GeneXpert
Powered By CEPHEID INNOVATION

Xpert® Omni SARS-CoV-2

Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only

℞only

REF **OMNISARS-COV2-10**

IVD

For Use with GeneXpert Omni System

REVOKED

Trademark, Patents, and Copyright Statements

Cepheid®, the Cepheid logo, GeneXpert®, and Xpert® are trademarks of Cepheid, registered in the U.S. and other countries.

All other trademarks are the property of their respective owners.

THE PURCHASE OF THIS PRODUCT CONVEYS TO THE BUYER THE NON-TRANSFERABLE RIGHT TO USE IT IN ACCORDANCE WITH THESE INSTRUCTIONS FOR USE. NO OTHER RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR BY ESTOPPEL. FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.

© 2020-2021 Cepheid. All rights reserved.

REVOKED

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

1 Proprietary Name

Xpert® Omni SARS-CoV-2

2 Common or Usual Name

Xpert Omni SARS-CoV-2

3 Intended Use

The Xpert Omni 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, anterior 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, anterior nasal, or mid-turbinate swab and nasal wash/aspirate specimens using the Xpert Omni SARS-CoV-2 test run on the GeneXpert Omni System is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high or moderate complexity tests.

Testing of nasopharyngeal, anterior nasal, or mid-turbinate swab specimens using the Xpert Omni SARS-CoV-2 test run on the GeneXpert Omni System is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate or waived complexity tests. Testing of these specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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 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 Omni SARS-CoV-2 test is intended for use by qualified laboratory personnel specifically instructed and trained in performing tests using the GeneXpert Omni System. The Xpert Omni SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

REVOKED

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 Omni SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Omni 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.

5 Principle of the Procedure

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

The GeneXpert Omni System automates and integrates sample preparation, nucleic acid extraction, reverse transcription, and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The system consists of an instrument and mobile device. The system requires 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 Omni System Operator Manual.*

The Xpert Omni SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, or mid-turbinate swab and/or nasal wash/aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert Omni 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, oropharyngeal, anterior nasal, or mid-turbinate swab specimen and/or nasal wash/aspirate specimen is collected and placed into a viral transport tube containing 3 mL transport medium, 3 mL of saline or 2 mL of eNAT transport media. 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

REVOKED

Omni SARS-CoV-2 cartridge. The Xpert Omni SARS-CoV-2 cartridge is loaded onto the GeneXpert Omni System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

6 Materials Provided

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

Xpert Omni 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**
Quick Reference Instructions	**1 per kit**
Flyer Directions to locate the product insert on www.cepheid.com	**1 per kit**

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 Omni 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 Omni System: Omni instrument with Omni instrument software version 1.2 or higher and mobile device with Omni Mobile Application 1.2 or higher

9 Materials Available but Not Provided

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

REVOKED

10 Warnings and Precautions

10.1 General

- For *in vitro* diagnostic use.
- For emergency use only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other virus or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Positive results are indicative of presence of SARS-CoV-2-RNA.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Performance characteristics of this test have been established with nasopharyngeal swab specimens 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 Prevention[3] 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.

REVOKED

10.3 Assay/Reagent

- Do not open the Xpert Omni 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 Omni 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.

REVOKED

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 Oropharyngeal Swab Collection Procedure, Section 12.3 for Anterior Nasal Swab Collection Procedure, Section 12.4 for Mid-turbinate Swab Collection Procedure, and Section 12.5 for Nasal Wash/aspirate Procedure.

Nasopharyngeal, anterior nasal, and mid-turbinate swabs and nasal wash/aspirate 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 Omni System. For oropharyngeal swab specimen transport and storage requirements and additional information, refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) using the link provided below:

https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

12.1 Nasopharyngeal Swab Collection Procedure

1. Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1).

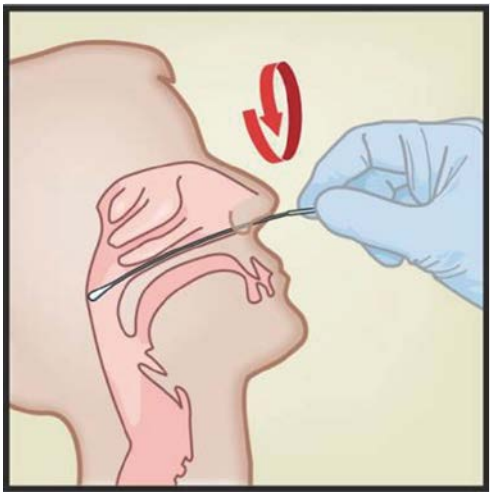


Figure 1. Nasopharyngeal Swab Collection

REVOKED

2. 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, 3 mL of saline, or 2 mL of Copan eNAT transport medium.
3. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.2 Oropharyngeal Swab Collection Procedure

1. Swab the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks, and teeth with the swab when collecting specimens.
2. Remove and place the swab into the tube containing 3 mL of viral transport medium, 3 mL of saline, or 2 mL of Copan eNAT transport medium. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.3 Anterior Nasal Swab Collection Procedure

1. Insert an anterior 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).

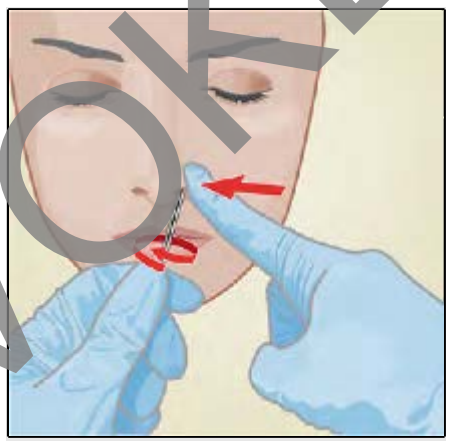


Figure 2. Anterior Nasal Swab Collection for First Nostril

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.

REVOKED

Figure 3. Anterior Nasal Swab Collection for Second Nostril

3. Remove and place the swab into the tube containing 3 mL of viral transport medium, 3 mL of saline, or 2 mL of Copan eNAT transport medium. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.4 Mid-Turbinate Swab Collection Procedure

1. Insert the mid-turbinate swab into either nostril, passing it into the mid-turbinate area (see Figure 4).

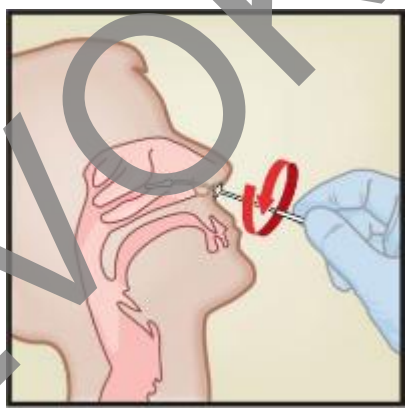


Figure 4. Mid-turbinate Swab Specimen Collection

2. Rotate swab by firmly brushing against the mid-turbinate area several times.
3. Remove and place the swab into the tube containing 3 mL of viral transport medium, 3 mL of saline, or 2 mL of Copan eNAT transport medium.
4. Break swab at the indicated break line and cap the specimen collection tube tightly.

