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

Cepheid *A better way.*

IVD · R only

For use under 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 accord- ing 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 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 (GeneXpert Xpress II or GeneXpert Xpress IV).
c. Turn on the computer. Windows 7: The Windows 7 account screen appears. Touch the Cepheid-Admin icon to continue. Windows 10: The Windows lock screen appears. Swipe up to continue.

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. Press the **TOUCH HERE TO BEGIN** button.
b. If applicable, enter your user name and password.

4 HOME Screen Displayed in 3 Minutes.*
GeneXpert Xpress IV screen shown below.

Note: If the Home screen does not display **RUN NEW TEST, the instrument was not powered up or is no longer powered on. Exit the software using the **EXIT** button. The GeneXpert Xpress instrument must first be turned on then turn on the computer. Click on the software icon to launch the software and enter the password.*

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 these Quick Reference Instructions.

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

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

2 Confirm if Patient/Sample ID Barcode is Present
a. If present, touch **YES** and go to Step 3a.
b. If not present, touch **NO** and go to Step 3b.

3a Scan and Confirm Cartridge.
Scan Patient/Sample ID barcode with a scanner.

3b Enter Patient/Sample ID
Manually enter Patient/Sample ID and touch **OK**.

4 Confirm Patient/Sample ID Information
Touch **YES**.

5 Scan Cartridge Barcode
a. Remove a cartridge and a transfer pipette from the cartridge kit box.
b. Scan the barcode on the cartridge.

6 Select Assay and Confirm Test
a. Select **Xpress CoV-2 plus**.
b. Touch **YES** to confirm test.

7 Watch Video. Mix Specimen.
a. Watch the video before performing Steps 8, 9, and 10. The video will repeat. Touch the **SKIP VIDEO AND 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.

8 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

9 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

10 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.

11 Remove Cartridge. View Results.
a. When the test is completed, the door will unlock and the Remove Cartridge screen will be displayed.
b. Follow the on-screen instructions to remove the cartridge. Touch **CONTINUE** to view the result of the test.

c. To print the results, touch the **PRINT RESULT** button.
d. Dispose of the cartridge and gloves according to your institution's policy.
e. Go to **How to Start a New Test (While a Test is Running)** if perform- ing a new test.
f. To log out, touch the **SIGN OUT** button.

12 How To 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. [HOME]
c. Start a new test following the steps in this **Section III, starting with Step 1, Start a Test**.
d. For starting a new test with another user, see **Step 13**.

13 Starting Another 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. [HOME]
c. Touch the **SIGN OUT** button to log out the previous user, if applicable. [SIGN OUT]
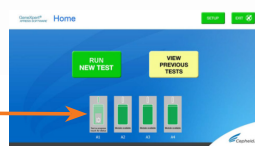d. Start a new test following the steps in this Section III, starting with **Step 1, Start a Test.**

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.
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.

"Test in progress, touch for status" button

3 View Completed Tests.
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. To print the results, touch the **PRINT RESULT** button.

"Test complete, touch to continue" button

NOTE: Refer to the Package Insert for information on reviewing or printing past results.

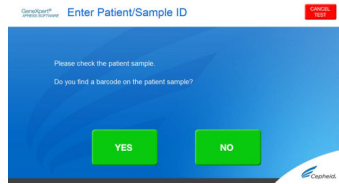# V How to Run External Controls-Positive and Negative Controls

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.
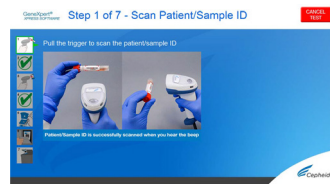
1 Start a Test.
a. Put on a new pair of clean gloves
b. Check that the quality external control tube cap is closed
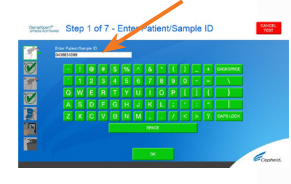c. Touch **RUN NEW TEST** on the Home screen

2 Confirm if Sample ID Barcode is Present.
a. If present, touch **YES** and go to Step 3a.
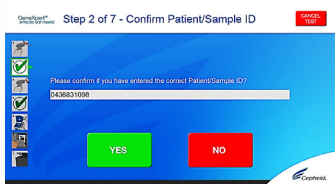b. If not present, touch **NO** and go to Step 3b

3a Scan Sample ID Barcode.
Scan Sample ID barcode with a scanner.

3b Enter Sample ID.
a. Type **negative control** for the Negative External Control or **positive control** for the Positive External Control.
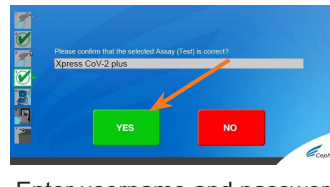b. Touch the **OK** button

4 Confirm Sample ID Information.
Touch **Yes**.

5 Scan Cartridge Barcode.
a. Remove a cartridge and a transfer pipette from the cartridge kit box.
b. Scan the barcode on the cartridge.

6 Select Assay and Confirm Test.
a. Select Xpert Xpress CoV-2 plus assay
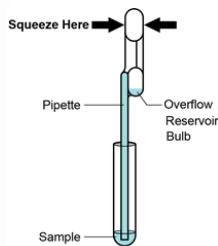b. Touch **YES** to confirm test
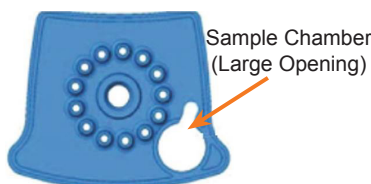c. Enter username and password if prompted.

7 Watch Video. Mix Control.
a. Watch the video before performing Steps 8, 9, and 10. The video will repeat. Touch the **SKIP VIDEO AND CONTINUE** button to exit the video.
b. Check that the quality control tube cap is closed.
c. Mix control by rapidly inverting the tube 5 times. Open the cap on the quality control tube.
d. Open the cartridge lid.

8 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 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

9 Transfer Control to Cartridge.
a. Squeeze the top bulb of the pipette **completely until the top bulb 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 the cartridge lid.

10 Load Cartridge.
a. Pull 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.

11 Remove Cartridge. View Results.
a. When the test is completed, the door will unlock, and the **Remove Cartridge** screen will be displayed.
b. Follow the on-screen instructions to remove the cartridge. Touch **CONTINUE** to view the result of the test.
c. To print the results, touch the **PRINT RESULT** button.
d. Dispose of the cartridge and gloves according to your institution's policy.
e. Go to **How to Start a New Test** (While a Test is Running) if performing a new test.
f. To log out, touch the **SIGN OUT** button.

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

302-6664 Rev. C May 2022

Cepheid
A better way.