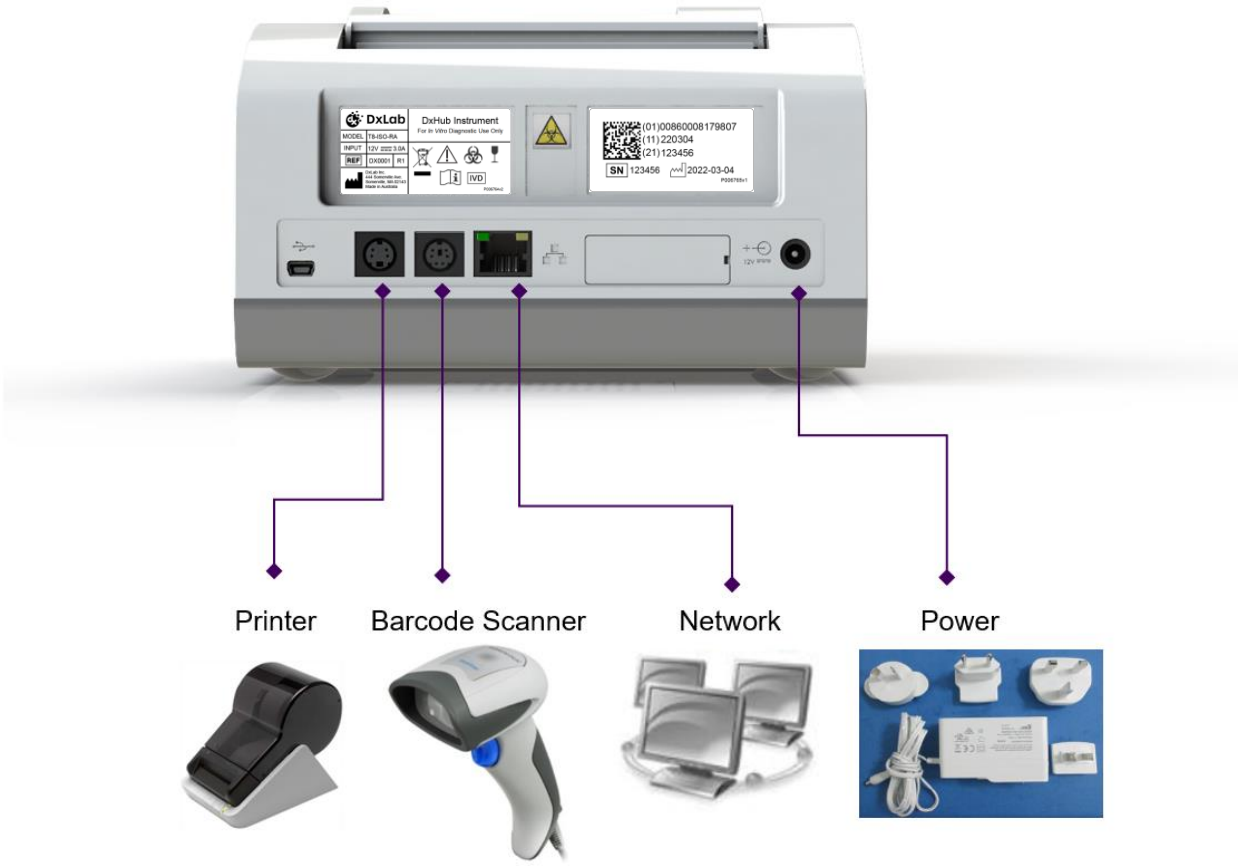
- For in vitro diagnostic use
- For use under Emergency Use Authorization (EUA) only
- For prescription use only
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only 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

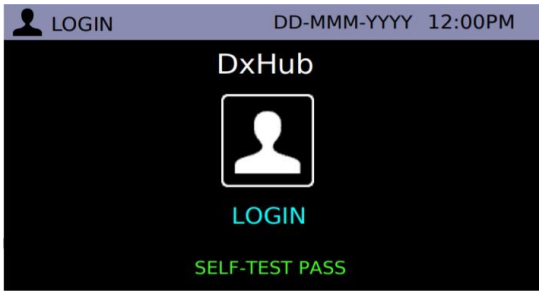
Unpack the DxHub and set up on a stable, level bench, in a clean environment.

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.



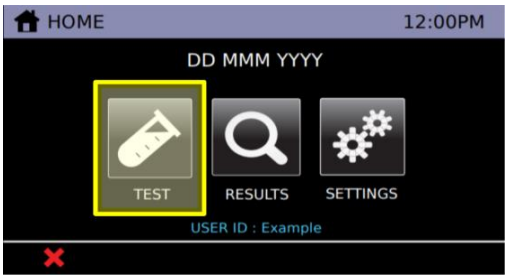
Enter username and password.
First-time login only: The user will be required to login using “admin” as the default username AND password.

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.

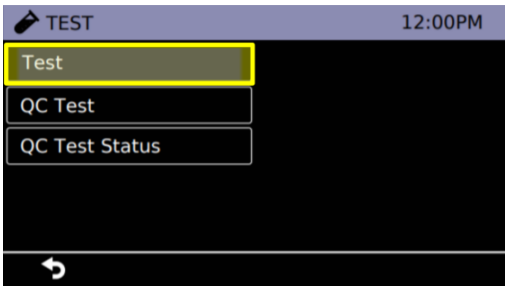
Barcode Scanner Details

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.

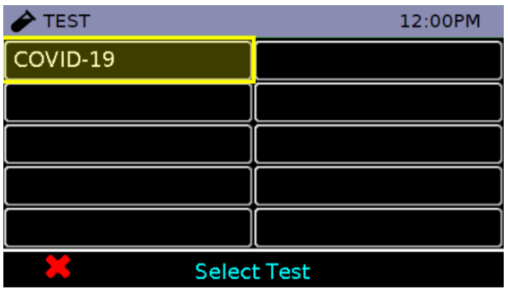
Plug the cable provided with the DxHub (**NOT** the cable included with the barcode scanner) into the bottom of the barcode scanner handle. Connect the barcode scanner cable to the DxHub's rear port.



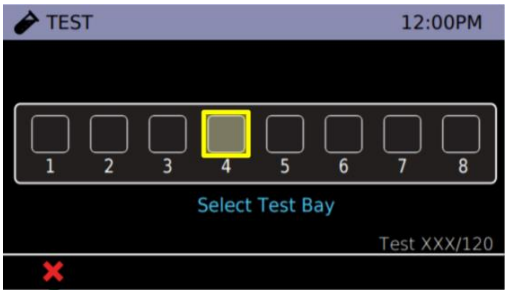
Select the "Test" icon.



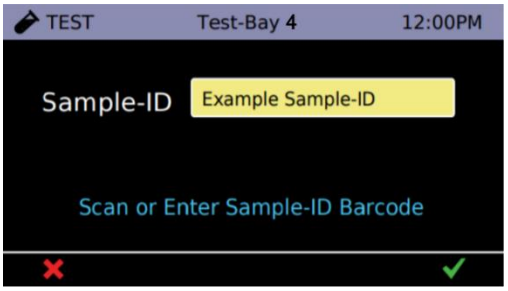
Select "Test".



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.



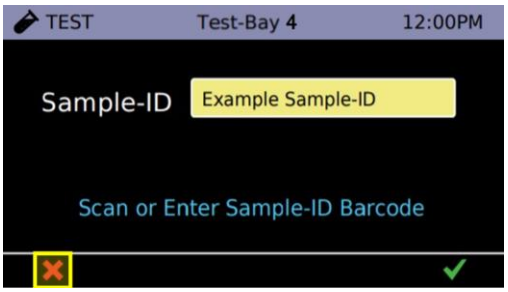
Once the Sample-ID screen has been reached, pick up the barcode scanner.

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 ✗ three times to return to the logout screen.
If testing external quality control samples, touch ✗ two times to return to the Home Menu, and proceed to I. Quality Control.
If testing patient samples, touch ✗ 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) for a root case investigation and suspend testing of patient specimens until a root cause has been identified and eliminated.

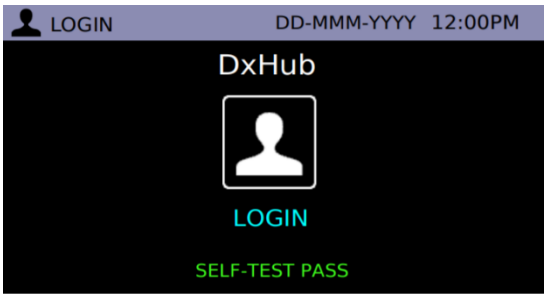
Refer to DxLab COVID-19 Test Quality Control Instructions for detailed instructions on performing a Quality Control Test with the external run control swabs.

Refer to J. Test Procedure, Section 5 and Section 6 for instructions on viewing QC Test results and QC Test status.

J. Test Procedure

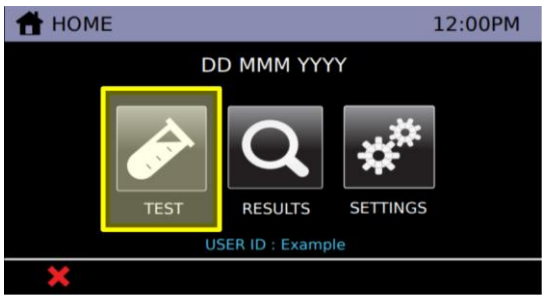
Preparing DxHub for Testing

- **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.**



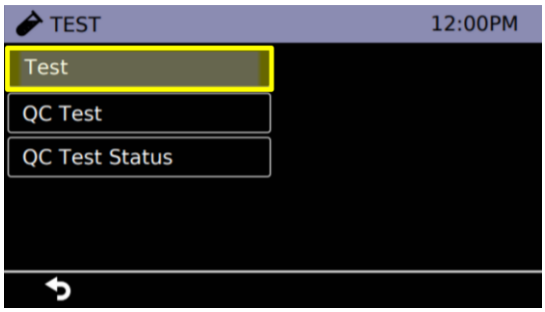
Step 1

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



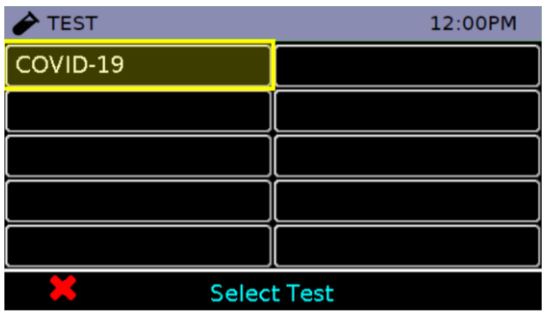
Step 2

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



Step 3

- Select “Test”.



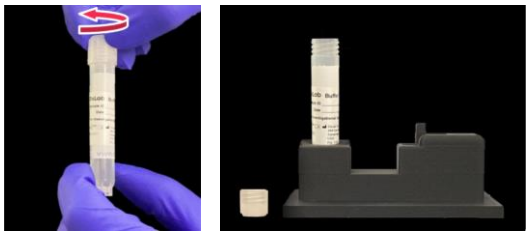
Step 4

- 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

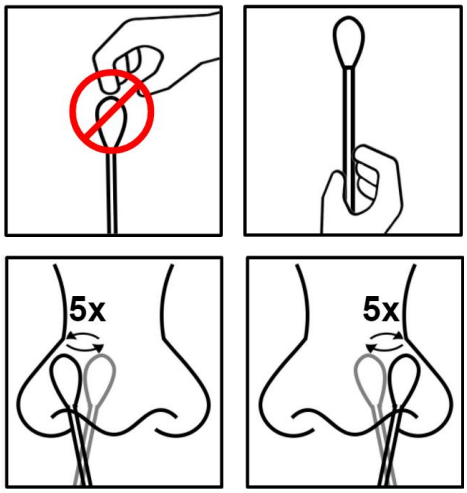
Skip step 2 if swab sample has been pre-collected.

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.



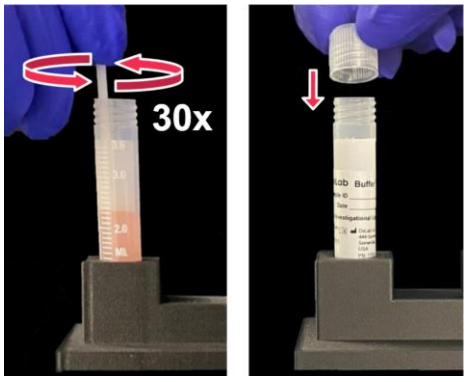
Step 1

- 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.

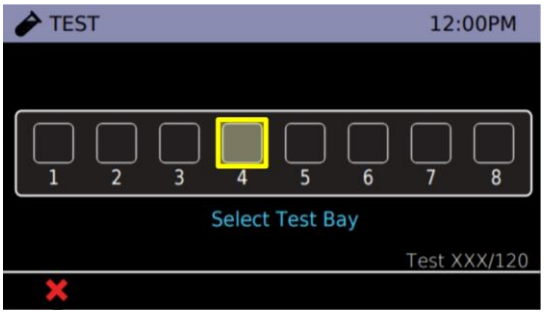


Step 3

- 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.

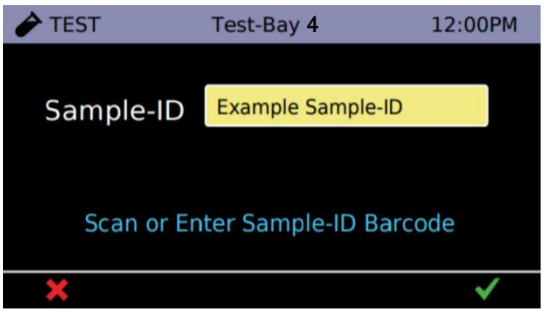
Section 2: Test Preparation

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.

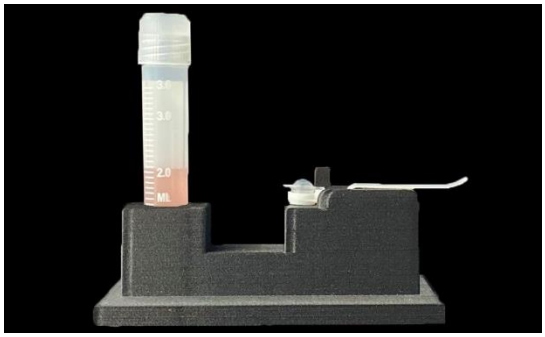


Step 2

- 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.

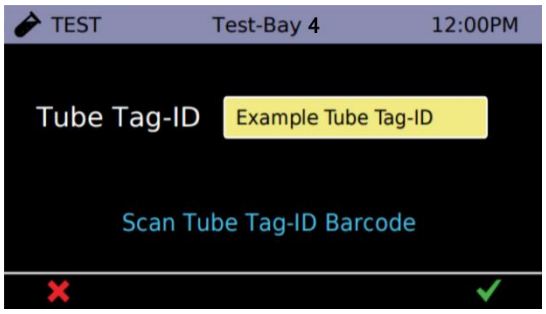
Step 3

- 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.**



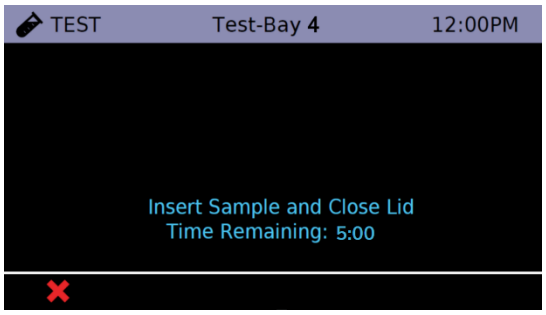
Step 4

- 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.

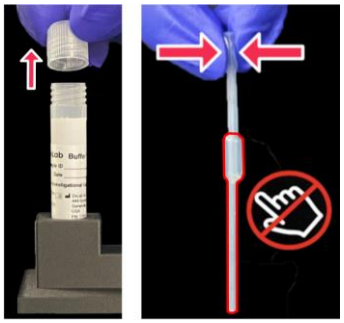


Step 6

- 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.

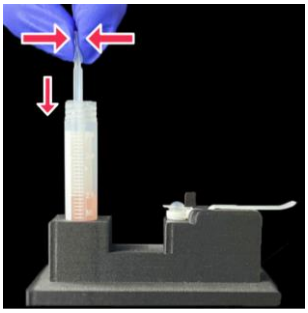
Section 3: Running the Test

- **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.**



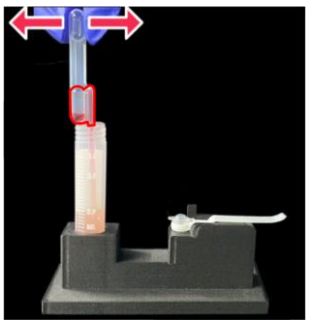
Step 1

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



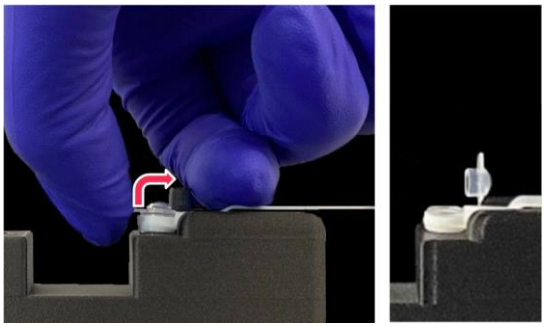
Step 2

- **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.

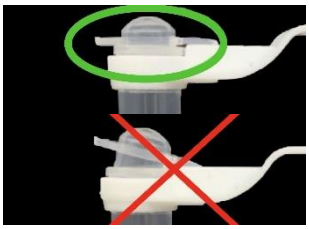


Step 4

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

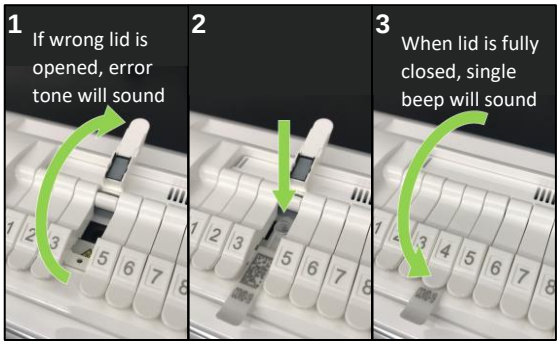
Step 5

- 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.



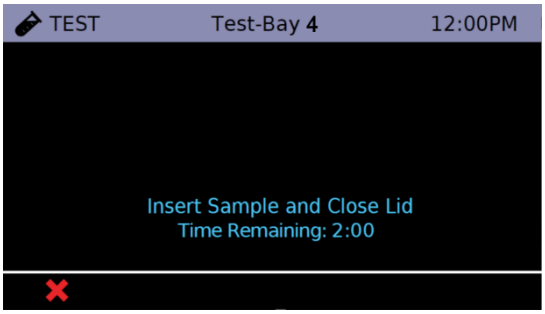
Step 6

- **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.



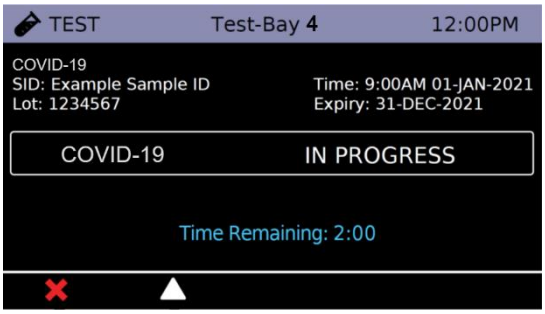
Step 7

- 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.



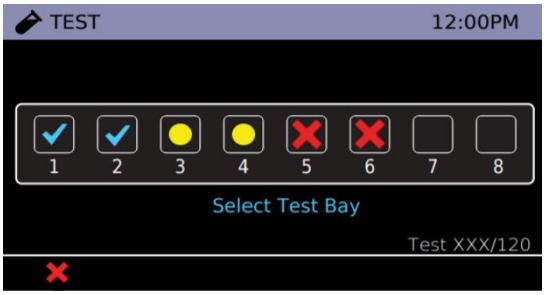
Step 8

- 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 Δ 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.

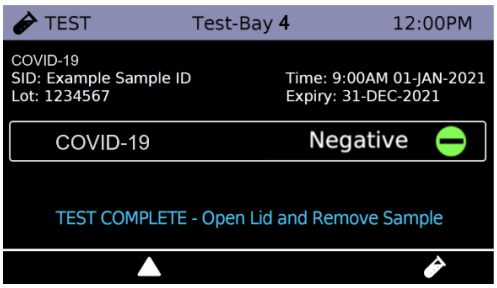


Step 10

- 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

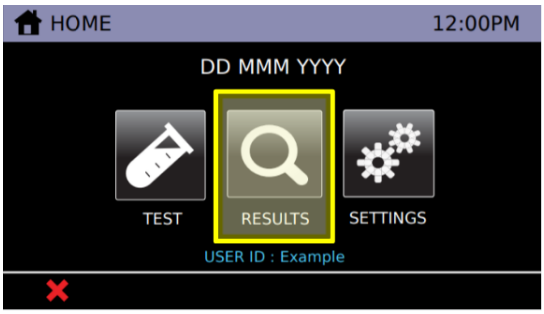


- Possible test outcomes are: Negative, Positive, Invalid, or Error
- Open the test bay lid and dispose of the tube assembly in a biohazard bin. Close the test bay lid **IMMEDIATELY** after removing the tube assembly.
- **Note:** Do **NOT** keep the test bay lid open for more than 10 seconds.
- **Note:** 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 Δ to return to the main test screen.

