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

For use under Emergency Use Authorization (EUA) only.

IVD Rx only

Cepheid® *A better way.*

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 anterior nasal, nasopharyngeal and mid-turbinate swab specimens in viral transport medium, saline and eNAT medium.

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 CoV-2 *plus* 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 use a cartridge that has a missing or damaged reaction tube. • 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 beyond its expiration date.

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 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.

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 are shown in a video within the software and in the Quick Reference Instructions.
• Start the test within 30 minutes of adding the specimen to the cartridge.
• The recommended environmental operating conditions for Xpress Xpress CoV-2 *plus* are 15-30°C, 20-80% relative humidity.

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.

Squeeze Here
Pipette — Overflow Reservoir Bulb
Sample

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.

Sample Chamber Large Opening

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 text 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 minimize 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.

14 Starting a New Test with Another User.
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 **Step1, 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.
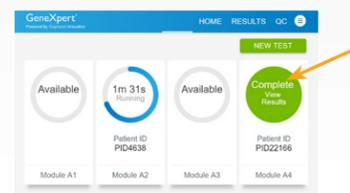
HOME

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.

NOTE: 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 (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).
- 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 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.

2 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.

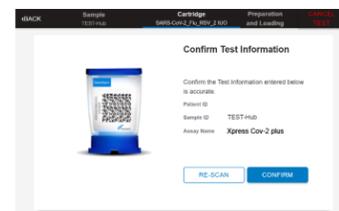c. Verify Sample ID and touch **CONFIRM**.

Confirm the Sample ID entered below is accurate.
Sample ID   Positive Control

RE-ENTER   CONFIRM

3 Scan and Confirm Cartridge.
a. Scan the barcode on the cartridge with the scanner.

b. Select and **CONFIRM** test information.
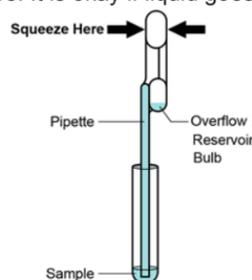

*If applicable, enter your user name and password.

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. Check that the cap on the quality control tube is closed.
c. Mix control by rapidly inverting the quality control tube 5 times. Open the cap on the quality control tube.
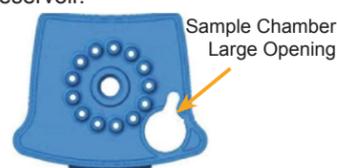d. Open the cartridge lid.

5 Fill Pipette with Control.
a. Remove the pipette from the wrapper.
b. Squeeze the top bulb of the pipette **completely 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. Check that the pipette does not contain air bubbles.

Squeeze Here
Pipette
Overflow Reservoir Bulb
Sample

6 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.

Sample Chamber Large Opening

b. Dispose of the used pipette in an appropriate waste container.
c. Close the cartridge lid.

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 and the green light stops flashing.

8 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. 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 POSITIVE	SARS-CoV-2 (coronavirus) target RNA is detected.
SARS-CoV-2 NEGATIVE	SARS-CoV-2 (coronavirus) target RNA is not detected.
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 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.

IVD   For IVD *In Vitro* Diagnostic Use   302-6663Rev. C May 2022