Quick Reference Instructions for Xpert® Xpress SARS-CoV-2 and GeneXpert Xpress System (Hub Configuration)

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

IVD **R**only

ℹ️ 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 nasopharyngeal swab, nasal swab, and mid-turbinate swab specimens.
Read the complete Quick Reference Instructions before performing the test. For assistance, call Cepheid Technical Support at (888) 838 3222.

I Storage and Handling and Warnings

Storage and Handling	Warnings
• Wear gloves. Change gloves between processing each sample. • Store the Xpert Xpress SARS-CoV-2 cartridges at 2-28 °C.	• DO NOT use a cartridge that is wet or has leaked. • DO NOT use a cartridge that has been dropped. • DO NOT open a cartridge lid until you are ready to perform testing. • DO NOT shake or tilt the cartridge after adding the sample. • DO NOT reuse disposable pipettes or cartridges. • DO NOT turn off or unplug the instrument while a test is in progress as this will stop the test. • DO NOT use a cartridge that has a missing or damaged reaction tube.

ℹ️ Refer to the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing.
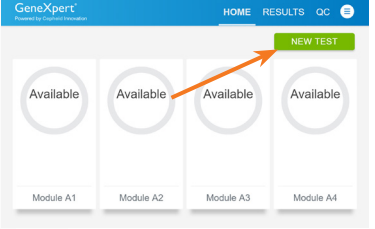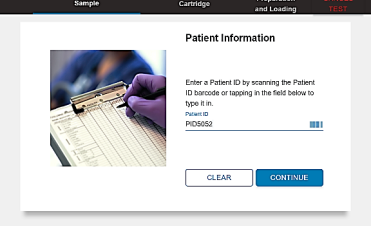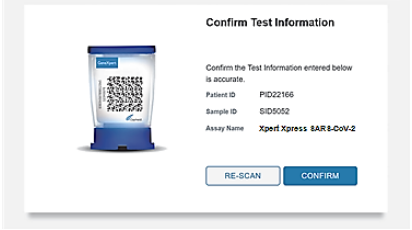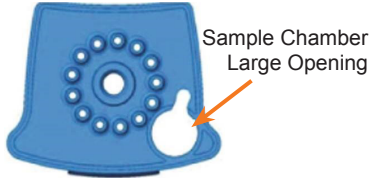
II How to Start the Software

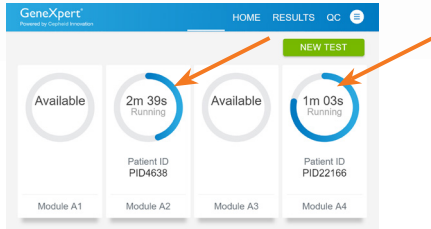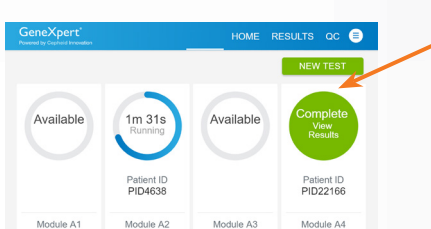| **1 Start Software** a. Put on a pair of clean gloves. b. Turn on the GeneXpert Xpress instrument. c. Turn on the Hub computer. The Windows lock screen appears. Swipe up to continue. d. Enter the Windows password and touch the arrow next to the password field. e. The GeneXpert Xpress Software login screen appears f. Manually enter user name and password in Step 2a or if enabled, scan ID card in Step 2b.	**2a 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.	**2b Scan ID Card** If enabled, log in by scanning the bar-code on your institutional ID, as shown below.	**3 The HOME Screen Displays.** The HOME screen will display the module status and the **NEW TEST** button.

III 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.

- Start the test within 30 minutes of adding the specimen to the cartridge.
- The recommended environmental operating conditions for Xpert Xpress SARS-CoV-2 are 15-30°C, 20-80% relative humidity.

1 Start a Test. a. Touch **NEW TEST** on the HOME screen. b. Check that the specimen tube cap is closed.	**2a Enter/Scan Patient ID** and touch **CONTINUE. Confirm Patient ID.** **2b Enter/Scan Sample ID** and touch **CONTINUE. Confirm Sample ID.**	**3 Scan and Confirm Cartridge** * If applicable, enter your user name and password.	**4 Watch Video. Mix Specimen.** a. Watch video before performing Steps 5, 6, and 7. The video will repeat. Touch the **CONTINUE** button to exit video. b. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube. c. Open the cartridge lid.
5 Fill Pipette with Sample. a. Remove the pipette from the wrapper. b. Squeeze the top bulb of the pipette **completely** and then place the pipette tip in the specimen transport tube. c. Release the top bulb of the pipette to fill the pipette with sample from the patient specimen tube. Squeeze Here Pipette — Overflow Reservoir Bulb Sample	**6 Transfer Sample to Cartridge.** a. Squeeze the top bulb of the pipette **completely** again to empty the contents of the pipette into the large cartridge opening (Sample Chamber). Sample Chamber Large Opening	**7 Close Cartridge Lid.** a. Close the cartridge lid. b. Dispose of the used pipette in an appropriate waste container.	**8 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.
9 Remove Cartridge. View Results. a. When the test is 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. To log out, tap the User Menu icon 🗐, then tap Logout.	**10 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**.	**11 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**.	