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

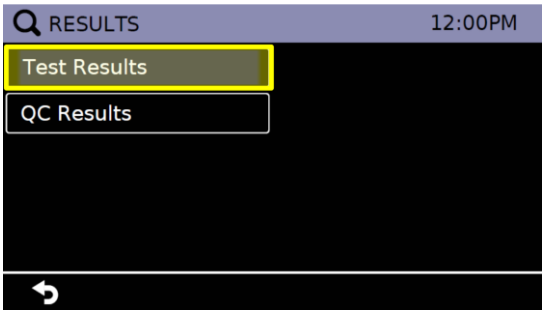
* Note: A negative result is presumptive and confirmation with a second molecular assay, if necessary for patient management, may be performed.
* Note: For serial testing programs, additional confirmatory testing is required when a negative result is obtained for the first sample. This second sample 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



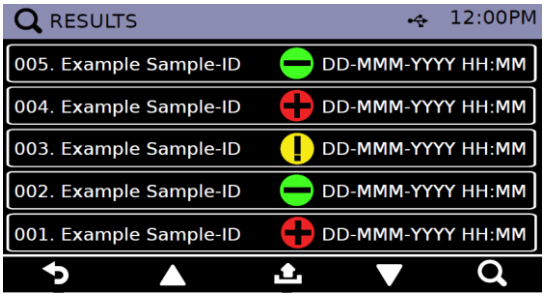
Step 1

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



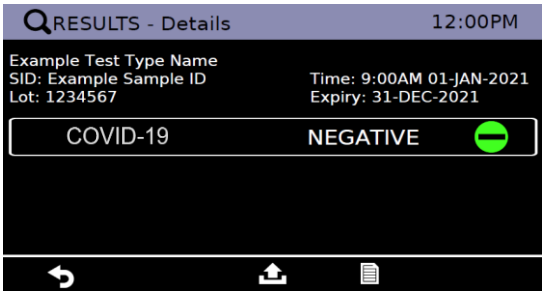
Step 2

- 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.

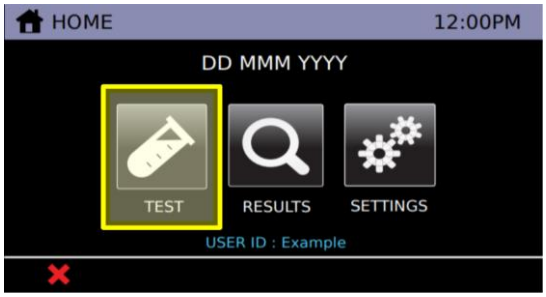


Step 4

- 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.

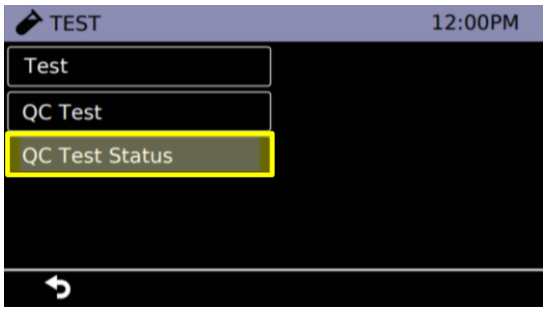
Note: The same procedure can be followed to view and export quality control test results by selecting “QC Results” in step 2.

Section 6: Viewing QC Test Status



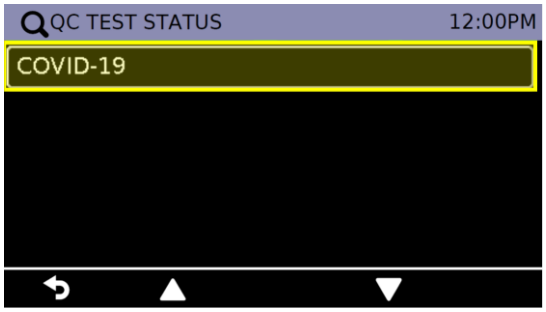
Step 1

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



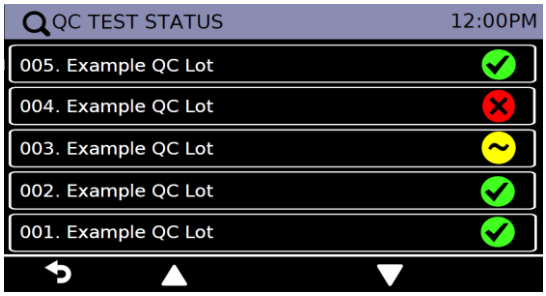
Step 2

- Select “QC Test.”



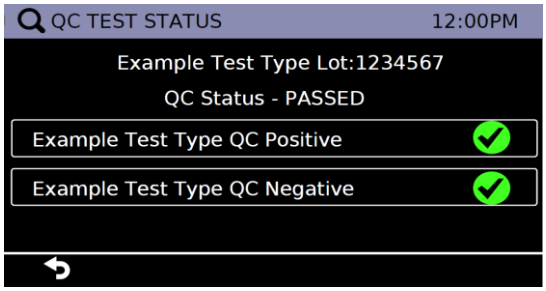
Step 3

- 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[1] 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) and DxLab Inc. (support@dxlab.bio or 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.

[1] 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 (Tm) 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 Tm due to the single-point mutation did not result in a decrease in Tm 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	Zeptometrix	$3.09x10^7$ TCID50/ml	0/3	No
Human Metapneumovirus (hMPV)	Zeptometrix	$3.8x10^5$ TCID50/mL	0/3	No
Parainfluenza virus 1	Zeptometrix	$1.26x10^5$ TCID50/ml	0/3	No
Parainfluenza virus 2	Zeptometrix	$1.51x10^5$ TCID50/ml	0/3	No
Parainfluenza virus 3	Zeptometrix	$3.39x10^6$ TCID50/ml	0/3	No
Parainfluenza virus 4a	Zeptometrix	$1.41x10^4$ TCID50/ml	0/3	No
Influenza A	Zeptometrix	$4.17x10^4$ TCID50/ml	0/3	No
Influenza B	Zeptometrix	$4.68x10^3$ TCID50/ml	0/3	No
Enterovirus 68 (e.g., EV68)	Zeptometrix	$1.51x10^5$ TCID50/ml	0/3	No
Enterovirus 71	Zeptometrix	$4.17x10^4$ TCID50/ml	0/3	No
RSV A	Zeptometrix	$1.05x10^5$ TCID50/mL	0/3	No
RSV B	Zeptometrix	$1.55x10^3$ TCID50/mL	0/3	No
Rhinovirus type 1A	Zeptometrix	$1.41x10^4$ TCID50/mL	0/3	No
Pneumocystis jirovecii (PJP)	Zeptometrix	$6.34x10^7$ cfu/mL	0/3	No
Human coronavirus OC43	Zeptometrix	$5.01x10^4$ TCID50/mL	0/3	No
Human coronavirus NL63	Zeptometrix	$1.70x10^4$ TCID50/mL	0/3	No

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

† 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 (~$3.7x10^5$ 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 (~3x 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 [1]			**Enrichment Study [2]**		
		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%)							

[1] Prospective enrollment

[2] 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										**%**
	1	**2**	**3**	**4**	5	6	7	8	9	10	**Agreement**
Positive (2xLoD)	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%)
Negative	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%)

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

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

N. Symbols

DxLab	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
REF	DxLab Reference Number
IVD	In Vitro Diagnostic Medical Device
	Fragile, handle with care.
	Refer to Instructions For Use or DxHub User Manual
SN	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
℞ Only	Prescription Only

O. Contact Information

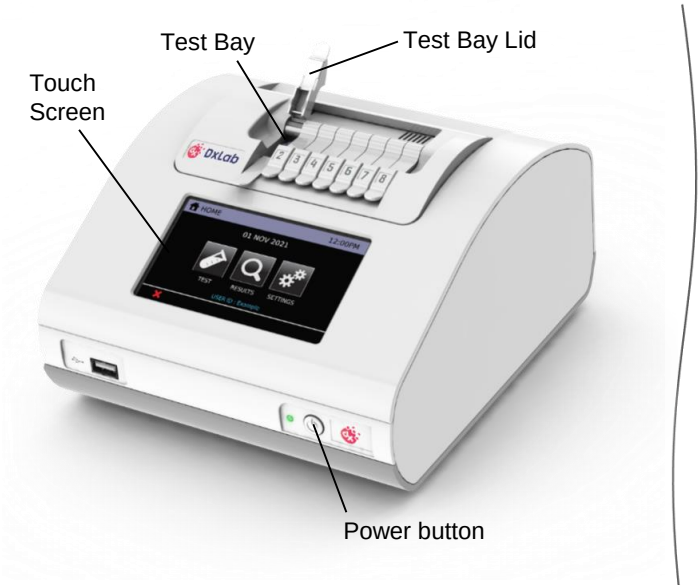
support@dxlab.bio
DxLab Inc.
444 Somerville Ave.
Somerville, MA 02143

DxLab

DxLab COVID-19 Test
Quick Reference Guide

Rx Only IVD

For use under Emergency Use Authorization only



DxHub Instrument

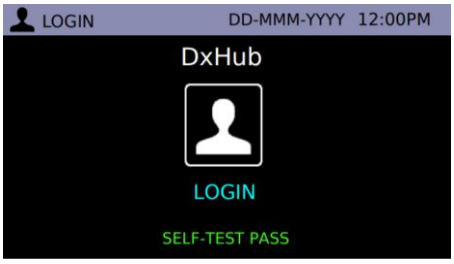
Materials Included

A. 1 Buffer Tube
B. 1 Collection Swab
C. 1 Test Pouch, containing:
C1. 1 Transfer Pipette
C2. 1 Tube Assembly
D. Tube holder, included with DxHub

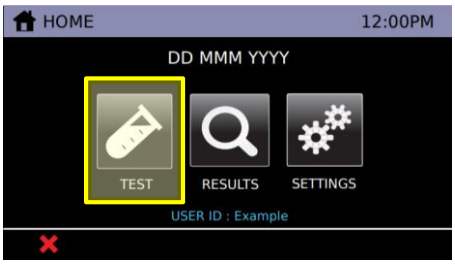
Barcode scanner is required but NOT included

- **Refer to the DxHub Quick Start Guide or Instructions For Use (IFU) for instrument setup.**
- **Refer to the DxLab COVID-19 Test Quality Control Instructions for QC testing procedures.**
- **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.**

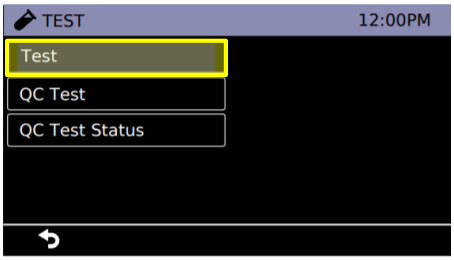
Preparing the DxHub for Testing



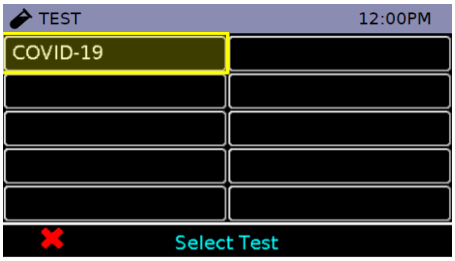
1
- Press & hold the power button on the DxHub.
- On the DxHub touchscreen, select the “Login” icon.
- Login with username & password if requested.



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 ✗ to cancel the current action/input or touch ⮌ to return to the previous screen.



3
- Select “Test”.



4
- Select “COVID-19” test.
- Wait for the instrument to reach 66°C.

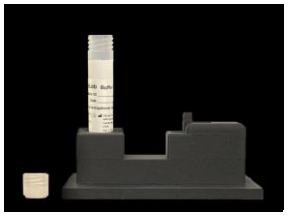
Do **NOT** proceed until “Select Test Bay” is displayed on the screen.

- **Every test should be performed with a new set of gloves.**
- **Gloves should be immediately discarded after disposing of the used tube assembly.**
- **Do NOT use a test kit that is wet or has leaked.**

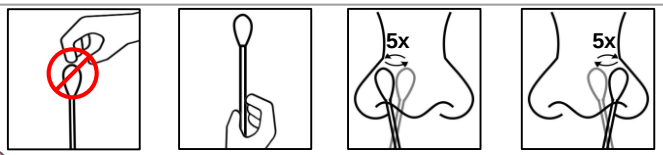
Skip step 2 if swab sample has been pre-collected.

Section 1: Nasal Swab Sample Collection

Swab sample can be stored at room temperature in its original packaging for up to 2 hours.

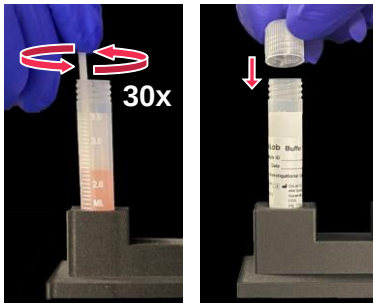


1
- Open the buffer tube. Do **NOT** dispose of the buffer tube cap.
- Place the buffer tube in the tube holder.



After collection, do **NOT** let the swab tip touch anything

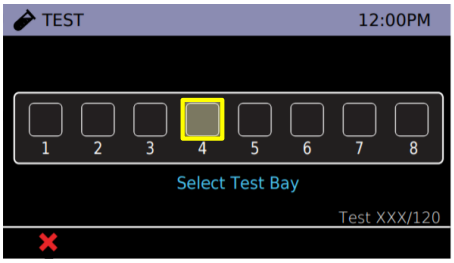
2
- Remove the collection swab from its pouch.
- **Note:** Do **NOT** touch the swab tip. Only hold the swab by its handle.
- Insert the swab tip fully into one nostril until resistance is met.
- Using moderate pressure, rub the swab against the inside wall of the nostril. **Make 5 big circles for 10 seconds**.
- Using the same swab, **repeat** the swabbing step for the other nostril.



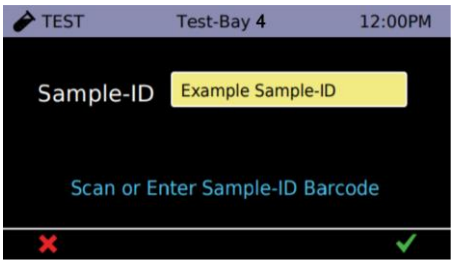
3
- Insert the swab tip into the buffer tube.
- Swirl the swab along the tube wall **30 times**. Keep the swab tip in contact with the bottom of tube.
- Dispose of the used swab in a biohazard bin.
- Screw on the buffer tube cap.
- **Note:** Colored liquid used for demonstration purposes only.

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

Section 2: Test Preparation

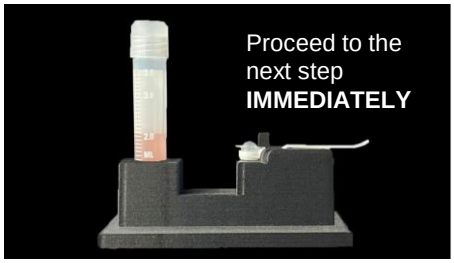


1
- The main test screen is shown on the DxHub touchscreen.
- Select any unoccupied test bay (empty box). #4 is highlighted for demonstration purposes.

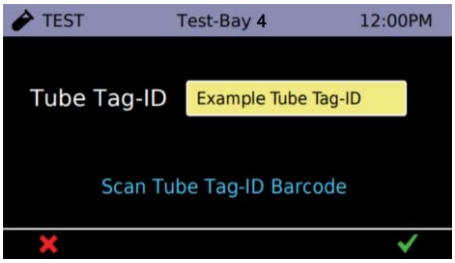


2
- Enter Sample ID by touching the yellow box next to “Sample ID” or scanning a barcode.
- Touch ✔ to continue.
- **Note:** Refer to DxHub Quick Start Guide for barcode scanner setup.

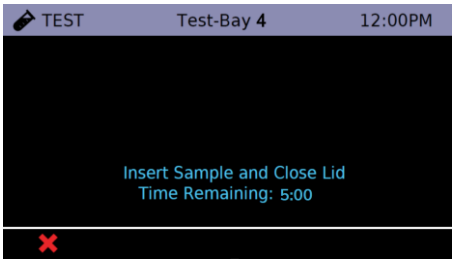
3
- Remove **ONLY** tube assembly from test pouch.
- **Note:** Do **NOT** remove transfer pipette from test pouch.
- **Note:** Do **NOT** touch the tube portion of the tube assembly.



4
- Place the tube assembly in the tube holder.
- **Note:** Do **NOT** use a tube assembly that has been dropped.



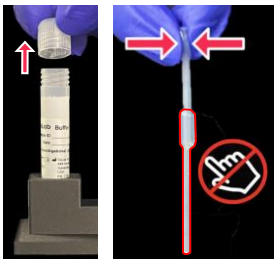
5
- Scan the Tube Tag ID barcode. The Tube Tag ID barcode is located on the tube assembly.
- Touch ✔ to continue.
- **Note:** Refer to DxHub Quick Start Guide for barcode scanner setup.



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.

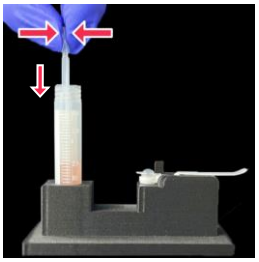
Section 3: Running the Test

- **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.**



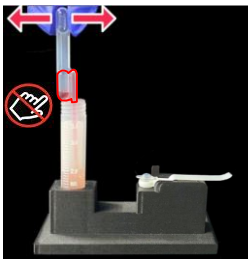
1

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



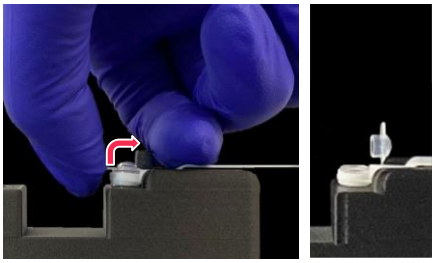
2

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



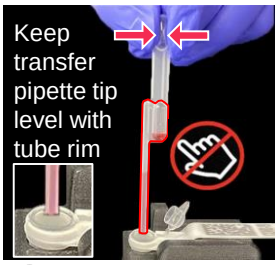
3

- 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.



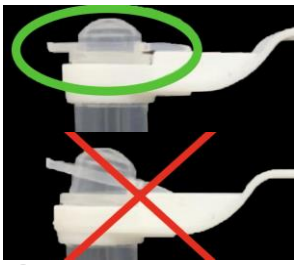
4

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



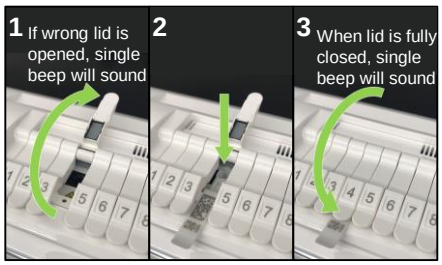
5

- 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.



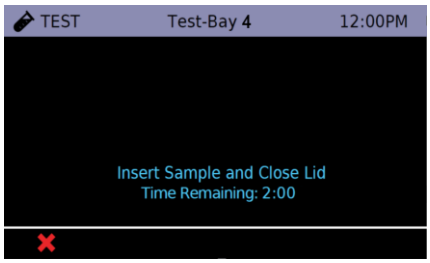
6

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



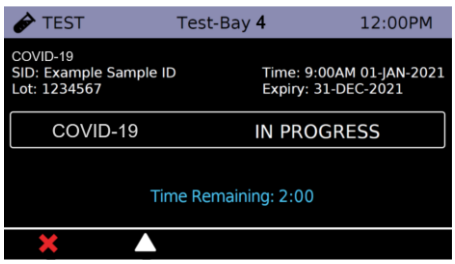
7

- (1) Open lid of test bay that was selected in Section 2, step 1, (2) insert tube assembly into test bay, and (3) firmly close test bay lid.
- 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.



8

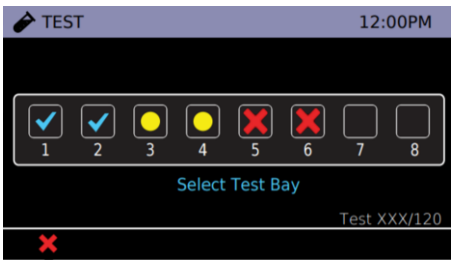
- The test will automatically start once the lid is shut.
- **Note:** Do **NOT** open the lid of the test bay while the test is running.



Two beeps will sound when a test is complete

9

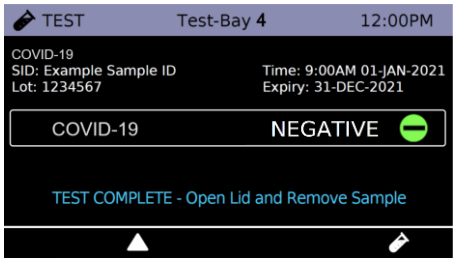
- While a test is in progress, the above screen is displayed. The test will complete in ~25 minutes.
- **Note:** Do **NOT** turn off or unplug the DxHub while a test is in progress.
- Touch the Δ icon to return to the main test screen.
- From the main test screen, you can view the result of a completed test, view the progress of a test in progress, or start a new test.



10

- ☑ Test complete: touch to view the test result. See Section 4 for possible results and interpretation.
- ● Test in progress: touch to view test in progress.
- ✖ Test cancelled: touch to view and clear test bay.
- ■ Ready for another sample: touch to start a new test, repeating Sections 1-3.
  Note: Put on **NEW** clean gloves for 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 Sections 1-3. Alternatively, touch Δ to return to the main test screen.

POSITIVE ⊕	**Positive test for SARS-CoV-2**
NEGATIVE ⊖	**Negative test for SARS-CoV-2***
INVALID !	**Test result is invalid, repeat test with new sample and new DxLab COVID-19 Test kit†**
ERROR XX !	**Device error, refer to error code in DxHub manual**
CANCELED !	**Test canceled, clear test bay to begin new test**

***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).
†**Note:** If repeat tests continue to return Invalid results, suspend testing of patient specimens. Contact DxLab Technical Support (support@dxlab.bio) for a root cause investigation.

Please refer to complete IFU for more details and guidance on result interpretation.

Please refer to the complete IFU for the intended use of this product. The IFU includes instructions for viewing and exporting previously saved results.

Storage Conditions
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.

Quality Controls
Internal Control: Each DxLab COVID-19 Test includes a built-in internal control. The internal control ensures that an adequate sample is added and the test is carried out properly through all of its stages.

External Positive and Negative Controls: DxLab Inc. recommends that a SARS-CoV-2 positive (Helix Elite™ Inactivated SARS-CoV-2 Whole Virus from Microbiologics®; Cat. No. HE0066NS) and negative (Helix Elite™ Inactivated Negative Cellularity Control from Microbiologics®; Cat. No. HE0067NS) control swab be tested:

- 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.