REVOKED

12.5 Nasal Wash/Aspirate Procedure

Using a clean transfer pipette, transfer 600 µL of the sample into the tube containing 3 mL of viral transport medium or 3 mL of saline and then cap the tube.

13 Procedure

13.1 Starting the Test

1. Turn on the Omni instrument. Press in and hold the red power button on the back of the Omni instrument for 2 seconds.

Note It takes about two minutes to start up the instrument. During this time, the instrument performs a self-test procedure that includes opening and closing the cartridge door. When the instrument is ready, the white flashing activity light illuminates.

2. Turn on the mobile device. Press and hold the power button on the right side of the mobile device.
3. Swipe the mobile device home screen to unlock the mobile device.
4. In the Launcher application, tap the **Omni** icon to start the Omni Mobile Application (see Figure 5). The Cepheid login screen appears.

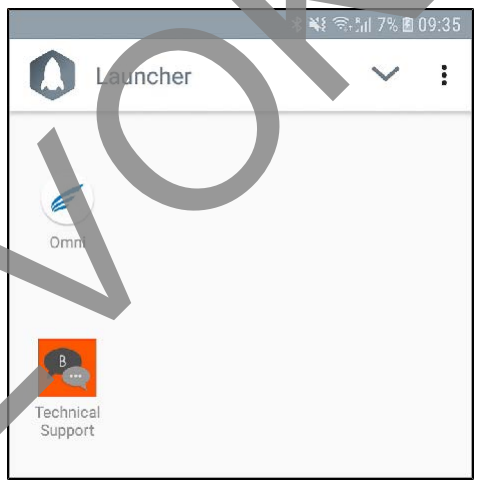


Figure 5. Omni Application

5. On the Cepheid login screen, tap **LOGIN**.
6. Tap in the **User Name** field and use the keyboard to type in your user name. Figure 6 shows an example of a user name typed into the field (e.g., my.institution01@gmail.com).

REVOKED

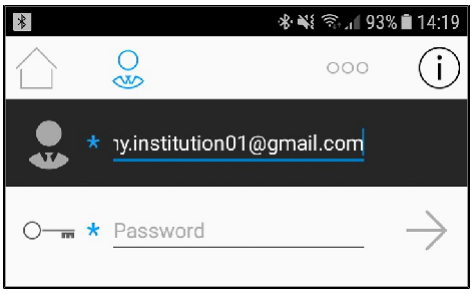


Figure 6. User Name and Password Fields

7. Tap in the **Password** field, type the password, and tap the forward arrow next to the Password field to enter login information (see Figure 6). The Home screen appears.
8. Verify that the instrument icon appears at the bottom of the screen as shown in Figure 7.

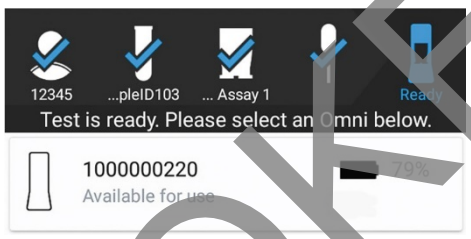


Figure 7. Example of an Omni Instrument Connected to Mobile Device

9. On the Home screen, tap the **Start New Test** icon (see Figure 8). The Patient ID screen appears.

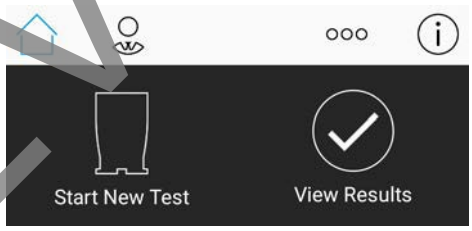


Figure 8. Start New Test Icon on Home Screen

10. Enter the Patient ID by manually entering or scanning the Patient ID.
    - **Manual Entry:** Tap in the **Patient ID** field and use the keyboard to type in the Patient ID.
    - **Barcode Scan:** If you have a Patient ID barcode on a paperwork test order, click the barcode icon adjacent to the **Patient ID** field. Aim the rear camera of the mobile device at the barcode on the paper to scan the barcode. When looking at the screen, overlay the barcode with the crosshairs and hold the mobile device still. When the mobile device recognizes the barcode, a beep sounds, and the Barcode dialog box opens. Verify that the ID in the dialog box matches the ID on the test order and click **CONFIRM**.

REVOKED

Note Omni Mobile Application version 1.3 or higher is required to enable the scanning of the Patient ID with the mobile device.

11. Scroll down to locate and tap the forward arrow at the bottom of the Patient ID screen. The Sample ID screen appears.

Note You can enter additional patient information (patient date of birth, patient name, patient gender, and patient address) in fields on the Patient ID screen, if pre-configured by your institutional administrator.

12. Enter the Sample ID by manually entering or scanning or randomly generating a Sample ID (see Figure 9):
    - **Manual Entry:** Tap the **Enter Sample ID** icon, then type the Sample ID in the **Sample ID** field. OR
    - **Barcode Scan:** Tap the **Scan Sample Barcode** icon. Aim the rear camera of the mobile device at the Sample ID barcode on the sample container. When the mobile device recognizes the barcode, a beep sounds, and the Sample ID appears in the **Sample ID** field. OR
    - **Generate ID:** Tap the **Generate Sample ID** icon. A random ID generator generates the Sample ID in the **Sample ID** field that you can record on the sample container or test order.

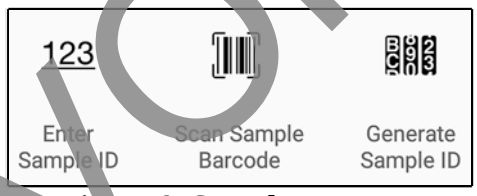


Figure 9. Sample ID Icons

Note You can enter additional sample information (test type, sample type description, and notes) in fields on the Sample ID screen.