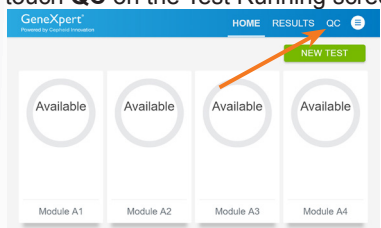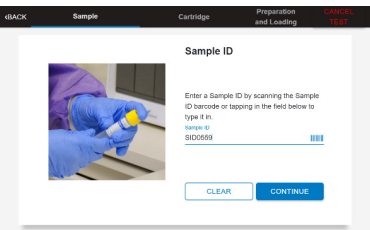## IV How to View Status of Tests in Progress and Completed Tests
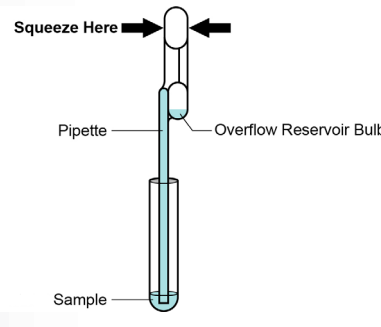
1 Touch HOME Button.
Touch the **HOME** button to view the status of tests in progress or completed tests.

HOME

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.

> ℹ️ Refer to the Package Insert for information on reviewing or printing past results.

V How to Run External Controls - Positive and Negative Controls

It is recommended that external controls (SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-126) be tested at the frequency noted below.

- Each time a new lot of Xpert Xpress SARS-CoV-2 is received.
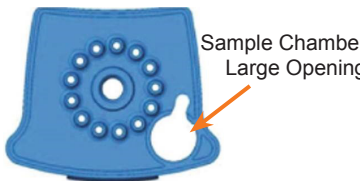- Each time a new shipment of Xpert Xpress SARS-CoV-2 is received even if it is the same lot previously received.
- Each time a new operator is performing the test (i.e., operator who has not performed the test before).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- 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 Enter and Confirm Sample ID.
a. On the Sample ID screen, type **Negative Control** for the **N**egative 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**.

3 Scan and Confirm Cartridge.
a. Scan the barcode on the cartridge with the scanner.
b. Touch **CONFIRM** if the displayed information is correct.
c. If applicable, enter your user name and password.

4 Watch Video. Mix Control.
a. Watch video before performing Steps 5, 6, and 7. The video will repeat. Touch the **CONTINUE** button to exit video.
b. Mix control by rapidly inverting the quality control tube 5 times. Open the cap on the quality control tube.
c. Open the cartridge lid.

5 Fill Pipette with Control.
a. Remove the pipette from the wrapper.
b. Squeeze the top bulb of the pipette **completely** and place the pipette tip in the quality control tube.
c. Release the top bulb of the pipette to fill the pipette with the quality control.

Squeeze Here → ←
Pipette — Overflow Reservoir Bulb
Sample

6 Transfer Control to Cartridge.
a. Squeeze the top bulb of the pipette **completely** again to empty the contents of the pipette into the large cartridge opening (Sample Chamber).

Sample Chamber Large Opening

b. Close the cartridge lid.

c. Dispose of the used pipette in an appropriate waste container.

7 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.

8 Remove Cartridge. View Results.
a. When the test is 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. Repeat 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.

VI Possible Results

Result	Interpretation
SARS-CoV-2 NEGATIVE	SARS-CoV-2 (coronavirus) target RNA is not detected.
SARS-CoV-2 POSITIVE	SARS-CoV-2 (coronavirus) target RNA is detected.
SARS-CoV-2 PRESUMPTIVE POS	If the result is **SARS-CoV-2 PRESUMPTIVE POS**, then retest with a new cartridge. If the retest is **SARS-CoV-2 PRESUMPTIVE POS, collect new specimen and REPEAT TEST.**
NO RESULT - REPEAT TEST	If the result is **NO RESULT- REPEAT TEST** with a new cartridge. If the retest is **NO RESULT, collect new specimen and REPEAT TEST.**
INSTRUMENT ERROR	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.

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.