To test external positive or negative control swabs, refer to the DxLab COVID-19 Test Quality Control Instructions or the IFU for detailed instructions.
If any External control testing fails, repeat the test using a new External Control Swab and DxLab COVID-19 Test kit. If repeat test fails, please contact DxLab Inc. Technical Support at support@dxlab.bio for assistance before testing patient samples.

Warning
- 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; and
- 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.

DxLab

Contact us
support@dxlab.bio
DxLab Inc.
444 Somerville Ave.
Somerville, MA 02143

www.dxlab.bio

DxLab

DxLab COVID-19 Test
Quality Control Instructions

℞ Only IVD

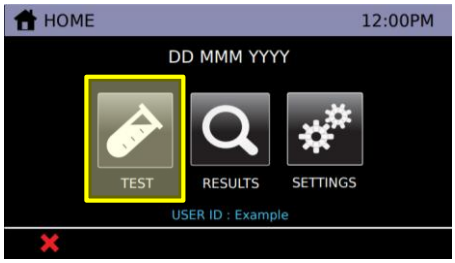
For use under Emergency Use Authorization only

DxLab Inc. recommends that BOTH SARS-CoV-2 positive (Helix Elite™ Inactivated SARS-CoV-2 Whole Virus from Microbiologics®; Cat. No. HE0066NS) and negative (Helix Elite™ Inactivated Negative Cellularity Control from Microbiologics®; Cat. No. HE0067NS) control swabs be tested:

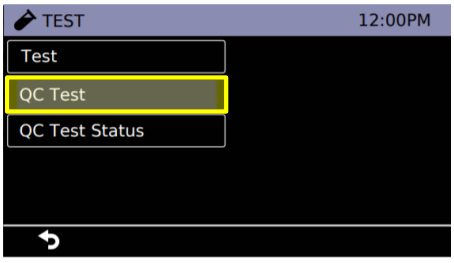
- **Once for each new lot or shipment of test kits**
- **Once for each new operator**
- **When problems are suspected or identified**
- **As required to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.**

- ➢ **Refer to the DxHub Quick Start Guide or Instructions For Use (IFU) for instrument setup.**
- ➢ **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 used tube assembly.**
- ➢ **Do NOT use a test kit that is wet or has leaked.**

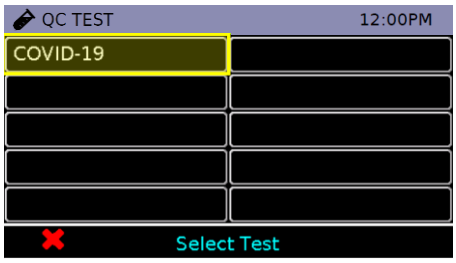
Preparing DxHub for Quality Control (QC) Testing



1. Press & hold the power button on the DxHub instrument.
   - On the touchscreen, select the "Login" icon. Login with username & password if requested.
   - To start a test, select "Test" icon.

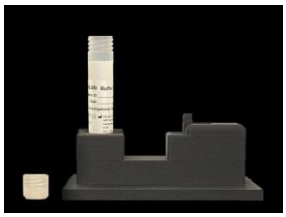


2. Select "QC Test".



3. Select "COVID-19" test.
   - Wait for the instrument to reach 66°C.
   - **Note:** Do **NOT** proceed until "Select Test Bay" is displayed on the screen.

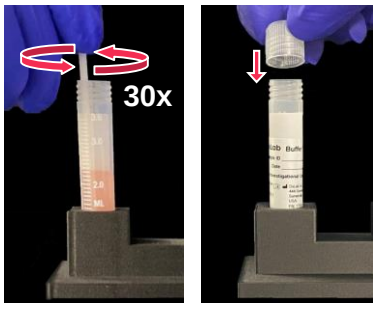
Section 1: QC Sample Preparation



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

Do **NOT** let the swab tip touch anything

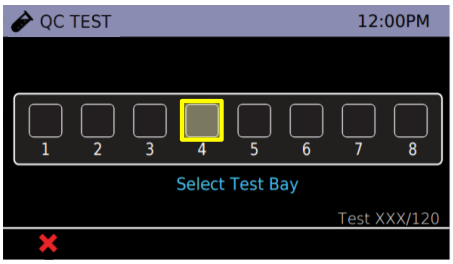
2. Open a positive (Inactivated SARS-CoV-2 Whole Virus) or negative (Negative Cellularity Control) control swab package.
   - **Note:** Only hold the swab by its handle.



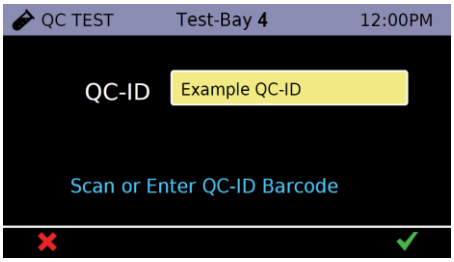
3. Insert the swab tip into the buffer tube.
   - Swirl the swab along the tube wall **30 times**. Keep the swab tip in contact with the bottom of the tube.
   - Dispose of the used swab in a biohazard bin.
   - Screw on the buffer tube cap.
   - **Note:** Colored liquid used for demonstration purposes only. **Proceed to Section 2 immediately after QC sample preparation**

Proceed to testing the QC sample **immediately** after sample preparation

Section 2: Test Preparation

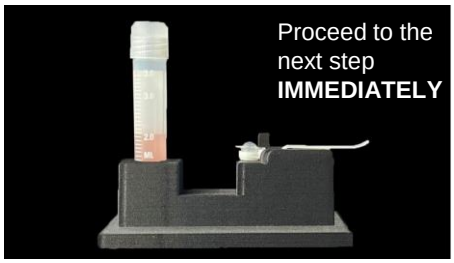


1
- The main QC test screen is shown on the DxHub touchscreen.
- Select any unoccupied test bay (empty box). #4 is highlighted for demonstration purposes.

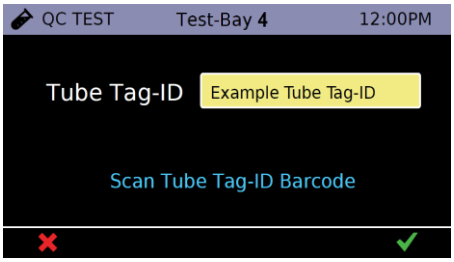


2
- Enter Sample ID by touching the yellow box next to "Sample ID" or scanning a barcode.
- Touch ✔ to continue.
- **Note:** Refer to DxHub Quick Start Guide for barcode scanner setup.

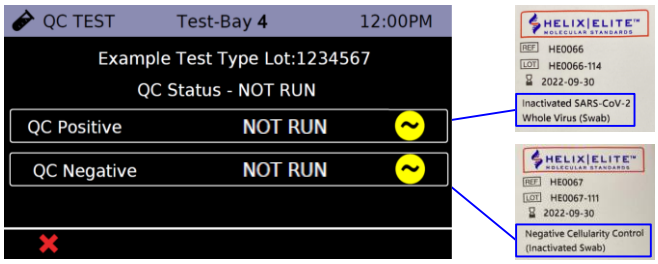
3
- Remove **ONLY** tube assembly from test pouch.
- **Note:** Do **NOT** remove transfer pipette from test pouch.
- **Note:** Do **NOT** touch the tube portion of the tube assembly.



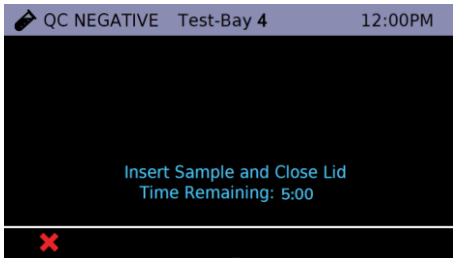
4
- Place the tube assembly in the tube holder.
- **Note:** Do **NOT** use a tube assembly that has been dropped.



5
- Scan the Tube Tag ID barcode. The Tube Tag ID barcode is located on the tube assembly.
- Touch ✔ to continue.
- **Note:** Refer to DxHub Quick Start Guide for barcode scanner setup.



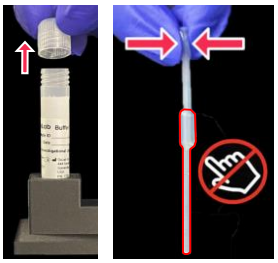
6
- Select "QC positive" if a positive control swab sample was prepared or "QC negative" if a negative control swab sample was prepared.
- The QC status for each control type is indicated by an icon on the right-hand side of the screen.
  - ✔ Passed: associated QC test has passed.
  - ✖ Failed: associated QC test has failed.
  - ~ Not Run: associated QC test has not been run.



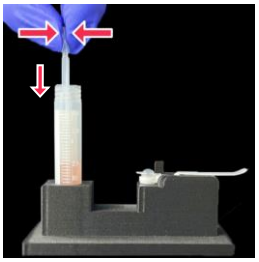
7
- You have 5 minutes to complete up to Section 3, step 8.
- If the timer expires and the DxHub times out, discard the buffer tube and the tube assembly. Return to Section 1.

Section 3: Running the Test

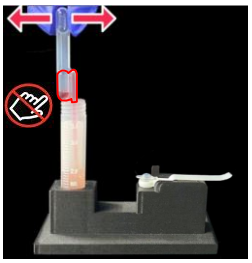
- **When handling the transfer pipette, touch ONLY the top bulb.**
- **If lower bulb or shaft of the transfer pipette is touched, dispose of all test materials (transfer pipette, buffer tube, and tube assembly) and restart the testing procedure with a new kit.**



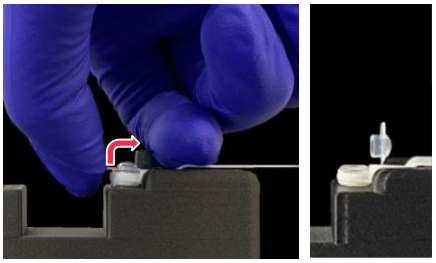
1
- Open buffer tube.
- Remove the transfer pipette from test pouch.
- Squeeze the **top bulb** until it is **fully flat**.



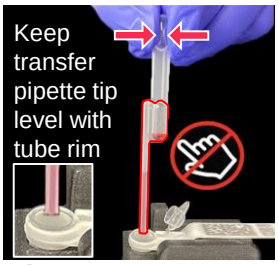
2
- **While keeping top bulb squeezed**, insert the transfer pipette tip into the buffer tube until it touches the bottom of the tube.



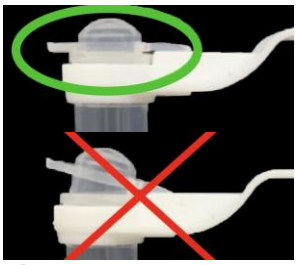
3
- Keep the tip fully under liquid and release the upper bulb to **fill the entire shaft** with liquid.
- **Note:** There should be some liquid in the lower bulb.
- **Note:** Do **NOT** invert transfer pipette.



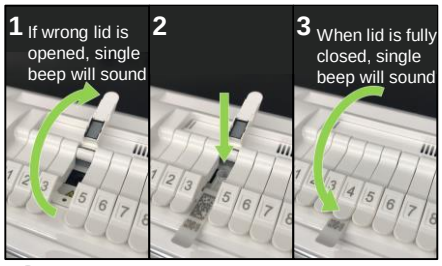
4
- Carefully flip open the cap of the tube assembly.
- **Note:** Once cap is open, sample must be added **IMMEDIATELY** (within 1 minute).



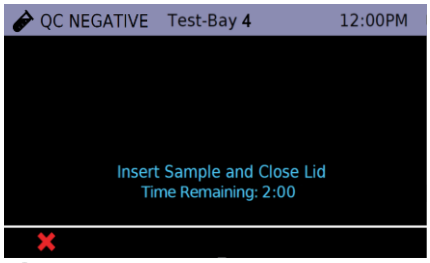
5
- Squeeze **top bulb** of transfer pipette to dispense liquid.
- **Note:** Some liquid will remain in the lower bulb.
- **Note:** Do **NOT** release top bulb.
- Dispose of the transfer pipette in a biohazard bin.



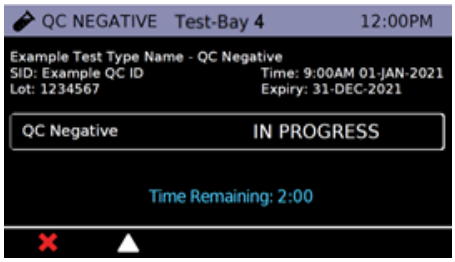
6
- **COMPLETELY** close the tube assembly cap (as shown in green circle).
- **Note:** Do **NOT** shake or tilt the tube assembly.
- Close the buffer tube.



7
- (1) Open lid of test bay that was selected in Section 2, step 1, (2) insert tube assembly into test bay, and (3) firmly close test bay lid.
- 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.

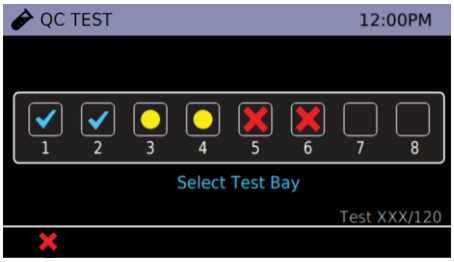


8
- The test will automatically start once the lid is shut.
- **Note:** Do **NOT** open the lid of the test bay while the test is running.



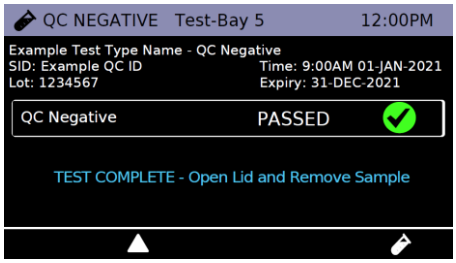
Two beeps will sound when a test is complete

9
- While a QC test is in progress, the above screen is displayed. The test will complete in ~25 minutes.
- **Note:** Do **NOT** turn off or unplug the DxHub while a test is in progress.
- Touch the Δ 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.



10
- ☑ Test complete: touch to view the test result. See Section 4 for possible results and interpretation.
- ● Test in progress: touch to view test in progress.
- ☒ Test cancelled: touch to view and clear test bay.
- ■ Ready for another sample: touch to start a new QC test, repeating Sections 1-3.
  Note: Put on **NEW** clean gloves for a new test.

Section 4: Test Results and Interpretation



- Possible test outcomes are:
  Passed ✔, Failed ✖, 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 QC test in the same test bay, repeating Sections 1-3. Alternatively, touch Δ to return to the main test screen.
- It is recommended to complete a QC test for positive control AND negative control prior to patient testing. Positive and negative control swabs can be run simultaneously in separate test bays.

PASSED ✔	**Pass** Quality control test has passed.
FAILED ✖	**Fail** Quality control test has failed. Repeat the test using a new external control swab and new DxLab COVID-19 Test kit. If repeat test fails, please contact DxLab Inc. Technical Support (support@dxlab.bio) for assistance before testing patient samples.
ERROR XX ⚠	**Device error, refer to error code in DxHub manual**
CANCELED ⚠	**Test canceled, clear test bay to begin new test**

Please refer to the complete IFU for the intended use of this product. The IFU includes instructions for viewing and exporting previously saved QC results.

Storage Conditions

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.

Warning

- 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; and
- 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.

DxLab

Contact us
support@dxlab.bio
DxLab Inc.
444 Somerville Ave.
Somerville, MA 02143

www.dxlab.bio

DxLab

DxLab COVID-19 Test
Product Information Card

℞ Only IVD

For use under Emergency Use Authorization only

Please visit the DxLab website (https://www.dxlab.bio/covid-19-test) for the current version of:

- **DxLab COVID-19 Test Instructions For Use (IFU)**
- **DxLab COVID-19 Test Quick Reference Guide**
- **DxLab COVID-19 Test Quality Control Instructions**
- **DxHub Quick Start Guide**
- **DxHub User Manual**

If you require a free printed copy or need any other support, please email us at support@dxlab.bio.

THANK YOU FOR YOUR ORDER

- 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; and
- 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.

DxLab

DxHub
Quick Start Guide

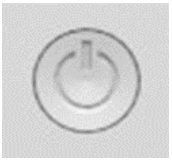
℞ Only IVD

For use under Emergency Use Authorization only

Setting Up the DxHub

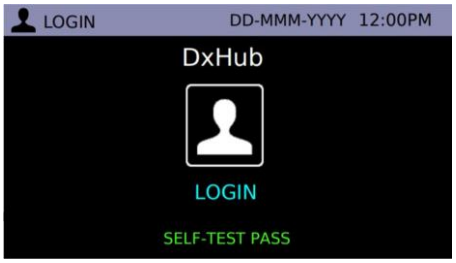
1. Unpack the DxHub and set up on a stable, level bench, in a clean environment.

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



3. Press the power button for one second to power up and start the instrument.
3. When desired, press and hold the power button for 3 seconds to shut down.

4. The loading screen will be displayed and the instrument will perform a self test.
4. If an error is found, refer to the DxHub user manual for further instruction.



5. On the DxHub touchscreen, select the "Login" icon
5. Enter username and password if requested.
5. **First-time login only:** The user will be required to login using "admin" as the default username AND password.

6. **First-time login only:** After first login using the default username and password, the user is prompted to change the password.
6. Enter a new admin password. Touch ✔ to confirm. Touch ✗ to cancel.
6. Re-enter the new admin password.

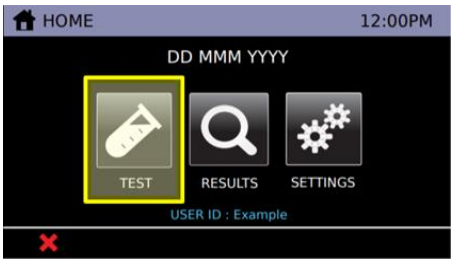
First-time Barcode Scanner Setup

Datalogic QuickScan Barcode Wand, QD2430

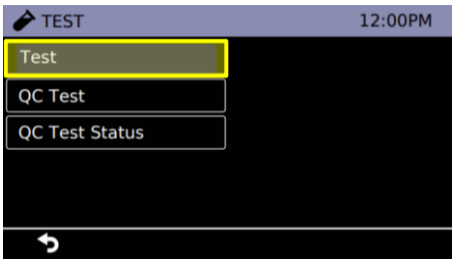
The DxHub **requires** input from a barcode scanner. The scanner is **NOT** provided with the DxLab COVID-19 Test or the DxHub and should be purchased separately. The barcode scanner will supply a character string that appears in the text box as if it was typed on the onscreen keyboard.

The recommended barcode scanner is the Datalogic QuickScan QD2430 (QD2430-BK or 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.

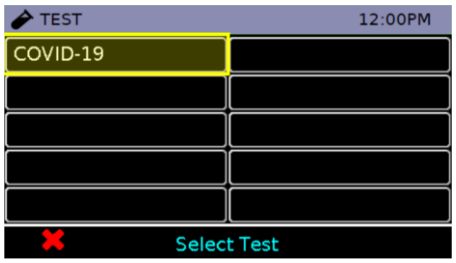
1. Plug the cable provided with the DxHub (**NOT** the cable included with the barcode scanner) into the barcode scanner handle. Connect the barcode scanner cable to the DxHub rear port.



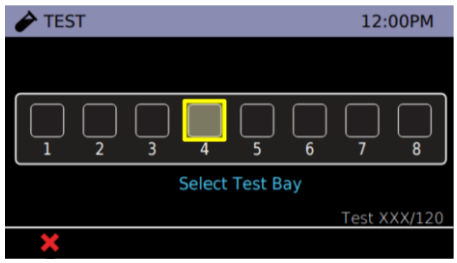
2. On the DxHub touchscreen, select the “Test” icon.



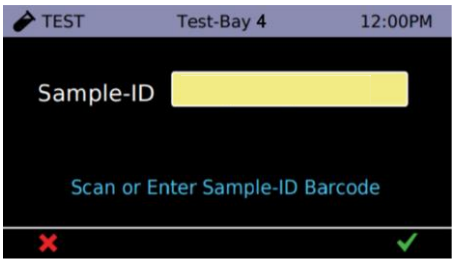
3. Select “Test”.



4. Select “COVID-19” test.
   - Wait for the instrument to reach 66°C.



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



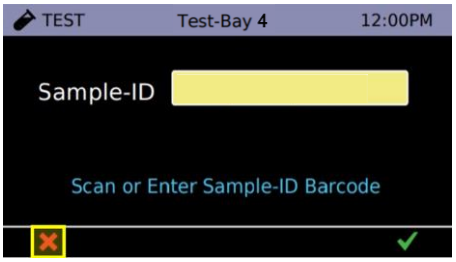
6. Once the Sample-ID screen has been reached, pick up the barcode scanner.

Reset Default Settings

7. Using the barcode scanner, scan the above barcode 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

8. Using the barcode scanner, scan the above barcode second. If scanned successfully, the scanner will generate a tone on the scan and then generate a second tone moments after. The barcode scanner is now ready for use.
   - If two tones are not heard, refer to the DxHub manual to troubleshoot.



9. Touch ✗ three times to return to the logout screen.

Warning

- 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; and
- 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.

DxLab

DxHub User Manual

REF DX0001

IVD

For Use Under Emergency Use Authorization (EUA) only

For prescription use only

Contents

1. Introduction

This document describes the setup and operation of the DxHub instrument – also referred to as "the instrument" in this user manual.

The DxHub is a portable instrument that provides measurement of fluorescence over 8 randomly accessible consumable entry ports.

DxHub Instrument

1.1 Intended Use

This instrument is intended for processing and analysis of DxLab tests, including the DxLab COVID-19 Test. This document is provided as an operational guide to describe the setup, configuration, and use of the DxHub. Please refer to the complete Instructions For Use (IFU) for a specific DxLab test.

1.2 System Components

The following system components are supplied with the instrument:

- DxHub Instrument
- Power Supply and region-specific power adapters
- Connector cable for barcode scanner
- Tube holder
- DxHub User Manual and DxHub Quick Start Guide are available on the DxLab website (https://www.dxlab.bio/covid-19-test)

1.3 Definitions

TERM	DEFINITION
ID	Identification
IVD	In Vitro Diagnostics
LAN	Local Area Network
LCD	Liquid Crystal Display

LED	Light-Emitting Diode
LIS	Laboratory Information System
PC	Personal Computer
QC	Quality Control
USB	Universal Serial Bus

2. General Information

2.1 Safety Information

The DxHub is intended to provide safe and reliable operation when used in accordance with this User Manual. If the instrument is used in a manner that is not specified in the User Manual, the protections provided by the equipment may be impaired.