13. Scroll down to locate and tap the forward arrow at the bottom of the Sample ID screen.
14. Using the screen animation on the mobile device as a guide, put the back of the mobile device close to the GeneXpert cartridge label to read the NFC tag embedded in the cartridge label (see Figure 10). **DO NOT** hold the reaction tube located at the back of the cartridge. When the mobile device reads the cartridge, it emits a single beep.

REVOKED

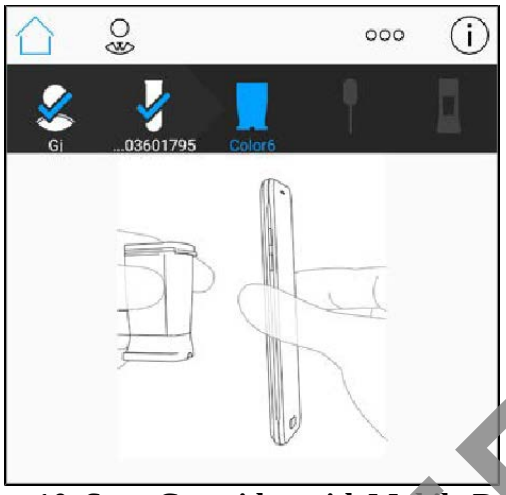


Figure 10. Scan Cartridge with Mobile Device

15. Verify that the correct cartridge was scanned and that the assay name shown on the screen matches closely with the assay name on the cartridge.

Note The assay name shown in the Assay Name field may not match exactly the assay name on the cartridge which may be abbreviated.

16. Scroll down to locate and tap the forward arrow at the bottom right of the screen. Animation on the screen appears as a guide to help you load the sample into the cartridge.

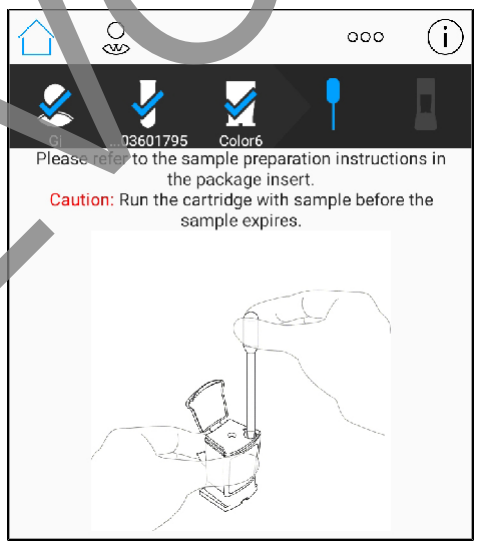


Figure 11. Loading Sample into Cartridge

13.2 Preparing the Cartridge

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

1. Check the specimen transport tube is closed.
2. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the

REVOKED

specimen transport tube.

3. Open the cartridge by lifting the front of the cartridge lid.
4. Remove the transfer pipette from the wrapper.
5. Squeeze the top bulb of the transfer pipette **completely until the top bulb is fully flat**. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube (see Figure 12).

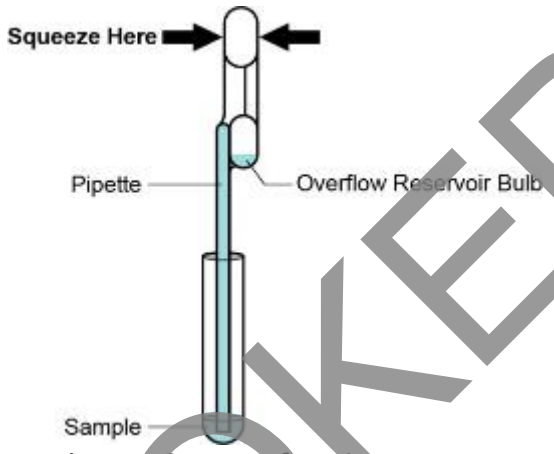


Figure 12. Transfer Pipette

6. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample will be seen in the overflow reservoir bulb of the pipette (see Figure 12). Check that the pipette does not contain bubbles.
7. To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette **completely until the top bulb is fully flat** to empty the contents of the pipette (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 13. Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

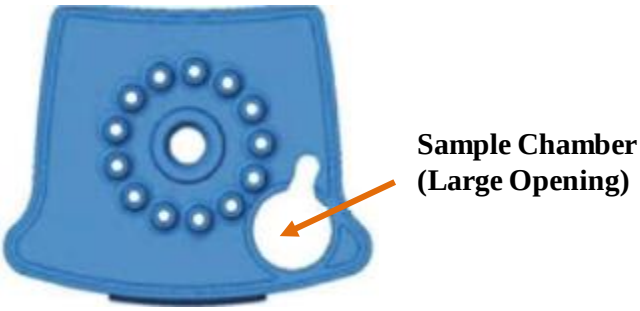


Figure 13. Xpert Omni SARS-CoV-2 Cartridge (Top View)

Note Dispense the entire volume of liquid into the sample chamber. False negative results

REVOKED

may occur if insufficient sample is added to the cartridge.

8. Close the cartridge lid.

13.3 External Controls

External controls described in Section 9 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable.

To run a control using the Xpert Omni SARS-CoV-2 test, perform the following steps:

1. Mix control by rapidly inverting the external control tube 5 times.
2. Open the cap on the external control tube.
3. Open the cartridge lid.
4. Using a clean transfer pipette, transfer one draw of the external control sample (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 13.
5. Close cartridge lid.

13.4 Loading Cartridge on the GeneXpert Omni

1. Scroll down to locate the forward arrow and tap the forward arrow at the bottom of the screen.
2. Tap the **instrument** icon. The door to the GeneXpert Omni instrument opens.

Note Wait until the door is fully open and all moving parts have stopped before inserting the cartridge. This wait time allows the loading mechanism to move into the correct position to receive the cartridge. Loading the cartridge prematurely can cause damage to the loading mechanism.

3. With the cartridge label facing the operator, load the cartridge onto the cartridge platform. Gently push the cartridge in place to allow the instrument to pull the cartridge. Remove hands immediately from instrument after loading cartridge. The door will close automatically, the test starts, and the screen shows the test is starting (see Figure 14). The screen changes to the test in process and the time remaining (see Figure 15). When the test completes, the instrument door opens, and the screen provides the test result. At the bottom of the screen, tap **Print Result**.

