GeneXpert.
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Xpert® Xpress SARS-CoV-2

Instructions for Use
For Use Under an Emergency Use Authorization (EUA) Only

℞only

REF **XPRSARS-COV2-10**

For Use with GeneXpert Xpress System (point of care system)

Cepheid.

For use under an Emergency Use Authorization (EUA) Only

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1   Proprietary Name

Xpert® Xpress SARS-CoV-2

2   Common or Usual Name

Xpert Xpress SARS-CoV-2

3   Intended Use

The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/ aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.

Testing of nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Dx and GeneXpert Infinity systems is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high and moderate complexity tests.

Testing of nasopharyngeal, nasal, or mid-turbinate swab specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Xpress System (Tablet and Hub Configurations) is authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the Xpert Xpress SARS-CoV-2 test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. The Xpert Xpress SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

4   Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

The Xpert Xpress SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2 test contains primers and probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in upper respiratory specimens.

The term "qualified laboratories" refers to laboratories in which all users, analysts, and any person reporting results from use of this device are proficient in performing real-time RT-PCR assays.

5   Principle of the Procedure

The Xpert Xpress SARS-CoV-2 test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The Xpert Xpress SARS-CoV-2 test is performed on GeneXpert Xpress System.

The GeneXpert Xpress System automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the GeneXpert Xpress System User's Guide.

The Xpert Xpress SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal, nasal, or mid-turbinate swab specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert Xpress System instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal, nasal, or mid-turbinate swab specimen is collected and placed into a viral transport tube containing 3 mL transport medium or 3 mL of saline. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2 cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Xpress System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

6   Reagents and Instruments

6.1   Materials Provided

The Xpert Xpress SARS-CoV-2 kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert Xpress SARS-CoV-2 Cartridges	
with Integrated Reaction Tubes	**10**

- Bead 1, Bead 2, and Bead 3 (freeze-dried)   **1 of each per cartridge**
- Lysis Reagent   **1.5 mL per cartridge**
- Binding Reagent   **1.5 mL per cartridge**
- Elution Reagent   **3.0 mL per cartridge**

Disposable Transfer Pipettes	**10-12 per kit**
CD	**1 per kit**

- Assay Definition File (ADF)

- Instructions to import ADF into GeneXpert software

Flyer	**1 per kit**

- Directions to locate the Product Insert and Quick Reference Instructions on www.cepheid.com

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7   Storage and Handling

- Store the Xpert Xpress SARS-CoV-2 cartridges at 2-28°C.
- Do not open a cartridge lid until you are ready to perform testing.
- Do not use a cartridge that is wet or has leaked.

8   Materials Required but Not Provided

- GeneXpert Xpress System (Tablet configuration): GeneXpert Xpress II and IV instruments with proprietary GeneXpert Xpress Software Version 5.0 and 5.1, tablet computer device with touchscreen, barcode scanner, external CD drive, wireless printer, Getting Started Guide, and GeneXpert Xpress System User's Guide.

- GeneXpert Xpress System (Hub configuration): GeneXpert Xpress IV instrument, GeneXpert Hub with proprietary GeneXpert Xpress Software Version 6.1 or higher, GeneXpert Hub with integrated computer, touchscreen monitor and barcode scanner, external CD drive, Getting Started Guide, and GeneXpert Xpress System User's Guide.

9   Materials Available but Not Provided

SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126 (Order Code CEPHEID)

10 Warnings and Precautions

10.1 General

- For in vitro diagnostic use.

- For emergency use only.

- Positive results are indicative of presence of SARS-CoV-2-RNA.

- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

- Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.

- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention3 and the Clinical and Laboratory Standards Institute.4

- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.

- Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.

10.2 Specimens

- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section 12, Specimen Collection, Transport, and Storage). Specimen stability under shipping conditions other than those recommended has not been evaluated.

10.3 Assay/Reagent

- Do not open the Xpert Xpress SARS-CoV-2 cartridge lid except when adding specimen.

- Do not use a cartridge that has been dropped after removing it from the packaging.

- Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.

- Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge.

- Do not use a cartridge with a damaged barcode label.

- Do not use a cartridge that has a damaged reaction tube.

- Each single-use Xpert Xpress SARS-CoV-2 cartridge is used to process one test. Do not reuse processed cartridges.

- Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.

- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.

- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.

- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

11   Chemical Hazards[5,6]
• **Signal Word: Warning**

• **UN GHS Hazard Statements**
- Harmful if swallowed.
- May be harmful in contact with skin.
- Causes eye irritation.

• **UN GHS Precautionary Statements**
- **Prevention**
  - Wash hands thoroughly after handling.
- **Response**
  - Call a POISON CENTER or doctor/physician if you feel unwell.
  - If skin irritation occurs: Get medical advice/attention.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - If eye irritation persists: Get medical advice/attention.

## 12   Specimen Collection, Transport, and Storage
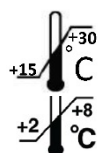
Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See Section 12.1 for nasopharyngeal swab collection procedure, Section 12.2 for nasal swab collection procedure, and Section 12.3 for mid-turbinate swab collection procedure. Nasopharyngeal, nasal, and mid-turbinate swab specimens can be stored at room temperature (15–30 °C) for up to 8 hours and refrigerated (2–8 °C) up to seven days until testing is performed on the GeneXpert Xpress System.

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

12.1 Nasopharyngeal Swab Collection Procedure

Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1). Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.
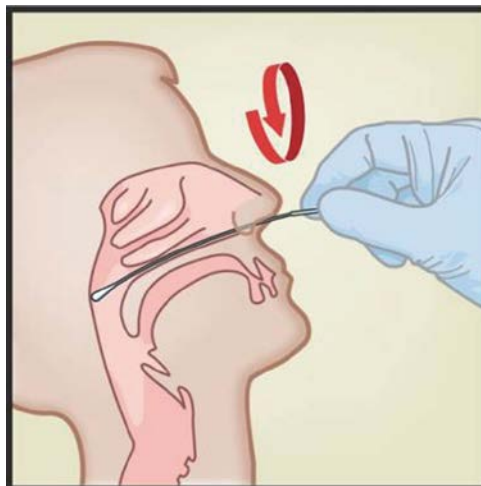

Figure 1. Nasopharyngeal Swab Collection

12.2 Nasal Swab Collection Procedure

1. Insert a nasal swab 1 to 1.5 cm into a nostril. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril (see Figure 2).

Figure 2. Nasal Swab Collection for First Nostril

2. Repeat on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.

Figure 3. Nasal Swab Collection for Second Nostril

3. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.3 Mid-Turbinate Swab Collection Procedure
1. Insert the mid-turbinate swab into either nostril, passing it into the mid-turbinate area (see Figure 4). Rotate swab by firmly brushing against the mid-turbinate area several times.
2. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.
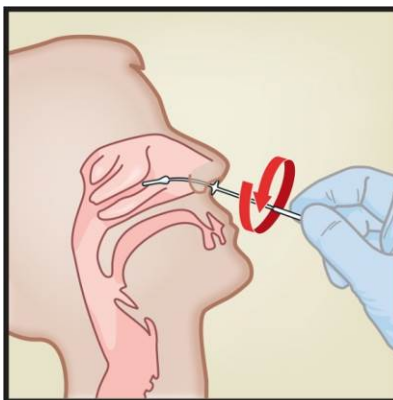
Figure 4. Mid-turbinate Swab Specimen Collection

13 Starting the System
The recommended environmental operating conditions for Xpert Xpress SARS-CoV-2 test are 15-30°C, 20-80% relative humidity.

1. Put on a clean pair of gloves.

2. Determine which system configuration you have (Figure 5).

Xpert Xpress SARS-CoV-2

Tablet Configuration   **Hub Configuration**
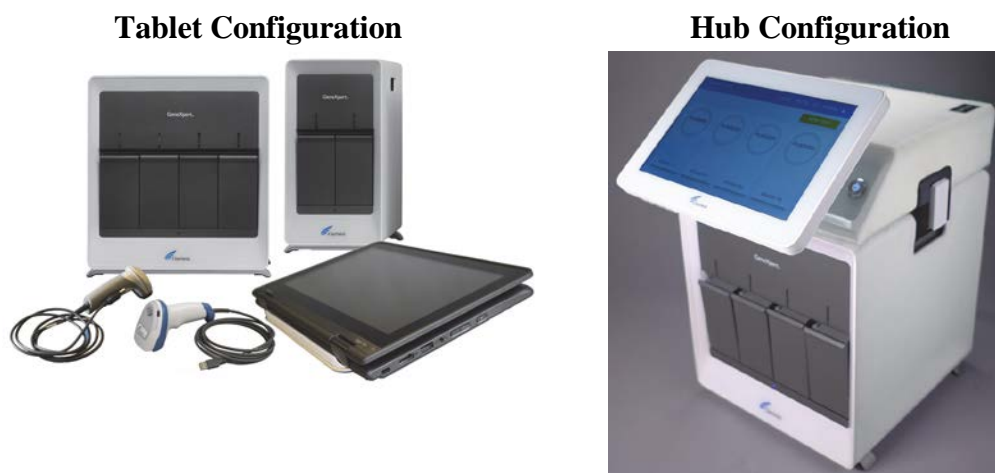
Figure 5. Tablet and Hub System Configurations

- For the *Tablet* configuration, see Section 13.1, Starting the Tablet Configuration.
- For the *Hub* configuration, see Section 13.2, Starting the Hub Configuration.

