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

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A better way.

IVD **Rx only**

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 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.

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.
The Home screen will be displayed with the **VIEW PREVIOUS TESTS** button appearing initially. The **RUN NEW TEST** button will appear on the Home screen within 1 minute. (GeneXpert Xpress IV screen shown below).
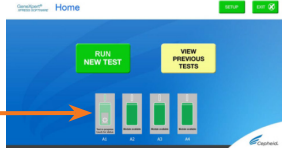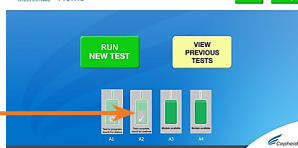
III How to Test a Patient Specimen

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 **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. If there is a 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. Remove a cartridge and a transfer pipette from the cartridge kit box.
b. Scan the barcode on the cartridge with the scanner. Touch **YES** if the displayed information is correct.
c. 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 SKIP VIDEO AND 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 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)

b. Close the cartridge lid. 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 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.

9 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. 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 or a new test with another user, see **Step 10**.

10 Starting Another 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. Touch the **SIGN OUT** button to log out previous user, if applicable.
d. Start a new test following the steps in this section starting with **Step 1, Start a Test**.

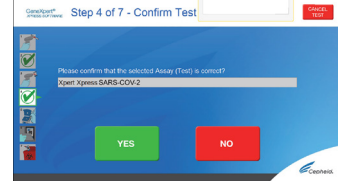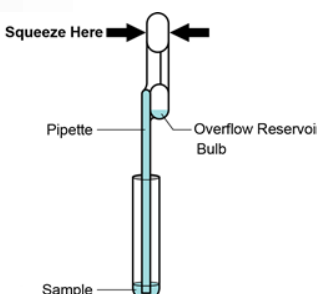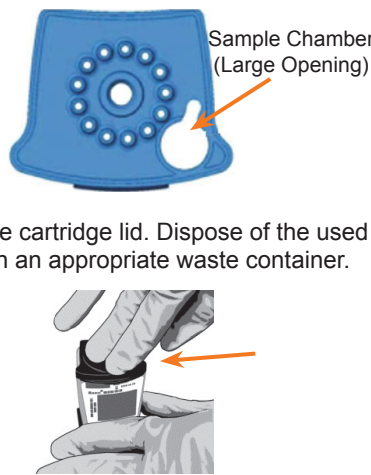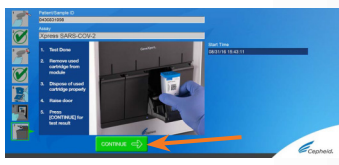## IV How to View Status of Tests in Progress and Completed Tests

1 Touch HOME Button.
Touch the **HOME** button to view the status of tests in progress or completed tests.

2 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.

"Test in progress, touch for status" button

3 View Completed Tests.
When a test in 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.

"Test complete, touch to continue" button

ℹ 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 pair of clean gloves.
b. Have a new Xpert Xpress SARS-CoV-2 cartridge, a control tube, and a transfer pipette ready.
c. Touch **RUN NEW TEST** on the home screen (GeneXpert Xpress IV shown below).

2 Enter & Confirm Sample ID.
a. Touch the **NO** button if there is no Sample ID barcode.
b. Type **negative control** for the Negative External Control or **positive control** for the Positive External Control in the Sample ID field. Touch the **OK** button.
c. Touch the **YES** button to confirm that the Patient/Sample ID is correct.

3 Scan and Confirm Cartridge.
a. Remove a cartridge and a transfer pipette from the cartridge kit box.
b. Scan the barcode on the cartridge with the scanner. Touch **YES** 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 **SKIP VIDEO AND 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 sample from the quality control tube.

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. 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. Do not try to insert the cartridge past the cartridge bay platform.

c. Close the door until it clicks.

8 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. Touch the **HOME** button to go to the Home Screen.
f. Repeat steps in this section to test the second control tube starting with **Step 1 Start a Test** before testing patient samples.

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.

For IVD In Vitro Diagnostic Use Only