GeneXpert
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Xpert® Xpress SARS-CoV-2/Flu/RSV

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

℞ only

REF **XPCOV2/FLU/RSV-10**

For Use with GeneXpert Dx or GeneXpert Infinity Systems

Cepheid

For use under an Emergency Use Authorization (EUA) Only

For *In Vitro* Diagnostic Use

IVD

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Xpert® Xpress SARS-CoV-2/Flu/RSV

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

1 Proprietary Name

Xpert® Xpress SARS-CoV-2/Flu/RSV

2 Common or Usual Name

Xpert Xpress SARS-CoV-2/Flu/RSV

3 Intended Use

The Xpert Xpress SARS-CoV-2/Flu/RSV test is a rapid, multiplexed real-time RT-PCR test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA in either nasopharyngeal swab, nasal swab or nasal wash/aspirate specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.[1] Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar.

Testing of nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV 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 meets requirements to perform high and moderate complexity tests.

Testing of nasopharyngeal or nasal swab specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV 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.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus and RSV nucleic acids in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A, influenza B and RSV RNA identified by this test are generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test.

Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, influenza A virus, influenza B virus and/or RSV 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/or epidemiological information.

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

4 Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has since spread globally, resulting in a pandemic of coronavirus disease 2019 (COVID-19). 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 International Committee on Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

[1] For this EU, a healthcare provider includes, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, epidemiologists, or any other practitioners or allied health professionals.

Influenza, or the flu, is a contagious viral infection of the respiratory tract. Transmission of influenza is primarily airborne (i.e., coughing or sneezing) and the peak of transmission usually occurs in the winter months. Symptoms commonly include fever, chills, headache, malaise, cough and sinus congestion. Gastrointestinal symptoms (i.e., nausea, vomiting or diarrhea) may also occur, primarily in children, but are less common. Symptoms generally appear within two days of exposure to an infected person. Pneumonia may develop as a complication due to influenza infection, causing increased morbidity and mortality in pediatric, elderly, and immunocompromised populations.[3,4]

Influenza viruses are classified into types A, B, and C, the former two of which cause the most human infections. Influenza A (Flu A) is the most common type of influenza virus in humans and is generally responsible for seasonal flu epidemics and potentially pandemics. Flu A viruses can also infect animals such as birds, pigs, and horses. Infections with influenza B (Flu B) virus are generally restricted to humans and less frequently cause epidemics.[5] Flu A viruses are further divided into subtypes on the basis of two surface proteins: hemagglutinin (H) and neuraminidase (N). Seasonal flu is normally caused by influenza A subtypes H1, H2, H3, N1 and N2.

Respiratory Syncytial Virus (RSV), a member of the *Pneumoviridae* family (formerly *Paramyxoviridae*), consisting of two strains (subgroups A and B) is also the cause of a contagious disease that affects primarily infants, and the elderly who are immunocompromised (e.g. patients with chronic lung disease or undergoing treatment for conditions that reduce the strength of their immune system).[6] The virus can remain infectious for hours on countertops and toys and can cause both upper respiratory infections, such as colds, and lower respiratory infections manifesting as bronchiolitis and pneumonia.[6] By the age of two years, most children have already been infected by RSV and because only weak immunity develops, both children and adults can be re-infected.[6] Symptoms appear four to six days after infection and are usually self-limiting, lasting approximately one to two weeks in infants. In adults, infection lasts about 5 days and presents as symptoms consistent with a cold, such as rhinorrhea, fatigue, headache, and fever. The RSV season mirrors influenza somewhat as infections begin to rise during the fall through early spring.[5,6]

Active surveillance programs in conjunction with infection prevention precautions are important components for preventing transmission of SARS-CoV-2, influenza and RSV. The use of assays providing rapid results to identify patients infected with these viruses can be an important factor for effective control, proper choice of treatment, and prevention of widespread outbreaks.

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

5 Principle of the Procedure

The Xpert Xpress SARS-CoV-2/Flu/RSV test is an automated *in vitro* diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert Instrument Systems.

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 and RT-PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

The Xpert Xpress SARS-CoV-2/Flu/RSV test includes reagents for the detection of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus in either nasopharyngeal swab, nasal swab, 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 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 swab, nasal swab, or nasal wash/ aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium or 3mL of saline. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

6 Reagents and Instruments

6.1 Materials Provided

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

Xpert Xpress SARS-CoV-2/Flu/RSV Cartridges with Integrated Reaction Tubes	**10**
• Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent	1.0 mL per cartridge
• Binding Reagent	1.0 mL per cartridge
• Elution Reagent	3.0 mL per cartridge
• Wash Reagent	0.4 mL per cartridge
Disposable Transfer Pipettes	**10-12 per kit**
Flyer	**1 per kit**
• Instructions to locate (and import) the ADF and EUA documentation such as the Product Insert on www.cepheid.com	
Quick Reference Instructions	**2 per kit**
(For use with the GeneXpert Xpress Systems - Tablet and Hub Configuration)	

Note Safety Data Sheets (SDS) are available at 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 postmortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling

- Store the Xpert Xpress SARS-CoV-2/Flu/RSV 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 Dx or GeneXpert Infinity systems (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner, 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

External controls in the form of inactivated virus(es) are available from ZeptoMetrix (Buffalo, NY).

- External Positive Control: Catalog #NATFRC-6C (NATtrol Flu/RSV/SARS-CoV-2)
- External Negative Control: Catalog #NATCV9-6C (Coxsackievirus A9)

10 Warnings and Precautions

10.1 General

- For *in vitro* diagnostic use.
- For emergency use only.
- Positive results are indicative of presence of Flu A, Flu B, RSV, or SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
- Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[7] and the Clinical and Laboratory Standards Institute.[8]
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- Consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.

