**TITLE: Xpert® Xpress CoV-2 *plus***

**Principle:**

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

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 that have spread globally, resulting in a pandemic

of coronavirus disease 2019 (COVID-19). Cases of severe illness and some deaths have been reported. The International Committee on Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.2. COVID-19 is associated with a variety of clinical outcomes, including asymptomatic infection, mild upper respiratory infection, severe lower respiratory disease including pneumonia and respiratory failure, and in some cases, death.

The Xpert Xpress CoV-2 *plus* is a molecular in vitro diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Xpress CoV-2 *plus* test contains primers and probes and internal controls used in RT-PCR for the in vitro qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, oropharyngeal swab or nasal wash/aspirate 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.

The Xpert Xpress CoV-2 *plus* test is an automated in vitro diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The Xpert Xpress CoV-2 *plus* test is performed on GeneXpert Instrument Systems. The primers and probes in the Xpert Xpress CoV-2 *plus* test are designed to amplify and detect unique sequences in the nucleocapsid (N), envelope (E) and RNA-dependent RNA polymerase (RdRP) genes of the SARS-CoV-2 virus genome.

The GeneXpert Instrument Systems 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 *GeneXpertDx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

The Xpert Xpress CoV-2 *plus* test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal swab or anterior nasal swabs. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert 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 specimen is collected and placed into a viral transport tube containing 3 mL viral transport medium or 3mL 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 CoV-2 *plus* cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

**6 Reagents and Instruments**

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

**Xpert Xpress CoV-2 *plus* Cartridges with** **10**

**Integrated Reaction Tubes**

Bead 1, Bead 2, and Bead 3 (freeze-dried) 1 of each per cartridge Lysis Reagent (Guanidinium Thiocyanate) 1.0 mL per cartridge Binding Reagent 1.0 mL per cartridge

Elution Reagent 2.0 mL per cartridge

Wash Reagent 0.5 mL per cartridge

**Disposable Transfer Pipettes 10–12 per kit**

**Flyer 1 per kit**

* Instructions to locate (and import) the ADF and documentation such as the Product Insert on [www.cepheid.com.](http://www.cepheid.com/)

Safety Data Sheets (SDS) are available at [www.cepheid.com](http://www.cepheid.com/) or [www.cepheidinternational.com](http://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 CoV-2 plus test cartridges at 2–28 °C.

Do not open the 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 Dx System or GeneXpert Infinity System (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner, and appropriate GeneXpert System operator manual.

For GeneXpert Dx System: GeneXpert Dx software version 4.7b or higher.

For GeneXpert Infinity-80 and Infinity-48s systems: Xpertise software version 6.4b or higher.

**9 Materials Available but not Provided**

ZeptoMetrix® External Controls

SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control, Catalog# NATSARS(COV2)-ERC

SARS Associated Coronavirus 2 (SARS-CoV-2) Negative Control, Catalog# NATSARS(COV2)-NEG

**10 Warnings and Precautions**

**10.1 General**

* For *in vitro* diagnostic use.
* For use under emergency use authorization only.
* For prescription use only.
* This product has not been FDA cleared or approved, but has been authorized 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 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 treated 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.
* Avoid direct contact between guanidine thiocyanate and sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures could release noxious gas.
* 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.
* Testing of nasopharyngeal swab, anterior nasal swab, nasal wash/aspirate, mid-turbinate nasal swab or oropharyngeal swab specimens using the Xpert Xpress CoV-2 plus 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, that meet requirements to perform high or moderate complexity tests.
* Testing of nasopharyngeal swab, mid-turbinate nasal swab or anterior nasal swab specimens using the Xpert Xpress CoV-2 plus test run on the GeneXpert Xpress System (Tablet and Hub Configurations), 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.

**10.2 Specimens**

Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see 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 CoV-2 plus 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.

● Do not use reagents beyond their expiry date

● Each single-use Xpert Xpress CoV-2 plus 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 Section12.1 for nasopharyngeal swab collection procedure, Section 12.2 for anterior nasal swab collection procedure.

Nasopharyngeal swab and anterior nasal swab specimens can be stored at room temperature (15–30 °C) for up to 48 hours in viral transport medium or saline until testing is performed on the GeneXpert Instrument Systems. Alternatively, nasopharyngeal swab and anterior nasal swab specimens can be stored refrigerated (2–8 °C) up to seven days in viral transport medium or saline until testing is performed on the GeneXpert Instrument Systems.

**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 Anterior 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. To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the 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.