13.1 Starting the Tablet Configuration

1. Turn on the GeneXpert Xpress instrument (GeneXpert Xpress II or GeneXpert Xpress IV).

2. Turn on the tablet 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.

The Windows Password screen appears.

3. Touch **Password** to display the keyboard, then type your password.

4. Touch the arrow button at the right of the password entry area. The GeneXpert Xpress Software starts.

13.2 Starting the Hub Configuration

1. Turn on the GeneXpert Xpress IV instrument (in two or four modules configuration).

2. Turn on the Hub computer. The Windows Lock screen appears.

3. Swipe up to continue. The Windows Password screen appears.

4. Touch **Password** to display the keyboard, then type your Windows password.

5. Touch the arrow button at the right of the password entry area. The GeneXpert Xpress Software starts and a login screen appears.

6. If enabled, you may log in by scanning a barcode on your institutional ID, using the

   barcode scanner (located behind the right side of the touchscreen). Then proceed to Step 9. Otherwise, follow the steps below to login manually.

7. Enter your User Name and Password (the virtual keyboard appears once you touch the entry fields).

8. Touch the **X** in the upper right of the virtual keyboard. The keyboard disappears and the **LOGIN** button appears at the bottom of the screen. Touch the **LOGIN** button to continue.

9. The Database Maintenance Reminder screen and the Archive Tests Reminder dialog boxes may appear, depending on your system configuration. For more information, see the GeneXpert Xpress System User's Guide.

13.3 Determining Your Software Version
When your Xpress opening screen appears, you can determine your software version and the procedure to follow, based on one of the following two screens (see Figure 6).
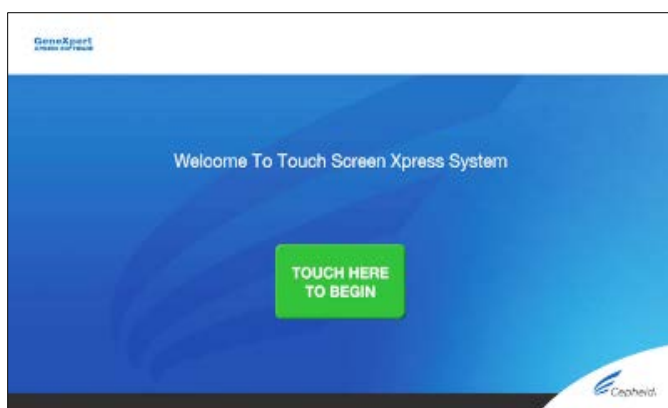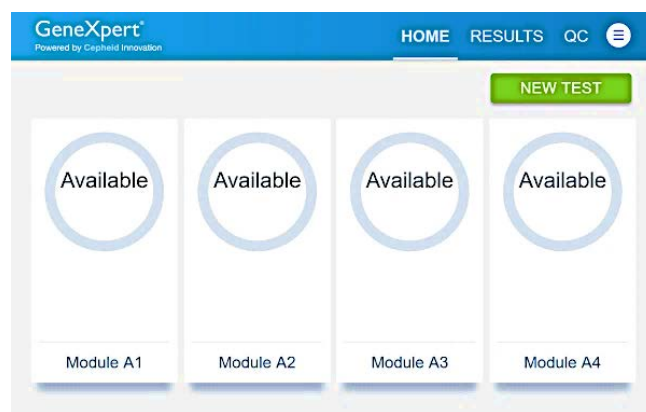
Software Version 5.0 or Software Version 5.1   **Software Version 6.1 or Higher**

Figure 6. Xpress Opening Screens and Software Versions

- For Software Version 5.0 or Software Version 5.1, see Section 14.

- For Software Version 6.1 or higher, see Section 16.

14 GeneXpert Xpress Software Version 5.0 or Software Version 5.1
1. On the Welcome screen, touch the **TOUCH HERE TO BEGIN** button (see Figure 7).
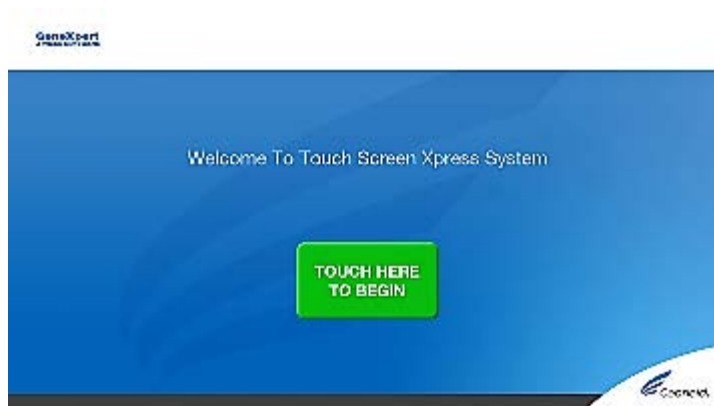
Figure 7. Welcome Screen

2. The **VIEW PREVIOUS TESTS** button appears. The **RUN NEW TEST** button will appear on the Home screen within 3 minutes.

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 software icon to launch software and enter password.

14.1 Starting a Test

Note Instructions showing how to prepare the sample and the cartridge are shown on-screen in a video and are also described in the Quick Reference Instructions (QRI).

Important Start the test within 30 minutes of adding the sample to the cartridge.

1. Put on a new pair of gloves if performing a new test. Touch the **RUN NEW TEST** button on the Home screen (see Figure 8) to run a patient specimen or an external control.
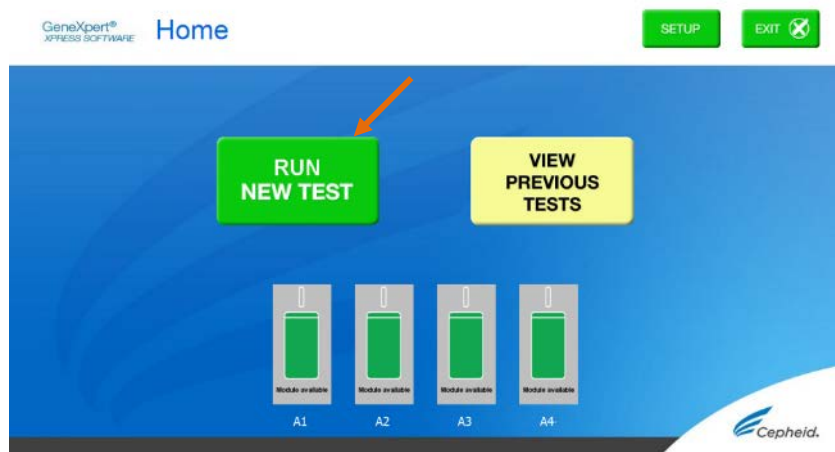
Figure 8. RUN NEW TEST button on Home Screen
(GeneXpert Xpress IV screen shown)

2. Check that the specimen transport medium tube cap is closed.

3. If there is a Patient/Sample ID barcode, touch the **YES** button, then scan the Patient/Sample ID with the scanner. If there is no Patient/Sample ID barcode, touch the **NO** button, then manually enter the Patient/Sample ID and touch the **OK** button. For external control, type **Positive Control** or **Negative Control**.

4. Confirm the Patient/Sample ID. Touch **YES** if the Patient/Sample ID is correct.

14.2 Preparing the Specimen or External Control and Cartridge

It is recommended that external controls be tested at the frequency noted below.

- Each time a new lot of Xpert Xpress SARS-CoV-2 kits is received.
- Each time a new shipment of Xpert Xpress SARS-CoV-2 kits 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 recently).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.

1. Remove a cartridge and a transfer pipette from the cartridge kit box.

2. Scan the barcode on the cartridge with the scanner.

Note If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan or scanning the barcode results in an error message stating the cartridge is expired, then repeat the test with a new cartridge.

If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will appear indicating the assay definition file is not loaded on the system. If this screen appears, contact Cepheid Technical Support.

3. Confirm that the name on the cartridge is Xpert Xpress SARS-CoV-2 (shown in Figure 9 below) and touch **YES** if the displayed information is correct. Enter your user name and password if prompted.

