

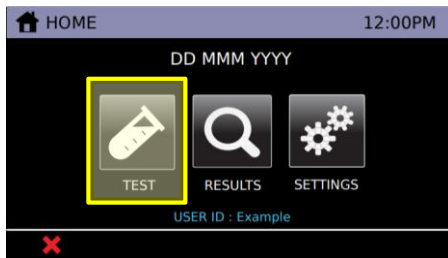


DxLab Inc. recommends that **BOTH** SARS-CoV-2 positive (Helix Elite™ Inactivated SARS-CoV-2 Whole Virus from Microbiologics®; Cat. No. HE0066NS) and negative (Helix Elite™ Inactivated Negative Cellularity Control from Microbiologics®; Cat. No. HE0067NS) control swabs be tested:

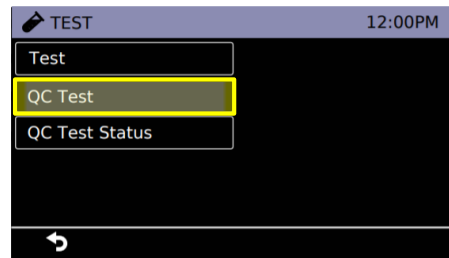
- Once for each new lot or shipment of test kits
- Once for each new operator
- When problems are suspected or identified
- As required to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

- 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.**

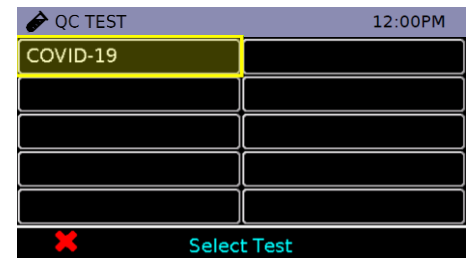
### Preparing DxHub for Quality Control (QC) Testing



- 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.

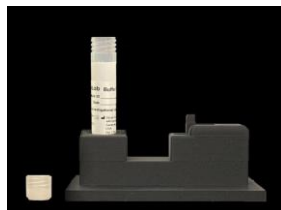


- 2 • Select "QC Test".

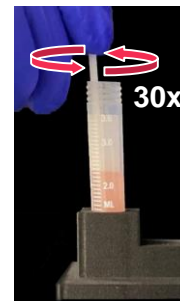


- 3 • Select "COVID-19" test.  
• Wait for the instrument to reach 66°C.  
• **Note:** Do **NOT** proceed until "Select Test Bay" is displayed on the screen.

### 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.



- 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**

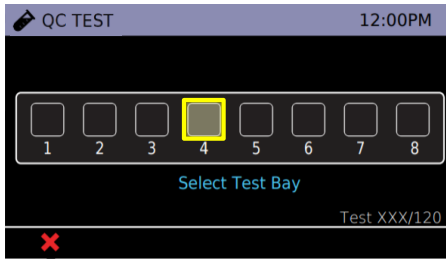


**Do NOT** let the swab tip touch anything

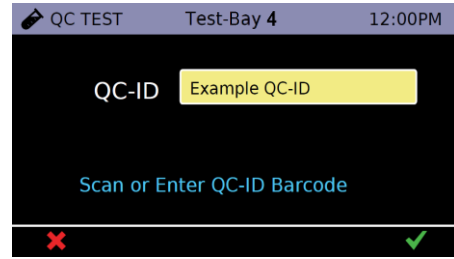
- 2 • Open a positive (Inactivated SARS-CoV-2 Whole Virus) or negative (Negative Cellularity Control) control swab package.  
• **Note:** Only hold the swab by its handle.

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

## Section 2: Test Preparation



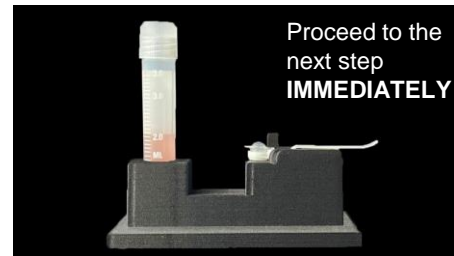
- The main QC test screen is shown on the DxHub touchscreen.
  - Select any unoccupied test bay (empty box). #4 is highlighted for demonstration purposes.



