T Storage and Handling and Warnings

<table>
<thead>
<tr>
<th>Storage and Handling</th>
<th>Warnings</th>
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<tbody>
<tr>
<td>• Wear gloves. Change gloves between processing each sample.</td>
<td>• DO NOT use a cartridge that is wet or has leaked.</td>
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<tr>
<td>• Store the Xpert Xpress CoV-2 plus cartridges at 2-28°C.</td>
<td>• DO NOT use a cartridge that has been dropped.</td>
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II How to Start the Software

1. Start Software
   a. Put on a pair of clean gloves.
   b. Turn on the GeneXpert Xpress instrument.
   c. Turn on the Home computer. The Windows logon screen appears. Swipe up or down to continue.
   d. Enter the Windows password and touch the arrow next to the password field.
   e. The GeneXpert Xpress Software login screen appears.
   f. Manually enter user name and password in Step 2a, or if enabled, scan your ID card in Step 2b.

2a. Enter User Name and Password Manually
   a. Touch the User Name field to display the virtual keyboard.
   b. Enter your user name and password.
   c. Touch the X in the upper right of the virtual keyboard. Touch the Login button.

2b. Or, Use Barcode Scanner Shown Below to Scan ID Card
   If enabled, log in by scanning the barcode on your institutional ID, as shown below.

3. HOME Screen Displays.
   The HOME screen will display the module status and the NEW TEST button.

II How to Test a Patient Specimen

Before You Begin:
- Refer to the package insert for more information.
- Read through the entire Quick Reference Instructions before beginning a test.
- Instructions on how to prepare the specimen and the cartridge are shown in a video within the software and in the Quick Reference Instructions.

1. Start a Test
   a. Put on a new pair of gloves.
   b. Check that the specimen tube cap is closed.
   c. Touch NEW TEST on the HOME screen.

2. Manually enter or Scan Patient ID. Touch CONTINUE.

3. Confirm Patient Information. Touch CONFIRM.

4. Manually Enter or Scan Sample. Touch CONTINUE.

5. Confirm Sample ID. Touch CONFIRM.

6. Scan Cartridge Barcode.

7. Select and Confirm Test Information. Touch Confirm.

8. Watch Video. Mix Specimen.
   a. Watch the video before performing Steps 9, 10, and 11. The video will repeat. Touch the CONTINUE button to exit the video.
   b. Check that the specimen tube cap is closed.
   c. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube.
   d. Open the cartridge lid.

9. Fill Pipette with Sample.
   a. Remove the pipette from the wrapper.
   b. Squeeze the top bulb of the pipette completely until the top bulb is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube.
   c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing it from the tube. It is okay if liquid goes into the overflow reservoir. Check that the pipette does not contain air bubbles.

10. Transfer Sample to Cartridge.
   a. Squeeze the top bulb of the pipette completely until it is fully flat to empty the contents of the pipette into the large cartridge opening (Sample Chamber). Some liquid may remain in the overflow reservoir.
   b. Dispose of the used pipette in an appropriate waste container.
   c. Close cartridge lid.

11. Load Cartridge.
   a. Open the instrument door with the flashing green light.
   b. Load the cartridge with the barcode facing the operator on the cartridge bay platform.
   c. Close the door until it clicks and green light stops flashing.

12. Remove Cartridge. View Results.
   a. When the test is completed, the screen will change to COMPLETE and the door unlocks.
   b. To view the test report, touch the REPORT button then swipe across the screen from left to right to mini-
      mize the screen and view the report.
   c. Dispose of the cartridge and gloves according to your institution’s policy.
   d. To log out, tap the User Menu icon then tap Logout.