In the following steps, keep the cartridges upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

Figure 9. Confirm Test Screen

4. Watch the video before continuing. The video will repeat. Touch the **SKIP VIDEO AND CONTINUE** button to exit video. The **Load Cartridge** screen appears.

5. Mix sample by rapidly inverting the specimen transport tube or external control tube 5 times. Open cap on the specimen transport tube or external control tube.

6. Open the cartridge lid by lifting the front of the cartridge lid.

7. Remove the transfer pipette from the wrapper.

Note Do not place unwrapped pipette on the workbench.

8. Squeeze the top bulb of the transfer pipette completely then place the pipette tip in the specimen transport tube or the external control tube (see Figure 10).
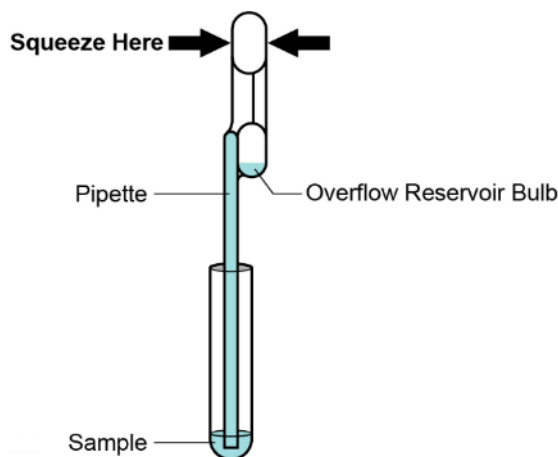
Figure 10. Transfer Pipette

9. Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample can be seen in the overflow reservoir bulb of the pipette (see Figure 10). Check that the pipette does not contain bubbles.

10. To transfer the patient specimen or external control to the cartridge, squeeze the top bulb of the transfer pipette **completely** again to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge shown in Figure 11. Dispose of the used pipette.

Sample Chamber (Large Opening)
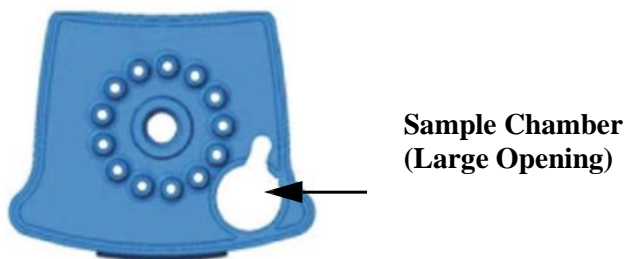
Figure 11. Xpert Xpress SARS-CoV-2 Cartridge (Top View)

Note Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

11. Close the cartridge lid.

14.3 Loading the Cartridge

1. Pull open the module door with the flashing green light.

2. Load the cartridge with the barcode facing the operator onto the cartridge bay platform. Do not try to insert the cartridge past the cartridge bay platform.

3. Close the door until it clicks. The green light will stop flashing and the test starts. The **Test in Progress** screen appears. When the test is completed (green light goes out), the door will automatically unlock and the **Remove Cartridge** screen appears.

4. Follow the on-screen instructions to remove the cartridge and to reset the module for a new test.

5. Touch **CONTINUE** to view the result of the test.

6. To print results, touch the **PRINT RESULT** button.

7. Remove cartridge. Dispose of the used cartridge and gloves according to your institution's standard practices.

8. To log out, touch the **SIGN OUT** button.

Note Do not turn off or unplug the instruments while a test is in progress. Turning off or unplugging the GeneXpert Xpress instrument or computer will stop the test.

Note If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan or scanning the barcode results in an error message stating that the cartridge is expired, then repeat the test with a new cartridge.

Note If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will appear indicating that the assay definition file is not loaded or that the product code was not found on the system. If this screen appears, contact Cepheid Technical Support.

14.4 Start A New Test While a Test is Running

1. Put on a clean pair of gloves if performing a new test.

2. Touch the **HOME** button to go to the Home Screen.

3. Touch the **SIGN OUT** button to log out the previous user, if applicable.

4. Start a new test following the steps in Section 14.1, Starting a Test.

15 View Status of Tests in Progress, Completed Tests, and View Results of Past Tests

15.1 Tests in Progress

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

2. To view a test in progress, touch the **Test in progress touch for status** button. The time remaining to complete the testing will appear on the progress bar at the bottom of the **Test in Progress** screen.

15.2 Completed Tests

1. When a test is completed, touch the **Test complete, touch to continue** button. The **Remove Cartridge** screen appears.

2. Follow the on-screen instructions to remove the cartridge. Touch the **CONTINUE** button to view the result of the test. To print results, touch the **PRINT RESULT** button.

15.3 Results of Past Tests

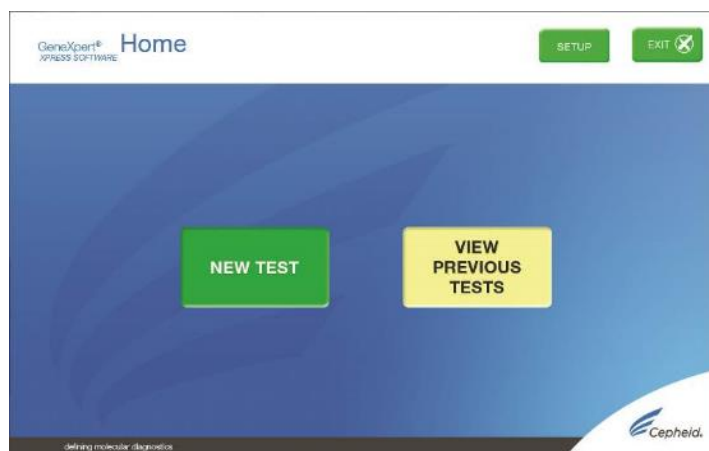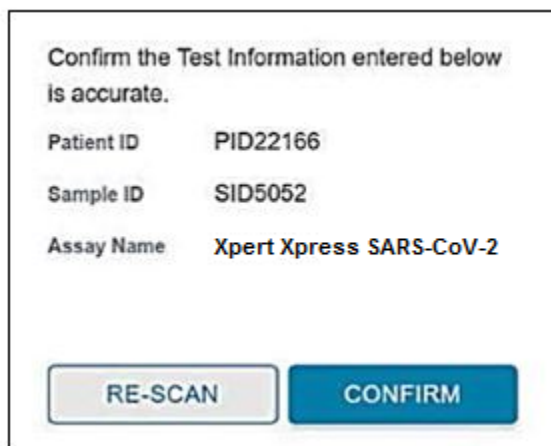1. Touch the **VIEW PREVIOUS TESTS** button on the Home screen shown in Figure 12.

Figure 12. VIEW PREVIOUS TESTS button on Home Screen

2. Select the test by either touching the test name or using the arrows to select the test.

3. Touch the **SELECT** button shown in Figure 13 to view results.

4. To print results, touch the **PRINT RESULT** button.
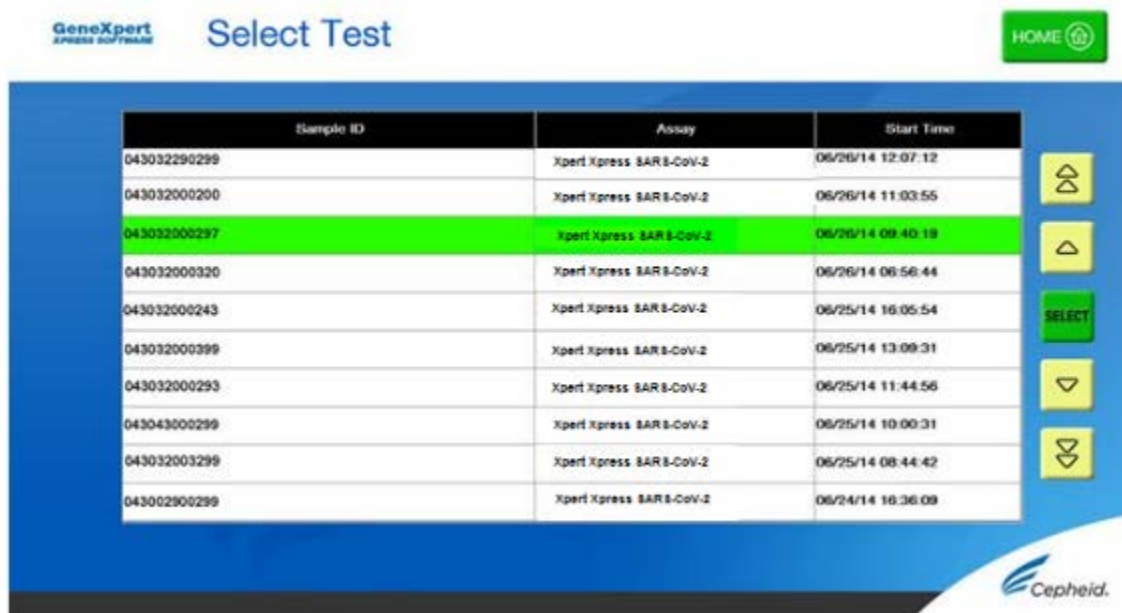
Figure 13. SELECT button

16 GeneXpert Xpress Software Version 6.1 or Higher

16.1 Starting a Test

Note Instructions showing how to prepare the sample and the cartridge are shown on-screen in videos and in the following procedure.