The instrument is designed to operate safely under these conditions:

- Indoor use (protected from water).
- Altitude up to 2000 m.
- Ambient temperature 10°C to 30°C.
- Relative humidity 20% to 80% non-condensing.
- Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage.
- Installation Categories (Overvoltage categories) II.
- Pollution Category 2.
- Use with specified and supplied external AC/DC power adaptor only.
- Mains socket for AC/DC power pack should be readily accessible.
- Set up the DxHub on a stable, level bench, in an office or laboratory environment.
- The DxHub is not intended as a hand-held device; only operate it on a flat and level surface.
- Install the DxHub at least 100 mm from all edges.
- Install cables to prevent risk of tripping or pulling that may cause damage to DxHub or personal injury.
- The DxHub is a non-serviceable part, opening the DxHub will void the DxHub warranty.
- Ensure ferrites are fitted to USB peripheral accessories before operation with the DxHub.

2.2 Warnings

- 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.
- Hot Surface. The heater block in the DxHub may cause contact burns or damage to materials in contact with the heater.
- Always operate the DxHub on a surface that is level, dry and not exposed to direct sunlight.
- Do not move the DxHub when conducting a test.
- Do not drop the DxHub.
- Do not cover or place objects on top of or directly against the DxHub.
- Only use approved listed peripheral accessories with the DxHub.
- Do not use the DxHub in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional radio frequency sources), as these may interfere with the proper operation.

- Any changes or modifications not explicitly approved could void the user's warranty and may introduce unintended risks to the operator.
- The DxHub is designed to operate only with the provided power supply plug pack. This module forms part of the system. Do not operate the system with a different power supply module. The correct power supply is required to maintain the safety and electromagnetic compatibility of the system.
- Risk of electrical shock. Do not operate the DxHub or the power supply plug pack if it has been opened, damaged or exposed to moisture, condensation or rain. The external power supply plug pack is sealed with no user serviceable parts. Do not operate this module with any damaged or exposed parts.
- Do not open or attempt to repair the DxHub or other accessories as there is a risk of damage to the instrument. The DxHub does not contain serviceable parts and should be returned for repair. Opening the DxHub will void the warranty.
    - The Real time clock coin battery included in the equipment will run for the operational life and is not a user replaceable item.
- Only operate the DxHub for its intended purpose and in accordance with this user manual and warnings. Protection provided by the equipment may be impaired if the equipment is operated in a manner contradictory to the above. The DxHub (including power supply) is designed to operate within the manufacturer's specifications. Do not exceed the manufacturer's specifications when in use.
- Position the DxHub with clear access to connectors. Keep connected cables clear of work areas such that tripping or catching will not pull the DxHub off its workbench. The mains socket outlet intended for use with the DxHub external power pack should be located near the equipment and should be readily accessible. It is recommended that the user unplug the DxHub when not in use for extended periods.
- USB, Serial and Ethernet Interfaces. If intended for connection to external equipment, please ensure that interfaces of such equipment are separated from mains by double reinforced insulation and present no risk of electrical shock.
- In the instance of sudden power loss due to the power cable being removed or instrument power failure, a test result file will not be retained during an existing test run. The power loss will void the current test run data. All other tests previously run on the DxHub will be retained per normal.
- It is the user's responsibility to follow all diagnostic test kit instructions for use with the DxHub. Any improper use leading to test failure such as contamination, lot expiry or incorrect sample handling is the responsibility of the user and falls outside the scope of DxLab.
- The user is responsible for confirming the instrument Time and Date settings are correct before proceeding to performing any diagnostic tests. Failure to correctly set the time and date could lead to incorrectly calling a lot expiry or incorrect time and date stamp on a test result file.
- 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.
- Do not use the Sample ID or User Name fields to record the patient name or other identifiable information.

3. DxHub Instrument Specifications

Number of Tube Assemblies	Configured for 8 single tube assemblies
Data Storage	Up to 300 test results can be stored on the instrument. Up to 299 QC test results can be stored on the instrument. History Records allow search and retrieval. Archive or export via USB/ Ethernet.
Color Touch Screen	4.3-inch LCD touch screen.
Communications	USB Port for Data Export and Software Update Serial Ports (2) for Printer & Barcode reader Ethernet RJ45 Port for Network Connectivity
Export Results in CSV/PDF Format	Export CSV or PDF Result files via USB port
Power	12 V DC from external AC/DC supplied plug pack. DC Voltage fluctuation ±10% DC Current consumption: 12V DC, 3.0 Amps Power supply adaptor is configured for different regions.
Dimensions	Width 185mm (7.24") Depth 203mm (7.99") Height 115mm (4.43")
Weight	Approx. 2.3 kg (5.1 lb)
Lifetime	5 years or 10,000 single tube equivalent tests, whichever occurs first
Printer Support	Label printer connected via Serial cable. Refer to Section 14.3.
Barcode Reader	Barcode reader connected via Serial cable. Refer to Section 14.2.
Operating Environment	Indoor Use. 10°C to 30°C, 20% to 80% RH (non-condensing). 0 to 2000m altitude. Pollution degree: 2. Minimum light conditions of 100 LUX. Maximum light intensity of 5,000 LUX.
Storage Environment	2°C to 45°C, 20% to 80% RH (non-condensing)
Cleaning	Isopropyl Alcohol (IPA) or 10% bleach solution, on a damp, lint-free wipe. (No free liquid). Refer to Section 15.

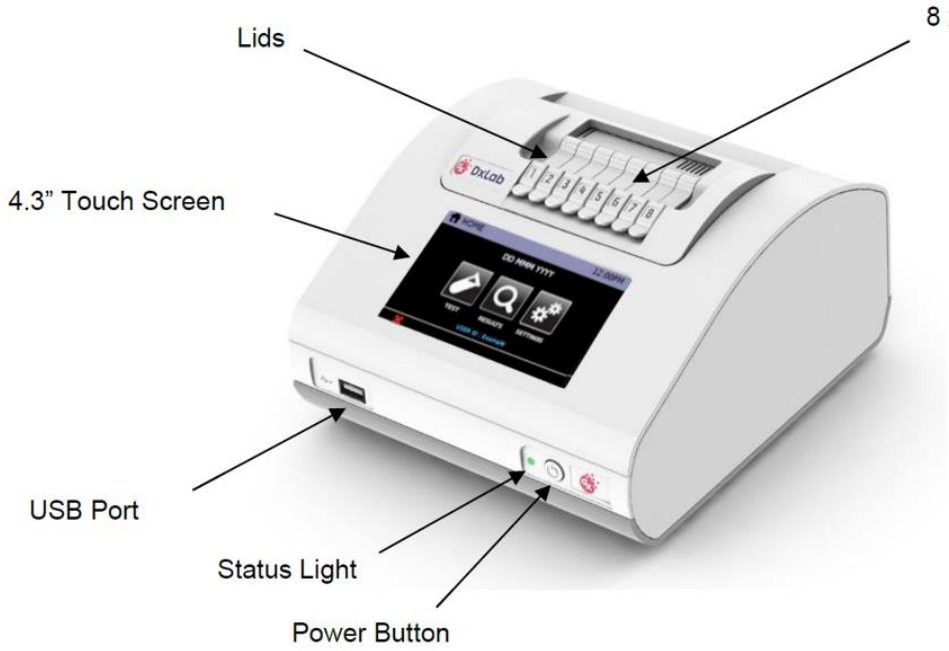
3.1 Symbols and Labels

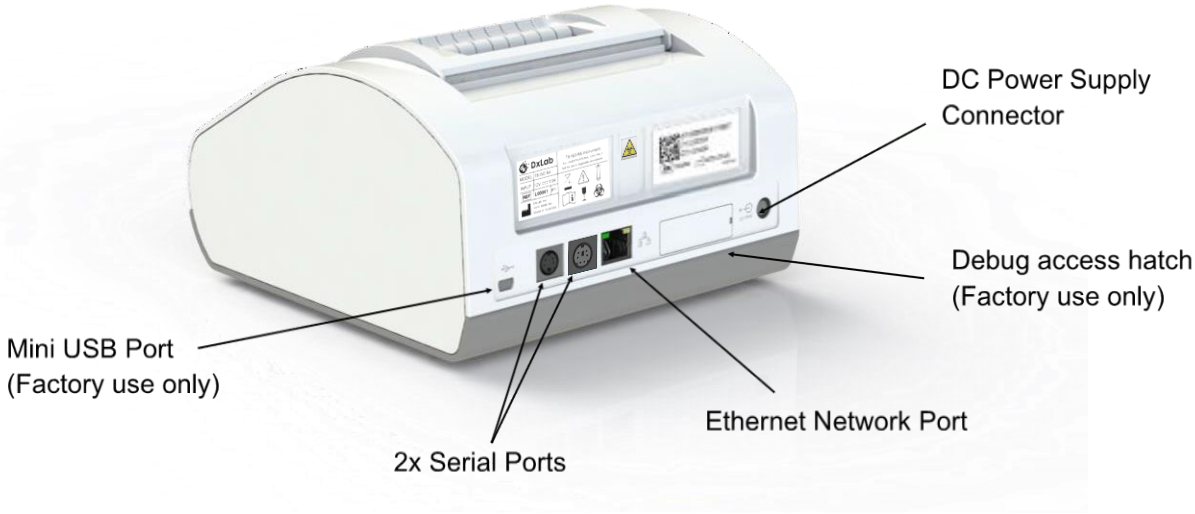
DxLab	DxLab Logo
	WEEE Directive Compliance: Waste Electrical and Electronic Equipment Directive Compliance
	Biological risk: Potential contamination with biological substances that pose a threat to the health
	Caution
REF	DxLab Reference Number
IVD	In Vitro Diagnostic Medical Device
	Fragile, handle with care
	Refer to DxHub User Manual
SN	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

3.2 Contact Information

support@dxlab.bio
DxLab Inc.
444 Somerville Ave.
Somerville, MA 02143

4. DxHub Overview





4.1 Front Status Light

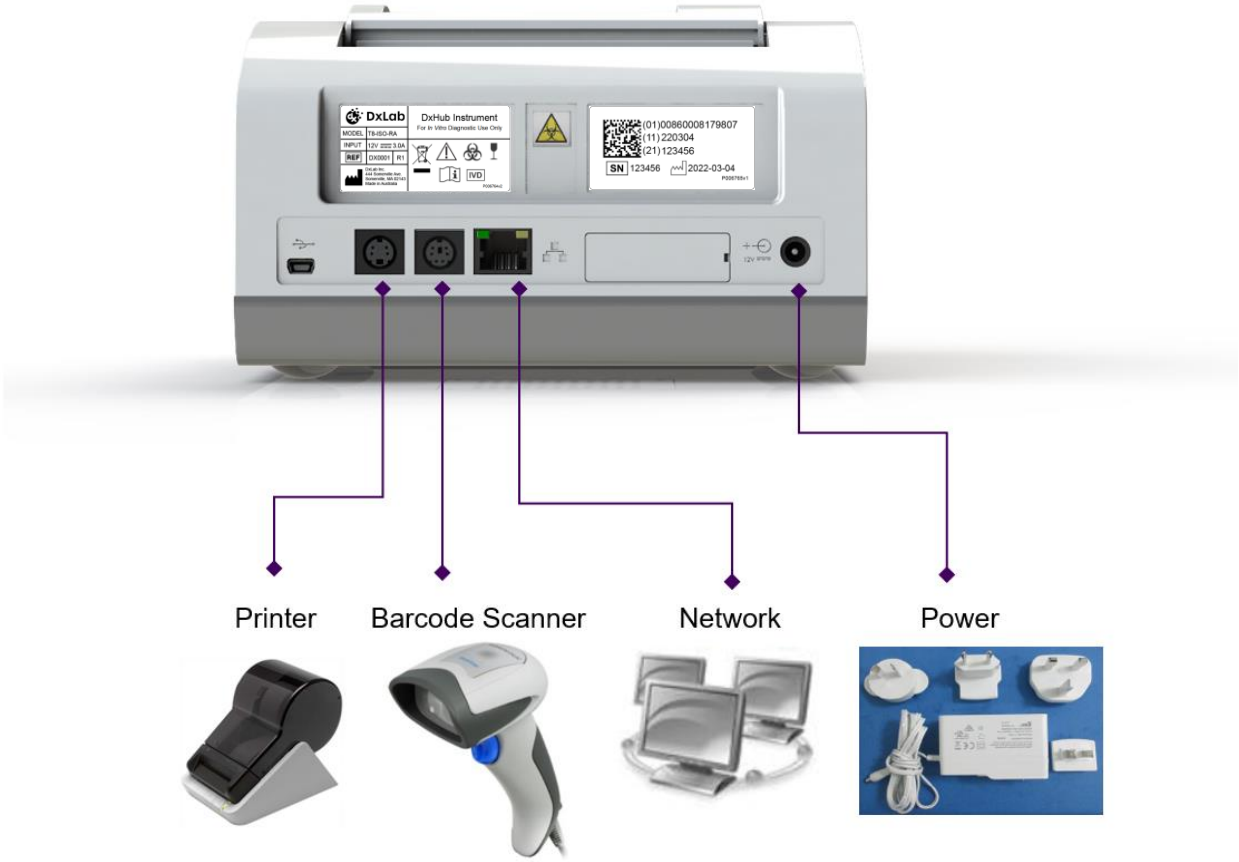
The instrument has a fixed intensity white LED on the front panel to indicate power status:

Rapid Flash	5 Hz: Instrument is in bootloader mode (shown during Instrument softwareupdates)
Medium Flash	Instrument is heating up to set temperature (approx. 2 flash per second)
Slow Flash	Instrument is in sleep mode (approx. 1 flash per 3 seconds)
On Solid	Instrument is running and at set temperature

4.2 Power Button

The DxHub instrument incorporates a front mounted power button. Once power is connected to the rear of the instrument, press the button for one second to power up and start the instrument. When the instrument is running, it can be turned off (shut down) by pressing and holding the power button for at least 3 seconds.

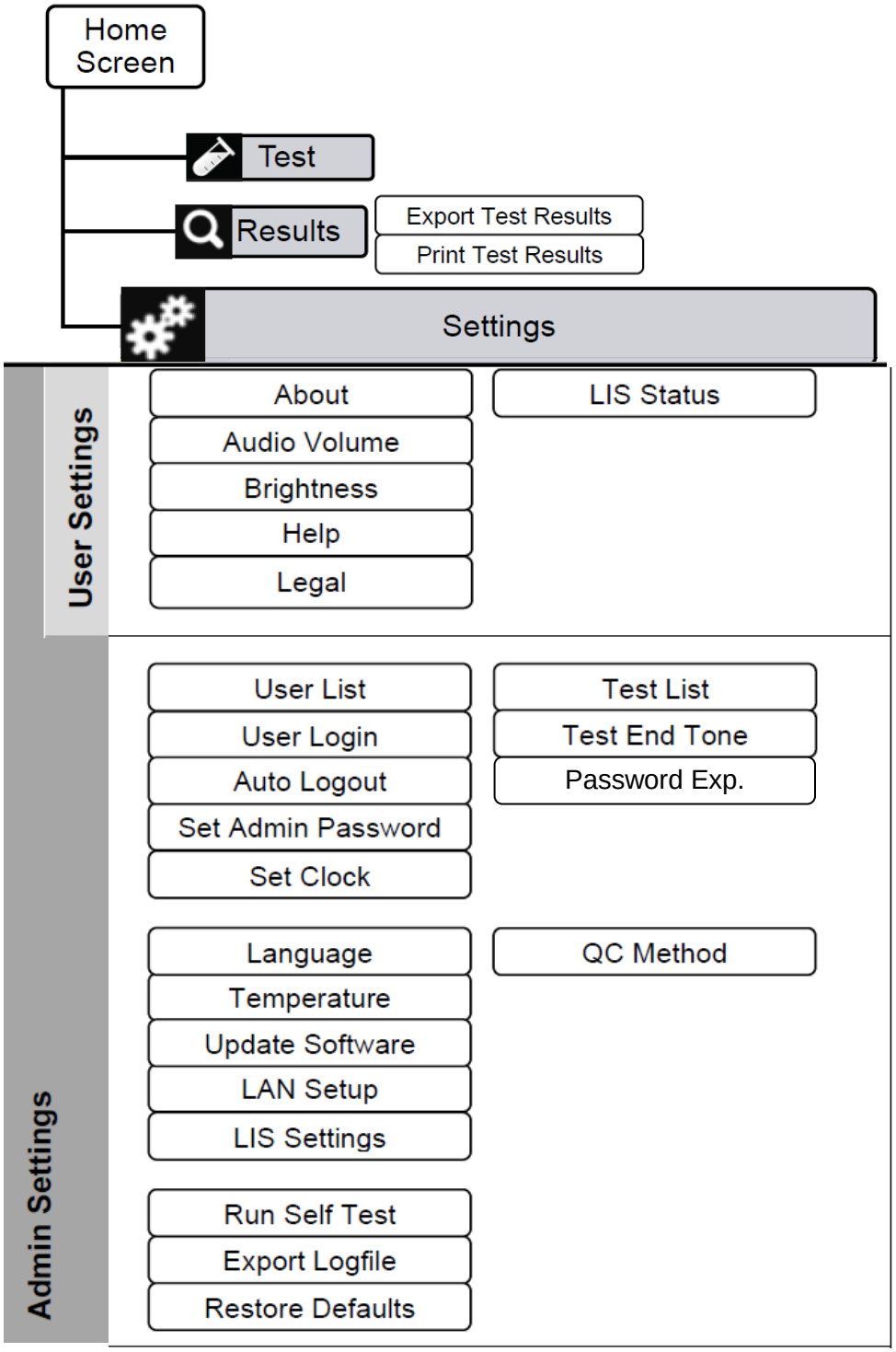
4.3 External Connections



4.4 Lids

The 8 lids are manually operated by the user, and when closed are held in place by magnets. Care should be taken not to open a lid while that test bay is running a test.

4.5 User Accessible Home Screen Menus



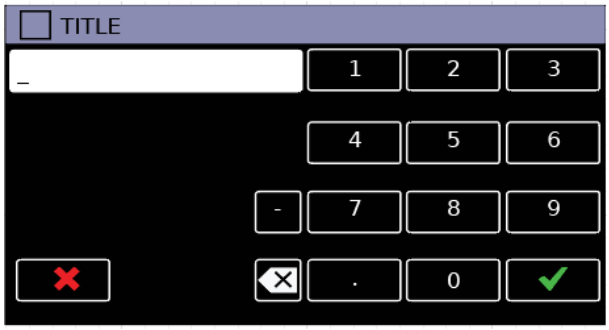
Refer to Section 6 for information on User Types and instructions on how to switch between users.

4.6 User Interface

Button: Touch the button to perform action.

Editable text: Touch the yellow text box to edit text.

If the text is a single digit, the digit will increase by 1 with each touch. If the text is a number, the numerical keypad will be displayed:



If the text is a text string, the QWERTY keypad will be displayed:

Test: Touch the Test button / icon to run a new test.

Test Results: Touch the Test Result button to navigate to the Test Results menu and access test result history.

Settings: Touch the Settings button to navigate to the settings menu.

In Standard User: Allows password input for user to change to either Admin or Factory User

In Admin User: Allows access to Admin settings menu

	**OK:** Touch the OK icon to confirm an action, input or settings change, acknowledge information or perform another action as specified by instructionson screen. The OK icon must be touched to proceed.
	**Cancel:** Touch the Cancel icon to cancel an action, input, settings change, or perform another action as specified by instructions on screen. The cancellation of an action may need to be confirmed e.g., when cancelling a running test.
	**Up / Down:** Touch Up or Down icons to navigate through screens, e.g., through alist or menu which flows over multiple screens.
	**Return:** Touch the Return icon to navigate back through screens, e.g., return to the menu screen from the selected menu option
	**Print:** Touch the Print icon to print information on screen. Printer must be connected to instrument.
	**Export:** Touch the Export icon to export test result or other content as specified by instructions on screen. An FAT32-formatted USB key must be connected to instrument.
	**Import:** Touch the Import icon to import test packages or other content as specified by instructions on screen. An FAT32-formatted USB key must be connected to instrument.
	**Error:** An error screen is displayed when an action could not be completed, e.g., a test could not be completed, USB key was not found, or the self test was failed. Touch the ✓ icon to acknowledge the error.
	**Warning:** A warning screen is displayed when confirmation of an action is required e.g., user cancels a test in progress. Touch the ✓ icon to confirm the action. Touch the ✖ icon to cancel the action.
	**Information:** An information screen is displayed to notify the user of information, e.g., export was successful. Touch the ✓ icon to acknowledge the information.

5. Setup

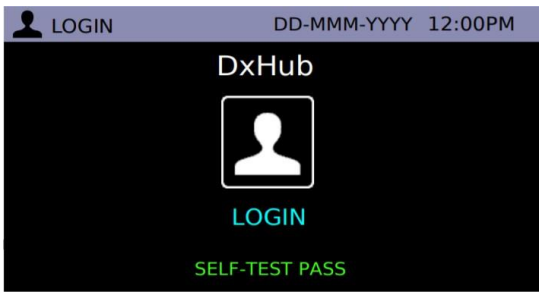
Unpack the DxHub and set up on a stable, level bench, in a clean environment.

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 Section 5.1.



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.

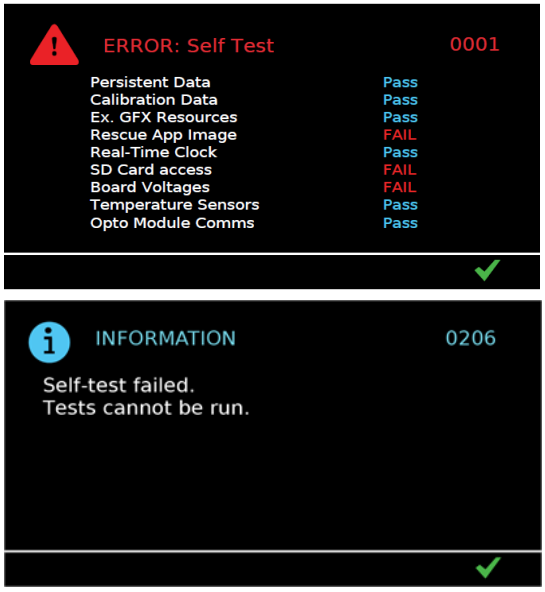
Enter a new admin password. Touch ✓ to confirm.