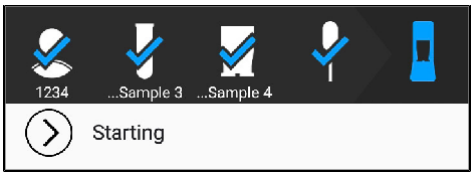


Figure 14. Test Starting Screen

REVOKED

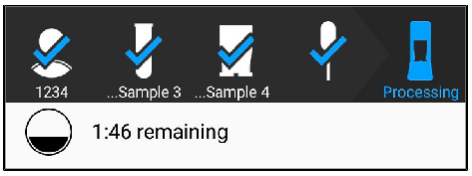


Figure 15. Test in Progress Screen

Note Do not try to manually open the instrument door at any time. Damage to the door mechanism can occur if the door is manually operated.

Note Do not move the instrument once a test has started. Invalid test results can occur if the instrument is moved during processing.

Note Do not tip the instrument when a test is running. In addition to causing an error and possible invalid test results, damage to the instrument can occur if the cartridge contents leak or spill into the interior of the instrument.

4. Remove the cartridge and dispose of the cartridge and gloves according to your institution's hazardous waste policies.

14 Viewing Results

1. On the Home screen, tap the **View Results** icon (see Figure 16).

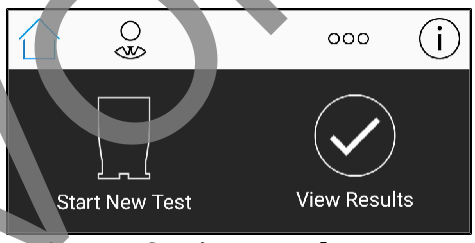


Figure 16. View Results Icon

The test results performed today are listed with the most recent test at the top (see Figure 17).

REVOKED

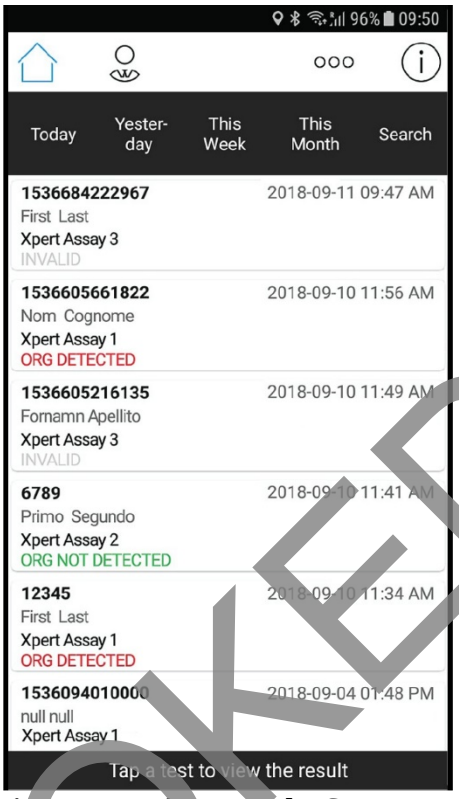


Figure 17. View Results Screen

2. To view the list of results for a different time period, tap one of the result period options shown at the top of the screen (see Figure 18).

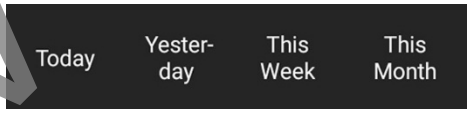


Figure 18. Select Result Period

3. Tap a listed test to view more information about the test and print the test result by tapping **Print Result** at the bottom of the screen. If results are not displayed, make sure that:
   - Omni instrument is turned on.
   - Mobile device is within 30 meters (100 feet) of the Omni instrument.

REVOKED

15 Quality Control

15.1 Internal Controls

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 Omni 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.

15.2 External Controls

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

Due to the COVID-19 pandemic and the resulting shortage of external control material, Cepheid recommends that all laboratories perform external QC with each new lot and shipment of reagents, at a minimum, while running the Xpert Omni SARS-CoV-2 test under Emergency Use Authorization (EUA).

16 Interpretation of Results

The results are interpreted automatically by the GeneXpert Omni System and are clearly shown in the **View Results** screen. The Xpert Omni 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 Omni SARS-CoV-2 Possible Results

Result Text	N2	E	SPC
SARS-CoV-2 POSITIVE	+	+/-	+/-
SARS-CoV-2 POSITIVE	+/-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
INVALID	-	-	-

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

REVOKED

Table 2. Xpert Omni SARS-CoV-2 Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE[a]	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. OR • The SARS-CoV-2 signal for the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting. Additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. NOTE: Specific target information can be accessed through the C360 portal, https://c360.cepheid.com. Refer to the GeneXpert C360 user's manual for additional instructions. • SPC: NA; SPC is ignored because coronavirus target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE[a]	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected. • The SARS-CoV-2 signals 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.
INVALID[b]	SPC does not meet acceptance criteria. Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). • SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting • Probe Check – PASS; all probe check results pass
ERROR[b]	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: FAIL; all or one of the probe check results fail. Note: If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, no sample added, or by a system component failure.

REVOKED

Result	Interpretation
NO RESULT[b]	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test according to the Retest Procedure (Section 17.2). A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress. • SARS-CoV-2: NO RESULT • SPC: NO RESULT • Probe Check: NA (not applicable)

a. Note: Error codes may be displayed for both SARS-CoV-2 POSITIVE & SARS-CoV-2 NEGATIVE valid results as they do not disrupt the assay; if a valid test result is provided with error code no repeat test is required.
b. Note**:** Error code with INVALID, ERROR or NO RESULT as a result will require the test to be repeated.

The Xpert Omni 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.

17 Retests

17.1 Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in Section 17.2, Retest Procedure.

- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

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

REVOKED

17.2 Retest Procedure

To retest a non-determinate result **(INVALID**, **NO RESULT**, or **ERROR**), use a new cartridge.

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

1. Follow Section 13, Procedure to initiate test using the Omni instrument and mobile device and follow the steps below to prepare a retest of the sample or external control.
2. Put on a clean pair of gloves. Obtain a new Xpert Omni SARS-CoV-2 cartridge and a new transfer pipette.
3. Check the specimen transport tube or external control tube is closed.
4. Mix the sample by rapidly inverting the specimen transport medium tube or external control tube 5 times.
5. Open the cap on the specimen transport tube or external control tube.
6. Open the cartridge lid.
7. Using a clean transfer pipette (supplied), transfer sample (one draw) to the large opening (Sample Chamber) on the cartridge (see Figure 13).
8. Close the cartridge lid.