Important Start the test within 30 minutes of adding the sample to the cartridge.

1. Put on a new pair of gloves if performing a new test.

2. Touch the **NEW TEST** button on the Home screen (see Figure 14).

Figure 14. Home Screen

3. Check that the specimen transport medium tube cap is closed.

If Patient Information is configured by an administrator, then the Patient Information screen appears (see Figure 15). If Patient Information is not configured, the Sample ID screen appears.

4. Skip to Section 16.2 if the Sample ID screen appears.

Figure 15. Patient Information Screen

5.   Scan patient ID barcode or manually enter the Patient ID.

6.   Touch **CONTINUE**. The Confirm Patient Information screen appears.

7.   Verify the Patient ID and touch **CONFIRM**. The Sample ID screen appears.

16.2   Preparing the Specimen

1.   Remove a cartridge and a transfer pipette from the cartridge kit box.

2.   Check that the transport medium tube cap is closed. Scan Sample ID barcode or manually enter the Sample ID for patient specimen.

3.   Touch **CONTINUE**. The Confirm Sample ID screen appears.

4.   Verify the Sample ID and touch **CONFIRM**. The Scan Cartridge Barcode screen appears (see Figure 16).

In the following steps, keep the cartridges upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

Note If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan or scanning the barcode results in an error message stating that the cartridge is expired, then repeat the test with a new cartridge.

If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will appear indicating the assay definition file is not loaded on the system. If this screen appears, contact Cepheid Technical Support.
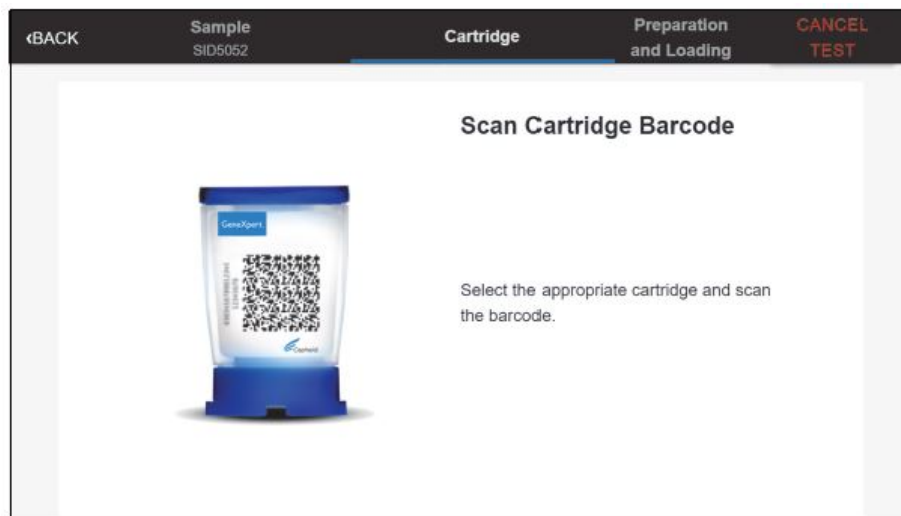
Figure 16. Scan Cartridge Barcode Screen

5.   Select the appropriate cartridge with the sample and scan the cartridge barcode. After scanning, the Confirm Test Information screen appears.

6.   Verify that the correct cartridge has been scanned and that the assay name matches the name of the assay on the cartridge (see Figure 17).
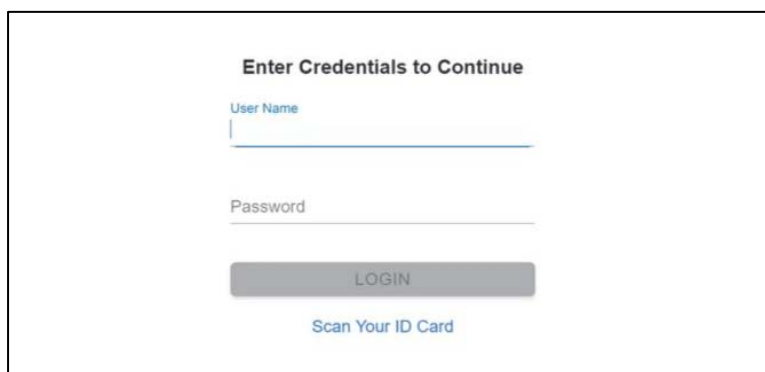
Figure 17. Confirm Test Information Screen

7. Touch **CONFIRM**. Depending on your configuration, the Enter Credentials to Continue screen may appear (see Figure 18). If enabled, you may log in by scanning your institutional ID. Otherwise, manually enter your User Name and Password and touch **LOGIN** to continue.

Figure 18. Enter Credentials to Continue Screen

The Cartridge Preparation screen appears (see Figure 19).

Figure 19. Cartridge Preparation Screen

8. Watch the video before continuing. The video will repeat. Touch the **SKIP VIDEO AND CONTINUE** button to exit video.

9. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the lid on the specimen transport tube.

10. Open the cartridge lid by lifting the front of the cartridge lid.

11. Remove the transfer pipette from the wrapper.

Note   Do not place unwrapped pipette on the workbench.

12. Squeeze the top bulb of the transfer pipette **completely** and then place the pipette tip in the specimen transport tube (see Figure 20).
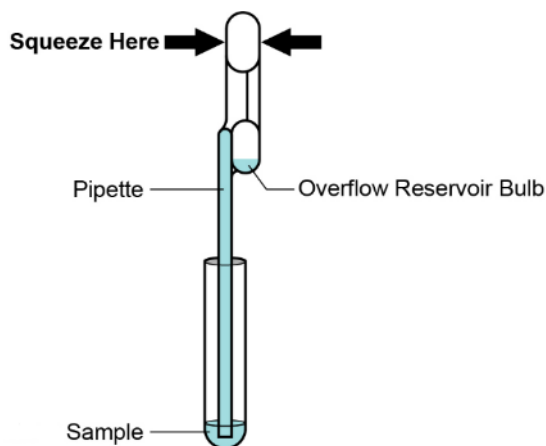
Figure 20. Transfer Pipette

13. Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample can be seen in the overflow reservoir bulb of the pipette (see Figure 20). Check that the pipette does not contain bubbles.

14. To transfer the patient specimen to the cartridge, squeeze the top bulb of the transfer pipette **completely** again to empty the contents of the pipette into the large opening (Sample Chamber) of the cartridge shown in Figure 21. Dispose of the used pipette.

Sample Chamber (Large Opening)
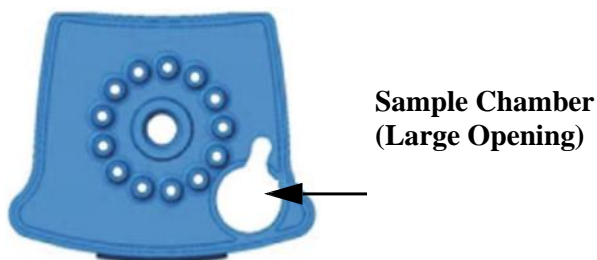
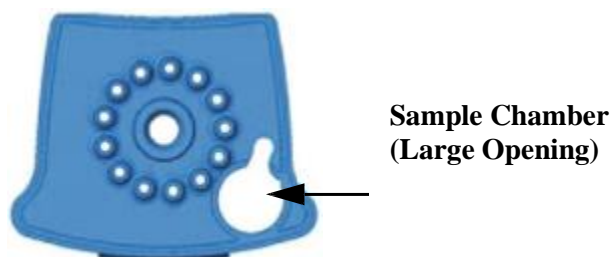**Figure 21. Xpert Xpress SARS-CoV-2 Cartridge (Top View)**

Note   Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

15. Close the cartridge lid.

16. Go to Section 16.4, Loading the Cartridge.

16.3 Running External Controls

It is recommended that external controls be tested at the frequency noted below.