Touch ✘ to cancel.

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

Touch ✘ to cancel.

5.1 Self Test (only shown if error is found)



The instrument runs a self test sequence at startup. If all tests pass, the instrument will automatically load to the “User Login” screen (above).

In the event of an error:
If the self test identifies a fault an error screen is displayed. Click the ✓ icon to acknowledge self test results.

Some errors will allow the user to continue to use the instrument with limited functionality. The user will not be able to run tests if doing so in the presence of the fault puts the test at risk.
If the error persists and use of the instrument is impaired, contact support@dxlab.bio for servicing.

6. User Types

6.1 Standard User

The standard user has access to the home menu, testing, results review and basic settings. The standard user can:

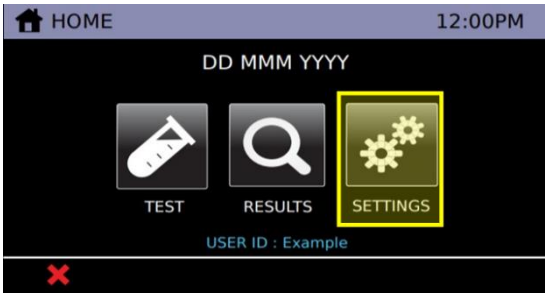
- Run a test.
- Review results.
- Print a single result.
- Export results to a USB key.
- View the DxHub "About" information.
- Adjust the DxHub's audio settings.
- Configure the LCD screen brightness level.
- Review the DxHub "Help & Legal" information.
- Review the LIS Status.

6.2 Admin User

The admin user has access to the same functionality as the standard user as well as access to the "Admin Settings" screens.
The admin user can:

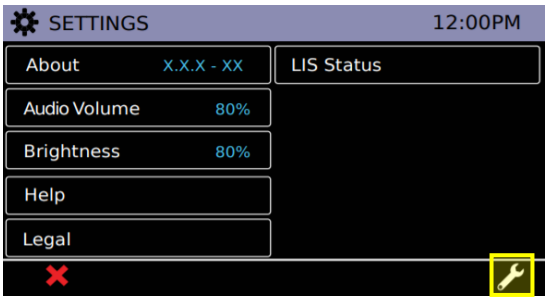
- Create and import 'User Lists' and login settings.
- Configure Password Expiry.
- Configure Test End Tone behavior.
- Export results to a USB key and delete the results at completion of export.
- Change the time and date.
- Import test types onto the DxHub.
- Change language settings.
- Review instrument temperatures and set default start-up temperature.
- Update the instrument software.
- Configure LAN setup.
- Review and adjust LIS Settings.
- Configure QC method.
- Return the DxHub to default settings.
- Run a Self-Test to check instrument functionality.
- Export instrument log file.

6.3 Changing User Types



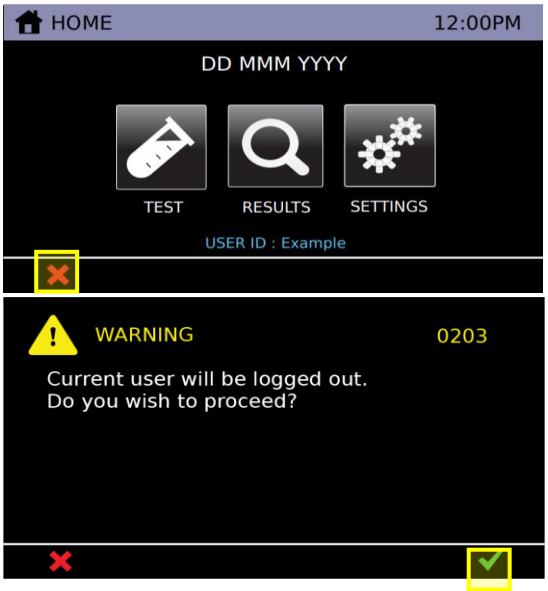
Login to Admin Users:

Select the settings icon on the home screen.



Select the  icon to enter a password.

*"**admin**" is the default password for access to Admin mode.*
The instrument will require the user to update the admin password upon first successful login as an admin user.



Logout:

Logout to return to Standard User mode.

Logout by selecting the ✘ icon on the homescreen.

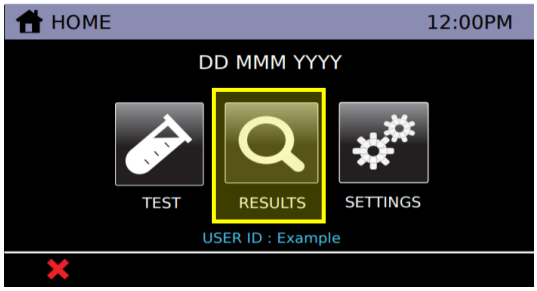
Touch the ✓ icon to confirm logging out.

7. Running a Test and Results History

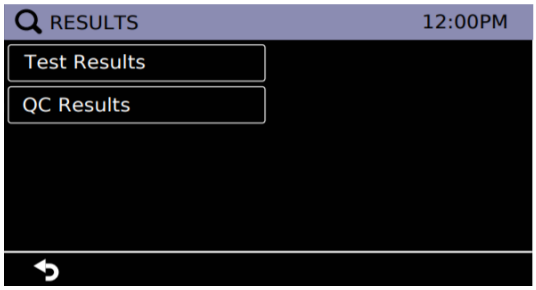
7.1 Running a Test

Refer to the complete Instructions For Use (IFU) for a specific DxLab test to run the diagnostic test with the DxHub.

7.2 Results List Menu



Touch the "Results" icon on the Home Screen.

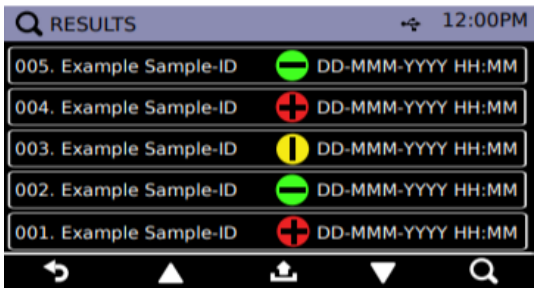


The Results History menu contains the following results:

- Test results
- QC Results*

* This option will not be available in this menu if “None” is selected for QC Method.

Select a test category to view saved results



A summary list of all test results saved in the instrument memory is displayed in order of newest to oldest. The following information is displayed:

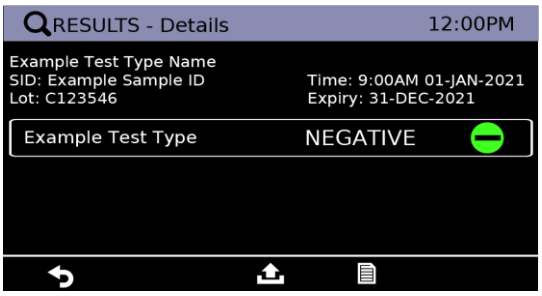
- Test ID (as entered by the user at the time of running the test)
- Test Date and Time

Touch ▼▲ to navigate through the “Results” screens. Touch a test result in the list to view detailed test result. Refer to Section 7.3 for details.

Touch Export icon to export all results to a USB key. Refer to Section 7.4 for details of exporting test results to a USB key.

Touch the Search icon to search for specific test results. Refer to Section 7.5 for details.

7.3 Detailed Test Results



Touch Export icon to export this particular result to a USB key. Refer to Section 7.4 for details of exporting test results to a USB key.

Touch Print icon to print this result via an attached label printer. Refer to Section 7.6 for details on result printing.

Touch the icon to return to previous screen.

7.4 Export Results

Test Results and Data Archive Recommendation: It is highly recommended that test results are exported to an external USB Key and that this data is stored separately from the instrument as a backup.

The results from each test on the instrument can be exported as:

- A single result summary .pdf file, which contains the final results and corresponds to the printed results page
- (Admin user only) A single result .rdf file, which is an encrypted data file that contains the test parameters, measured data and final result

A user can export individual test results or all test results on the instrument.

An admin user can delete all tests on the instrument at the completion of a successful export.

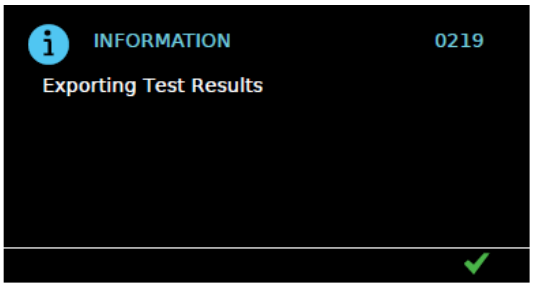
7.4.1 Export Result Process

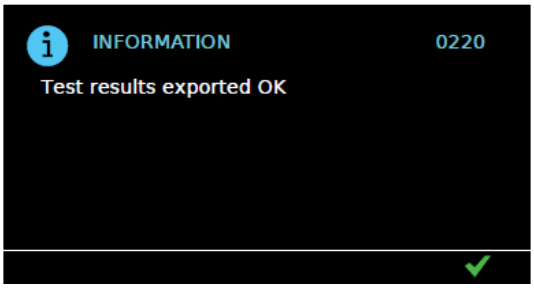
Insert USB key

Insert a FAT32 formatted USB flash memory key into the USB port of DxHub.

Touch the ✓ icon to export results.

Touch the ✘ icon to cancel.

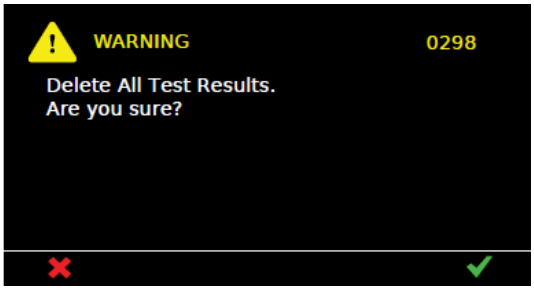




Export Success

Test results were successfully exported to the connected USB key.

Touch the ✓ icon to acknowledge.

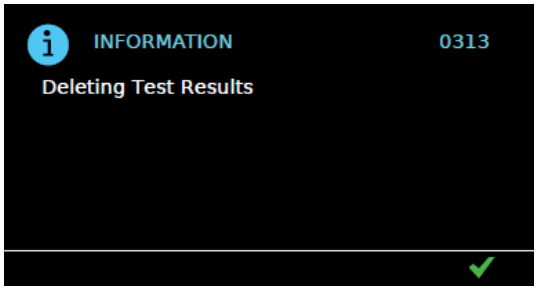


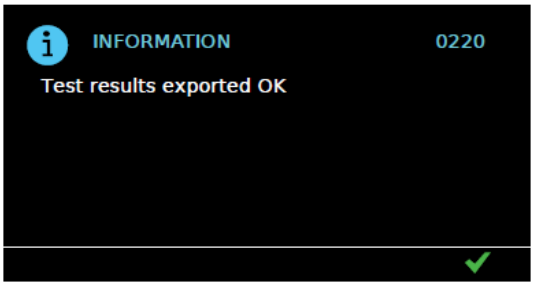
Delete Results

If logged in as Admin User, an additional screen asks if you wish to delete all test results in the instrument's test result history.

Touch the ✓ icon to confirm removal.

If you want to retain the test results on the instrument, touch the ✖ icon.

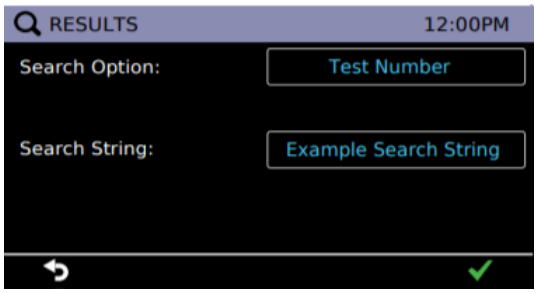


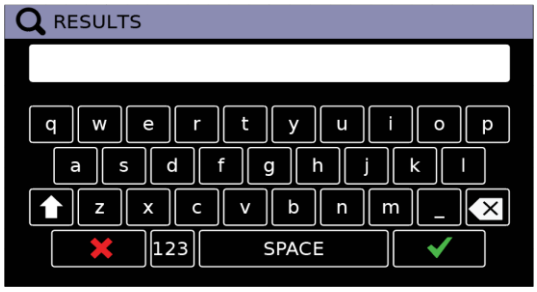


Results Deleted

If the ✓ icon was selected on the previous screen, this message will indicate that the instrument's test result history was successfully deleted.

7.5 Search Results





Touch the Search icon on the "Results" screen to access the search function.

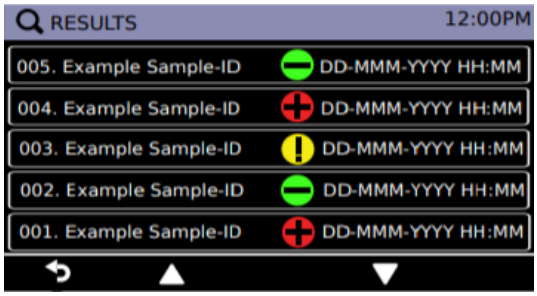
Touch the 'Search Option' button to cycle through the search options available:

- Show All – will return to the "Results" screen and show a list of all test result files.
- Test Number/QC Test Number – to search by test numbers.
- Test Sample-ID/QC-ID – to search by Sample-IDs only
- Test Positive – to show positive results only
- QC Lot Number – to search by Lot Number only

Touch the 'Search String' button to enter a search term. After selecting the Search String Box, a keyboard input screen will appear. Field allows for 20 alpha-numeric characters input.

Note: 'Test Positive' is not a search option for QC Results

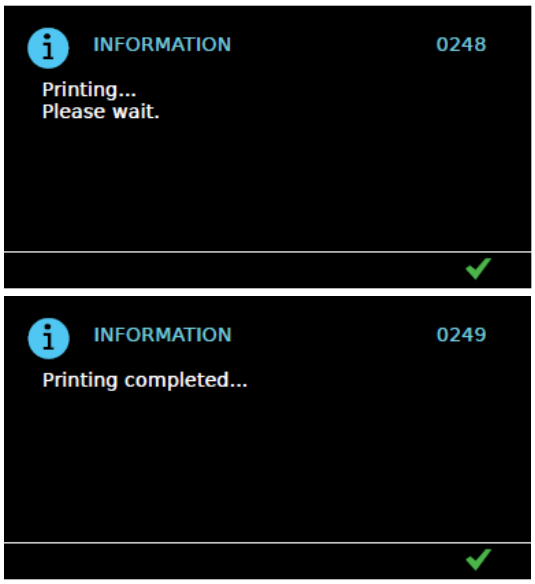
Note: 'QC Lot Number' is not a search option for 'Test Results'



After a search parameter is entered, a new "Results" screen will appear, displaying all matches found within the specified search criteria. User may click on the specific test to view detailed results and have the option to export the found results.

Selecting the return icon will return to the original "Results" screen that shows all test results.

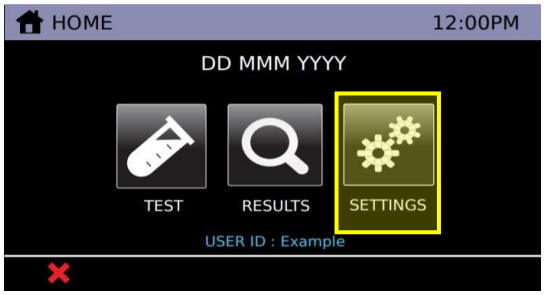
7.6 Print Results

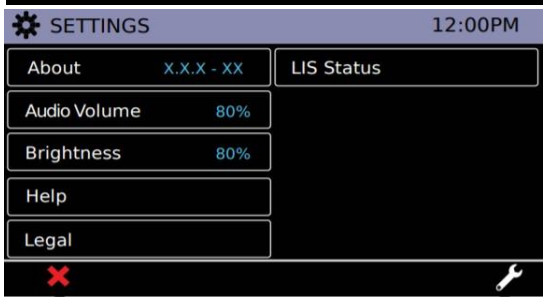


For a selected result, a result summary can be printed.

Printer must be connected to the printer port at the back of the instrument. Refer to Section 14.3 for details on the label printer.

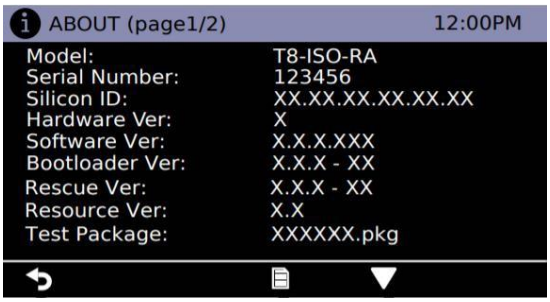
8. Settings

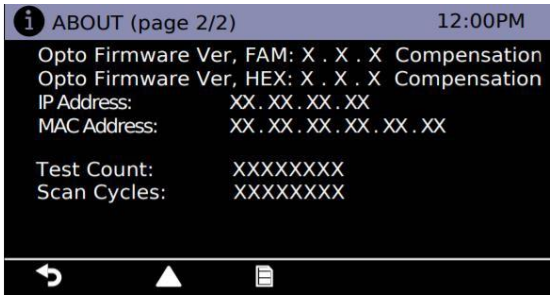




The “Settings” menu is available to all Users. Touch the Settings icon on the “Home Screen”. Touch a menu button to navigate to that item.

8.1 About Screen





The “About” screen provides instrument configuration information, including:

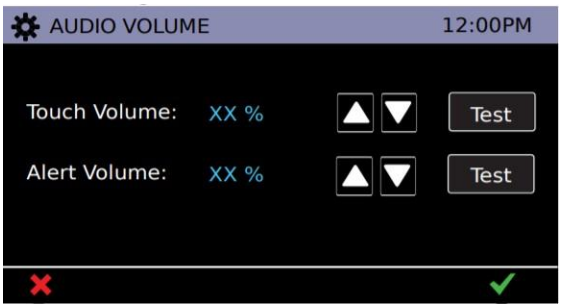
- Model
- Serial Number
- Silicon ID
- Hardware Version (Ver.)
- Software Version
- Bootloader Version
- Rescue Version
- Resource Version
- Test Package
- FAM/HEX Optical Module Firmware (Compensation or Not)
- IP Address
- MAC Address
- Test Count
- Scan Cycles

Touch the ▲▼ icons to navigate between screens.

Touch the icon to print the information (refer to Section 14.3).

Touch the icon to return to the “Settings” menu.

8.2 Audio Volume



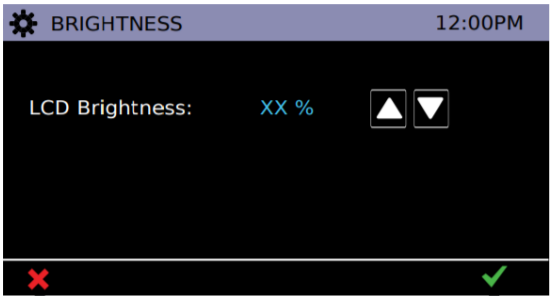
Touch the ▲▼ icons to adjust volume levels.

Touch the "Test" icons to play a test sound.

Touch the ✓ icon to save the settings for this current session.

Touch the ✖ icon to cancel.

8.3 Brightness



Touch the ▲▼ icons to adjust LCD screen brightness.

Touch the ✓ icon to save the settings for this current session.

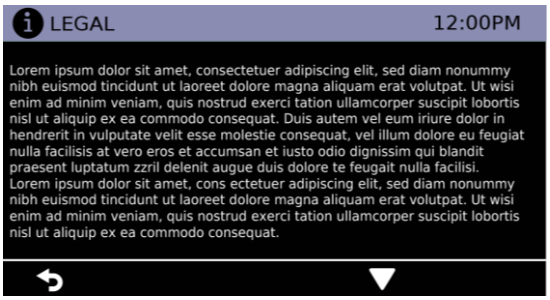
Touch the ✖ icon to cancel.

8.4 Help

DxLab contact information is provided:

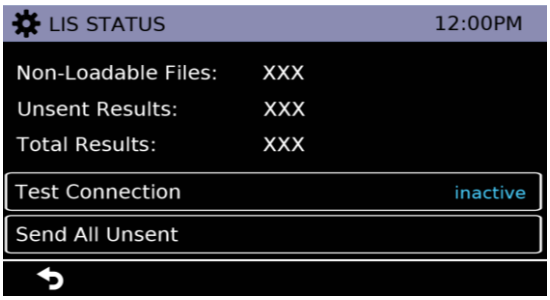
www.dxlab.bio
support@dxlab.bio
Copyright information is also displayed.

8.5 Legal



This page contains the software licensing and legal information.

8.6 LIS Status



To view transmission data statistics with the LIS Server, select the 'LIS STATUS' option from the settings menu.

The categories shown are:
- Unsent Results (results not yet sent to LIS)
- Total Results (total number of results in instrument memory)

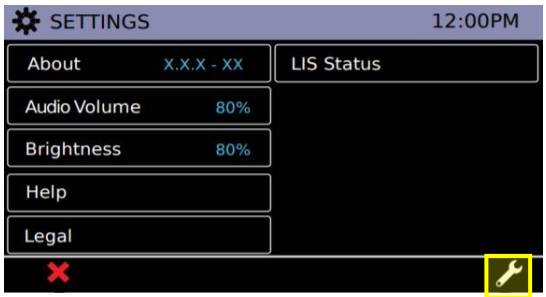
"Test connection" functions identically to the same in the LIS Setup menu. Refer to Section 9.11 for further information.