REVOKED

18 Limitations

- Performance of the Xpert Omni SARS-CoV-2 test has only been established in nasopharyngeal swab specimens. Use of the Xpert Omni SARS-CoV-2 test with other specimen types has not been assessed and performance characteristics are unknown.
- Anterior nasal swabs and mid-turbinate swabs (self-collected under supervision of or collected by a healthcare provider), oropharyngeal swabs collected by a healthcare provider, as well as nasal wash/aspirate specimens are considered acceptable specimen types for use with the Xpert Omni 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.
- The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- As with any molecular test, mutations within the target regions of Xpert Omni SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- As the E gene target of the Xpert Omni SARS-CoV-2 test detects other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV, the presence of these viruses may cause a false positive result for detection of SARS-CoV-2. None of these other coronaviruses is known to currently circulate in the human population. Additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV or other Sarbecovirus currently unknown to infect humans.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

REVOKED

19 Conditions of Authorization for the Laboratory

The Cepheid Xpert Omni 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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

However, to assist clinical laboratories using the Xpert Omni SARS-CoV-2 (referred to in the Letter of Authorization as "Your Product"), the relevant Conditions of Authorization are listed below.

- Authorized laboratories[a] using this product must include with test result reports, 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 this product must use this product as outlined in the Xpert Omni SARS-CoV-2 Instructions for Use. 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 Omni SARS-CoV-2 test are not permitted.
- Authorized laboratories must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories that receive this product must notify the relevant public health authorities of their intent to run this product prior to initiating testing.
- Authorized laboratories using the Xpert Omni SARS-CoV-2 test must 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 this product must be appropriately trained in RT-PCR techniques and use appropriate personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling.
- Cepheid, authorized distributors, and authorized laboratories using this product must 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.

a. The letter of authorization refers to "authorized laboratories" as follows: "Testing of nasopharyngeal, oropharyngeal, anterior nasal, or mid-turbinate swab or nasal wash/aspirate specimens using the Xpert Omni SARS-CoV-2 test run on the GeneXpert Omni System is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests. Testing of nasopharyngeal, anterior nasal, or mid-turbinate swab specimens using the Xpert Omni SARS-CoV-2 test run on the GeneXpert Omni System is limited to laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. Testing of these specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

REVOKED

20 Performance Characteristics

20.1 Clinical Evaluation – Laboratory Setting

The performance of the Xpert Omni SARS-CoV-2 test on the GeneXpert Omni System was evaluated using archived clinical nasopharyngeal (NP) swab specimens in universal transport media (UTM) or viral transport medium (VTM). A total of 52 known SARS-CoV-2 positive and 52 SARS-CoV-2 negative NP swab specimens, were tested with Xpert Omni SARS-CoV-2 in a randomized and blinded fashion.

All 52 SARS-CoV-2 positive specimens were collected during the COVID-19 pandemic in the US and had previously been characterized as positive for SARS-CoV-2 by an EUA RT-PCR test. All of the 52 SARS-CoV-2 negative NP swab specimens were collected at least one year before the onset of the COVID-19 pandemic in the US and are expected to be negative for SARS-CoV-2.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Omni SARS-CoV-2 test relative to the expected results. Results of these 104 archived clinical NP swab specimens are shown in Table 3. The PPA was 100.0% (95% CI: 93.1% - 100%) and the NPA was 100.0% (95% CI: 93.1% - 100%).

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

		Expected Results		
		Positive	**Negative**	**Total**
Xpert Omni SARS-CoV-2	**Positive**	52	0	52
	Negative	0	52	52
	Total	52	52	104
PPA		100.0% (95% CI: 93.1% - 100%)		
NPA		100.0% (95% CI: 93.1% - 100%)		

REVOKED

20.2 Clinical Evaluation – Point of Care Setting

Performance characteristics of the Xpert Omni SARS-CoV-2 test using the GeneXpert Omni System in a point-of-care environment was established in a multi-site study that compared the Xpert Omni SARS-CoV-2 test to a high sensitive FDA authorized molecular assay. Two study sites were used; one site was a point-of-care environment and one site was a reference laboratory. Clinical NP swab specimens, both prospectively collected and archived, as well as contrived NP swab samples were used in this study. A total of 226 specimens (187 clinical NP swab specimens [100 prospectively collected and 87 archived specimens] ; 39 contrived NP swab samples) were tested with the Xpert Omni SARS-CoV-2 test. The 187 clinical NP swab specimens were tested with the Xpert Omni SARS-CoV-2 test and the comparator on-market EUA NAAT test. The 39 contrived NP swab samples were tested with the Xpert Omni SARS-CoV-2 test and those results were

compared to their expected results.

For clinical NP swab specimens, the Xpert Omni SARS-CoV-2 test demonstrated a PPA of 97.6% (95% CI: 91.5-99.3) and an NPA of 99.1% (95% CI: 94.8-99.8). Results are shown in Table 4.

Table 4. Xpert Omni SARS-CoV-2 Performance Using Clinical NP Swab Specimens – Prospectively Collected and Archived Combined

		FDA authorized molecular assay		
Xpert Omni SARS-CoV-2		**Positive**	**Negative**	**Total**
	Positive	80	1	81
	Negative	2	104	106
	Total	82	105	187
PPA		97.6% (95% CI: 91.5-99.3)		
NPA		99.1% (95% CI: 94.8-99.8)		

For the 100 prospectively collected NP swab specimens, the Xpert Omni SARS-CoV-2 test demonstrated a PPA of 94.6% (95%CI: 82.3-98.5) and an NPA of 98.4% (91.5-99.7). Results are shown in Table 5.

Table 5. Xpert Omni SARS-CoV-2 Performance Using Clinical NP Swab Specimens – Prospectively Collected

		FDA authorized molecular assay		
Xpert Omni SARS-CoV-2		**Positive**	**Negative**	**Total**
	Positive	35	1	36
	Negative	2	62	64
	Total	37	63	100
PPA		94.6% (95%CI: 82.3-98.5)		
NPA		98.4% (95%CI: 91.5-99.7)		

For the 87 archived NP swab specimens, the Xpert Omni SARS-CoV-2 test demonstrated a PPA of 100.0% (95%CI: 92.1-100.0) and an NPA of 100.0% (95%CI: 91.6-100.0). Results are shown in Table 6.

