Quick Reference Instructions for Xpert® Xpress SARS-CoV-2/Flu/RSV and GeneXpert Xpress System (Tablet Configuration)

For use under the Emergency Use Authorization (EUA) only.

The user should be trained in the procedure. Wear the appropriate protective attire for your safety when handling patient samples. Clean testing surfaces according to your institution’s policy. This test is only for nasal and nasopharyngeal swab specimens.

Read the complete Quick Reference Instructions before performing the test. For assistance, call Cepheid Technical Support at (888) 838-3222.

## How to Start the Software

1. **Start Software.**
   - a. Put on a pair of clean gloves.
   - b. Turn on the GeneXpert Xpress instrument (GeneXpert Xpress or GeneXpert Xpress II).
   - c. Turn on the computer.
   - d. Open the instrument door with the 9 bay platform.

2. **Enter Password.**
   - a. Touch Password to display the keyboard.
   - b. Enter your password.
   - c. Touch the arrow button at the right of the password entry area.

3. **Touch Begin Button.**
   - a. Touch START button to go to the Home Screen.

4. **HOME Screen Displayed.**
   - a. Touch ADMIN button to go to the Home Screen. Touch the Cepheid-Admin icon to continue.
   - b. Windows 7: The Windows 7 account screen appears. Touch the Cepheid-Admin icon to continue.

## How to Test a Patient Specimen

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

1. **Start a Test.**
   - a. Touch RUN NEW TEST on the Home screen (GeneXpert Xpress IV screen shown below).
   - b. Check that the specimen tube cap is closed.

2. **Enter & Confirm Patient/Sample ID.**
   - a. Touch the Patient/Sample ID barcode, touch the YES button then scan the Patient/Sample ID with the scanner.
   - b. If there is no Patient/Sample ID barcode, touch the NO button then manually enter the Patient/Sample ID and touch the OK button.
   - c. Touch the YES button to confirm that the Patient/Sample ID is correct.

3. **Scan and Confirm Cartridge.**
   - a. Touch the arrow button at the right of the password entry area.
   - b. Touch the SKIP VIDEO AND CONTINUE button to exit video.
   - c. If applicable, enter your user name and password.

4. **Scan Cartridge.**
   - a. Touch the Cartridge to Scan button.
   - b. The Home screen will be displayed with the VIEW PREVIOUS TESTS button appearing initially.
   - c. The Run NEW TEST button will appear on the Home screen within 1 minute. (GeneXpert Xpress IV screen shown below).

5. **Fill Pipette with Sample.**
   - a. Touch the arrow button at the right of the password entry area.
   - b. Mix specimen by rapidly inverting the transport tube 5 times. Open the cap on the specimen transport tube.
   - c. To print the results, touch the PRINT RESULT button.
   - d. Dispose of the cartridge and gloves according to your institution’s policy.

6. **Transfer Sample to Cartridge.**
   - a. Touch the arrow button at the right of the password entry area.
   - b. Close the cartridge lid. Dispose of the used pipette in an appropriate waste container.

7. **Load Cartridge.**
   - a. Touch the arrow button at the right of the password entry area.
   - b. Touch the Cartridge to Scan button.
   - c. Touch the SIGN OUT button to log out previous user, if applicable.
   - d. Touch the CARTRIDGE button to continue.

8. **Load Cartridge.**
   - a. Touch the arrow button at the right of the password entry area.
   - b. Touch the Cartridge to Scan button.
   - c. Touch the SIGN OUT button to log out previous user, if applicable.
   - d. Touch the CARTRIDGE button to continue.

## Storage and Handling and Warnings

<table>
<thead>
<tr>
<th>Storage and Handling</th>
<th>Warnings</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>• Store the Xpert SARS-CoV-2/Flu/RSV cartridges at 2-28°C.</td>
<td>• DO NOT use a cartridge that has been dropped.</td>
</tr>
<tr>
<td>• DO NOT open a cartridge lid until you are ready to perform testing.</td>
<td>• DO NOT shake or tilt the cartridge after adding the sample.</td>
</tr>
<tr>
<td>• DO NOT reuse disposable pipettes or cartridges.</td>
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</tr>
<tr>
<td>• DO NOT turn off or unplug the instrument while a test is in progress as this will stop the test.</td>
<td>• DO NOT use a cartridge that has a missing or damaged reaction tube.</td>
</tr>
</tbody>
</table>

Refer to Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing.
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 Test in Progress. To view a test in progress, touch the Test in progress touch for status button. The time remaining to complete the testing will be displayed on the progress bar at the bottom of the Test in Progress screen.

3 View Completed Tests. When a test is completed, touch the Test complete, touch to continue button. The Remove Cartridge screen will be displayed. Follow the on-screen instructions to remove the cartridge. Touch the CONTINUE button to view the result of the test.

V How to Run External Controls-Positive and Negative Controls

It is recommended that external controls (ZeptoMetrix Catalog# NATFRC-6C as a positive control and ZeptoMetrix Catalog# NATCV9-6C as a negative control) be tested at the frequency noted below.

• Each time a new lot of Xpert Xpress SARS-CoV-2/Flu/RSV cartridge, a control tube, and a transfer pipette are used (after first 5 tests).
• Each time a new shipment of Xpert Xpress SARS-CoV-2/Flu/RSV 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).

VI Possible Results

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 POSITIVE</td>
<td>SARS-CoV-2 (coronavirus) target RNA is detected.</td>
</tr>
<tr>
<td>SARS-CoV-2 NEGATIVE</td>
<td>SARS-CoV-2 target RNA is not detected.</td>
</tr>
<tr>
<td>Flu A POSITIVE</td>
<td>Flu A target RNA is detected.</td>
</tr>
<tr>
<td>Flu A NEGATIVE</td>
<td>Flu A target RNA is not detected.</td>
</tr>
<tr>
<td>Flu B POSITIVE</td>
<td>Flu B target RNA is detected.</td>
</tr>
<tr>
<td>Flu B NEGATIVE</td>
<td>Flu B target RNA is not detected.</td>
</tr>
<tr>
<td>RSV POSITIVE</td>
<td>RSV target RNA is detected.</td>
</tr>
<tr>
<td>RSV NEGATIVE</td>
<td>RSV 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 result is NO RESULT, collect new specimen and REPEAT TEST.</td>
</tr>
</tbody>
</table>

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.

NOTE: If only one viral target is positive but coinfection with multiple targets is suspected, the sample should be re-tested with another FDA cleared, approved, or authorized test, if coinfection would change clinical management.

VII Limitations

• This test has not been FDA cleared or approved.
• This test has been authorized by FDA under an EUA for use by authorized laboratories.
• This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.
• This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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