### How to Start a Test

**Before You Begin:**
- Read through the 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.

**I. Storage and Handling**

<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 Xpress SARS-CoV-2/Flu/RSV cartridges at 2-28 °C.</td>
<td>• DO NOT use a cartridge that has been dropped.</td>
</tr>
</tbody>
</table>

**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. Sweep across the screen from left to right to minimize screen and view report.
   d. Dispose of the cartridge and gloves.

2. **Enter Password**
   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.
   d. Touch the Login button.

3. **Scan, Select Assay and Confirm Cartridge**
   a. Start the test within 30 minutes of adding the specimen to the cartridge.
   b. The recommended environmental operating conditions for Xpert Xpress SARS-CoV-2/Flu/RSV are 15-30°C, 20-80% relative humidity.

**III. How to Test a Patient Specimen**

**Before You Begin:**
- Refer to the package insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing.

**Enter/Scan Sample ID**

1. **Fill Pipette with Sample**
   a. Remove the pipette from the wrapper.
   b. 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 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 from the tube. It is okay if liquid goes into the overflow reservoir. Check that the pipette does not contain air bubbles.

2. **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) in the cartridge. Some liquid may remain in the overflow reservoir.

3. **Close Cartridge Lid**
   a. Close the cartridge lid.

4. **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.

5. **Remove Cartridge, View Results**
   a. When the test is completed, the screen 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. To log out, tap the User Menu icon, then Tap Logout.

6. **How to Start a New Test**
   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. For a new user log in, touch the User Menu icon to log in.
   d. Start a new test following the steps in this section starting with Step 1, Start a Test. Or for starting a test while a test is running, see Step 11.

7. **Starting a Test While a Test is Running**
   a. Put on a new pair of gloves if performing a new test.
   b. Touch the HOME button on the Test Running screen to go to the Home Screen.
   c. For a new user log in, touch the User Menu icon to log in.
   d. Start a new test following the steps in this section 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# 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 SARS-CoV-2/Flu/RSV is received.
- 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).

- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.

1. Start a Test.
   - a. Put on a new pair of gloves if performing a new test.
   - b. Touch QC on the Home screen or touch QC on the Test Running screen.
   - c. Select RUN POSITIVE CONTROL, RUN NEGATIVE CONTROL or RUN PROFICIENCY TEST option.

2. Fill Pipette with Control.
   - a. Remove the pipette from the wrapper.
   - b. 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 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 from the tube. It is okay if liquid goes into the overflow reservoir.
   - d. Check that the pipette does not contain air bubbles.

3. Transfer Control 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) in the cartridge. Some liquid may remain in the overflow reservoir.
   - b. Close the cartridge lid.
   - c. Dispose of the used pipette in an appropriate waste container.

4. 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.

5. Remove Cartridge. View Results.
   - a. When the test is completed, the screen 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. Dispose of the control media in your institution's policy.
   - e. To log out, tap the User Menu icon then tap Logout.

**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 (coronavirus) 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>
</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.*

**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.