10.2 Specimens

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

10.3 Assay/Reagent

- Do not open the Xpert Xpress SARS-CoV-2/Flu/RSV 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 SARS-CoV-2/Flu/RSV 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[9,10]

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

12 Specimen Collection, Transport, and Storage

Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See Section 12.1 for nasopharyngeal swab collection procedure, Section 12.2 for nasal swab collection procedure, and Section 12.3 for nasal wash/aspirate procedure. Nasopharyngeal swab, nasal swab, and nasal wash/aspirate specimens can be stored at room temperature (15-30 °C) for up to 24 hours in viral transport medium or 48 hours in saline until testing is performed on the GeneXpert Instrument Systems. Alternatively, nasopharyngeal swab, nasal swab, and nasal wash/aspirate 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. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

12.1 Nasopharyngeal Swab Collection Procedure

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

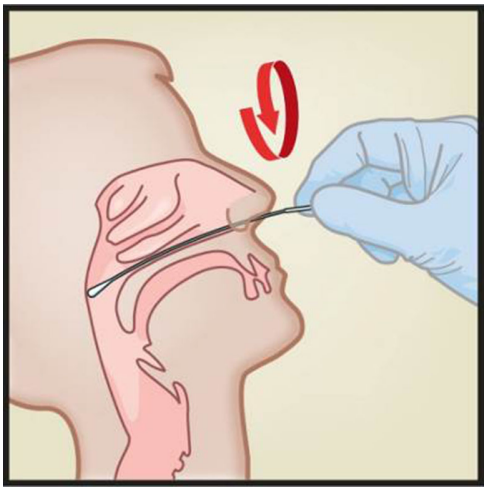

Figure 1. Nasopharyngeal Swab Collection

12.2 Nasal Swab Collection Procedure

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

Figure 2. Nasal Swab Collection for First Nostril

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

Figure 3. Nasal Swab Collection for Second Nostril

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

12.3 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 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 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 4).

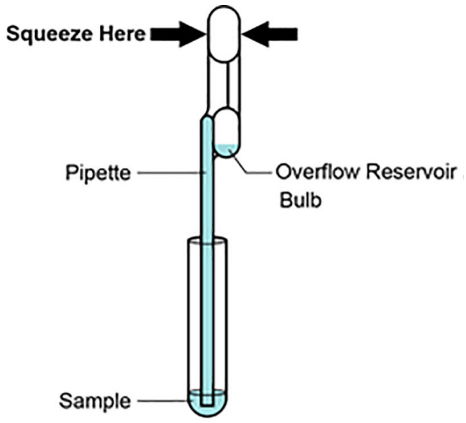

Figure 4. Transfer Pipette

7. 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 (see Figure 4). Check that the pipette does not contain bubbles.
8. To transfer the sample to the cartridge, squeeze the top bulb of the pipette completely again until it is fully flat to empty the contents of the pipette (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 5. Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

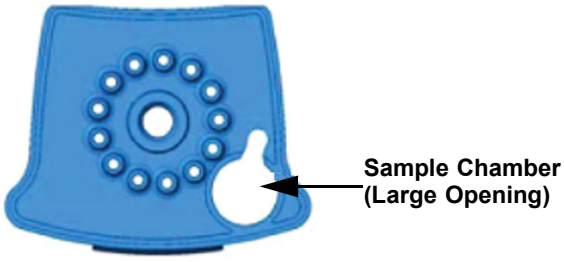

Figure 5. Xpert Xpress SARS-CoV-2/Flu/RSV Cartridge (Top View)

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

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 SARS-CoV-2/Flu/RSV 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 (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 5.
4. Close cartridge lid.

13.3 Starting the Test

Before you start the test, make sure that the system contains modules with GeneXpert Dx software version 4.7b or higher or Infinity Xpertise software 6.4b or higher, and that the Xpert Xpress SARS-CoV-2/Flu/RSV Assay Definition File is imported into the software.

Note

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 Instrument System:
   - **GeneXpert Dx:**
     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 the Windows® desktop.

     or
   - **GeneXpert Infinity System:**
     If using the GeneXpert Infinity instrument, power up the instrument by turning the power switch clockwise to the **ON** position. On the Windows desktop, double-click the Xpertise Software shortcut icon to launch the software.
2. Log on to the System software. The login screen appears. Type your user name and password.
3. In the GeneXpert System window, click **Create Test** (GeneXpert Dx) or **Orders** followed by **Order Test** (Infinity).
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 View Results 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 SARS-CoV-2/Flu/RSV 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 SARS-CoV-2/Flu/RSV cartridge does not scan, then repeat the test with a new cartridge.

7. Click **Start Test** (GeneXpert Dx) or **Submit** (Infinity) if Auto-Submit is not enabled. In the dialog box that appears, type your password, if required.

   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.

   or

For the GeneXpert Infinity System

A. After clicking **Submit**, you will be asked to place the cartridge on the conveyor belt. After placing the cartridge, click **OK** to continue. The cartridge will be automatically loaded, the test will run, and the used cartridge will be placed onto the waste shelf for disposal.

B. When all samples are loaded, click on the **End Order Test** icon.

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.

14 Viewing and Printing Results

For detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

15 Quality Control

15.1 Internal Controls

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

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

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

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 Xpress SARS-CoV-2/Flu/RSV test under Emergency Use Authorization (EUA).

16 Interpretation of Results

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

The format of the test results presented will vary depending on the user's choice to run either an Xpert Xpress_SARS-CoV-2_Flu_RSV, Xpert Xpress_SARS-CoV-2_Flu or Xpert Xpress_SARS-CoV-2 test.

Table 1 shows the possible result outcomes when the Xpert Xpress SARS-CoV-2_Flu_RSV test mode is selected.