REVOKED

Table 6. Xpert Omni SARS-CoV-2 Performance Using Clinical NP Swab Specimens – Archived

		FDA authorized molecular assay		
		Positive	**Negative**	**Total**
Xpert Omni SARS-CoV-2	**Positive**	45	0	45
	Negative	0	42	42
	Total	45	42	87
PPA		100.0% (95%CI: 92.1-100.0)		
NPA		100.0% (95%CI: 91.6-100.0)		

Contrived positive NP swab samples near the LoD of the test and negative NP swab specimens were tested on the GeneXpert Omni System. The Xpert Omni SARS-CoV-2 test demonstrated a PPA of 100.0% (95%CI: 83.2-100.0) and an NPA of 100.0% (95%CI: 83.9-100.0). Results are shown in Table 7.

Table 7. Xpert Omni SARS-CoV-2 Performance Using Contrived NP Swab Specimens

		Expected Results		
		Positive	**Negative**	**Total**
Xpert Omni SARS-CoV-2	**Positive**	19	0	19
	Negative	0	20	20
	Total	19	20	39
PPA		100.0% (95% CI: 83.2-100.0)		
NPA		100.0% (95% CI: 83.9-100.0)		

REVOKED

21 Analytical Performance

21.1 Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Omni SARS-CoV-2. The LoD was estimated with limiting dilutions of heat-inactivated SARS-CoV-2 virus (USA WA1/2020) using two lots of reagents in viral transport medium. The LoD of the assay was estimated using heat-inactivated SARS-CoV-2 virus diluted in nasopharyngeal swab clinical matrix (Table 8).

Table 8. LoD Determination Using USA WA1/2020 Strain Using One Reagent lot

Concentration (copies/mL)	Assay Positives / Replicates	Assay Positive Hit Rate (%)	E Positives / Replicates	E Mean Ct	E Hit Rate (%)	N2 Positives / Replicates	N2 Mean Ct	N2 Hit Rate (%)
0	0/22	0	0/22	0.0	0	0/22	0	0
12.5	5/22	22.7	0/22	0.0	0	5/22	42.3	22.7
25	13/22	59.1	2/22	40.2	9.1	13/22	41.6	59.1
35	14/21[a]	66.7	1/21	42.5	4.8	13/21	41.7	61.9
50	20/22	90.9	3/22	42.6	13.6	19/22	41.7	86.4
100	19/22	86.4	3/21[b]	38.5	14.3	18/22	41.1	81.8
125	21/22	95.5	8/21[b]	39.8	38.1	21/22	40.5	95.5
150	21/21[a]	100	10/20[b]	40.4	50.0	21/21	40.8	100
350	22/22	100	19/21[b]	36.8	90.5	22/22	38.6	100
500	22/22	100	21/21[b]	35.8	100.0	22/22	38.1	100

a. One test gave INVALID overall result with INVALID for E and N2 target.
b. One test gave INVALID result for E target and positive result for N2 target.

Verification of the estimated LoD claim was performed on one reagent lot in replicates of 22 prepared in pooled NP swab clinical matrix. The LoD is the lowest concentration (reported as copies/mL) of heat-inactivated SARS-CoV-2 virus samples that can be reproducibly distinguished from negative samples ≥ 95% of the time with 95% confidence. The claimed LoD is 400 copies/mL (Table 9).

Table 9. Limit of Detection of the Xpert Omni SARS-CoV-2

Strain	Concentration (copies/mL)	Positives/ Replicates	E Hit Rate (%)	E Mean Ct	N2 Hit Rate (%)	N2 Mean Ct
SARS-CoV-2 USA WA1/2020	400	22/22	100	36.1	100	38.8
	0	0/22	0	-	0	-

REVOKED

21.2 Analytical Reactivity (Inclusivity)

The inclusivity of Xpert Omni SARS-CoV-2 was evaluated using *in silico* analysis of the assay primers and probes in relation to 412,389 SARS-CoV-2 sequences available (as of February 19, 2021) in the GISAID gene database for two targets, E and N2.

For the E target, 523 matching sequences were excluded due to ambiguity codes, which reduced the total to 411,866 sequences. Xpert Omni SARS-CoV-2 had 98.69% match to the sequences with the exception of 5,362 sequences that had a single mismatch and 50 sequences with additional mismatches. None of these mismatches are predicted to have a negative impact on the performance of the assay.

For the N2 target, 586 matching sequences were excluded due to ambiguity codes, which reduced the total to 411,803 sequences. Xpert Omni SARS-CoV-2 had 96.65% match to the sequences with the exception of 13,511 sequences that had a single mismatch and 280 sequences with two or more mismatches. None of these mismatches are predicted to have a negative impact on the performance of the assay.

21.3 Analytical Specificity (Exclusivity)

An *in silico* analysis for possible cross-reactions with all the organisms listed in Table 10 was conducted by mapping primers and probes in the Xpert Omni 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 cross reactivity with other organisms listed in Table 10 is predicted based on the *in silico* analysis.

Table 10. Xpert Omni 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

REVOKED

Microorganisms from the Same Genetic Family	High Priority Organisms
	Candida albicans
	Corynebacterium diphtheriae
	Legionella non-*pneumophila*
	Bacillus anthracis (Anthrax)
	Moraxella catarrhalis
	Neisseria elongata and N. meningitidis
	Pseudomonas aeruginosa
	Staphylococcus epidermidis
	Staphylococcus salivarius
	Leptospira
	Chlamydia psittaci
	Coxiella burnetii (Q-Fever)
	Staphylococcus aureus

REVOKED

22 References

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

REVOKED

23 Cepheid Headquarters Locations

Corporate Headquarters

Cepheid
904 Caribbean Drive
Sunnyvale, CA
94089 USA

Telephone: + 1 408 541 4191
Fax: + 1 408 541 4192
www.cepheid.com

European Headquarters

Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont
France

Telephone: + 33 563 825 300
Fax: + 33 563 825 301
www.cepheidinternational.com

24 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 Tag number

United States

Telephone: + 1 888 838 3222
Email:
techsupport@cepheid.com

France

Telephone:+ 33 563 825 300

Email:
support@cepheideurope.com

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

REVOKED

25 Table of Symbols

Symbol	Meaning
	Catalog number
	*In vitro* diagnostic medical device
	Do not reuse
	Batch code
	Consult instructions for use
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
	Expiration date
	Temperature limitation
	For prescription use only
	Near Field Communication (NFC) (label with NFC embedded tag)
	Near Field Communication (NFC) product

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

For use under Emergency Use Authorization (EUA) Only

REVOKED

Quick Reference Instructions for Xpert® Omni SARS-CoV-2 and GeneXpert Omni System

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. Nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate swab or nasal wash/aspirate specimens is limited to laboratories certified under CLIA that meet the requirements to perform high or moderate complexity tests. Testing of nasopharyngeal, anterior nasal, or mid-turbinate swab specimens are also authorized for use at the point of care, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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 Omni SARS-CoV-2 cartridges at 2-28°C.	• DO NOT try to manually open or close the instrument door at any time. • DO NOT move the mobile device more than 30 meters (~100 feet) from the instrument. • 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, unplug, move or tip 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 the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing. Refer to the GeneXpert Omni Reference Guide for a description of instrument, mobile device, and key to commonly used icons.