- Each time a new lot of Xpert Xpress SARS-CoV-2 kits is received.
- Each time a new shipment of Xpert Xpress SARS-CoV-2 kits 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 recently).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.
  1. Put on a new pair of gloves if performing a new test. Touch the **QC** button on the Home screen (see Figure 22).
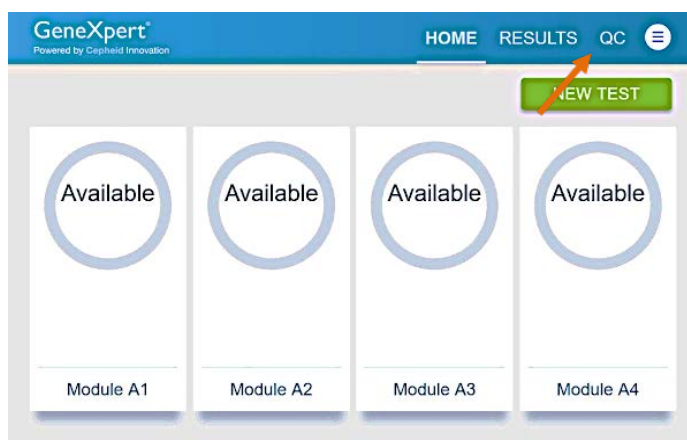
Figure 22. Home Screen

  2. The Quality Control screen appears. Touch **RUN QC POSITIVE Test**, **RUN QC NEGATIVE TEST** or **RUN PROFICIENCY TEST** option (Figure 23).

Figure 23. Quality Control Screen

  3. The Sample ID appears.

4. Enter the Sample ID, by typing **Positive Control** or **Negative Control** or scan the Sample ID barcode.

5. Touch **CONTINUE**. The Confirm Sample ID screen appears.

6. Verify the Sample ID and touch **CONFIRM**. The Scan Cartridge Barcode screen appears (see Figure 24).

In the following steps, keep the cartridges upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

Note If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan or scanning the barcode results in an error message stating that the cartridge is expired, then repeat the test with a new cartridge.

If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will appear indicating the assay definition file is not loaded on the system. If this screen appears, contact Cepheid Technical Support.

Figure 24. Scan Cartridge Barcode Screen

7. Select the appropriate cartridge with the sample and scan the cartridge barcode. After scanning, the Confirm Test Information screen appears.

8. Confirm the test information is correct then touch **CONFIRM** (see Figure 25).

Figure 25. Confirm Test Information

9. Watch the video before continuing. The video will repeat. Touch the **CONTINUE** button to exit video.

10. Mix control by rapidly inverting the external control tube 5 times. Open the lid on the external control tube.

11. Open the cartridge lid by lifting the front of the cartridge lid.

12. Remove the transfer pipette from the wrapper.

Note Do not place unwrapped pipette on the workbench.

13. Squeeze the top bulb of the transfer pipette **completely** and then place the pipette tip in the external control tube (see Figure 26).
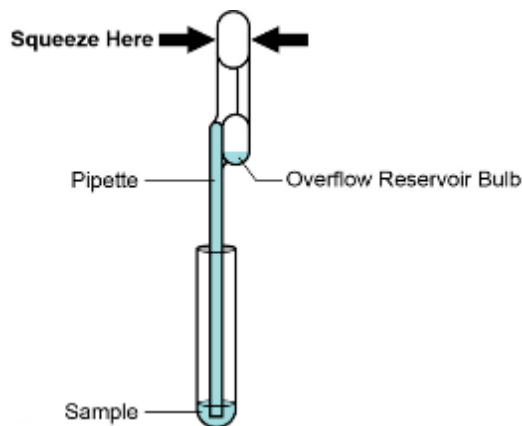
Figure 26. Transfer Pipette

14. Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample can be seen in the overflow reservoir bulb of the pipette (see Figure 26). Check that the pipette does not contain bubbles.

15. To transfer the external control to the cartridge, squeeze the top bulb of the transfer pipette **completely** again to empty the contents of the pipette into the large opening (Sample Chamber) of the cartridge shown in Figure 27. Dispose of the used pipette.

Sample Chamber
(Large Opening)

Figure 27. Xpert Xpress SARS-CoV-2 Cartridge (Top View)

Note Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

16. Close the cartridge lid.

17. Go to Section 16.4, Loading the Cartridge.

16.4 Loading the Cartridge
1. Touch the **CONTINUE** button on the Cartridge Preparation screen. The Load Cartridge into Module screen appears (see Figure 28).

2. Open the module door with the flashing green light.

Flashing green light.

Load Cartridge into Module

Load cartridge into the module with the flashing green light, and close the module door.

Figure 28. Load Cartridge into Module Screen

3. Load the cartridge with the barcode facing the operator on the cartridge bay platform. Do not try to insert the cartridge past the cartridge bay platform.

4. Close the door until it clicks. The green light will stop blinking and the test starts.

5. When the cartridge is loaded, the Test Loading screen appears, followed by the Test Running screen showing that the test is running. A circular graphic indicator at the right indicates the progress of the test and the time remaining until a test result is available.

Note While a test is running, you can start another test. See Section 16.5, Start a New Test While a Test is Running.

Note Do not turn off or unplug the instrument while a test is in progress. Turning off or unplugging the GeneXpert Xpress instrument or Hub stops the test. If necessary, touch the **STOP TEST** button to cancel a test while it is loading or running.

6. When the test is done, the green light goes out and the door automatically unlocks. The screen text changes to Test Completed. The Test Completed screen provides the results for the test just completed.

Note If an unexpected result occurs (e.g., Negative Quality Control result is positive or Positive Quality Control result is negative), test a new Quality Control sample using a new cartridge. If an unexpected result occurs upon retest, contact Cepheid Technical Support.

7. Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution's policy.

8. Touch **HOME** to go back to the Home screen.

9. To log out, touch the **User Menu** icon , then select Logout.

16.5 Start a New Test While a Test is Running

You can start a new test while another test is in progress.

1. Touch the **HOME** button on the Test Running screen.

2. For a new user log in, touch the **User Menu** icon to log in.

3. Repeat the steps in Section 16.1, Starting a Test, Section 16.2, Preparing the Specimen, and Section 16.4, Loading the Cartridge.