**13 Procedure**

**13.1 Preparing the cartridge**

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

1. Remove a cartridge from the package.

2. Check the specimen transport tube is closed.

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

4. Open the cartridge lid.

5. Remove the transfer pipette from the wrapper.

6. Squeeze the top bulb of the transfer pipette completely and then place the pipette tip in the specimen transport tube (see Figure 3).



**Figure 3. Transfer Pipette**

7. Slowly 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. Check that the pipette does not contain bubbles.

8.To transfer the sample 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 below. Dispose of the used pipette.



**Sample Chamber**

**(Large Opening)**

**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.

9. Close the cartridge lid.

**13.2 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 Xpress CoV-2 plus test, perform the following steps:

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

2. Open the cartridge lid.

3. Using a clean transfer pipette, transfer one draw of the external control sample(300uL) into the large opening (Sample Chamber) in the cartridge shown in Figure 3.

4. Close cartridge lid.

**Starting the Test**

**Note** Before you start the test, make sure that the system contains modules with GeneXpert Dx software version 4.7b or higher and that the Xpert Xpress SARS-CoV-2 *plus* Assay Definition File is imported into the software.

This section lists the default steps to operate the GeneXpert Instrument System. For detailed instructions, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*, depending on the model that is being used.

**Note** The steps you follow may be different if the system administrator has changed the default workflow of the system.

1. Turn on the GeneXpert InstrumentSystem:

If using the GeneXpert Dx instrument, first turn on the instrument and then turn on the computer. Log into the Windows operating system. The GeneXpert software may launch automatically or may require double- clicking on the GeneXpert Dx shortcut icon on theWindows® desktop.

2. Log on to the System software. The login screen appears. Type your username and password.

3. In the GeneXpert System window, click **Create Test** (GeneXpert Dx).

4. Scan or type in the Patient ID (optional). If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is shown on the left side of the ViewResults window and is associated with the test result.

5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.

6. Scan the barcode on the Xpert Xpress CoV-2/Flu/RSV plus cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date and Selected Assay.

**Note** If the barcode on the Xpert Xpress CoV-2/Flu/RSV plus cartridge does not scan, then repeat the test with a new cartridge.

7. Click **Start Test** (GeneXpert Dx)

**For the GeneXpert Dx Instrument**

A. Locate the module with the blinking green light, open the instrument module door and load the cartridge.

B. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.

C. Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.

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

**13.3 Viewing and Printing Results**

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the GeneXpert Dx System Operator Manual.

1. Click the View Results icon to view results.

2. Upon completion of the test, click the Report button of the View Results window to view and/or generate a PDF report file.

**14 Quality Control**

**14.1 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 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.

**14.2 External Controls**

● External Positive Control: Catalog #NATSARS(COV-2)-ERC (Zeptometrix)

● External Negative Control: Catalog# NATSARS(COV2)-NEG (Zeptometrix)

Positive and Negative Controls will be performed following New lot/shipment QC protocols.

**15 Interpretation of Results**

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

**Table 1. Xpert Xpress CoV-2 *plus* Possible Results**

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

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

**Table 2. Xpert Xpress CoV-2 *plus* Test Results and Interpretation**

|  |  |
| --- | --- |
| **Result** | **Interpretation** |
| **SARS-CoV-2 POSITIVE** | SARS-CoV-2 target RNA is detected.   * The SARS-CoV-2 signal has a Ct within the valid range and endpoint above the minimum setting for one or more nucleic acid targets (N2, E, RdRP). * SPC: NA; SPC is ignored because coronavirus target amplification occurred. * Probe Check: PASS; all probe check results pass. |
| **SARS-CoV-2 NEGATIVE** | SARS-CoV-2 target RNA is not detected.   * The SARS-CoV-2 signals for nucleic acid targets (N2, E and RdRP) 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** | SPC does not meet acceptance criteria. Presence or absence of SARS-CoV-2 nucleic acids cannot be determined. Repeat test according to Section 16.2.   * 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** | Presence or absence of SARS-CoV-2 cannot be determined. Repeat test according to Section 16.2.   * SARS-CoV-2: NO RESULT * SPC: NO RESULT * Probe Check: FAIL[a](#_bookmark0); all or one of the probe check results fail. |
| **NO RESULT** | Presence or absence of SARS-CoV-2 cannot be determined. Repeat test according to Section 16.2. 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 If the probe check passed, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.

The Xpert Xpress CoV-2 *plus* 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 PCR cycles have been completed. When SARS CoV-2 titers are high enough to initiate the EAT function, the SPC and/or other target amplification curves may not be seen and their results may not be reported.