Table 1. Xpert Xpress SARS-CoV-2_Flu_RSV Possible Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE	The 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. • SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred. • Probe Check: PASS; all probe check results pass.
Flu A POSITIVE	• The Flu A signal for either the Flu A1 RNA target or the Flu A2 RNA target or signals for both RNA targets has a Ct within the valid range and endpoint above the threshold setting. • SPC - NA; SPC is ignored because the Flu A target amplification occurred. • Probe Check - PASS; all probe check results pass.

Table 1. Xpert Xpress SARS-CoV-2_Flu_RSV Possible Results and Interpretation (Continued)

Result	Interpretation
Flu B POSITIVE	• The Flu B signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because Flu B target amplification occurred. • Probe Check: PASS; all probe check results pass
RSV POSITIVE	• The RSV signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because RSV target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B NEGATIVE; RSV NEGATIVE	SARS-CoV-2 target RNA is not detected; Flu A target RNA is not detected; Flu B target RNA is not detected; RSV target RNA is not detected. • SARS-CoV-2, Flu A, Flu B and RSV target RNAs are not detected. • 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 and all targets are not detected. Repeat test according to the Retest Procedure in Section 17.2. • SPC: FAIL; SPC and SARS-CoV-2, Flu A, Flu B and RSV signals do not have a Ct within valid range and endpoint is below minimum setting. • Probe Check - PASS; all probe check results pass
ERROR	Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV RNA cannot be determined. Repeat test according to the Retest Procedure in Section 17.2. • SARS-CoV-2: NO RESULT • Flu A: NO RESULT • Flu B: NO RESULT • RSV: NO RESULT • SPC: NO RESULT • Probe Check: FAIL[1]; all or one of the probe check results fail [1] 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.
NO RESULT	Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV RNA cannot be determined. Repeat test according to the Retest Procedure in 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 • Flu A: NO RESULT • Flu B: NO RESULT • RSV: NO RESULT • SPC: NO RESULT • Probe Check: NA
If the SPC is negative and the results for any of the targets are positive, the results for all targets are considered valid.	

If only one viral target is positive but coinfection with multiple targets is suspected, the sample should be re-tested with another FDA cleared, approved, or authorized test, if coinfection would change clinical management.

Table 2 shows the possible result outcomes when the Xpert Xpress_SARS-CoV-2_Flu test mode is selected.

Table 2. Xpert Xpress_SARS-CoV-2_Flu Possible Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE	The 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. • SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred. • Probe Check: PASS; all probe check results pass.
Flu A POSITIVE	• The Flu A signal for either the Flu A1 RNA target or the Flu A2 RNA target or signals for both RNA targets has a Ct within the valid range and endpoint above the threshold setting. • SPC – NA; SPC is ignored because the Flu A target amplification occurred. • Probe Check – PASS; all probe check results pass.
Flu B POSITIVE	• The Flu B signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because Flu B target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B NEGATIVE	SARS-CoV-2 target RNA is not detected; Flu A target RNA is not detected; Flu B target RNA is not detected. • SARS-CoV-2, Flu A, and Flu B target RNAs are not detected. • 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 and all targets are not detected. Repeat test according to the Retest Procedure in Section 17.2. • SPC: FAIL; SPC and SARS-CoV-2, Flu A, and Flu B signals do not have a Ct within valid range and endpoint is below minimum setting. • Probe Check - PASS; all probe check results pass
ERROR	Presence or absence of SARS-CoV-2, Flu A, and Flu B RNA cannot be determined. Repeat test according to the Retest Procedure in Section 17.2. • SARS-CoV-2: NO RESULT • Flu A: NO RESULT • Flu B: NO RESULT • SPC: NO RESULT • Probe Check: FAIL[1]; all or one of the probe check results fail [1] 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.

Table 2. Xpert Xpress_SARS-CoV-2_Flu Possible Results and Interpretation (Continued)

Result	Interpretation
NO RESULT	Presence or absence of SARS-CoV-2, Flu A, and Flu B RNA cannot be determined. Repeat test according to the Retest Procedure in 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 • Flu A: NO RESULT • Flu B: NO RESULT • SPC: NO RESULT • Probe Check: NA (not applicable)
If the SPC is negative and the results for any of the targets are positive, the results for all targets are considered valid.	

If only one viral target is positive but coinfection with multiple targets is suspected, the sample should be re-tested with another FDA cleared, approved, or authorized test, if coinfection would change clinical management.

Table 3 shows the possible result outcomes when the Xpert Xpress_SARS-CoV-2 test mode is selected.

Table 3. Xpert Xpress_SARS-CoV-2 Possible Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE	The 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. • SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE	SARS-CoV-2 target RNA is not detected. • SARS-CoV-2 target RNA is not detected. • 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 and SARS-CoV-2 is not detected. Repeat test according to the Retest Procedure in Section 17.2. • SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint is below minimum setting. • Probe Check - PASS; all probe check results pass
ERROR	Presence or absence of SARS-CoV-2 RNA cannot be determined. Repeat test according to the Retest Procedure in Section 17.2. • SPC: NO RESULT • Probe Check: FAIL[1]; all or one of the probe check results fail [1] 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.

Table 3. Xpert Xpress_SARS-CoV-2 Possible Results and Interpretation (Continued)

Result	Interpretation
NO RESULT	Presence or absence of SARS-CoV-2 RNA cannot be determined. Repeat test according to the Retest Procedure in 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

The Xpert Xpress SARS-CoV-2/Flu/RSV test can be run to detect SARS-CoV-2, Flu and RSV by selecting Xpert Xpress_SARS-CoV-2_Flu_RSV from the Select Test menu; SARS-CoV-2 and Flu only by selecting Xpert Xpress_SARS-CoV-2_Flu; or SARS-CoV-2 only by selecting Xpert Xpress_SARS-CoV-2. The Xpert Xpress_SARS-CoV-2 test mode includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the SARS-CoV-2 target 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 Test

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.