4. After a second test has started, touch the **HOME** button. The status of both tests appears. The Home screen displays the module(s) in use with a circular graphic indicator around each test, and Patient Identification below the module graphic (see Figure 29).
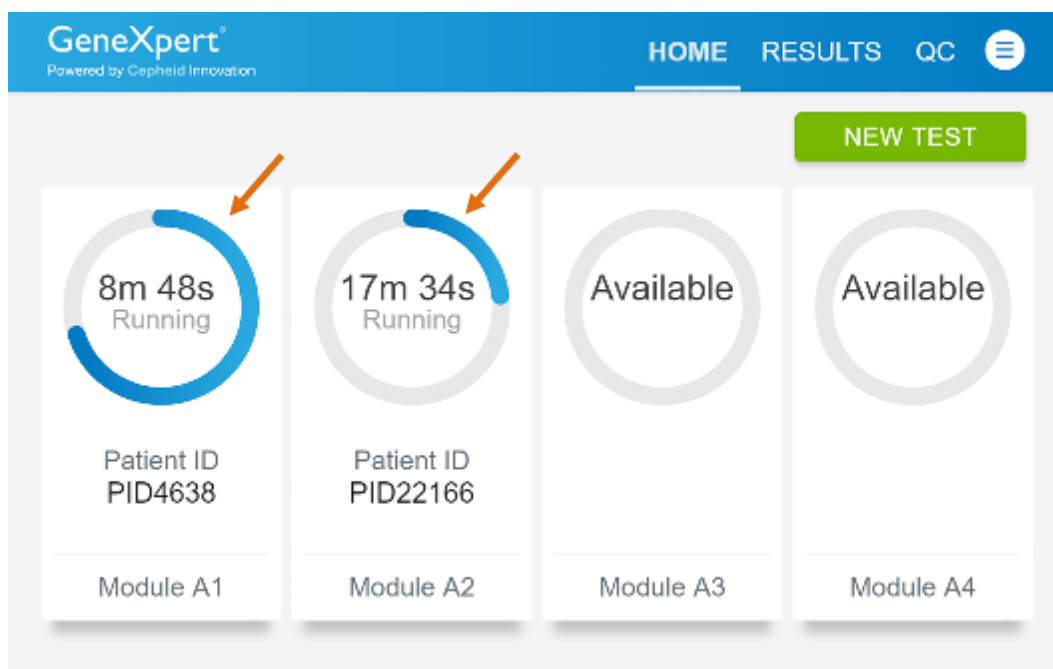
Figure 29. Home Screen showing Two Tests Running
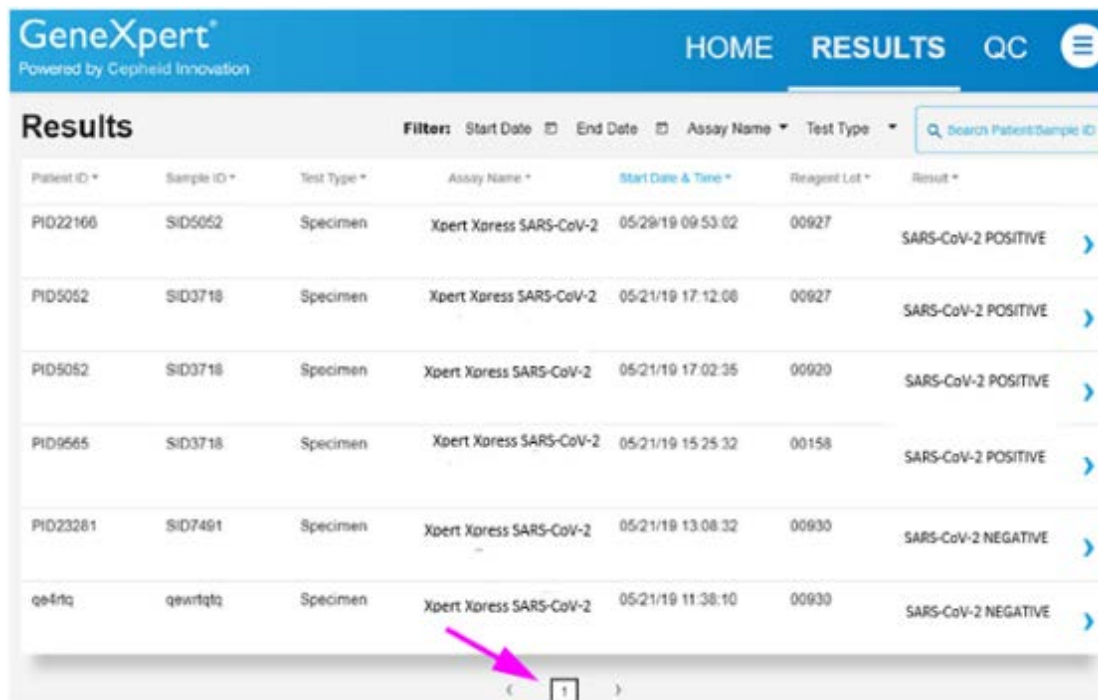
5. After a test has completed, the module icon text changes to Complete (see Figure 30). Touch Complete View Result to view test results.
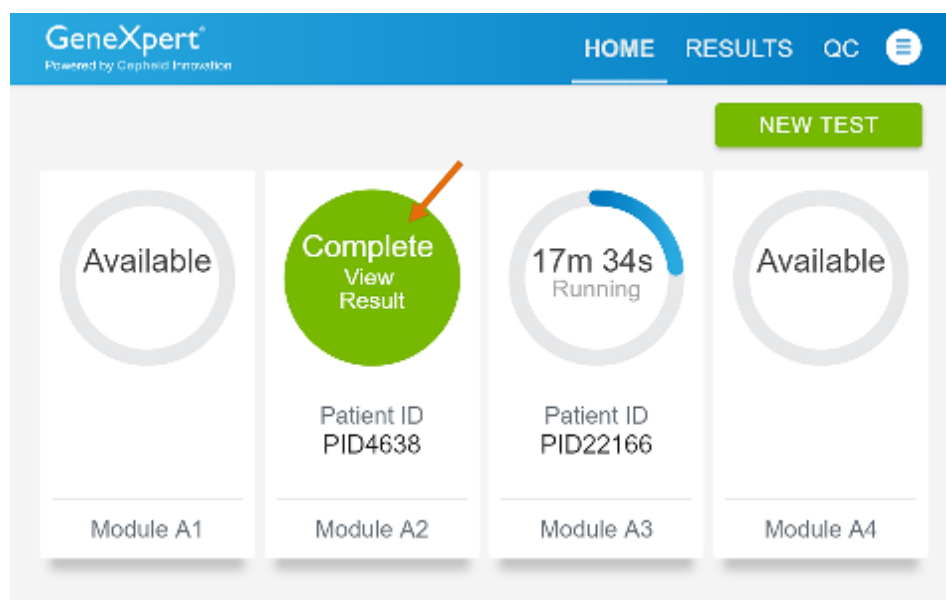
Figure 30. Home Screen with One of Two Tests Completed

16.6 Viewing Test Results

1. Touch the **RESULTS** button located on the panel at the top of the screen (see Figure 30). The Results screen appears (see Figure 31). Test results are, by default, in order of the date and time that the test was run. Navigate through the test result pages by touching the numbered buttons or arrows at the bottom of the screen.

Figure 31. Results Screen

2. Touch the desired result to open the Test Result screen (see Figure 32).
3. To view test report, touch the **REPORT** button then swipe across the screen from left to right to minimize screen and view report.

Figure 32. Test Result Screen (Example)

Note If an unexpected result occurs (e.g., Negative Quality Control result is positive or Positive Quality Control result is negative), test a new Quality Control sample using a new cartridge. If an unexpected result occurs upon retest, contact Cepheid Technical Support.

17   Quality Control

17.1   Internal Controls

CONTROL   Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

Sample Processing Control (SPC) – Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

Probe Check Control (PCC) – Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.

17.2   External Controls

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable.

18   Interpretation of Results

The results are interpreted automatically by the GeneXpert System and are clearly shown in the **View Results** window. The Xpert Xpress SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table 1.

Table 1. Xpert Xpress SARS-CoV-2 Possible Results

Result Text	N2	E	SPC
SARS-CoV-2 POSITIVE	+	+/-	+/-
SARS-CoV-2 PRESUMPTIVE POS	-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
NO RESULT – REPEAT TEST	-	-	-

See Table 2 to interpret test result statements for the Xpert Xpress SARS-CoV-2 test.

Xpert Xpress SARS-CoV-2

Table 2. Xpert Xpress SARS-CoV-2 Results and Interpretations

Result	Interpretation
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected. • The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because coronavirus target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 PRESUMPTIVE POS	The 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. Sample should be retested according to the Retest Procedure in Section 19.2. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. • The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting. • SPC – NA (not applicable); SPC is ignored because target amplification may compete with this control. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected. • The SARS-CoV-2 signal for two nucleic acid targets (N2 and E) do not have a Ct within the valid range and endpoint above the minimum setting. • SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting. • Probe Check: PASS; all probe check results pass.
NO RESULT – REPEAT TEST	If result is **NO RESULT - REPEAT TEST**, retest with a new cartridge according to the Retest Procedure in Section 19.2. If retest is **NO RESULT - REPEAT TEST**, obtain a new specimen for testing.
INSTRUMENT ERROR	If result is **INSTRUMENT ERROR**, touch **CLEAR ERROR** and follow the on-screen instructions. When the Home screen appears, repeat the test using a new cartridge according to the Retest Procedure in Section 19.2.

The Xpert Xpress SARS-CoV-2 test includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the target nucleic acid reaches a predetermined threshold before the full 45 PCR cycles have been completed. When SARS-CoV-2 titers are high enough to initiate the EAT function, the SPC amplification curve may not be seen and its results may not be reported.

19   Retests

19.1   Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in Section 19.2, Retest Procedure.

- An **INSTRUMENT ERROR** result could be due to, but not limited to, a system component failure, or the maximum pressure limits were exceeded.

- A **NO RESULT- REPEAT TEST** indicates that insufficient data were collected. For example, cartridge failed integrity test, Probe Check Control failure, no sample added, the operator stopped a test that was in progress, or a power failure occurred.

- A **PRESUMPTIVE POS** result indicates the 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. Only one of the SARS-CoV-2 nucleic acid target was detected (E gene) while the other SARS-CoV-2 nucleic acid target (N2 gene) was not detected.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid Technical Support for assistance.

19.2   Retest Procedure

To retest a non-determinate result **(NO RESULT-REPEAT TEST, INSTRUMENT ERROR)** or a **PRESUMPTIVE POS** result, use a new cartridge.

Use the leftover sample from the original specimen transport tube or new external control tube.

1. Put on a clean pair of gloves. Obtain a new Xpert Xpress SARS-CoV-2 cartridge and a new transfer pipette.

2. Check the specimen transport tube or external control tube is closed.

3. Mix the sample by rapidly invert the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.

4. Open the cartridge lid by lifting the front of the cartridge lid.

5. Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.

6. Close the cartridge lid.

20   Limitations

- Performance of the Xpert Xpress SARS-CoV-2 has only been established in nasopharyngeal swab specimens. Use of the Xpert Xpress SARS-CoV-2 test with other specimen types has not been assessed and performance characteristics are unknown.

- Nasal swabs and mid-turbinate swabs (self-collected under supervision of or collected by a healthcare provider) are considered acceptable specimen types for use with the Xpert Xpress SARS-CoV-2 test but performance with these specimen types has not been established.

- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.