II. How to Start the Software

1 Start Software.

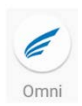
a. Put on a pair of clean gloves.

b. Turn on the GeneXpert Omni instrument by holding the power button for at least 2 seconds.

c. An instrument self-test will run for about 2 minutes.

d. Turn on the mobile device. Swipe mobile device screen to unlock.

e. Tap the **Omni** icon to start the Omni mobile application.



2 Login.

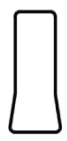
a. Tap the **LOGIN** icon.

b. Tap the **User Name** icon and enter user name.

c. Tap **Password** icon and enter password.

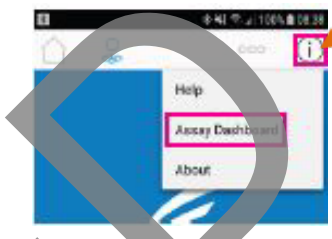
d. Tap the forward arrow next to the **Password** field. The **Home** screen appears.

e. Verify the **instrument** icon appears at the bottom of the **Home** screen.



3 How to Access Instructions for Use (optional).

a. Tap the **Information** icon then select **Assay Dashboard** from the drop down menu.



b. Follow the instructions on the documentation home page to open and read the instructions for use for the Xpert Omni SARS-CoV-2 test.

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.
- Start the test within 30 minutes of adding the specimen to the cartridge.
- The recommended environmental operating conditions are 15-30°C, 20-80% relative humidity and the allowable operating conditions are 15-40°C, 16-90% relative humidity.

1 Start a Test on the Mobile Device.

a. If needed, tap **Home** icon at top of screen to go to Home screen.

b. Tap the **Start New Test** button on the **Home** screen.

2 Choose to Manually Enter or Scan the Patient ID. Enter Patient Information. Scroll down to Tap Forward Arrow.

To scan patient barcode, aim the rear camera of the mobile device at barcode. A beep sounds and the Patient ID will appear in the **Patient ID** field.

NOTE: To allow for the Patient ID scanning feature, Omni mobile application 1.3 or higher must be used with the mobile device.

3 Choose to Manually Enter, Scan or Generate the Sample ID. Enter Test Type and Sample Type description. Scroll down to Tap Forward Arrow.

4 Scan Cartridge.

a. Place the back of the mobile device close to the GeneXpert cartridge label. The cartridge should be aimed to the center back of the mobile device.

b. Verify the correct cartridge has been scanned: Xpert Omni SARS-CoV-2.

REVOKED

© 2020-2021 Cepheid. All rights reserved.

5 Mix Specimen.

a. Check that the specimen transport tube cap is closed.

b. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube.

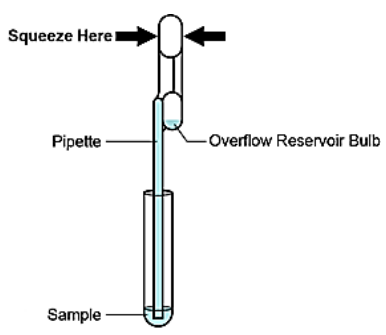
c. Open the cartridge lid.

6 Fill Pipette with Sample.

a. Remove the transfer pipette from wrapper.

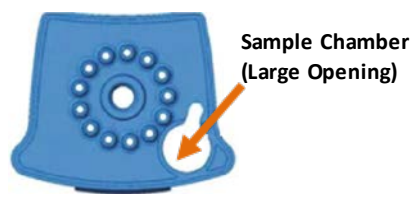
b. Squeeze the top bulb of the pipette **completely until the top bulb is fully flat**. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube.

c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing from the tube. It is okay if liquid goes into the overflow reservoir.



7 Transfer Sample to Cartridge.

a. Squeeze the top bulb of the pipette **completely until it is fully flat** to empty the contents of the pipette into the large opening (Sample Chamber). Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

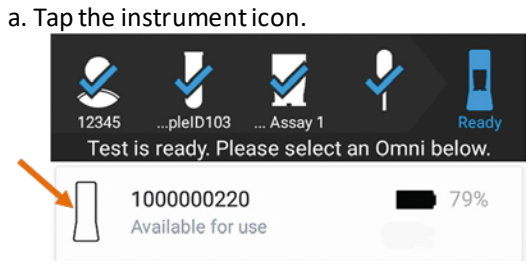


b. Close the cartridge lid.

c. Tap the forward arrow at the bottom right of the screen to move to the next screen.

8 Loading/Unloading Cartridge and Viewing Results.

a. Tap the instrument icon.



b. An instrument self-test will run then the instrument door automatically opens.

c. Load the cartridge on instrument as shown below.

d. Remove hands immediately from instrument after loading cartridge. The door will close automatically. When the test is done, the door will open.

e. Result is displayed. At the bottom of the screen, tap **Print Result**.

f. Dispose of the cartridge and gloves.

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

IV. How To Start a New Test

a. Put on a new pair of clean gloves.

b. Tap **Home** icon at top of screen.

c. To start a new test, follow the test procedure above, starting with Step 1.

V. How to Run External Controls – Positive and Negative Controls

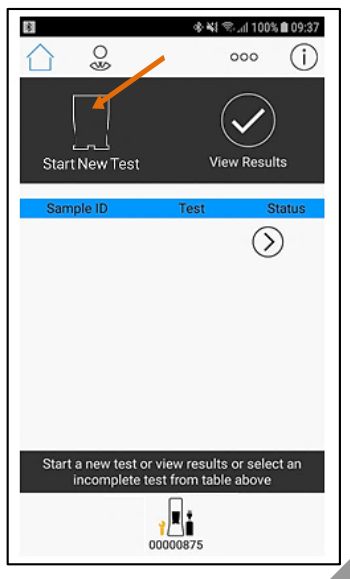
It is recommended that external controls (SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126) be tested at the frequency noted below.

- Each time a new lot or a new shipment of Xpert Omni SARS-CoV-2 is received.
- Each time a new operator is performing the test.
- When problems are suspected or identified.
- Per your institution's standard Quality Control (QC) procedures.