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. Put on a clean pair of gloves. Obtain a new Xpert Xpress SARS-CoV-2/Flu/RSV cartridge and a new transfer pipette.
2. Check the specimen transport tube or external control tube is closed.
3. Mix the sample by rapidly invert the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.
4. Open the cartridge lid.
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.

18 Limitations

- Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test has only been established in nasopharyngeal swab specimens. Use of the Xpert Xpress SARS-CoV-2/Flu/RSV test with other specimen types has not been assessed and performance characteristics are unknown.
- Nasal swabs (self-collected under supervision of, or collected by, a healthcare provider) and nasal wash/aspirate specimens are considered acceptable specimen types for use with the Xpert Xpress SARS-CoV-2/Flu/RSV test but performance with these specimen types has not been established.
- As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2/Flu/RSV test could affect primer and/or probe binding resulting in failure to detect the presence of virus or the virus being detected less predictably.
- 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.
- False negative results may occur if virus is present at levels below the analytical limit of detection.
- Negative results do not preclude SARS-CoV-2, influenza or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.
- Results from the Xpert Xpress SARS-CoV-2/Flu/RSV test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- Viral nucleic acid may persist *in vivo*, independent of virus viability. 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, influenza or RSV.
- 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.
- Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, influenza or RSV was present at 1X LoD levels.
- Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.
- Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.
- As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.
- This test is not intended to differentiate RSV subgroups, influenza A subtypes or influenza B lineages. If differentiation of specific RSV or influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Specimen transport media that contain guanidine thiocyanate (GTC) may interfere with the test, causing false negative results.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.

- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

19 Conditions of Authorization for Laboratory and Patient Care Settings

The Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV 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 and/or Patient Care Settings using the Xpert Xpress SARS-CoV-2/Flu/RSV (referred to in the Letter of Authorization as "Your Product"), the relevant Conditions of Authorization are listed below.

- Authorized laboratories[ii] settings using your product will include with result reports of the Xpert Xpress SARS-CoV-2/Flu/RSV test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the Xpert Xpress SARS-CoV-2/Flu/RSV Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity systems. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Xpert Xpress SARS-CoV-2/Flu/RSV test are not permitted.
- Authorized laboratories operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation using your product will use your product as outlined in the Xpert Xpress SARS-CoV-2/Flu/RSV Instructions for Use - For Use with GeneXpert Xpress System and associated Quick Reference Instructions for Xpert Xpress SARS-CoV-2/Flu/RSV and GeneXpert Xpress System (Hub configuration), and Quick Reference Instructions for Xpert Xpress SARS-CoV-2/Flu/RSV and GeneXpert Xpress System (Tablet configuration). Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using the Xpert Xpress SARS-CoV-2/Flu/RSV test will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA Reporting@fda.hhs.gov) and Cepheid (+1 888 838 3222 or techsupport@cepheid.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Cepheid, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

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

20 Performance Characteristics

20.1 Clinical Evaluation

The performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test was evaluated using archived clinical nasopharyngeal (NP) swab specimens in viral transport medium. Archived specimens were selected consecutively by date and previously known analyte result. A total of 240 NP swab specimens were tested with Xpert Xpress SARS-CoV-2/Flu/RSV side by side with a SARS-CoV-2 EUA RT-PCR test and the FDA-cleared Xpert Xpress Flu/RSV test in a randomized and blinded fashion. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Xpress SARS-CoV-2/Flu/RSV test relative to the results of a SARS-CoV-2 EUA RT-PCR test for the SARS-CoV-2 target, and Xpert Xpress Flu/RSV for the Flu A, Flu B, and RSV targets, respectively. Xpert Xpress SARS-CoV-2/Flu/RSV demonstrated a PPA and NPA of 97.9% and 100.0% for SARS-CoV-2, respectively; 100.0% and 100.0% for Flu A, respectively; 100.0% and 99.0% for Flu B, respectively; 100.0% and 100.0% for RSV, respectively (Table 4).

Table 4. Xpert Xpress SARS-CoV-2/Flu/RSV Performance Results

Target	Number of Specimens	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
SARS-CoV-2	240	46	0	193	1	97.9% (88.9% - 99.6%)	100.0% (98.1% - 100.0%)
Flu A	240	48	0	192	0	100% (92.6% - 100.0%)	100.0% (98.0% - 100.0%)
Flu B	240	46	2	192	0	100.0% (92.3% - 100.0%)	99.0% (96.3% - 99.7%)
RSV	240	47	0	193	0	100.0% (92.4% - 100.0%)	100.0% (98.1% - 100.0%)

TP: True Positive; FP: False Positive; TN: True Negative; FN: False Negative; CI: Confidence Interval

20.2 Analytical Sensitivity (Limit of Detection)

The analytical sensitivity of the Xpert Xpress SARS-CoV-2/Flu/RSV test was assessed with one lot of reagent and limiting dilutions of the six respiratory viruses (NATtrol SARS-CoV-2, Flu A H1, Flu A H3, Flu B, RSV A and RSV B) into pooled negative clinical NP swab matrix following the guidance in Clinical and Laboratory Standards Institute (CLSI) document EP17-A2. The estimated LoD values as determined by Probit regression analysis were verified using two lots of Xpert Xpress SARS-CoV-2/Flu/RSV reagents. The verified LoD values for the viruses tested are summarized in Table 5.