- As with any molecular test, mutations within the target regions of Xpert Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.

- This test cannot rule out diseases caused by other bacterial or viral pathogens.

- 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 detection of nucleic acid from SARS-CoV-2, 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.

21 Conditions of Authorization for Laboratory and Patient Care Settings

The Cepheid Xpert Xpress SARS-CoV-2 Letter of Authorization, along with the authorized   Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd
However, to assist clinical laboratories and/or Patient Care Settings using the Xpert Xpress SARS-CoV-2 (referred to in the Letter of Authorization as "Your Product"), the relevant Conditions of Authorization are listed below.

- Authorized laboratories[1] and patient care settings using your product will include with result reports of the Xpert Xpress SARS-CoV-2 test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories using your product will use your product as outlined in the Xpert Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity systems. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Xpert Xpress SARS-CoV-2 test are not permitted.

- Patient Care Settings using your product will use your product as outlined in the Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Xpress System and associated Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Hub configuration), and Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Tablet configuration). Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

- Authorized laboratories and patient care settings that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

- Authorized laboratories and patient care settings using the Xpert Xpress SARS-CoV-2 test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories and patient care settings will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA Reporting@fda.hhs.gov) and Cepheid (+ 1 888 838 3222 or techsupport@cepheid.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

- You, authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The Letter of Authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate or high complexity tests" as "authorized laboratories."

22 Performance Characteristics

22.1 Clinical Evaluation

The performance of the Xpert Xpress SARS-CoV-2 test was evaluated using archived clinical nasopharyngeal (NP) swab specimens in viral transport medium. A total of 45 SARS-CoV-2 positive and 45 SARS-CoV-2 negative NP swab specimens were tested with Xpert Xpress SARS-CoV-2 in a randomized and blinded fashion.

All the 45 SARS-CoV-2 positive specimens and 30 of the 45 SARS-CoV-2 negative specimens were collected during COVID-19 pandemic in the US and had previously been characterized as positive or negative for SARS-CoV-2 by an EUA RT-PCR test. Fifteen of the 45 SARS-CoV-2 negative NP swab specimens were collected before December 2019 and are expected to be negative for SARS-CoV-2.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Xpress SARS-CoV-2 test relative to the expected results. Results of these 90 archived clinical NP swab specimens are shown in Table 3. The PPA was 97.8% (95% CI: 88.4% - 99.6%) and the NPA was 95.6% (95% CI: 85.2% - 98.8%).

Table 3. Xpert Xpress SARS-CoV-2 Performance Results

		Expected Results		
		Positive	Negative	Total
Xpert Xpress SARS-CoV-2	Positive	44[a]	2[b]	46
	Negative	1	43	44
	Total	45	45	90
PPA		97.8% (95% CI: 88.4% - 99.6%)		
NPA		95.6% (95% CI: 85.2% - 98.8%)		

a. One specimen was reported as "SARS-CoV-2 Presumptive Pos" in initial testing and yielded a "SARS-CoV-2 Positive" test result upon retesting.
b. The two false positive specimens were collected during the COVID-19 pandemic.

23 Analytical Performance

23.1 Analytical Sensitivity (Limit of Detection) – Live SARS-CoV-2 Virus

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Xpress SARS-CoV-2. The LoD of Xpert Xpress SARS-CoV-2 was established using one lot of reagent and limiting dilutions of live SARS-CoV-2 virus (USA_WA1/2020 strain) prepared in viral transport medium and NP swab clinical matrix. The concentration level with observed hit rates greater than or equal to 95% in the LoD determination study were 0.0050 and 0.0200 PFU/mL for the N2 target and E target, respectively (Table 4).

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Xpert Xpress SARS-CoV-2

Verification of the estimated LoD claim was performed on one reagent lot in replicates of 20 prepared in pooled NP swab clinical matrix. The LoD is the lowest concentration (reported as PFU/mL) of live SARS-CoV-2 virus samples that can be reproducibly distinguished from negative samples ≥ 95% of the time with 95% confidence. The claimed LoD is 0.0200 PFU/mL (Table 4).

Table 4. LoD Determination using USA-WA1/2020 Strain

Strain	Concentration (PFU/mL)	Total Valid Results	Hit Rate (%) N2 Target	Hit Rate (%) E Target	Mean Ct N2 Target	Mean Ct E Target
SARS-CoV-2 virus (USA_WA1/2020)	0.0200	20	100	95.0	38.3	36.4
	0.0050	22	95.5	68.2	40.5	39.1
	0.0025	22	90.9	36.4	41.5	39.6
	0.0010	22	50.0	18.2	42.0	42.0
	0.0005	22	45.5	18.2	41.7	41.5
	0.0003	22	18.2	4.5	42.1	44.9
	0.0001	22	9.1	0	42.9	N/A
	0	0	0	0	N/A	N/A

23.2 Analytical Reactivity (Inclusivity)

The inclusivity of Xpert Xpress SARS-CoV-2 was evaluated using *in silico* analysis of the assay primers and probes in relation to 36,863 SARS-CoV-2 sequences available in the GISAID gene database for two targets, E and N2.

For the E target, 142 matching sequences were excluded due to ambiguity codes, which reduced the total to 36,721 sequences. Xpert Xpress SARS-CoV-2 had 99.4% match to the sequences with the exception of 187 sequences that had a single mismatch and 18 sequences with additional mismatches. Of the 18 sequences with additional mismatches, one sequence contained 2 mismatches in the forward primer region, three sequences contained a 5 nucleotide gap, 2 sequences contained multiple mismatches at the 3' end of the amplicon, and twelve sequences contained a 'AA' dinucleotide but this lies between the oligonucleotides used in the assay. None of these mismatches are expected to affect the performance of the assay.

For the N2 target, 132 matching sequences were excluded due to ambiguity codes, which reduced the total to 36,731 sequences. Xpert Xpress SARS-CoV-2 had 98.9% match to the sequences with the exception of 262 sequences that had a single mismatch and one sequence contained 3 mismatches. None of these mismatches are predicted to have a negative impact on the performance of the assay.

23.3 Analytical Specificity (Exclusivity)

An *in silico* analysis for possible cross-reactions with all the organisms listed in Table 5 was conducted by mapping primers and probes in the Xpert Xpress SARS-CoV-2 test individually to the sequences downloaded from the GISAID database. E primers and probes are not specific for SARS-CoV-2 and will detect Human and Bat SARS-coronavirus. No potential unintended cross reactivity with other organisms listed in Table 5 is expected based on the *in silico* analysis.

Table 5. Xpert Xpress SARS-CoV-2 Analytical Specificity Microorganisms

Microorganisms from the Same Genetic Family	High Priority Organisms
Human coronavirus 229E	Adenovirus (e.g. C1 Ad. 71)
Human coronavirus OC43	Human Metapneumovirus (hMPV)
Human coronavirus HKU1	Parainfluenza virus 1-4
Human coronavirus NL63	Influenza A
SARS-coronavirus	Influenza B
MERS-coronavirus	Influenza C
Bat coronavirus	Enterovirus (e.g. EV68)
	Respiratory syncytial virus
	Rhinovirus
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jirovecii (PJP)
	Parechovirus
	Candida albicans
	Corynebacterium diphtheriae
	Legionella non-pneumophila
	Bacillus anthracis (Anthrax)
	Moraxella catarrhalis
	Neisseria elongate and meningitidis
	Pseudomonas aeruginosa
	Staphylococcus epidermidis
	Staphylococcus salivarius
	Leptospira
	Chlamydia psittaci
	Coxiella burnetii (Q-Fever)
	Staphylococcus aureus

24 References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed February 9, 2020.

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2. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 3, 2020.

3. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical laboratories* (refer to latest edition). http://www.cdc.gov/biosafety/publications/

4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline*. Document M29 (refer to latest edition).

5. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).

6. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

25 Cepheid Headquarters Locations

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Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France
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Fax: +1 408 541 4192	Fax: +33 563 825 301
www.cepheid.com	www.cepheidinternational.com

26 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:
• Product name
• Lot number
• Serial number of the instrument
• Error messages (if any)
• Software version and, if applicable, Computer Service Tagnumber

Region	Telephone	Email
US	+ 1 888 838 3222	techsupport@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Australia New Zealand	1800 130 821 0800 001 028	techsupportANZ@cepheid.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

27   Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	*In vitro* diagnostic medical device
	Do not re-use
LOT	Batch code
	Consult instructions for use
	Caution
	Manufacturer
CC	Country of manufacture
Σ	Contains sufficient for \<n\> tests
CONTROL	Control
	Expiration date
°C	Temperature limitation
	Biological risks
Rx only	For prescription use only

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IVD

For use under Emergency Use Authorization (EUA) Only

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

IVD **Rx only** **Cepheid®** A better way.