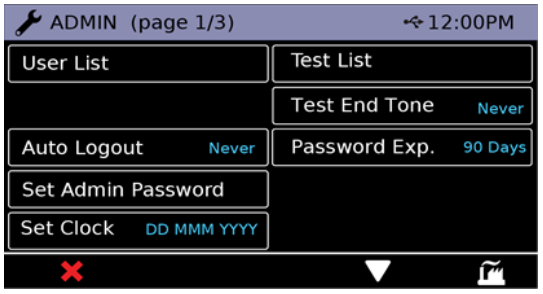
The 'Send All Unsent' option performs an immediate transmission to the LIS of all unsent test results. During transmission, a ✘ icon will appear on the bottom right corner of the screen. This will allow the user to stop the current transmission and leave the remaining results as unsent.

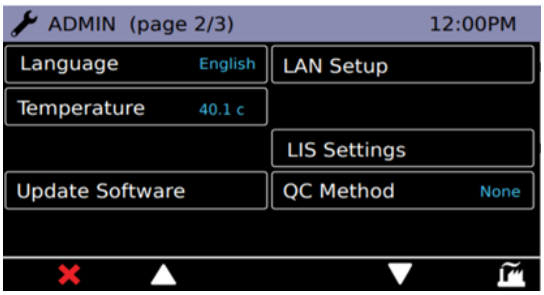
When sending the results, the unsent result count will reset to 0 as all previously unsent results have been sent to the LIS server.

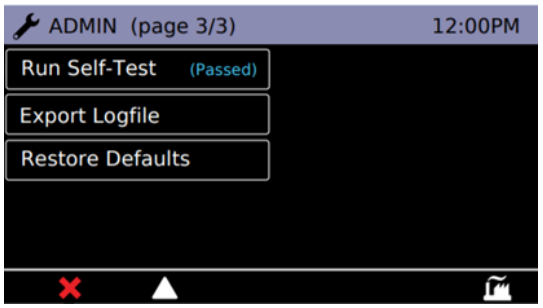
9. Admin Settings

*"**admin**" is the default password for access to Admin mode. The instrument will require the user to update the admin password upon first successful login as an admin user.*









Admin settings are available to Admin Users.

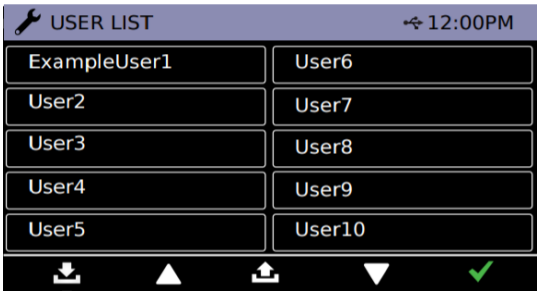
Navigate to the Admin Settings by touching the icon on the "Settings" screen.

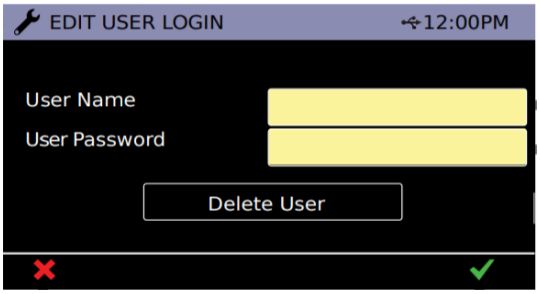
Touch a menu button to navigate to that item.

Touch the ▲▼ icons to navigate between screens.

Touch the ✖ icon to return the basic settings menu.

9.1 User List





Touch the "User List" button on the Admin Settings page to delete users or add or edit users and passwords.

Touch ▼▲ to navigate through the User List screens.

Touch the Import icon to import a user list from a USB device.

Touch the Export icon to export the user list to a USB device.

To make changes, touch a user name. Edit the user name or password by typing in the yellow fields.

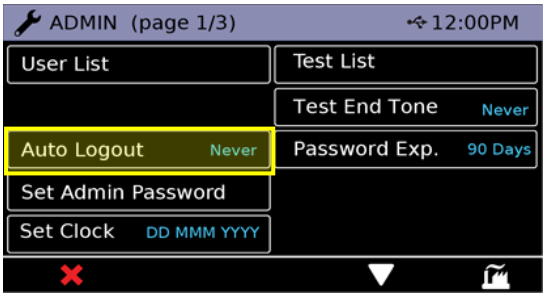
Note: Do NOT use the User Name field to record the patient name or other identifiable information.

Touch the "Delete User" button to delete that user.

Touch ✓ to confirm settings or ✖ to cancel.

Duplicate user names cannot be entered.

9.2 Auto Logout



Touch the "Auto Logout" button on the Admin Settings page to scroll through logout settings. Touch button repeatedly to switch between the following options:

- Never: the instrument will not auto logout.
- 5 mins: Auto logout after 5 minutes idleness.
- 10 mins: Auto logout after 10 minutes idleness.
- 30 mins: Auto logout after 30 minutes idleness.
- 60 mins: Auto logout after 60 minutes idleness.

9.3 Set Admin Password

Touch the “Set Admin Password” button on the Admin Settings page to update the administrator password.

Enter a new admin password.

Touch ✓ to confirm.

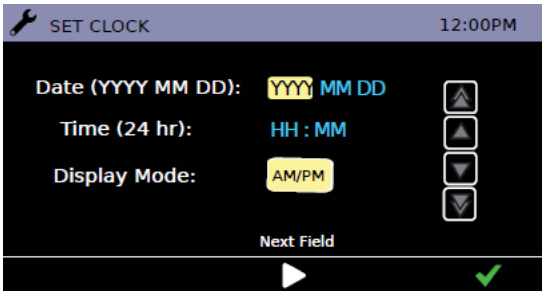
Touch ✖ to cancel.

Re-enter the new admin password.

Touch ✓ to confirm.

Touch ✖ to cancel.

9.4 Set Clock



Touch the “Set Clock” button on the Admin Settings page to configure the instrument time and date.

Touch ▲▼ to adjust selected value.

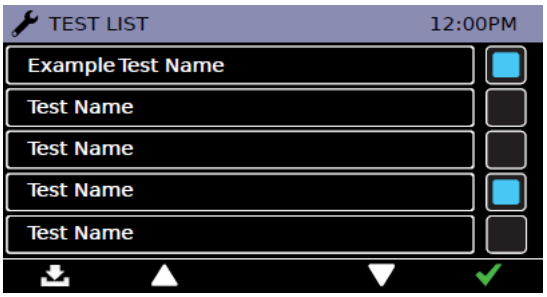
Touch ▲▼ to adjust in increments of 5.

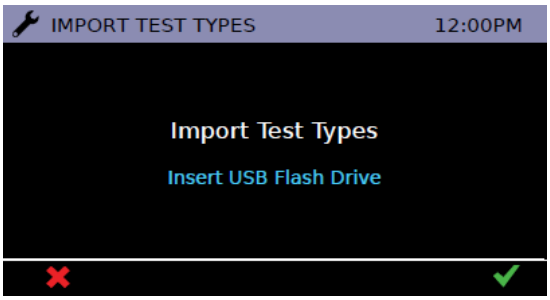
Touch ▶ to move to the next field.

Touch the “Display Mode” button to select 24-hour (24 hr) or 12-hour (AM/PM) time format.

Touch ✓ to confirm setting.

9.5 Test List





Touch the “Test List” button on the Admin Settings page to manage the test types loaded on the instrument.

Touch the ☐ icons to enable or disable test types. Enabled test types will be available to all users in the “Test” menu.

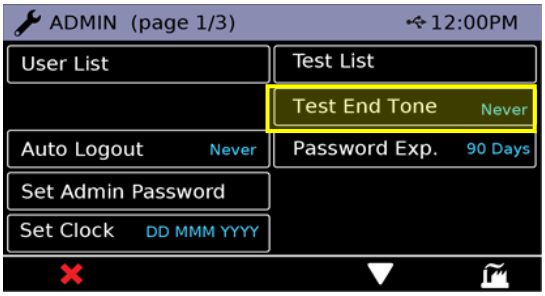
Touch ▼▲ to navigate through the “Test List” screens.

Touch ✓ to confirm setting.

Touch the Import icon to import the Test List from a USB device.

Touch ✓ to confirm setting.

9.6 Test End Tone



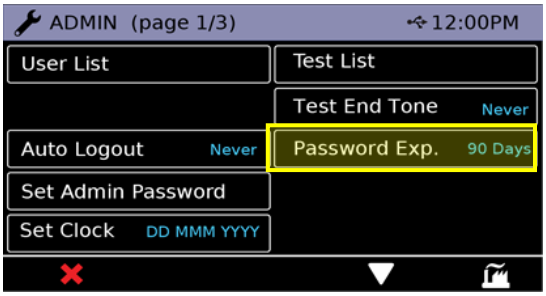
Touch the “Test End Tone” button to scroll through End Tone settings. Touch button repeatedly to switch between the following options:

- Never: the instrument will not sound a tone at the completion of the test

- Single: The instrument will sound a tone at the completion of each test bay

- Batch: The instrument will sound a tone at the completion of all currently running test bays.

9.7 Password Expiry



Touch the “Password Exp.” button to scroll through the password expiry times. Touch button repeatedly to switch between the following options:

- Off: the instrument will not require standard users to periodically change their password.

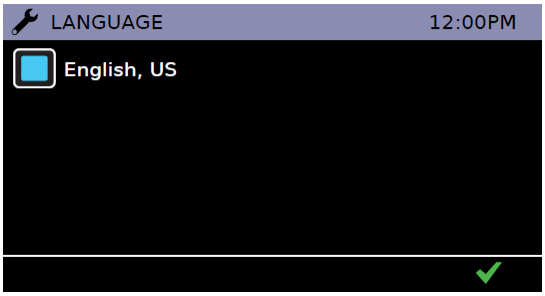
- 30 Days: the instrument will require standard users to change their password every 30 days.

- 60 Days: the instrument will require standard users to change their password every 60 days.

- 90 Days: the instrument will require standard users to change their password every 90 days

- 120 Days: the instrument will require standard users to change their password every 120 days

9.8 Language



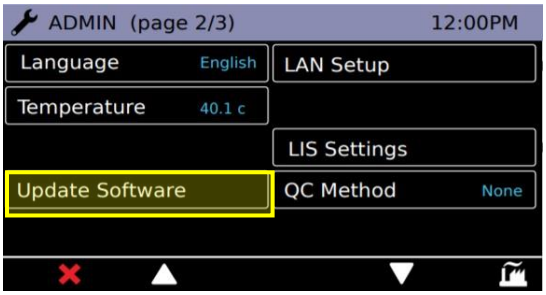
Touch the “Language” button on the Admin Settings page to manage the language for the instrument.

Touch the ▣ buttons to select language.

The instrument will reboot if the language is changed.

Touch ✓ to confirm setting.

9.9 Update Software



Insert a USB device with the software PKG file.

Touch the “Update Software” button in admin settings.

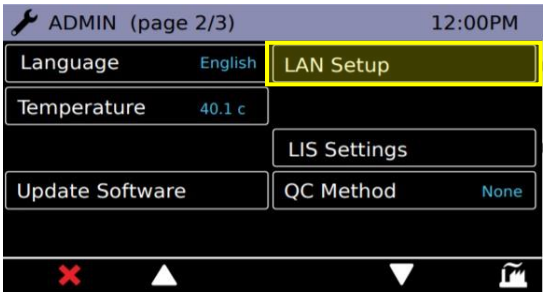
Touch ✓ to confirm new software update.

The instrument will load the new software and reboot.

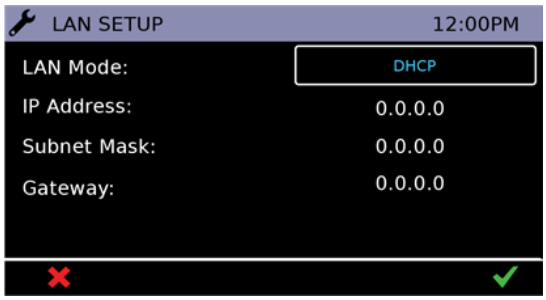
Touch ✗ to return to settings menu.

Refer to Section 12 for detailed software update process description.

9.10 LAN Setup

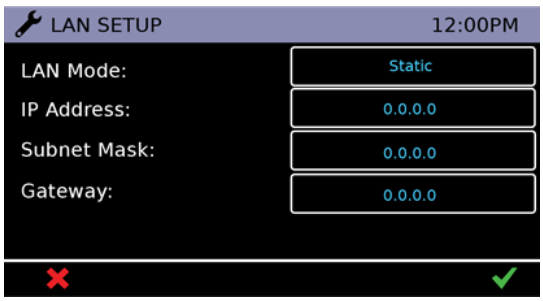


The user can configure a Local Area Network using a connected Ethernet cable on the rear port of the instrument.



The User can toggle between ‘DHCP’ or ‘Static’ type connections based on the network settings.

In general, the typical mode will be DHCP, where the network is allocating the IP address and related settings for the instrument to use.



If the user wishes to manually set and configure all network settings, the ‘Static’ mode enables all fields to be edited.

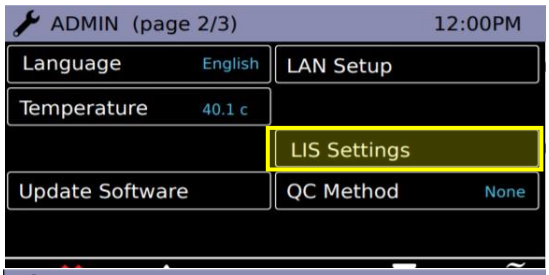
Toggling to the ‘Disabled’ option will disable the Network function altogether.

Touch ✓ to confirm settings.

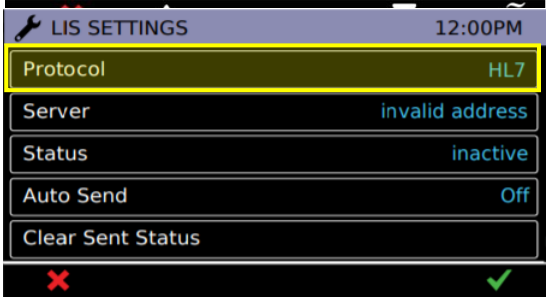
Touch ✗ to exit without saving updated settings.

9.11 LIS Settings

Note: Only operate the DxHub instrument on wired network interfaces on trusted networks that have a properly configured firewall in place.



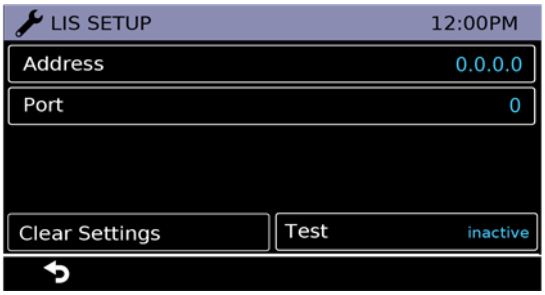
To set up the DxHub for LIS communications, select the 'LIS Settings' button.



The protocol has the following toggle options:

- None: the instrument will not communicate via a LIS
- HL7: the instrument will communicate to a connected LIS using the HL7 protocol

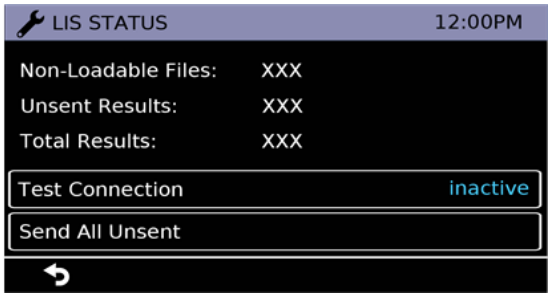
Note: If protocol is 'none' then only protocol button is visible



Touch the "Server" button on the LIS Settings page to enter LIS server details.

Setting up communications to the LIS Server requires knowledge of the server credentials. Contact your IT provider to acquire the IP Address, Port Number, and User Credential details of the LIS Server to be used.

The Port Number must lie between the range 49152 – 65535.



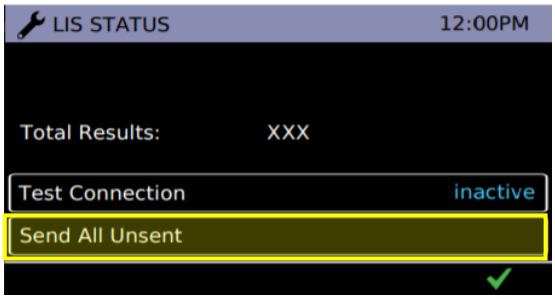
To view transmission data statistics with the LIS Server, touch the "Status" button on the LIS Settings page.

The categories shown are:

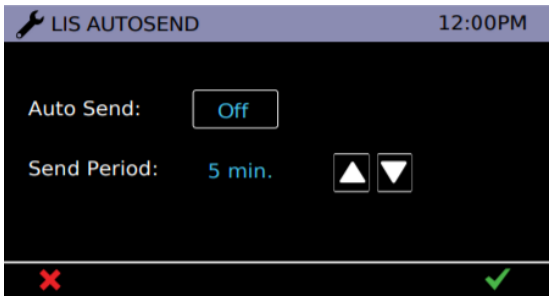
- Non-Loadable Files: displays the number of files that cannot be sent via LIS due to file corruption
- Unsent Results: displays number of test results not yet sent to LIS
- Total Results: displays total number of results in instrument memory

To Test the connection between the instrument & the LIS Server, run the 'Test Connection' option. One of three states will be displayed:

- Pending: Test Connection not yet run
- Success: Instrument successfully connects to LIS
- Failed: Instrument failed connection with LIS
-



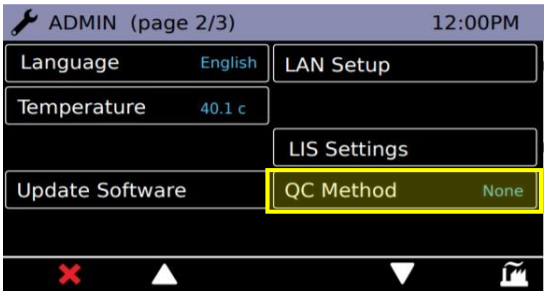
The 'Send All Unsent' option performs an immediate transmission to the LIS of all unsent test results. During transmission, a stop button (✘) will appear on the bottom right corner of the screen. This will allow the user to stop the current transmission and leave the remaining results as unsent. When sending the results, the unsent result count will reset to 0 as all previously unsent results have been sent to the LIS server.



Touch the "Auto Send" button on the LIS Settings page to configure when the Instrument will automatically attempt to send results to the LIS Server. When the period elapses, all unsent results will be sent to the LIS Server.

Touch the "Auto Send" button on the LIS Autosend page to toggle the Auto Send feature On or Off.
Touch the ▼▲ icons to set the period between results sending. This can be set from 1 min to 30 mins.
Touch the ✓ icon to confirm the applied settings.
Touch the ✘ icon to exit without saving applied settings.

9.12 QC Method



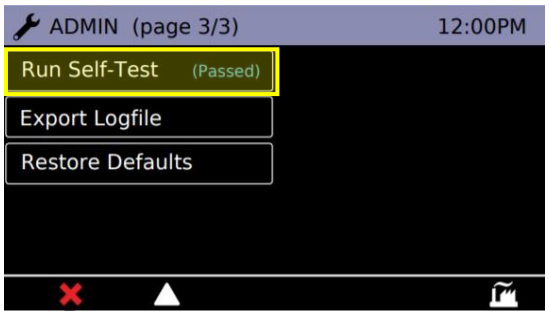
Touch the "QC Method" button to cycle through the following options:

-Warning: Upon test attempt, warning will be displayed if the QC Test Status is set to 'fail' or 'due'. (Default)

-Lockout: Testing will be locked out if the QC Test Status is set to 'fail' or 'due'.

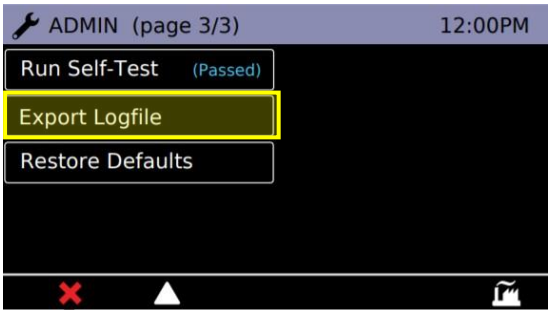
-None: QC Test Status does not affect testing availability. QC Test option is hidden from Test Menu.

9.13 Run Self-Test



Touch the "Run Self-Test" button to run the instrument self test.

9.14 Export Log File

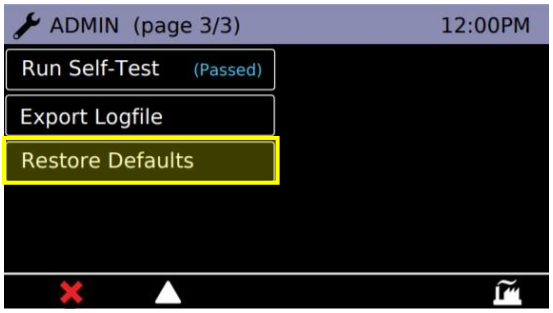


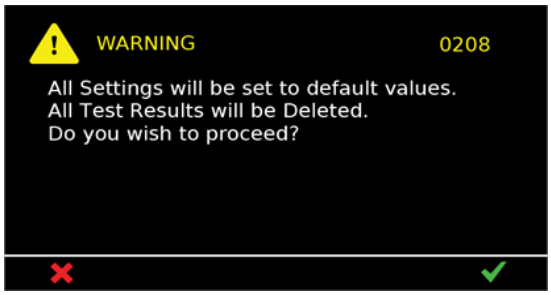
Click on "Export Logfile" button (with a USB key inserted) to export the instrument's log.

Touch the ✓ icon to confirm action.

The log file tracks the results of every Self-Test run, instrument details, calibration records and other pieces of information, and can be exported out as a .csv file.

9.15 Restore Defaults





Note: *This cannot be undone. Please ensure that any important data such as User Lists and Test Results are exported to a USB Memory Key prior to performing Reset to User Default.*

Select the “Reset to User Default” button to return all settings to default.

See Section 13 for list of default settings.