Table 5. Xpert Xpress SARS-CoV-2/Flu/RSV Limit of Detection

Virus/Strain	LoD Concentration
SARS-CoV-2 (USA-WA1/2020)	131 copies/mL
Influenza A/ California/7/2009	0.004 $TCID_{50}$/mL
Influenza A/Victoria/361/2011	0.087 $TCID_{50}$/mL
Influenza B/Mass/2/2012	0.04 $TCID_{50}$/mL
RSV A/2/Australia/61	0.43 $TCID_{50}$/mL
RSV B/Wash/18537/62	0.22 $TCID_{50}$/mL

20.3 Analytical Reactivity (Inclusivity)

The inclusivity of Xpert Xpress SARS-CoV-2/Flu/RSV was evaluated using *in silico* analysis of the assay amplicons in relation to 48,461 SARS-CoV-2 sequences available in the GISAID gene database for two targets, E and N2.

For analysis of the E target, 113 sequences were excluded due to ambiguous nucleotides, which reduced the total to 48,348 sequences. Of the 48,348 GISAID sequences, 48,108 (99.5%) were an exact match to the SARS-CoV-2 E target amplicon generated in the Xpert Xpress SARS-CoV-2/Flu/RSV test. Single nucleotide mismatches were observed for 223 sequences and two mismatches were observed for 17 sequences. Of the 17 sequences with two mismatches, two sequences contained 2 mismatches in the forward primer region, three sequences have a 'GA" dinucleotide in the reverse primer, and twelve sequences contained a 'AA' dinucleotide that lies between the oligonucleotides used in the assay. None of these mismatches are expected to affect the performance of the assay.

For analysis of the N2 target, 129 sequences were excluded due to ambiguous nucleotides, which reduced the total used in the evaluation to 48,332 sequences. Of the 48,332 GISAID sequences, 47,962 (99.2%) were an exact match to the SARS-CoV-2 N2 target amplicon generated in the Xpert Xpress SARS-CoV-2/Flu/RSV test. Single nucleotide mismatches were observed for 369 sequences and three (3) mismatches were observed for one sequence. For the one sequence with three variant positions, two of the mismatched nucleotides are in the probe region and could have an impact on probe binding. None of the other mismatches are predicted to have a negative impact on the performance of the assay.

The inclusivity of the Xpert Xpress SARS-CoV-2/Flu/RSV for Flu and RSV viruses are as reported for the analytical reactivity evaluation of the Xpert Xpress Flu/RSV test.

Xpert Xpress Flu/RSV test was evaluated against multiple strains of influenza A H1N1 (seasonal pre-2009), influenza A H1N1 (pandemic 2009), influenza A H3N2 (seasonal), avian influenza A (H5N1, H5N2, H6N2, H7N2, H7N3, H2N2, H7N9, and H9N2), influenza B (representing strains from both Victoria and Yamagata lineages), and respiratory syncytial virus subgroups A and B (RSV A and RSV B) at levels near the analytical LoD. A total of 53 strains comprised of 48 influenza viruses (35 influenza A and 13 influenza B) and 5 RSV strains were tested in this study with the Xpert Xpress Flu/RSV test. Three replicates were tested for each strain. All Flu and RSV strains tested positive in all three replicates, except for one Flu A H1N1 strain (A/New Jersey/8/76), which tested positive in 2 of 3 replicates at 0.1 $TCID_{50}$/mL. Results are shown in Table 6. Predicted cross reactivity from *in silico* analyses showed 100% sequence homology for additional pH1N1 strains.

Table 6. Analytical Reactivity (Inclusivity) of the Xpert Xpress Flu/RSV Test

Virus	Strain	Target Concentration	Result		
			Flu A	Flu B	RSV
No Template Control		N/A	NEG	NEG	NEG
Influenza A H1N1 (pre-2009)	A/swine/Iowa/15/30	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/WS/33	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/PR/8/34	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Mal/302/54	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Denver/1/57	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/New Jersey/8/76	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/New Caledonia/20/1999	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/New York/55/2004	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Solomon Island/3/2006	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Taiwan/42/06	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Brisbane/59/2007	0.1 $TCID_{50}$/mL	POS	NEG	NEG

Influenza A H1N1 (pdm2009)	A/swine/NY/02/2009	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Colorado/14/2012	0.1 $TCID_{50}$/mL	POS	NEG	NEG
	A/Washington/24/2012	0.1 $TCID_{50}$/mL	POS	NEG	NEG
Influenza A H3N2 (Seasonal)	A/Aichi/2/68	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Hong Kong/8/68	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Port Chalmers/1/73	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Hawaii/15/2001	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Wisconsin/67/05	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Brisbane/10/2007	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Minnesota/11/2010 (H3N2)v	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Indiana/08/2011 (H3N2)v	2.0 $TCID_{50}$/mL	POS	NEG	NEG
	A/Texas/50/2012	2.0 $TCID_{50}$/mL	POS	NEG	NEG
Avian influenza A	A/duck/Hunan/795/2002 (H5N1)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/chicken/Hubei/327/2004 (H5N1)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/Anhui/01/2005 (H5N1)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/Japanese white eye/Hong Kong/ 1038/2006 (H5N1)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/mallard/WI/34/75 (H5N2)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/chicken/CA431/00 (H6N2)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/duck/LTC-10-82743/1943 (H7N2)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/chicken/NJ/15086-3/94 (H7N3)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/Anhui/1/2013 (H7N9)	N/A[b]	POS	NEG	NEG
	A/Shanghai/1/2013 (H7N9)	N/A[b]	POS	NEG	NEG
	A/chicken/Korea/38349-p96323/ 1996 (H9N2)	≤ 1pg/µL[a]	POS	NEG	NEG
	A/Mallard/NY/6750/78 (H2N2)	≤ 1pg/µL[a]	POS	NEG	NEG