**POSITIVE REPORTING**

All Covid results will autopost and autoverify if Positive or Negative

SARS-CoV-2 RNA: DETECTED

?Internal QC OK

Comment: The 2019 novel coronavirus (SARS-CoV-2) target

Nucleic acids are detected. Positive results are indicative

of active infection with SARS-CoV-2.

Methodology: Detection of SARS-CoV-2 RNA is based upon the

real-time detection amplification of nucleic targets in

the SARS-CoV-2 viral genome.

Performance characteristics for the Xpert Xpress SARS-CoV-2

assay have been determined by Cepheid, Inc. as part of

the Emergency Use Authorization. Provider and patient fact

sheets are available at <https://www.fda.gov/medical-devices>

/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

**NEGATIVE REPORTING**

Auto posted/ Auto verified result - NEGATIVE

SARS-CoV-2 RNA: Not detected

?Internal QC OK

Comment: The 2019 novel coronavirus (SARS-CoV-2) target

nucleic acids are not detected. Negative results do not

preclude infection with the SARS-CoV-2 and should not be

the sole basis of a patient treatment/management or public

health decision. Follow up testing should be performed

according to the current CDC recommendations.

Methodology: Detection of Sars-CoV-2 RNA is based upon the

real-time detection and amplification of nucleic acid targets

in the SARS-Cov-2 viral genome.

Performance characteristics for the Xpert Xpress SARS-CoV-2

assay have been determined by Cepheid, Inc. as part of the

FDA Emergency Use Authorization. Provider and patient fact

sheets are available at https://www.fda.gov/medical-devices

/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

**INVALID REPORTING**

Auto posted Results after initial test failure shown below. If the repeated test obtains results they must be manually verified even if Negative.

CV: ?Test error. Repeat Test

If the repeated test also fails the above results will be listed twice. The keypad must then be used to manually choose the QC Fail result. }QCFR ?QC fail recollect

CV: ?Test error. Repeat Test

?Test error. Repeat Test

Possible interfering substance present. Recollection required.

?Mult internal QC failure. Call for recollection and reorder.

?Call for recollection and reorder

Document call to caregiver

**16 Retests**

* 1. **Reasons to Repeat the Assay**

If any of the test results mentioned below occur, repeat the test once according to instructions in Section 16.2.

* 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, 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 perfo rm as expected, repeat external control test and/or contact Cepheid for assistance.

**16.2 Retest Procedure**

To retest a non-determinate result (**INVALID**,**NORESULT**,or **ERROR**),use a new cartridge.

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

1. Put on a clean pair of gloves. Obtain a new Xpert Xpress CoV-2 *plus* cartridge and a new transfer pipette.
2. Check the specimen transport tube or external control tube is closed.
3. Mix the sample by rapidly inverting 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.
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.

**17 Limitations**

* Performance of the Xpert Xpress CoV-2 *plus* for individuals suspected of COVID-19 has only been established in nasopharyngeal swab and anterior nasal swab specimens. Specimen types other than nasopharyngeal swab and anterior nasal swab have not been assessed and performance characteristics are unknown.
* Performance of Xpert Xpress CoV-2 *plus* for asymptomatic screening population has only been established in anterior nasal swab specimens. Specimen types other than anterior nasal swab have not been assessed and performance characteristics are unknown.
* Nasopharyngeal swab, oropharyngeal swab and anterior nasal swab samples collected into saline should not be frozen.
* Performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.
* The performance of this device has not been assessed in a population vaccinated against COVID-19 or treated with COVID-19 therapies.
* Negative results do not preclude SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions.
* Results from the Xpert Xpress CoV-2 *plus* test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
* As with any molecular test, mutations within the target regions of Xpert Xpress CoV-2 *plus* could affect primer and/or probe binding and result in failure to detect the presence of virus.
* This test cannot rule out diseases caused by other bacterial or viral pathogens.
* The performance of this test was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
* Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.
* Viral nucleic acid may persist *in vivo*, independent of virus infectivity. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
* This test has been evaluated for use with human specimen material only.
* This test is a qualitative test and does not provide the quantitative value of detected organism present.
* This test has not been evaluated for monitoring treatment of infection.
* This test has not been evaluated for screening of blood or blood products for the presence of SARS-CoV-2.
* The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.
* Performance has not been established with media containing guanidine thiocyanate (GTC) other than eNAT.
* Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.

**19 References**

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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).

**20 Technical Assistance**

**Before Contacting Us**

Collect the following information before contacting Cepheid Technical Support:

* 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](mailto:techsupport@cepheid.com)