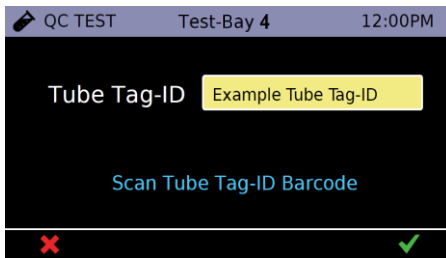
- Enter Sample ID by touching the yellow box next to "Sample ID" or scanning a barcode.
  - Touch to continue.
  - Note:** Refer to DxHub Quick Start Guide for barcode scanner setup.



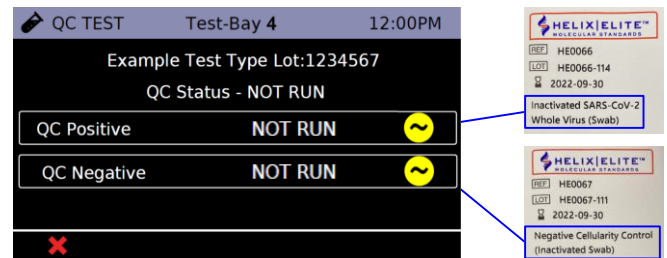
- Remove **ONLY** tube assembly from test pouch.
  - Note:** Do **NOT** remove transfer pipette from test pouch.
  - Note:** Do **NOT** touch the tube portion of the tube assembly.



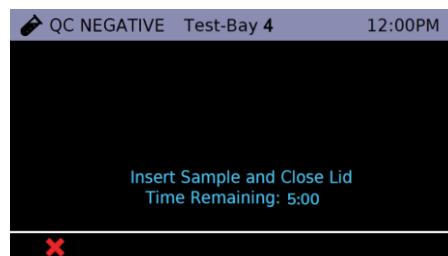
- Place the tube assembly in the tube holder.
  - Note:** Do **NOT** use a tube assembly that has been dropped.



- 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.



- 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.

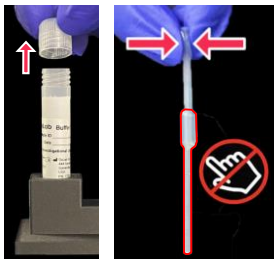


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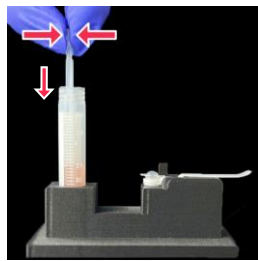
- You have 5 minutes to complete up to Section 3, step 8.
- If the timer expires and the DxHub times out, discard the buffer tube and the tube assembly. Return to Section 1.

## Section 3: Running the Test

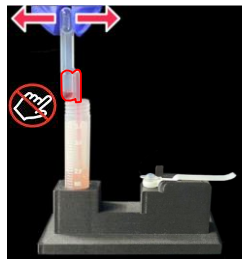
- **When handling the transfer pipette, touch ONLY the top bulb.**
- **If lower bulb or shaft of the transfer pipette is touched, dispose of all test materials (transfer pipette, buffer tube, and tube assembly) and restart the testing procedure with a new kit.**



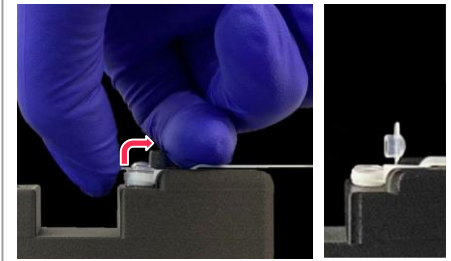
- 1**
- Open buffer tube.
  - Remove the transfer pipette from test pouch.
  - Squeeze the **top bulb** until it is **fully flat**.