Influenza B	B/Lee/40	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Allen/45	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/GL/1739/54	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Maryland/1/59	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Panama/45/90[c]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Florida/07/2004[d]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Florida/02/06[c]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Florida/04/06[d]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Hong Kong/5/72	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Wisconsin/01/2011[d]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Malaysia/2506/04[c]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Taiwan/2/62	1.0 $TCID_{50}$/mL	NEG	POS	NEG
	B/Brisbane/60/2008[c]	1.0 $TCID_{50}$/mL	NEG	POS	NEG
RSV A	RSV-A/NY (Clinical unknown)	3.0 $TCID_{50}$/mL	NEG	NEG	POS
	RSV-A/WI/629-8-2/2007	3.0 $TCID_{50}$/mL	NEG	NEG	POS
	RSV-A/WI/629-11-1/2008	3.0 $TCID_{50}$/mL	NEG	NEG	POS
RSV B	RSV-B/WV14617/85	7.0 $TCID_{50}$/mL	NEG	NEG	POS
	RSV-B/CH93(18)-18	7.0 $TCID_{50}$/mL	NEG	NEG	POS

a. Purified viral RNA in simulated background matrix was used for avian influenza A viruses due to biosafety regulations.
b. Inactivated avian influenza A (H7N9) viruses without viral titer was diluted 100,000-fold in simulated background matrix and tested due to biosafety regulations.
c. Known Victoria lineage.
d. Known Yamagata lineage.

20.4 Analytical Specificity (Exclusivity)

An *in silico* analysis for possible cross-reactions with all the organisms listed in Table 7 was conducted by mapping primers and probes in the Xpert Xpress SARS-CoV-2/Flu/RSV test individually to the sequences downloaded from the GISAID database. E primers and probes are not specific for SARS-CoV-2 and will detect Human and Bat SARS-coronavirus. No potential unintended cross reactivity with other organisms listed in Table 7 is expected based on the *in silico* analysis.

Table 7. Xpert Xpress SARS-CoV-2/Flu/RSV 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 viruses 1-4
Human coronavirus NL63	Influenza A
SARS-coronavirus	Influenza B
MERS-coronavirus	Influenza C
Bat coronavirus	Enterovirus (e.g. EV68)
	Respiratory syncytial virus
	Rhinovirus
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jirovecii (PJP)
	Parechovirus
	Candida albicans
	Corynebacterium diphtheriae
	Legionella non-pneumophila
	Bacillus anthracis (Anthrax)
	Moraxella catarrhalis
	Neisseria elongata and N. meningitidis
	Pseudomonas aeruginosa
	Staphylococcus epidermidis
	Streptococcus salivarius
	Leptospira
	Chlamydia psittaci
	Coxiella burnetii (Q-Fever)
	Staphylococcus aureus

The analytical specificity of the Xpert Xpress SARS-CoV-2/Flu/RSV for Flu A, Flu B and RSV viruses are as reported for the analytical exclusivity evaluation of the Xpert Xpress Flu/RSV test. The analytical specificity of the Xpert Xpress Flu/RSV test was evaluated by testing a panel of 44 cultures consisting of 16 viral, 26 bacterial, and two yeast strains representing common respiratory pathogens or those potentially encountered in the nasopharynx. Three replicates of each bacterial and yeast strain were tested at concentrations of $\geq 1 \times 10^6$ CFU/mL with the exception of one strain that was tested at 1×10^5 CFU/mL (*Chlamydia pneumoniae*). Three replicates of each virus were tested at concentrations of $\geq 1 \times 10^5$ TCID 50 /mL. The analytical specificity was 100%. Results are shown in Table 8.

Table 8. Analytical Specificity of the Xpert Xpress Flu/RSV Test

Organism	Concentration	Influenza A	Influenza B	RSV
No Template Control	N/A	NEG	NEG	NEG
Adenovirus Type 1	1.12E+06 $TCID_{50}$/mL	NEG	NEG	NEG
Adenovirus Type 7	1.87E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Human coronavirus OC43	2.85E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Human coronavirus 229E	1.00E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Cytomegalovirus	1.00E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Echovirus	3.31E+07 $TCID_{50}$/mL	NEG	NEG	NEG
Enterovirus	3.55E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Epstein Barr virus	7.16E+07 $TCID_{50}$/mL	NEG	NEG	NEG
Herpes simplex virus	8.90E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Measles	6.31E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Human metapneumovirus	1.00E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Mumps virus	6.31E+06 $TCID_{50}$/mL	NEG	NEG	NEG
Human parainfluenza virus Type 1	1.15E+06 $TCID_{50}$/mL	NEG	NEG	NEG
Human parainfluenza virus Type 2	6.31E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Human parainfluenza virus Type 3	3.55E+06 $TCID_{50}$/mL	NEG	NEG	NEG
Rhinovirus Type 1A	1.26E+05 $TCID_{50}$/mL	NEG	NEG	NEG
Acinetobacter baumannii	1.00E+06 CFU/mL	NEG	NEG	NEG
Burkholderia cepacia	3.30E+06 CFU/mL	NEG	NEG	NEG
Candida albicans	3.20E+06 CFU/mL	NEG	NEG	NEG
Candida parapsilosis	3.00E+06 CFU/mL	NEG	NEG	NEG
Bordetella pertussis	3.30E+06 CFU/mL	NEG	NEG	NEG
Chlamydia pneumoniae	1.00E+05 CFU/mL	NEG	NEG	NEG