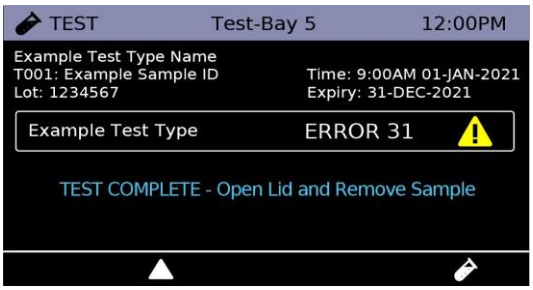
The instrument requires on screen confirmation.

Once completed the instrument will reboot.

10. In-Test Errors

This section provides troubleshooting steps for specific error codes for test runs and explains information messages. This is inclusive of Patient and QC test.

In a test, errors can occur without affecting the test result. If the number of errors exceeds a limit, the instrument aborts the test run and displays a test error code in place of a result. The image below is an example of the in-test error screen.



The following table contains the In-test Error codes and the events that cause them. Some circumstances may permit a user to complete actions to resolve them. Where the user action is absent or not successful, complete the following:

- Re-run the test.
- If errors remain, restart the instrument and re-run the test.
- If errors remain, contact the administrator for technical assistance.

NOTE: Errors are detected and counted per fluorescence channel.

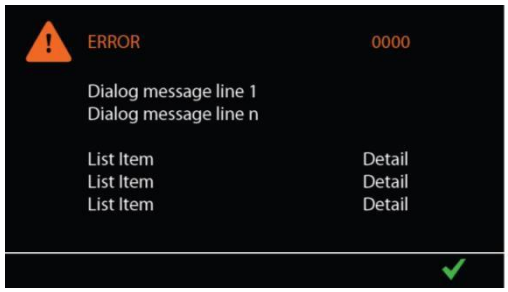
In-Test Error Code	Description	User Action
10	Detected event: Test Bay, Lid Open. Detections: Two consecutive Lid Open Error detections.	Ensure consumable is seated correctly. Ensure the lid area is clear of obstructions.
11	Detected event: Test Bay, Lid Open. Detections: Three Lid Open Error detections, where no two are consecutive Lid Open Errors.	
12	Detected event: Test Bay, Lid Open. Detections: Two consecutive Errors, where the Lid Open Error detection was the second of the detected Errors and the first Error was not a Lid Open Error.	
13	Detected event: Test Bay, Lid Open. Detections: Three Errors, where the Lid Open Error detection was the third of the detected Errors and the first and/or second Error was not a Lid Error.	

20	Detected event: Optical Module, homing Error. Detections: Two consecutive homing Error detections on a channel.	Ensure the instrument is on a level surface. Ensure to avoid excessive vibration or shaking during tests.
21	Detected event: Optical Module, homing Error. Detections: Three homing Error detections on a channel, where no two are consecutive homing Errors.	
22	Detected event: Optical Module, homing Error. Detections: Two consecutive Errors, where the homing Error detection was the second of the detected Errors and the first Error was not a homing Error.	
23	Detected event: Optical Module, homing Error. Detections: Three Errors, where the homing Error detection was the third of the detected Errors and the first and/or second Error was not a homing Error.	
30	Detected event: Heater Error. Detections: Single Heater Error event.	No user corrective action. Contact support@dxlab.bio for assistance.
31	Detected event: Heater Error Detections: Two consecutive Errors, where the Heater Error detection was the second of the detected Errors and the first Error was not a Heater Error.	
32	Detected event: Heater Error. Detections: Single Heater Error event, where there was previously two non-consecutive Errors of any other type.	
40	Detected event: Optical Module, Read Error. Detections: Two consecutive Read Error detections on a channel.	Ensure the instrument is on a level surface. Ensure to avoid excessive vibration or shaking during tests.
41	Detected event: Optical Module, Read Error. Detections: Three Read Error detections on a channel, where no two are consecutive Errors.	
42	Detected event: Optical Module, Read Error. Detections: Two consecutive Errors, where the Read Error detection was the second of the detected Errors and the first Error was not a Read Error.	
43	Detected event: Optical Module, Read Error. Detections: Three Errors, where the Read Error detection was the third of the detected Errors and the first and/or second Error was not a Read Error.	

11. Errors, Warnings, and Information

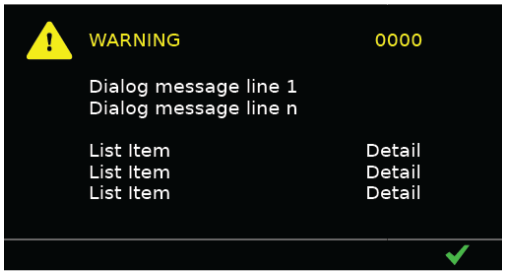
This section provides troubleshooting steps for specific error and warning codes and explains information messages. Once the steps listed below are executed, if the error or warning persists, contact: support@dxlab.bio.

Note: After unexpected power loss, the instrument will boot up when power is reconnected. In the event of file corruption due to power loss, self test at power up and the test results will indicate any issues caused.



Error: An error screen is displayed when an action could not be completed, e.g., a test could not be completed, USB key was not found, or self test was failed.

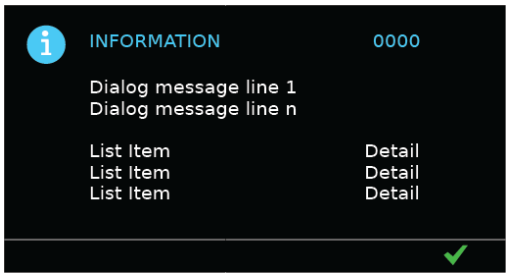
Touch the ✓ icon to acknowledge the error.



Warning: A warning screen is displayed when confirmation of an action is required e.g., user cancelsa test in progress.

Touch the ✓ icon to confirm the action.

Touch the ✘ icon to cancel the action.



Information: An information screen is displayed to notify the user of information, e.g., export was successful.

Touch the ✓ icon to acknowledge the information.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0001	ERROR: Self Test [the displayed screen shows either {Pass} or {FAIL} for each item part of the self-test]	The instrument self test has failed and testing has been locked out. Run a new self test to confirm the result, then refer to the failure the self test has recorded to identify what the issue is.
Error: 0002	ERROR: Voltage Test [the displayed screen shows mV readings for each voltage test item]	The instrument voltage test has failed and testing has been locked out. Re-power the instrument and attempt to run a new voltage test. Ensure correct power supply is being used. If error continues contact supplier.
Error: 0201	Incorrect Password	The password entered does not match the password for the admin or factory user access. Please re-attempt password entry. If admin or factory password has been forgotten, please contact the instrument supplier.
Error: 0202	Incorrect Username or Password	The password entered does not match the password for the associated user ID. Please re-attempt user ID and password entry. If password has been forgotten, please contact the instrument administrator.
Error: 0213	Invalid password entered – no change	The new password entered does not meet the security requirements. A password must not include: - Less than 4 characters or more than 20 characters - Two identical characters in succession (if password length is 4 characters) - Three identical characters in succession (if password length is greater than 4 characters) - ASCII characters in sequential order, including reverse sequential order Please re-attempt password change.
Error: 0221	Test results export failed	The instrument was unable to export to an attached USB Flash memory key. Ensure the USB Flash memory key is correctly inserted into the instrument's USB serial port at the point of export. Ensure the USB Flash memory key is formatted correctly, incorrect formatting means the USB key cannot be recognized by the DT-ISO instrument. See USB requirements.
Error: 0226	Invalid update file: {filename}	The instrument was unable to identify a valid update file. Check that the correct update file is saved on the USB Flash memory key and that the USB Flash memory key is correctly attached, then reattempt task
Error: 0229	Software update failed.	An error has occurred in the software update process. Ensure only one software update file is loaded on the USB key. Please re-boot the instrument and re-attempt software update. If the problem persists, please contact the instrument supplier.
Error: 0231	Invalid Home Offset Value. Valid range is 530 to 850.	The Home Offset Value does not fall within the valid input range. Re-attempt input of a value between 530 and 850.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0232	Invalid Inter-Tube Distance Value. Valid range is 685 to 740.	The Inter Tube Distance Value does not fall within the valid input range. Re-attempt input of a value between 685 and 740.
Error: 0233	Invalid Heater Set Point Value. Valid range is {0} to {0}	The Heater Set Point Value does not fall within the valid input range. Re-attempt input between the input range.
Error: 0234	Invalid Temperature Offset Value. Valid range is -5.0 to +5.0	The Temperature Offset Value does not fall within the valid input range. Re-attempt input of a value between -5.0 and +5.0.
Error: 0237	Failed to Normalize Opto module. Cannot achieve target	Failed to Normalize the Optical Module Please reboot instrument and re-attempt normalization. If the problem persists, please contact the instrument supplier.
Error: 0240	Invalid Target Opto Reading. Enter a value from 100 to 4500.	The Target Opto Reading Value does not fall within the valid input range. Re-attempt input of a value between 100 and 4500.
Error: 0242	Invalid Target LED Intensity. Enter a value from 5 to 95.	The Target LED Intensity Value does not fall within the valid input range. Re-attempt input of a value between 5 and 95 degrees.
Error: 0250	Printing failed…	A printing error has occurred. Ensure the printer is set-up according to the printer instructions and attached to the instrument correctly. Please re-attempt to print. If printing error persists, please contact the instrument supplier.
Error: 0255	Test Type Import Failed: No USB file: {0}	Test Type import could not be completed. Ensure a valid Test Type file is loaded onto the USB Flash Memory Key.
Error: 0255	Test Type Import Failed: File format error	Test Type import could not be completed. Ensure a valid Test Type file is loaded onto the USB Flash Memory Key.
Error: 0255	Test Type Import Failed: CRC error	Test Type import could not be completed. Ensure a valid Test Type file is loaded onto the USB Flash Memory Key.
Error: 0255	Test Type Import Failed: Test Type Import Error {0}	Test Type import could not be completed. Ensure a valid Test Type file is loaded onto the USB Flash Memory Key.
Error: 0255	Test Type Import Failed: Too many Test Types	Test Type import could not be completed. Ensure a valid Test Type file is loaded onto the USB Flash Memory Key.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0261	Importing User List Failed	User List import could not be completed. Ensure the USB Flash memory key is correctly inserted into the instrument's USB serial port at the point of export. Ensure the USB Flash memory key is formatted correctly, incorrect formatting means the USB key cannot be recognized by the instrument. See USB requirements.
Error: 0261	No valid user/password data in file: {0}	User List import could not be completed. Ensure a valid User List file is loaded onto the USB Flash Memory Key.
Error: 0261	User List import failed	User List import could not be completed. Ensure a valid User List file is loaded onto the USB Flash Memory Key. Ensure the USB Flash Memory Key is attached to the instrument correctly.
Error: 0261	Too many user names	User List import could not be completed. Ensure a valid User List file including 20 or fewer user profiles is loaded onto the USB Flash Memory Key.
Error: 0261	Invalid user name	User List import could not be completed. Ensure a valid User List file is loaded onto the USB Flash Memory Key.
Error: 0261	User List is too long.	User List import could not be completed. Ensure a valid User List file including 20 or fewer user profiles is loaded onto the USB Flash Memory Key.
Error: 0262	Duplicate Username: {0}	User List import could not be completed. Ensure a valid name or password are in use.
Error: 0262	Invalid (Blank) Password	User List import could not be completed. Ensure a valid name or password are in use.
Error: 0262	Invalid Username: {0}	User List import could not be completed. Ensure a valid name or password are in use.
Error: 0262	Invalid Username.	User List import could not be completed. Ensure a valid name or password are in use.
Error: 0262	Invalid Password.	User List import could not be completed. Ensure a valid name or password are in use.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0266	Exporting User List Failed	User List export could not be completed. Ensure the USB Flash memory key is correctly inserted into the instrument's USB serial port at the point of export. Ensure the USB Flash memory key is formatted correctly, incorrect formatting means the USB key cannot be recognized by the DT-ISO instrument. See USB requirements.
Error: 0271	Importing Resource File Failed	Resource File import could not be completed. Ensure a valid Resource File is loaded onto the USB Flash Memory Key.
Error: 0273	Power supply input voltage is over-range Please use approved 12V DC power pack. (Instrument is now inoperative.)	An incorrect power supply has been plugged into the instrument. Please use approved 12V DC power pack.
Error: 0274	Invalid Factory Test Duration. Valid range is 10 to 3600.	The Duration Value does not fall within the valid input range. Re-attempt input of a value between 10 and 3600 seconds.
Error: 0275	Invalid Test Temperature. Valid range is 35.0 to 72.0.	The Temperature Value does not fall within the valid input range. Re-attempt input of a value between 35.0 to 72.0 degrees.
Error: 0276	Invalid Opto{0} PWM Value. Valid range 5.0 to 95.0.	The Opto LED PWM Value does not fall within the valid input range. Re-attempt input of a value between 5.0 and 95.0%.
Error: 0277	Invalid Heater-B Temperature Value. Valid range is 35 to 72 Degrees.	The Heater-B Temperature Value does not fall within the valid input range. Re-attempt input of a value between 35 and 72 Degrees.
Error: 0281	Exporting LogFile Failed.	Logfile export could not be completed. Ensure the USB Flash memory key is correctly inserted into the instrument's USB serial port at the point of export. Ensure the USB Flash memory key is formatted correctly, incorrect formatting means the USB key cannot be recognized by the DT-ISO instrument. See USB requirements.
Error: 0299	Invalid IPv4 Address	The IPv4 Address entered is invalid.Re-attempt entry.
Error: 0299	Invalid Subnet Mask	The Subnet Mask entered is invalid. Re-attempt entry.
Error: 0299	Invalid Gateway	The Gateway entered is invalid. Re-attempt entry.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0302	Invalid LIS Port. Range is 1 to 65535.	The LIS Port value entered is not valid Re-attempt input of a valid LIS Port value
Error: 0311	Invalid User Name	The username entered is invalid. A user name must be between 1 and 20 characters in length Re-attempt entry of a user name.
Error: 0312	Invalid or recently used password.	The password entered does not meet the security requirements. A Standard User password must not be identical to the previous 8 passwords used by that user profile. Please re-attempt password entry.
Error: 0313	Multiple Test Type Packages found	More than 1 Test Type Package was identified on the connected USB key. USB key must contain only 1 Test Type package for a successful import. Using a computer, remove unnecessary Test Type Packages from the USB and re-attempt import.
Error: 0315	Maximum number of tests reached. To run more tests, you must export existing test results to a USB Key.	The maximum number of tests has been reached. Test results must be exported to a USB key before running more tests.
Error: 0316	Barcode contains invalid characters.	The barcode contains invalid characters. Ensure barcode contains only valid characters before entering. Valid characters are: 0...9, A..Z, a..z, #_-, +
Error: 0317	Invalid Barcode. Check correct barcode was scanned.	The barcode is invalid. The barcode must be in the correct format expected by the instrument.
Error: 0318	Barcode must be 1 to 22 characters.	The barcode contains invalid characters. The barcode must be 1 to 22 characters.
Error: 0320	Barcode Lot Number has Expired.	If an expired Lot is detected then the instrument will not permit the activation of the Test Lot.
Error: 0323	Invalid {Red/Green/Blue} pixel. Range is 0 to 255.	The pixel values entered is not valid. Re-attempt input of a valid pixel values.
Error: 0324	Invalid Date Setting. Set Clock to current Date and Time.	The Date entered is not valid. Re-attempt input of a valid Date and Time values.

11.1 Error Dialogues

CODE	DESCRIPTION	ACTION
Error: 0325	Barcode's Test-Type does not match current selected Test-Type.	If an internally read barcode test selection does not match a known test type on the instrument the instrument will not permit the test to proceed.
Error: 0328	QC failed. Please re-run QC test for this lot.	The QC Test for this lot has failed Please re-run QC test for this lot to proceed.
Error: 0329	QC testing not completed. Please run QC test for this lot.	The QC Test for this lot has not been completed. Please run QC test for this lot to proceed.
Error: 0331	Test Cancelled. Tube was not inserted within 5 minutes.	The test has been cancelled as the tube was not inserted within 5 minutes. Please re-run this test.
Error: 0332	No Test Types available. Please contact Administrator.	There are no Test Types available. Please re-run this test.
Error: 0333	Failed to write results file. Bays affected : {0}	The results file could not saved to the internal storage. Please reboot instrument and re-attempt test. If the problem persists, please contact the instrument supplier.
Error: 0334	Cannot start a new test due to file write errors.	The instrument cannot detect the internal SD Card to start a test. Please reboot instrument and re-attempt test. If the problem persists, please contact the instrument supplier.
Error: 0335	Test Canceled. Target Temperature not reached within 10 minutes.	The test has been cancelled as the target temperature was not reached within 10 minutes. Please re-run this test.
Error: 0341	Maximum login attempts exceeded. See administrator to reset password.	A user has attempted to login multiple times unsuccessfully. For security purposes the user account is temporarily suspended. An admin user must reset the password of the affected user through the admin settings 'User List' function.
Error: 0342	Password reused or invalid.	When setting a password, the user has entered a password that has previously been used or is not a valid password. Please check password entry requirements and enter a valid password.

11.2 Warning Dialogues

CODE	DESCRIPTION	ACTION
0203	Current user will be logged out. Do you wish to proceed?	The instrument requires confirmation that the user intends to logout.
0208	All Settings will be set to default values. All Imported Test Types Deleted. All Test Results will be Deleted. Do you wish to proceed?	The instrument requires confirmation that all settings will be set to default values with all imported test types and test results to be deleted.
0211	Admin password not changed. Do you wish to proceed?	The instrument requires confirmation that the admin password has not been changed.
0222	Saved test results will be deleted. Do you wish to proceed?	The instrument requires confirmation that the user intends to delete the test results that have been successfully exported. If confirmed, the instrument will delete the internal test result files. If cancelled, the instrument will return to the Results List.
0222	Saved QC test results will be deleted. Do you wish to proceed?	The instrument requires confirmation that the user intends to delete the QC test results that have been successfully exported. If confirmed, the instrument will delete the internal QC test result files. If cancelled, the instrument will return to the Results List.
0224	Continuous Mode will be exited. Do you wish to proceed?	The instrument requires confirmation that the user intends to stop and exit Continuous Mode. The instrument will stop and exit Continuous mode, once confirmed. The instrument will continue in Continuous Mode, once cancelled.
0227	Ready to install software update. File: {0} Update version: {0} Current version: {0} Do you wish to proceed?	The instrument requires confirmation that the user intends to install the software update. The software update will take place once confirmed.
0246	Internal memory is nearly full. Less than five test runs remaining. Do you wish to proceed?	The instrument requires confirmation that the internal memory available for storing test results is nearly full. The instrument will continue testing once confirmed.
0247	Heater-B is not ready. Do you wish to proceed?	Factory only calibration warning. Ensure instrument is being operated under the recommend environmental conditions Wait for instrument to reach required temperature. If the problem persists, please contact the instrument supplier.

11.2 Warning Dialogues

CODE	DESCRIPTION	ACTION
0303	LIS Server Settings will be cleared. Do you wish to proceed?	The instrument requires confirmation that the user intends to clear the LIS server settings. This step, once confirmed, cannot be undone.
0304	LIS File Sent Status will be cleared. Do you wish to proceed?	The instrument requires confirmation that the user intends to clear the LIS file sent status. This step, once confirmed, cannot be undone.
0321	Cannot Exit Test Mode. Test are still in Progress.	The instrument warns the user that Test Mode cannot be exited as testing is still in progress.
0322	Test will be cancelled. Do you wish to proceed?	The instrument requires confirmation that the user intends to cancel the test that is in progress.
0326	The QC status for this lot number is Failed. Do you wish to proceed?	The instrument informs the user that QC testing has failed. User confirmation is required to continue.
0327	QC testing has not been completed for this lot number. Do you wish to proceed?	The instrument informs the user that QC testing has not been completed. User confirmation is required to continue.
0336	Confirm cancel of LIS Auto Send Settings. Do you wish to proceed?	The instrument requires confirmation that the user intends to clear the LIS Auto Send settings.
0345	All Import Test Types will be deleted. Do you wish to proceed?	The instrument requires confirmation that the user intends to delete all test types.

11.3 Information Dialogues

CODE	DESCRIPTION	ACTION
0003	Shutting down… Please wait.	The instrument informs the user that instrument shutdown is in progress.
0204	Factory Mode activated.	The instrument requires confirmation to enter factory user profile.
0205	Self-Test Passed OK	The instrument informs the user that the Self-Test that has been manually run has passed.
0206	Cannot run tests Because T8-ISO Power-on Self-Test Failed	The instrument informs the user that the Self-Test performed at instrument Power-On had failed, and the user cannot run a test.
0207	Sorry, Function not available	The instrument informs the user that the function the user had selected is not available.
0210	Default settings restored	The instrument informs the user that the software default settings have been restored.
0212	Admin password change confirmed	The instrument informs the user that the admin password change has been confirmed.
0216	Test Completed	The instrument informs the user that the test is complete.
0218	No test results to export!	The instrument informs the user that there are no test results available for export.
0219	Exporting Test Results	The instrument informs the user that there are no test results available for export.
0220	Test results exported OK	The instrument informs the user that test result export has completed successfully.
0223	Test result deleted OK	The instrument informs the user that the test results have successfully deleted.
0228	Update file transfer in progress. Please wait.	The instrument informs the user that the update file transfer is in progress.
0230	Update file transfer complete. System reset pending. Do not disconnect power cable. Please wait for automatic re-boot.	The instrument warns the user that a system reset is pending, and therefore to ensure the power cable is not disconnected. The instrument shall then re-boot automatically.
0241	Normalization successful… Tick to save factor ({0})	The instrument informs the user that Normalization was successful.
0243	Clear Normalization Factor to default Factor will be set to 1.00 Tick to Save	The instrument informs the user that the Normalization factor to the FAM optical module will be set to 1.00.