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 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.	2a Enter Password.	2b Scan ID Card.	3 Home Screen Displays.
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.	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.	If enabled, log in by scanning the barcode on your institutional ID, as shown below.	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.	2a Enter/Scan and touch CONTINUE. Confirm Patient ID.	3 Scan and Confirm Cartridge	4 Watch Video. Mix Specimen.
a Touch **NEW TEST** on the Home screen. b. Check that the specimen tube cap is closed.	 **2b Enter/Scan and touch CONTINUE Confirm Sample ID.** 	 *If applicable, enter your user name and password.	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.	6 Transfer Sample to Cartridge.	7 Close Cartridge Lid.	8 Load Cartridge.
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. 	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)** 	a. Close the cartridge lid. b. Dispose of the used pipette in an appropriate waste container.	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.	10 How To Start a New Test.	11 Starting a Test While a Test is Running
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.	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**.	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**.

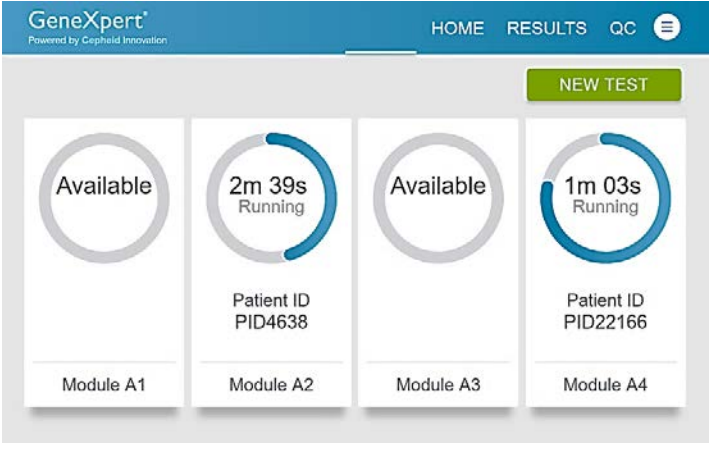## IV. How to View Status of Tests in Progress and Completed Tests

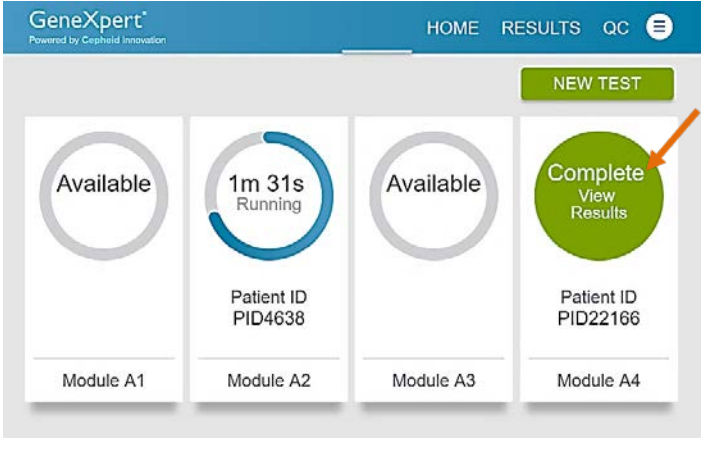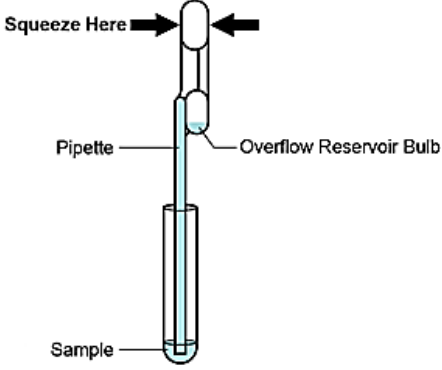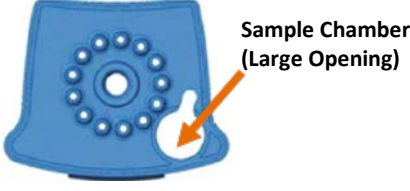| 1 Touch HOME Button.	2 View Test In Progress.	3 View Results of Completed Tests.
Touch the **HOME** button to view the status of tests in progress or completed tests.	Tests in progress are shown on the HOME screen with a circular graphic indicator around each test and the Patient ID number below the module graphic. Touch the corresponding circular indicator to view the details.	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 (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.	2 Enter and Confirm Sample ID.	3 Scan and Confirm Cartridge	4 Watch Video. Mix Control.
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.	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**.	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.	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.	6 Transfer Control to Cartridge.	7 Load Cartridge.	8 Remove Cartridge. View Results.
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.	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.	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.	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.

In step 5 pipette diagram: **Squeeze Here**, **Pipette**, **Overflow Reservoir Bulb**, **Sample**

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 POSITIVE	If the result is **SARS-CoV-2 PRESUMPTIVE POSITIVE**, then retest with a new cartridge. If the retest is **SARS-CoV-2 PRESUMPTIVE POSITIVE**, **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.

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

IVD | **Rx only** | Cepheid. *A better way.*

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 specimens.

ℹ️ 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 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

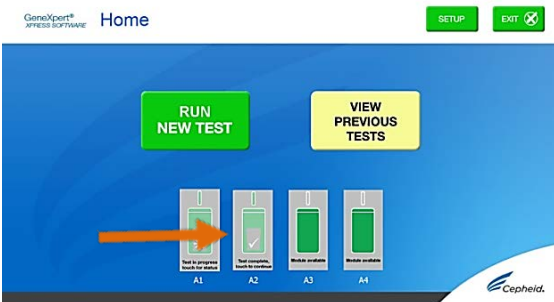| **1 Touch HOME Button.**	**2 View Test in Progress.**	**3 View Completed Tests.**
Touch the **HOME** button to view the status of tests in progress or completed tests.	To view a test in progress, touch the **Test in progress touch for status** button. The time remaining to complete the testing will be displayed on the progress bar at the bottom of the **Test in Progress** screen.	When a test is 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 in progress, touch for status" 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 (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.
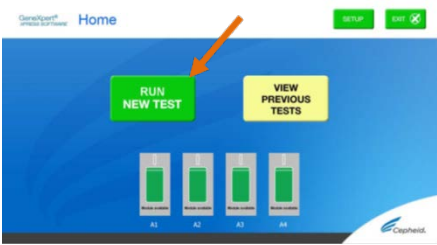- Each time a new operator is performing the test (i.e., operator who has not performed the test before).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.

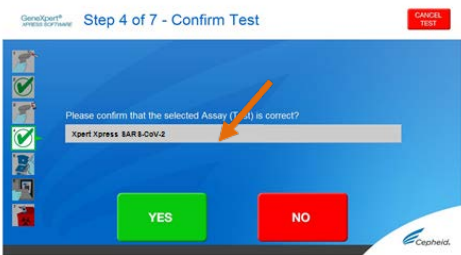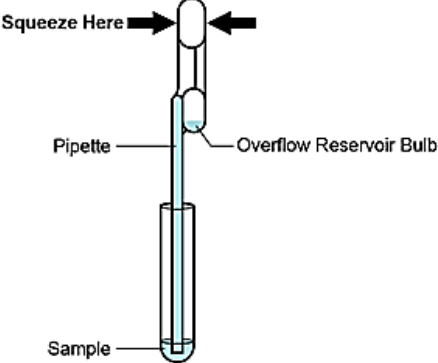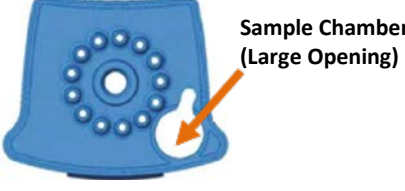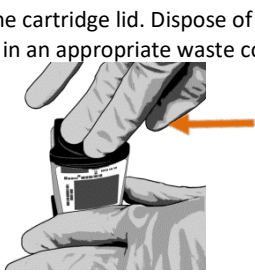| **1 Start a Test.**	**2 Enter & Confirm Patient/Sample ID.**	**3 Scan and Confirm Cartridge.**	**4 Watch Video. Mix Control.**
a. Put on a pair of clean gloves. b. Have a new Xpert Xpress SARS-CoV-2 cartridge, a control tube, and a transfer pipette ready. c. Touch **RUN NEW TEST** on the home screen (GeneXpert Xpress IV shown below).	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.	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.	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.	**6 Transfer Control to Cartridge.**	**7 Load Cartridge.**	**8 Remove Cartridge. View Results.**
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. 	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. 	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. 	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 POSITIVE	If the result is **SARS-CoV-2 PRESUMPTIVE POSITIVE** , then retest with a new cartridge. If the retest is **SARS-CoV-2 PRESUMPTIVE POSITIVE**, obtain a new specimen for testing.
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.

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