Citrobacter freundii	3.30E+06 CFU/mL	NEG	NEG	NEG
Corynebacterium sp.	3.30E+06 CFU/mL	NEG	NEG	NEG
Escherichia coli	1.00E+07 CFU/mL	NEG	NEG	NEG
Enterococcus faecalis	1.30E+06 CFU/mL	NEG	NEG	NEG
Hemophilus influenzae	1.00E+06 CFU/mL	NEG	NEG	NEG
Lactobacillus reuteri	1.00E+06 CFU/mL	NEG	NEG	NEG
Legionella spp.	1.00E+06 CFU/mL	NEG	NEG	NEG
Moraxella catarrhalis	1.00E+07 CFU/mL	NEG	NEG	NEG
Mycobacterium tuberculosis (avirulent)	1.00E+06 CFU/mL	NEG	NEG	NEG
Mycoplasma pneumoniae	1.00E+06 CFU/mL	NEG	NEG	NEG
Neisseria meningitidis	2.15E+06 CFU/mL	NEG	NEG	NEG
Neisseria mucosa	1.00E+07 CFU/mL	NEG	NEG	NEG
Propionibacterium acnes	2.40E+07 CFU/mL	NEG	NEG	NEG
Pseudomonas aeruginosa	3.70E+06 CFU/mL	NEG	NEG	NEG
Staphylococcus aureus (protein A producer)	2.20E+06 CFU/mL	NEG	NEG	NEG
Staphylococcus epidermidis	3.40E+06 CFU/mL	NEG	NEG	NEG
Staphyolcoccus haemolyticus	4.00E+06 CFU/mL	NEG	NEG	NEG
Streptococcus agalactiae	3.50E+06 CFU/mL	NEG	NEG	NEG
Streptococcus pneumoniae	1.00E+06 CFU/mL	NEG	NEG	NEG
Streptococcus pyogenes	1.00E+07 CFU/mL	NEG	NEG	NEG
Streptococcus salivarius	1.00E+07 CFU/mL	NEG	NEG	NEG
Streptococcus sanguinis	3.10E+06 CFU/mL	NEG	NEG	NEG

20.5 Competitive Interference

Competitive interference of the Xpert Xpress SARS-CoV-2/Flu/RSV caused by co-infections were evaluated by testing individual SARS-CoV-2, Flu A, Flu B or RSV strains at 1x LoD in the presence of different target strains at a higher concentration in a simulated background matrix. The concentration at LoD was 131 copies/mL for SARS-CoV-2 and ranged from 0.004 $TCID_{50}$/mL to 0.43 $TCID_{50}$/mL for the Flu and RSV strains; the competitive strains were evaluated at 10^4 titer units (copies/mL, $TCID_{50}$/mL, $CEID_{50}$/mL or PFU/mL). The corresponding concentration of RNA (copies/mL) for the Flu and RSV strains was determined by ddPCR.

Analytical competitive interference was assessed using a strain of SARS-CoV-2 (inactivated USA-WA1/2020), Flu A H3 (H3/Victoria/361/2011), Flu B (B/Mass/02/2012), RSV A (RSV-A/2/Australia/61), and RSV B (RSV-B/Wash/18537/62). Replicates of 20 were tested for each target strain and each competitive strain combination. The normal binomial distribution with 20 replicate samples at LoD is between 17 and 20 positive results based on the binomial distribution with N=20, p=0.95 (X~Bin(20,0.95)). Therefore, sets of 20 with 16 or less positives would be rare and an indication of a competitive inhibitory effect due to high levels of a competing analyte. Below is a summary of the results:

Table 9. Summary of Results for Competitive Interference

		Correct Calls (n/20)					
		Test Strain at LoD and Interferent at:					
Test Strain at LoD	**Interferent Strain**	**10^4* (2.1e7 cp/mL)**	**10^3* (2.1e6 cp/mL)**	**10^2* (2.1e5 cp/mL)**	**10* (2.1e4 cp/mL)**	**1* (2.1e3 cp/mL)**	**0.1* (2.1e2 cp/mL)**
Flu B	Flu A	*6/20*	**20/20**				
RSV A	Flu A	*9/20*	**17/20**				
RSV B	Flu A	*11/20*	**18/20**				
SARS-CoV-2	Flu A	*6/20*	**17/20**	**20/20**			
Test Strain at LoD	**Interferent Strain**	**10^4* (5.2e7 cp/mL)**	**10^3* (5.2e6 cp/mL)**	**10^2* (5.2e5 cp/mL)**	**10* (5.2e4 cp/mL)**	**1* (5.2e3 cp/mL)**	**0.1* (5.2e2 cp/mL)**
Flu A	Flu B	*1/20*	*4/20*	*8/20*	*9/19*	*15/20*	**20/20**
RSV A	Flu B	*0/20*	*0/20*	*3/20*	**18/20**		
RSV B	Flu B	*7/20*	*8/20*	*11/20*	**18/20**		
SARS-CoV-2	Flu B	*3/20*	*4/20*	*11/20*	**17/20**	**20/20**	
Test Strain at LoD	**Interferent Strain**	**10^4* (3.7e7 cp/mL)**	**10^3* (3.7e6 cp/mL)**	**10^2* (3.7e5 cp/mL)**	**10* (3.7e4 cp/mL)**	**1* (3.7e3 cp/mL)**	**0.1* (3.7e2 cp/mL)**
Flu A	RSV A	*15/20*	**12/20**	**20/20**			
Flu B	RSV A	*15/20*	**17/20**				
SARS-CoV-2	RSV A	**17/20**	**19/20**				
Test Strain at LoD	**Interferent Strain**	**10^4* (1.1e7 cp/mL)**	**10^3* (1.1e6 cp/mL)**	**10^2* (1.1e5 cp/mL)**	**10* (1.1e4 cp/mL)**	**1* (1.1e3 cp/mL)**	**0.1* (1.1e2 cp/mL)**
Flu A	RSV B	*9/20*	*7/20*	*6/20*	*14/20*	**20/20**	
Flu B	RSV B	*10/20*	*10/20*	*16/20*	**19/20**		
SARS-CoV-2	RSV B	**17/20**	*16/20*	*15/20*	**20/20**		
Test Strain at LoD	**Interferent Strain**	**10^4 ***	**10^3 ***	**10^2 ***	**10 ***	**1 ***	**0.1 ***
Flu A	SARS-CoV-2	**19/20**					
Flu B	SARS-CoV-2	**18/20**					
RSV A	SARS-CoV-2	**19/20**					
RSV B	SARS-CoV-2	**19/20**					