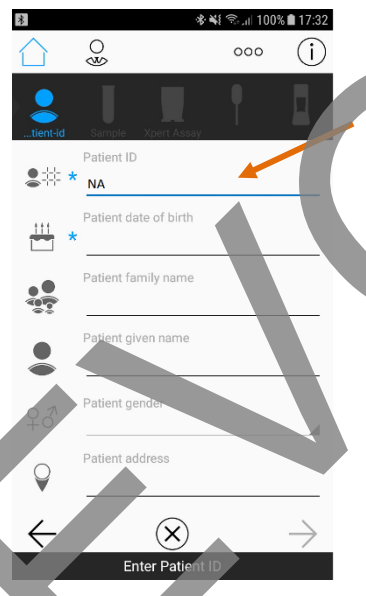
1 Start a Test on Mobile Device.

a. If needed, tap **Home** icon at top of screen to go to Home screen.

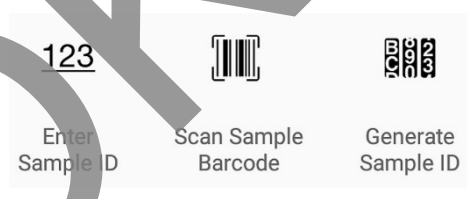
b. Tap the **Start New Test** icon on the **Home** screen.



2 Enter "NA" for Patient ID. Scroll Down to Tap Forward Arrow.



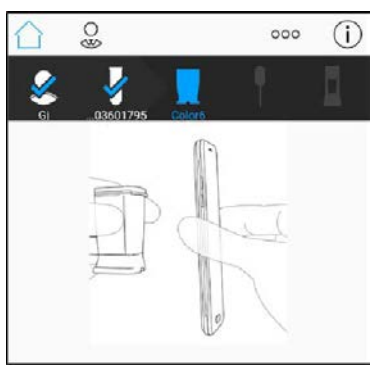
3 Choose to Manually Enter, Scan or Generate the Sample ID. Scroll down to Tap Forward Arrow.



To scan sample barcode, aim the rear camera of the mobile device at barcode. A beep sounds and the Sample ID will appear in the **Sample ID** field.

4 Scan Cartridge.

a. Place the back of the mobile device close to the GeneXpert cartridge label. The cartridge should be aimed to the center back of the mobile device.



b. Verify the correct cartridge has been scanned: Xpert Omni SARS-CoV-2.

5 Mix External Control.

a. Check that the external control tube cap is closed.

b. Mix external control tube by rapidly inverting the external control tube 5 times. Open the cap on the external control tube.

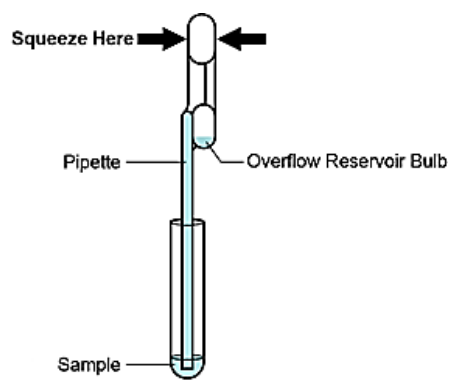
c. Open the cartridge lid.

6 Fill Pipette with External Control.

a. Remove the transfer pipette from wrapper.

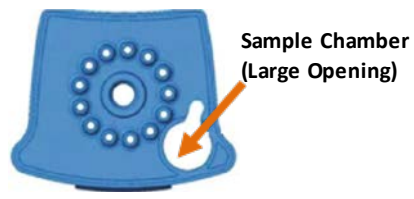
b. Squeeze the top bulb of the pipette **completely until the top bulb is fully flat**. While continuing to hold the bulb fully flat, place the pipette tip in the external control tube.

c. Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with the external control before removing from the tube. It is okay if liquid goes into the overflow reservoir.



7 Transfer External Control to Cartridge.

a. Squeeze the top bulb of the pipette **completely until it is fully flat** to empty the contents of the pipette into the large opening (Sample Chamber). Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

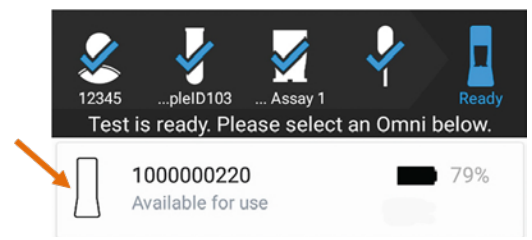


b. Close the cartridge lid.

c. Tap the forward arrow at the bottom right of the screen to move to the next screen.

8 Loading/Unloading Cartridge and Viewing Results.

a. Tap the instrument icon.



b. An instrument self-test will run then the instrument door automatically opens.

c. Load the cartridge on instrument as shown below.

d. Remove hands immediately from instrument after loading cartridge. The door will close automatically. When the test is done, the door will open.

e. Result is displayed. At the bottom of the screen, tap **Print Result**

f. Dispose of the cartridge and gloves.

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

REVOKED

© 2020-2021 Cepheid. All rights reserved.

VI. Possible Results

Result	Interpretation
SARS-CoV-2 NEGATIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected.
INVALID	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new cartridge.
ERROR	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new cartridge.
NO RESULT	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with 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.

Warnings

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA
Tel: +1 408 541 4191
Fax: +1 408 541 4192

Technical Support
888-838-3222 option 2
techsupport@cepheid.com
http://www.cepheid.com/en/support/contact-us

REVOKED

© 2020-2021 Cepheid. All rights reserved.

REVOKED

© 2020-2021 Cepheid. All rights reserved.

Xpert® Omni SARS-CoV-2

Electronic Labeling Flyer
For Use Under an Emergency Use Authorization (EUA) Only

Rx only

REF

IVD

OMNISARS-COV2-10

The Xpert Omni SARS-CoV-2 ADF and Package Insert should be downloaded as part of the assay bundle during system setup. If the Package Insert and/or ADF is missing from the Omni mobile device, please contact technical support.

Additional Xpert Omni SARS-CoV-2 documentation is available on the website www.Cepheid.com/Omni. Under the Product Resources section on the webpage, select the Xpert Omni SARS-CoV-2 EUA item you wish to view. A new tab on your internet browser will open to allow access to the Xpert Omni SARS-CoV-2 EUA item selected. A paper version can be requested at no additional cost.

Warnings:

- This product has not been FDA cleared or approved, but been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

REVOKED

Technical Assistance

Telephone: + 1 888 838 3222 Email: techsupport@cepheid.com