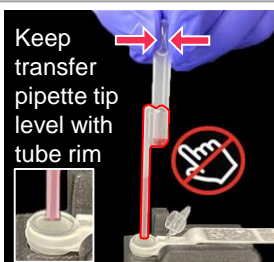
- 2**
- **While keeping top bulb squeezed**, insert the transfer pipette tip into the buffer tube until it touches the bottom of the tube.



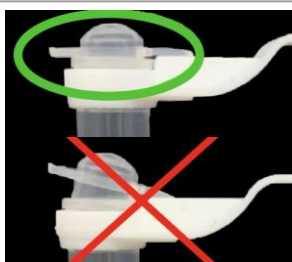
- 3**
- Keep the tip fully under liquid and release the upper bulb to **fill the entire shaft** with liquid.
  - **Note:** There should be some liquid in the lower bulb.
  - **Note:** Do **NOT** invert transfer pipette.



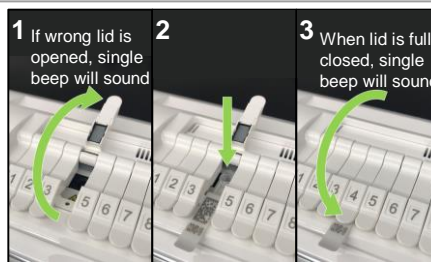
- 4**
- Carefully flip open the cap of the tube assembly.
  - **Note:** Once cap is open, sample must be added **IMMEDIATELY** (within 1 minute).



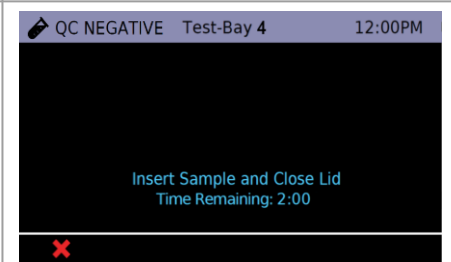
- 5**
- Squeeze **top bulb** of transfer pipette to dispense liquid.
  - **Note:** Some liquid will remain in the lower bulb.
  - **Note:** Do **NOT** release top bulb.
  - Dispose of the transfer pipette in a biohazard bin.



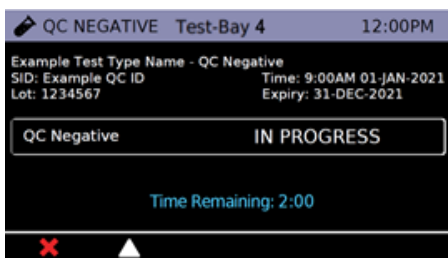
- 6**
- **COMPLETELY** close the tube assembly cap (as shown in green circle).
  - **Note:** Do **NOT** shake or tilt the tube assembly.
  - Close the buffer tube.



- 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.

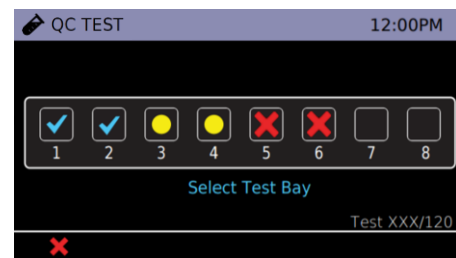


- 8**
- The test will automatically start once the lid is shut.
  - **Note:** Do **NOT** open the lid of the test bay while the test is running.



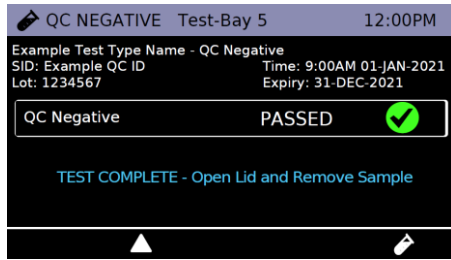
Two beeps will sound when a test is complete







- 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  $\Delta$  icon to return to the main test screen.
  - From the main test screen, you can view the result of a completed test, view the progress of a test in progress, or start a new test.







- 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  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      | <b>Pass</b><br>Quality control test has passed.   |
| FAILED     | <b>Fail</b><br>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  | <b>Device error, refer to error code in DxHub manual</b>  |
| CANCELED  | <b>Test canceled, clear test bay to begin new test</b>  |



**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.



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