* Units for the concentration of each organism are as follows: Flu A H3 - $CEID_{50}$/mL; Flu B and RSV B - $TCID_{50}$/mL; RSV A - PFU/mL; SARS-CoV-2 - copies/mL

Italicized font indicates inhibitory effects

Bold font indicates no inhibition (SARS-CoV-2 tested to ≥19/20)

Flu A/Victoria/361/2011 at a concentration of 1 x 10^4 $CEID_{50}$/mL (2.1e7 copies/mL), inhibited Flu B, RSV A, RSV B and SARS-CoV-2 at the LoD.

Flu B/Mass/2/2012 at concentrations shown in Table 9, inhibited SARS-CoV-2, Flu A, RSV A and RSV B at concentrations at the LoD of those targets.

RSV A/2/Australia/61 at a concentration of 1 x 10^4 PFU/mL (3.7e7 copies/mL), inhibited SARS-CoV-2, Flu A and Flu B at the LoD.

RSV-B/Wash/18537/62 at concentrations shown in Table 9, inhibited SARS-CoV-2, Flu A and Flu B at concentrations at the LoD of those targets.

20.6 Potentially Interfering Substances

Potentially interfering substances that could be present in the nasopharynx (or introduced during specimen collection and handling) and interfere with accurate detection of SARS-CoV-2, Flu A, Flu B and RSV were evaluated with select direct testing on the Xpert Xpress SARS-CoV-2/Flu/RSV. Additional substances have also been previously evaluated on the Xpert Xpress Flu/RSV assay.

Potentially interfering substances in the nasal passage and nasopharynx may include, but are not limited to: blood, nasal secretions or mucus, and nasal and throat medications used to relieve congestion, nasal dryness, irritation, or asthma and allergy symptoms, as well as antibiotics and antivirals. Positive and negative samples were prepared in simulated nasal matrix. Negative samples (N = 8) were tested in the presence of each substance to determine the effect on the performance of the sample processing control (SPC). Positive samples (N = 8) were tested per substance with viruses spiked at 3x the analytical LoD determined for each strain. Positive samples tested with the Xpert Xpress SARS-CoV-2/Flu/RSV included one SARS-CoV-2, two influenza A, one influenza B and two RSV (RSV A and RSV B) strains, whereas those tested with the Xpert Xpress Flu/RSV consisted of six influenza (four influenza A and two influenza B) and four RSV (two RSV A and two RSV B). The substances evaluated are listed in Table 10 with active ingredients and final concentrations tested shown. None of the substances caused interference of the assay performance at the concentrations tested in this study. All positive and negative replicates were correctly identified by the Xpert Xpress SARS-CoV-2/Flu/RSV and/or Xpert Xpress Flu/RSV tests.

Table 10. Potentially Interfering Substances in the Xpert Xpress SARS-CoV-2/Flu/RSV Test and/or Xpert Xpress Flu/RSV Test

Substance/Class	Description/Active Ingredient	Concentration Tested
Control	Simulated nasal matrix	100% (v/v)
Beta-adrenergic bronchodilator[a]	Albuterol Sulfate	0.83 mg/mL (equivalent to 1 dose per day)
Blood	Blood (Human)	2% (v/v)
BD Universal Transport System	Transport Media	100% (v/v)
Remel M4®	Transport Media	100% (v/v)
Remel M4RT®	Transport Media	100% (v/v)
Remel M5®	Transport Media	100% (v/v)
Remel M6®	Transport Media	100% (v/v)
Throat lozenges, oral anesthetic and analgesic[a]	Benzocaine, Menthol	1.7 mg/mL

Mucin[a]	Purified Mucin protein (Bovine or porcine submaxillary gland)	1% (w/v)[a,b]
Antibiotic, nasal ointment[a]	Mupirocin	10 mg/mL
Saline Nasal Spray[a]	Sodium Chloride (0.65%)	15% (v/v)
Anefrin Nasal Spray	Oxymetazoline, 0.05%	15% (v/v)
PHNY Nasal Drops	Phenylephrine, 0.5%	15% (v/v)
Tamiflu anti-viral drugs[a]	Zanamivir	7.5 mg/mL
Antibacterial, systemic	Tobramycin	4 µg/mL
Zicam Nasal Gel	Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum Sulfur	15% (w/v)
Nasal corticosteroid	Fluticasone Propionate	5 µg/mL

a. Substances/active ingredients and concentrations directly evaluated with the Xpert Xpress SARS-CoV-2/Flu/RSV test.
b. No interference to the Xpert Xpress Flu/RSV performance observed at a concentration of 2.5%

20.7 Carry-over Contamination

Carry-over studies to establish that single-use, self-contained GeneXpert cartridges prevent carry-over contamination have been conducted for previous Xpert tests developed for the GeneXpert systems, including the Xpert Xpress Flu/RSV. The studies demonstrated that a negative sample when preceded by very a high positive sample in the same GeneXpert module resulted in no carry-over.

21 References

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22 Cepheid Headquarters Locations

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23 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

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www.cepheid.com/en_US/support/contact-us

24 Table of Symbols

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

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IVD

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