11.3 Information Dialogues

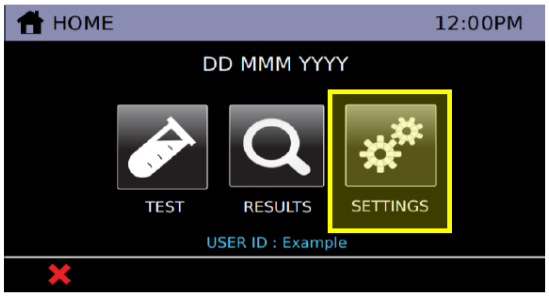
CODE	DESCRIPTION	ACTION
0244	Clear Normalization Factor to default Factor will be set to 1.00 Tick to Save	The instrument informs the user that the Normalization factor to the HEX optical module will be set to 1.00.
0248	Printing. Please wait.	The instrument informs the user that printing is in progress.
0249	Printing completed.	The instrument informs the user that printing is completed
0254	Imported Test Types OK	The instrument has successfully imported Test Types. Press OK to continue.
0260	Imported User List OK	The instrument informs the user that a User List has been imported successfully.
0263	No User List file to export.	The instrument informs the user that there are no saved User List files on the instrument to export.
0265	Exported User List OK	The instrument informs the user that a User List has been exported successfully.
0279	Exporting Logfile.	The instrument informs the user that the instrument is exporting a Logfile.
0280	Exported LogFile OK	The instrument informs the user that it has successfully exported a Logfile.
0314	Deleting All Test Results	The instrument informs the user that it is currently deleting All Test Results.
0321	Cannot Exit Test Mode. Tests are still in progress.	The instrument informs the user that it Tests are still in progress and therefore, Test Mode cannot be exited.
0330	Security: Instrument Setup. Please set your admin level password.	The instrument informs the user that setting of the admin level password is required.
0343	User password changed.	The instrument informs the user that a user password has been changed
0344	Password Expired Please change your password.	The instrument informs the user that a password change is required and progresses the user to the password change function
0346	Test Package Deleted	The instrument informs the user that the test package has been deleted
0347	Factory Defaults restored	The instrument informs the user that the instrument has been reset to factory default settings

12. Software Update

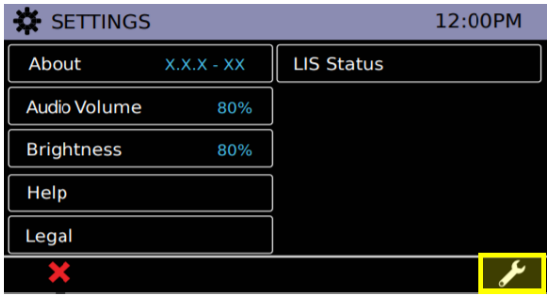
The Instrument update process consists of a single file packaged release that is loaded onto the DxHub using a USB Flash Memory Key. This packaged release can be obtained by contacting support@dxlab.bio and it can be simply copied to a blank FAT-32 USB Flash Memory Key and then used to update one or multiple instruments.

Caution: Stored test data may be at risk of being deleted during the software update process! It is highly recommended that the test results saved on the instrument are archived to an external formatted, USB Key prior to performing a software update.

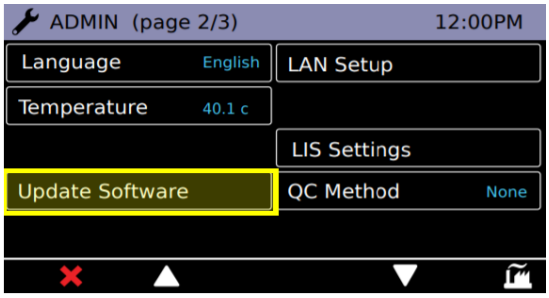
Copy the update file ("DxHub_Update_vXXX.bin") onto a USB flash drive. **NOTE: Ensure this is the only .bin file on the USB, and do not place the file in a folder.** Turn on the DxHub, and insert the USB with the software update file into the DxHub's USB port, located on the front of the instrument.



Touch on the "Settings" button from the home screen.

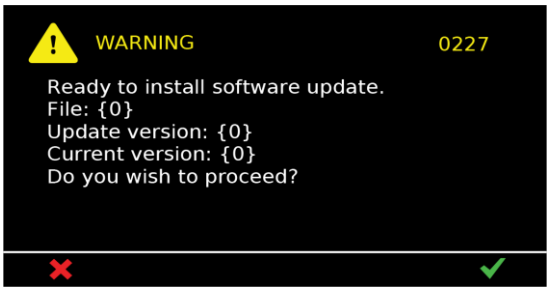


Navigate to Admin Settings by touching on the  icon and login with the admin password.

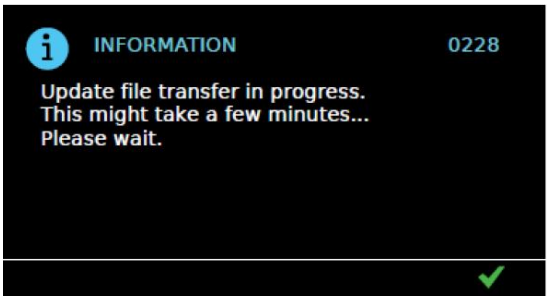


Touch the "Update Software" button located on the second page of Admin Settings.

Insert USB flash drive.



A warning message will display.
Touch ✓ to confirm installation of software update.



An information page will display.

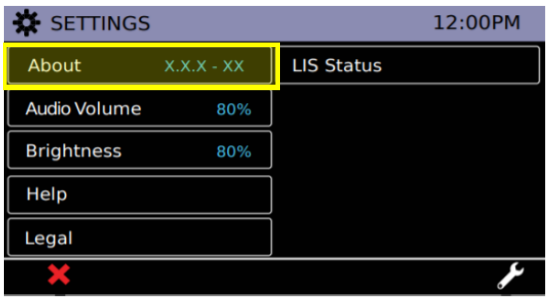
Wait for the transfer to complete.

The instrument will go to a black screen and the front panel white LED will flash rapidly during the software update process.

This process may take up to 3 minutes.

DO NOT remove power during the software update.

When the update has completed, the front panel white LED will return to a slow flash (idle) mode. Press the front panel power button to start the instrument.



To confirm that the software is updated, navigate to the About screen by touching on the “About” button in the “Settings” menu.

The current running software version number will be displayed.
The USB key can be removed.

13. Restoring Default Settings

Refer to Section 9.15 for details of how to restore default settings.

The list below shows all parameters that will be updated after restoring default settings:

Parameter	Item	Default Setting
Settings	Touch Volume	60%
	Alert Volume	80%
	Brightness	80%
Results	Test Results	None (all deleted)
	QC Test Results	None (all deleted)
Admin Settings	User List	None (all deleted)
	Auto Logout Timer	30 minutes
	Admin Password	admin
	Network	DHCP
	LIS Settings	No LIS profiles (all deleted)
	QC Method	Warning
	Test End Tone	Single
	Password Expiry	90 days
Misc. Parameters		
	Start Up Temp Set Point (Heater Block)	65
	Results File Sequence Number	1
	QC Statuses	None (all deleted)

14. Peripherals

14.1 USB Flash Drive

The SanDisk, Cruzer Blade key is an example of a typical USB key proven to work with the instrument:

- Formatted for FAT32, minimum 1GB with only 1 partition.
- The USB Key doesn't perform CD-ROM emulation
- The USB Key does not require loaded proprietary software to run.

NOTE: There is only one USB Key present during a software update process.

Test List on USB Key

Use a USB key to import test list onto the instrument.

Blank USB for Archive of Test Results

Use a blank USB key to export test results and instrument data from the instrument.

Software Update on USB Key

Use a USB key loaded with a software update to install the latest software onto the instrument.

14.2 Barcode Scanner

The instrument accepts a serial connected barcode scanner.

Datalogic QuickScan Barcode Wand, QD2430

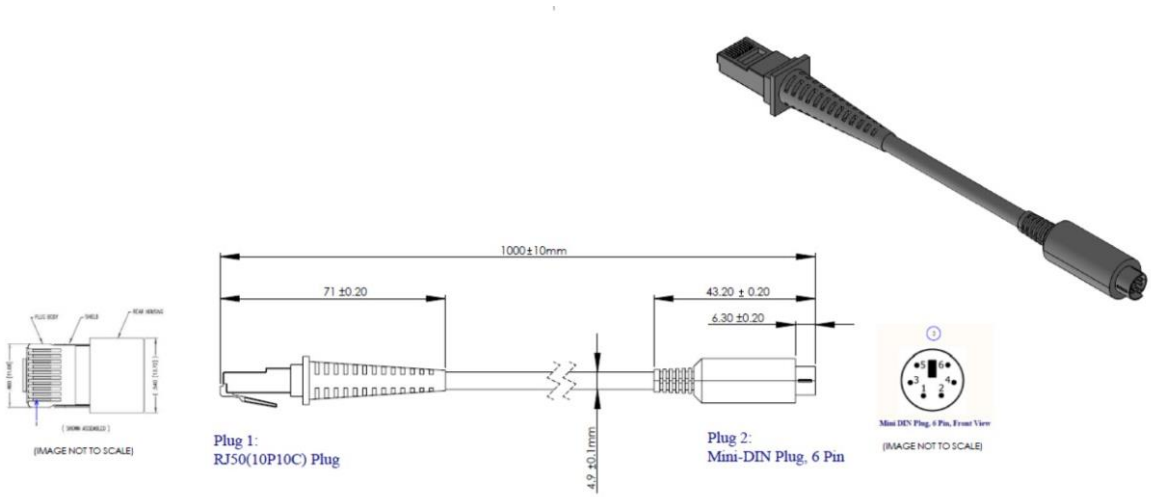
The DxHub **requires** input from a barcode scanner. The scanner is **NOT** provided with the DxHub instrument and should be purchased separately. The barcode scanner will supply a character string that appears in the text box as if it was typed on the onscreen keyboard. The recommended barcode scanner 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 (refer to Section 14.2.1). Once connected and set up, the scanner is typically operated in default mode and will read both standard barcodes and 2D,QR-type barcodes.

Light Source	LED
Roll (Tilt) Tolerance	Up to ±360°
Pitch Tolerance	±65°
Skew (Yaw) Tolerance	±60°
Print Contrast Minimum	25% minimum reflectance
Operating Temperature	0° to 50°C (32°F to 122°F)
Storage Temperature	-40° to 70°C (-40°F to 158°F)
Humidity	0% to 95% relative humidity, non-condensing
Drop test	Scanner withstands 18 drops from 1.5m (5ft)
Ambient Light Immunity	Up to 86,000 Lux
ESD Level	16 KV
Supply Voltage	4.5-14.0 V (DC)
Operating Current	140mA (typical)380mA (max)
Idle/Standby	50mA (typical)
Dimension	Height: 163mm (6.4”) Length: 91mm (3.6”) Width: 41mm (1.6”)
Weight	~145g (~5.1oz) without cable
Types	Code 39, EAN, PDF-417, DataMatrix, QR Code.
Interface	RS232, Keyboard Wedge, SERIAL Com Std., SERIAL Keyboard, SERIAL OEM

More information is available at: http://www.datalogic.com/eng/products/automatic-data-capture/general-purpose-handhelds/quickscan-qd2400-pd-612.html

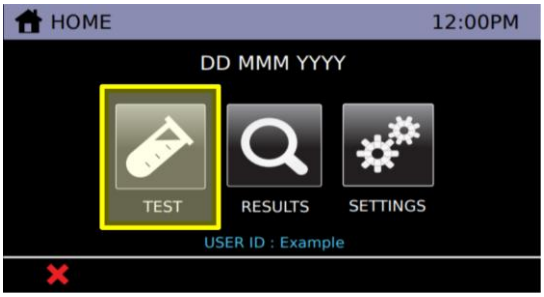
14.2.1 Barcode Scanner Cable

A specific cable is required to connect the scanner to the DxHub. The cable is provided with the DxHub. *Refer to Section 4.3 for the cable connection location located on the rear of the instrument.*

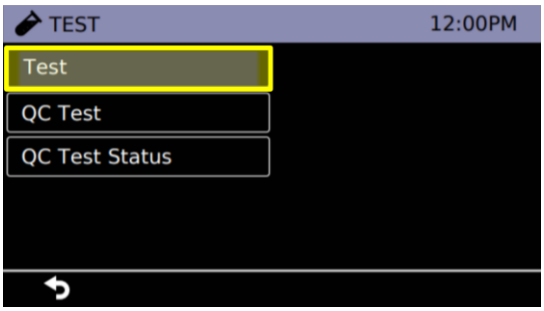


14.2.2 Barcode Scanner Setup

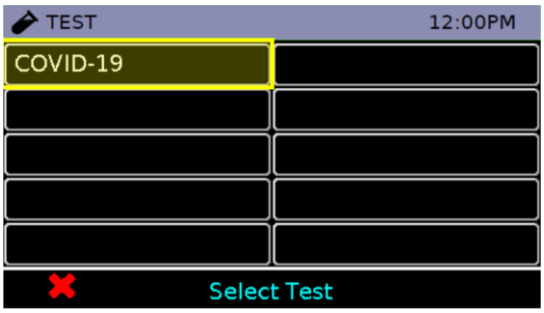
Plug the 'Serial to Ethernet' cable provided with the DxHub (**NOT** the 'USB to Ethernet' cable included with the barcode scanner) into the bottom of the barcode scanner handle. Connect the barcode scanner cable to the DxHub's rear port.



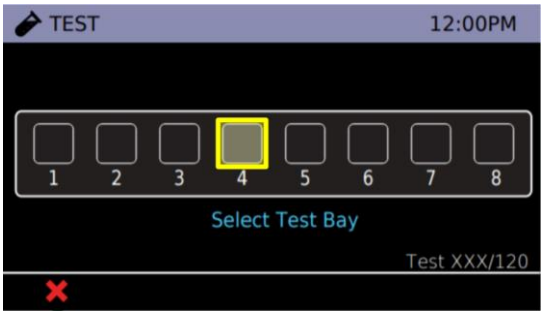
Select the "Test" icon.



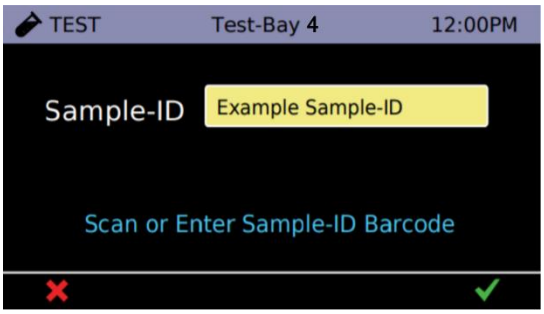
Select “Test”.



Select “COVID-19” test. Please wait for the instrument to warm the heat block.



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

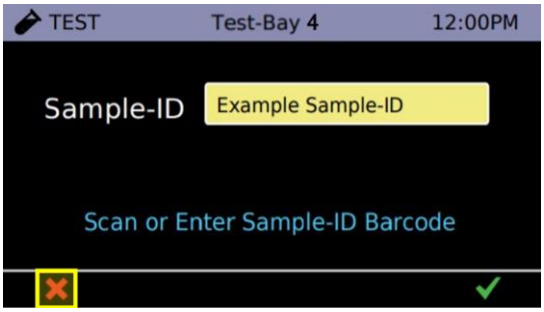


Once the Sample-ID screen has been reached, pick up the barcode scanner.

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, try scanning the barcode again or refer to Section 14.2.3 to troubleshoot.

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, try scanning the barcode again or refer to Section 14.2.3 to troubleshoot.



Touch ✗ three times to return to the logout screen.

14.2.3 Barcode Scanner Troubleshooting

If the barcode scanner is not functioning properly, complete the steps in Section 14.2.2. If the barcode scanner is still not functioning properly, proceed onto the following steps.

1. Unplug the barcode scanner cable from the DxHub.
2. Remove the 'Serial to Ethernet' cable from the barcode scanner. This can be accomplished by applying pressure in the release hole found on the barcode scanner handle using a paper clip or pin. Be sure to simultaneously pull on the 'Serial to Ethernet' cable.
3. Connect the 'USB to Ethernet' cable provided with the barcode scanner (**NOT** the 'Serial to Ethernet' cable included with the DxHub).
4. Plug the scanner via the USB A connector into a **powered** USB port (said port cannot be the instrument USB port).
5. Scan the following barcodes in succession, waiting approximately ten seconds between scanning the two barcodes. Scan them in the order they are displayed below.

a. 

b. 

6. Disconnect the 'USB to Ethernet' cable using the release hole as described in step 2 and reconnect the 'Serial to Ethernet' cable provided with the DxHub.
7. Reconnect the barcode scanner to the DxHub's rear port. Check if the DxHub and barcode scanner are now operating as expected. If not, refer to the barcode scanner's user manual for troubleshooting or contact support@dxlab.bio.

14.3 Label Printer

The instrument supports a connected label printer. The recommended printer is the Seiko SLP 650-SE operating in serial mode. The printer will print the instrument's test report on a receipt or adhesive shipping label.

The SLP 650-SE label printer is connected to the instrument via a specific cable that can be ordered separately from DxLab. For printer troubleshooting, reference printer manufacturer documentation.

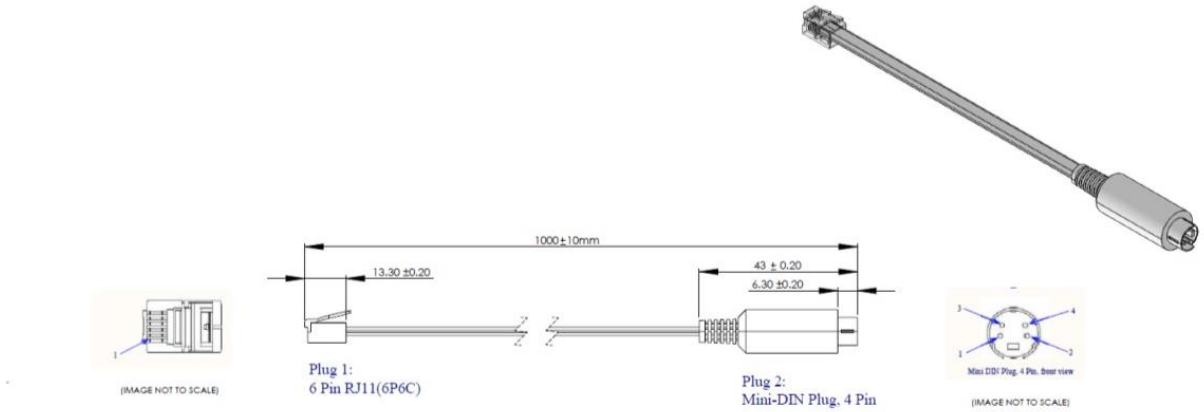
Serial Label Printer

Seiko SLP 650-SE

Label Part Number: SLP-SRL
Label Size: 2-1/8" x 4" (53.98 x 101.6mm)

14.3.1 Label Printer Cable

A specific cable is required to connect the printer to the DxHub. The cable can be ordered from DxLab.
Refer to Section 4.3 for the cable connection location on the rear of the instrument.



15. Cleaning and Decontamination

WARNING: The isopropyl alcohol used in this procedure is flammable.

Ensure instrument is not powered.

Do not use isopropyl alcohol within 3 m of open flames or sources of ignition. Avoid contact with skin.

WARNING: The instrument may be contaminated.

Avoid contact with skin.

Wash hands with hand wash after completing decontamination.

Suggested materials:

- **Gloves:** Disposable laboratory gloves
- **Wipes:** Lint free wipes
- **Swabs:** Foam Tipped Swab

Name: Chemtronics, Foamtips™ #140
Product No.: CF4050
Swab Length: 2.87" (7.3 cm)
Head Material: 100 ppi Open Cell Foam
Head W/L: 0.19" x 0.50" (4.8 x 12.7 mm)

- **Isopropyl Alcohol:** 99% Isopropyl Alcohol in a spray dispenser
- **Hand wash:** Disinfectant hand wash

The DxHub can be cleaned using a lint free wipe dampened with Isopropyl Alcohol (IPA). DxLab does not recommend using free liquids to clean the instrument.
To clean the tube wells, DxLab advises the use of a Foam tip Swab such as the Chemtronics, Foam Tip Swabs with Product Number CF4050.

1. **Inspect:** Inspect for damage or visible contamination.
2. **Dispose:** Dispose of any materials left on the instrument such as test parts.
3. **Wipe surfaces:** Wipe all surfaces of the instrument with wipes wetted with isopropyl alcohol. Use sufficient alcohol such that the surfaces are clearly wetted by the cleaning process. Surfaces include the LCD display and touch screen.
4. **Dip:** Dip the Foam tip Swap into the Isopropyl Alcohol and allow any excess fluid to flow off the swap.
5. I**nsert:** the swab into each Tube well and circle the tube wall. If any lint or dust remains on the swab head once swab is removed after cleaning, dispose of swab
6. **Dispose:** Dispose of all used materials and gloves.
7. **Wash hands:** Wash hands with the disinfectant hand wash.

16. Warranty

The DxHub instrument is warranted against defects in materials and workmanship for a period of one (1) year. For specific warranty information, contact support@dxlab.bio. If any defects should occur during the warranty period, DxLab will replace or repair the instrument with defective parts without charge.

However, the following defects are specifically excluded:

- Defects caused by using the instrument in a manner inconsistent with the User Manual.
- Defects caused by improper storage in environmental conditions outside of the recommended range.
- Defects caused by tampering with any portion of the instrument.
- Defects caused by improper packaging of returned goods.
- Repair or modifications done by anyone other than DxLab Inc.
- Materials not specified by DxLab Inc.
- Deliberate or accidental misuse or abuse.
- Damage caused by disaster.
- Damage due to use of improper test kits or sample.

The warranty does not apply to fuses. For inquiry or request for repair service, contact support@dxlab.bio after confirming the unique serial number of your DxHub instrument.

The DxHub instrument is provided with no other warranties of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability or fitness for a particular purpose, or the warranty of non-infringement.

IN NO EVENT SHALL DXLAB INC. BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, OR ANY DAMAGES WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THOSE RESULTING FROM LOSS OF USE, DATA OR PROFITS, WHETHER OR NOT DXLAB INC. HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND ON ANY THEORY OF LIABILITY, ARISING OUT OF OR IN CONNECTION WITH THE USE OF THE INSTRUMENT. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

DxLab

DxHub
Product Information Card

℞ Only IVD

For use under Emergency Use Authorization only

Please visit the DxLab website (https://www.dxlab.bio/covid-19-test) for the current version of:

- **DxHub Quick Start Guide**
- **DxHub User Manual**

If you require a free printed copy or need any other support, please email us at support@dxlab.bio.

THANK YOU FOR YOUR ORDER

- 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; and
- 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.