13. Start a New Test (While a Test is Running).
   a. Put on a new pair of gloves if performing a new test.
   b. Touch the HOME button to go to the Home Screen.
   c. Start a new test following the steps in Section III starting with Step 1, Start a Test.
   d. For starting a new test with another user, see Step 14.

   a. Put on a new pair of gloves if performing a new test.
   b. Touch the HOME button to go to the Home Screen.
   c. Touch the SIGN OUT button to log out the previous user, if applicable.
   d. Start a new test following the steps in Section III, starting with Step 1, Start a Test.
IV How to View Status of Tests in Progress and Completed Tests

1. Touch HOME Button. Touch the HOME button to view the status of tests in progress or completed tests.
2. View Test In Progress. Tests in progress are shown on the HOME screen with a circular graphic indicator around each test and the Patient ID number below the module graphic. Touch the corresponding circular indicator to view the details.
3. View Results of Completed Tests. When the test is completed, touch the Complete View Results button on the HOME screen.

V How to Run External Controls - Positive and Negative Controls

It is recommended that external controls (ZeptoMetrix Catalog# NATSARS(COV2)-ERC as a positive control and ZeptoMetrix Catalog# NATSARS(COV2)-NEG as a negative control) be tested at the frequency noted below.
- Each time a new lot of Xpert Xpress CoV-2 plus is received.
- Each time a new shipment of Xpert Xpress CoV-2 plus is received even if it is the same lot previously received.
- Each time a new operator is performing the test (i.e., operator who has not performed the test before).

1. Start a Test.
   a. Put on a clean pair of gloves.
   b. Check that the cap on the quality control tube is closed.
   c. Touch QC on the HOME screen or touch QC on the Test Running screen.
   d. Select RUN POSITIVE CONTROL, RUN QC NEGATIVE TEST or RUN PROFICIENCY TEST option.
   e. Enter and Confirm Sample ID.
      a. On the Sample ID screen, type Negative Control for the Negative Control or Positive Control for the Positive Control, or scan sample ID barcode if available.
      b. Touch CONTINUE if the displayed information is correct.
      c. Verify Sample ID and touch CONFIRM.
2. Transfer Control to Cartridge.
   a. Squeeze the top bulb of the pipette completely until it is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the quality control tube.
   b. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing from the tube. It is okay if liquid goes into the overflow reservoir. Check that the pipette does not contain air bubbles.
3. Load Cartridge.
   a. Open the instrument door with the blinking green light.
   b. Load the cartridge with barcode facing the operator on the cartridge bay platform.
   c. Close the door until it clicks and the green light stops flashing.
4. Remove Cartridge. View Results.
   a. When the test has completed, the screen text will change to COMPLETE and the door unlocks.
   b. To view test report, touch the REPORT button then swipe across the screen from left to right to minimize screen and view report.
   c. Dispose of the cartridge and gloves according to your institution’s policy.
   d. Repeating steps in this section to test the second control tube starting with Step 1, Start a Test before testing patient samples.
   e. To log out, tap the User Menu icon , then tap Logout.
5. Fill Pipette with Control.
   a. Remove the pipette from the wrapper.
   b. Squeeze the top bulb of the pipette completely until the top bulb is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the quality control tube.
   c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing from the tube. It is okay if liquid goes into the overflow reservoir.
6. Mix Control.
   a. Mix control by rapidly inverting the quality control tube 5 times. Open the cap on the quality control tube.
   b. Dispose of the used pipette in an appropriate waste container.
   c. Close the cartridge lid.

VI Possible Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>SARS-CoV-2 POSITIVE</td>
<td>SARS-CoV-2 (coronavirus) target RNA is detected.</td>
</tr>
<tr>
<td>SARS-CoV-2NEGATIVE</td>
<td>SARS-CoV-2 (coronavirus) target RNA is not detected.</td>
</tr>
<tr>
<td>NO RESULT -REPEAT TEST</td>
<td>If the result is NO RESULT - REPEAT TEST with a new cartridge. If the retest is NO RESULT, collect new specimen and REPEAT TEST.</td>
</tr>
<tr>
<td>INSTRUMENT ERROR</td>
<td>Result is an instrument error. Touch CLEAR ERROR and follow the on-screen instructions. When the Home screen appears, repeat the test using a new cartridge.</td>
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NOTE: If an incorrect result is provided for the external control, repeat the external control run. If repeated control runs do not produce the expected results, contact Cepheid Technical Support at (888)838-3222.

VII Limitations

- This product has not been FDA cleared or approved, but 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.