Keywords: 4plex, cepheid, coronavirus, covid, covid-19, genexpert, SARS-CoV-2, xpert, xpress

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I. PRINCIPLE/CLINICAL SIGNIFICANCE

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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. 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, several lower respiratory diseases including pneumonia and respiratory failure, and in some cases, death. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

Influenza is a contagious viral infection of the respiratory tract, with primarily airborne transmission that peaks during the winter months. 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. Infections with influenza B (Flu B) virus less frequently cause epidemics.

Respiratory Syncytial Virus (RSV) also causes a contagious respiratory disease, affecting primarily infants and immunocompromised elderly individuals. The RSV season is similar to the influenza season, as infections rise during the fall through early spring.

SARS-CoV-2, influenza, and RSV can cause infections with similar symptomology. 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.


II. ORDER
A. Physician's order, standard protocol, or order by another health professional authorized to request laboratory tests is required for Xpert® Xpress SARS-CoV-2 testing at the point-of-care. The Xpert® Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2 Tests on the GeneXpert Xpress System are authorized for use under FDA Emergency Use Authorization (EUA) only; upon expiration of the EUA or at the discretion of the experts, these test(s) may be discontinued at any time.

III. SAFETY REQUIREMENTS
Refer to the Quality Assurance Plan for Molecular Point-of-Care Testing (see Appendix A) for additional guidelines.

A. Follow Standard Precautions and CDC handwashing guidelines when performing this test.
B. Proper PPE must be worn at all times when performing testing using the Xpert® Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2 cartridges on the GeneXpert Xpress System.
   1. The following PPE, at a minimum, must be worn at all times:
      a. Two layers of gloves.
      b. Gown.
      c. N95 Mask and Face Shield. (or)
      d. PAPR Hood with HEPA Filter.
C. All specimens and Xpert Xpress SARS-CoV-2 test consumables must be considered potentially infectious, handled with care, and disposed of in a JHMI-approved biohazard container.
1. Consumables for the Xpert Xpress SARS-CoV-2 tests include used pipettes and cartridges (SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2), patient and QC specimens, gloves, and disposable gowns.

D. The reagent(s) and/or chemicals used in this assay may be hazardous to health if handled incorrectly.
1. The Microbiologics Flu/RSV/SARS-CoV-2 Control Panel, SARS-CoV-2 Negative Cellularity Control, and Inactivated SARS-CoV-2 Whole Virus Control contain inactivated swabs; however, there is no known test or inactivation method that can assure that this product will not transmit infection.
2. The Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2 cartridges contain a chemical that may be harmful if swallowed or if in contact with the skin. Additionally, it may cause eye irritation.

E. The working surface is to be decontaminated at least once daily, and following any suspected or actual spills, using Sani-Cloth Bleach Germicidal Wipes, a 10% bleach solution, or an appropriate commercial surface decontamination preparation that has been approved by the Hospital Epidemiology and Infection Control (HEIC) Department.
1. Refer to Section XV: Maintenance for specific instructions to complete all regularly scheduled maintenance activities.

IV. MATERIALS

<table>
<thead>
<tr>
<th>Xpert® Xpress SARS-CoV-2/Flu/RSV Kit Contents</th>
<th>Source</th>
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<tbody>
<tr>
<td>Xpert Xpress SARS-CoV-2/Flu/RSV Cartridges with Integrated Reaction Tubes (10)</td>
<td>Test kit supply allocation to be coordinated with Point of Care Testing Office/Microbiology Laboratory</td>
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<tr>
<td>Disposable Transfer Pipettes (10-12)</td>
<td>Note: Each kit contains sufficient reagents to process 10 specimens or quality control (QC) samples.</td>
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<td>Quick Reference Instructions (2)</td>
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<td>Disposable Transfer Pipettes (10-12)</td>
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**Quality Control Materials**

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<tr>
<td>Microbiologics Flu/RSV/SARS-CoV-2 Control Panel (12 Inactivated Swabs/Kit)</td>
<td>Catalog #8246</td>
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<tr>
<td>Microbiologics Inactivated SARS-CoV-2 Whole Virus Swab (6 Inactivated Swabs/Kit)</td>
<td>Catalog #HE0066NS</td>
</tr>
<tr>
<td>Microbiologics Negative Cellularity Control (Inactivated)</td>
<td>Catalog #HE0067NS</td>
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</table>
GeneXpert Xpress System

Xpert Xpress Instrument
GeneXpert Xpress Hub

Additional Supplies

| Specimen Collection Kits: 3 mL VTM/UTM Transport Tube and NP Swab | Central Stores |
| Latex-free Disposable Gloves | Central Stores |
| N95 Mask or PAPR Hood with HEPA Filter | HEIC (determined via FIT Testing) |
| Gown | Central Stores |
| Face Shield | Personal PPE Pack |
| JHMI-approved Biohazard Waste Containers | |
| Sani-Cloth Bleach or HEIC-approved commercial surface decontamination preparations (both bleach- and alcohol-based required) | Central Stores |

V. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Expiration Date</th>
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<tr>
<td>Xpert® Xpress SARS-CoV-2/Flu/RSV Test Kit</td>
<td>2-28°C</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Xpert® Xpress CoV-2/Flu/RSV plus Test Kit</td>
<td>2-28°C</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Xpert® Xpress SARS-CoV-2 Test Kit</td>
<td>2-28°C</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Microbiologics Control Materials (Inactivated Swabs)</td>
<td>2-25°C</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>GeneXpert Xpress System</td>
<td>15-30°C (20-80% humidity)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A. Maintain at least 6-8 inches of clearance on each side of the GeneXpert Xpress system. Do not block the fan exhaust or air intake on the instrument or hub, as this may cause malfunction.

B. Upon opening each Xpert® Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2 Test Kit, the Open Date must be recorded on the outside of the box.

C. Upon opening each kit of Microbiologics Control Materials, the Open Date must be recorded.

D. After opening a control swab foil pouch, use the swab immediately.
   1. Reconstituted Negative Cellularity Control may be stored refrigerated (2-8°C) and used up to 5 days after hydration.
   2. Reconstituted Inactivated SARS-CoV-2 Whole Virus Swab Control may be stored refrigerated (2-8°C) and used up to 8 days after hydration.

E. All test kit contents and control swabs are single use; do not reuse.

F. Never use kit contents or external controls past the manufacturer's expiration date.
VI. SPECIMEN TYPE
Each patient test requires collection of a nasopharyngeal (NP) swab, prepared in 3 mL Viral Transport Media (VTM), 3 mL of saline, or 2mL of eNAT.

VII. SPECIMEN COLLECTION AND HANDLING
Correct specimen collection technique, storage, and transport are paramount for obtaining an accurate test result. Proper PPE (double gloves, gown, N95 mask and face shield, or PAPR Hood with HEPA Filter) must be worn at all times during Specimen Collection and Handling.

A. NP Swab Sample Collection and Preparation:
   1. Gather one specimen collection kit, containing an NP swab and Viral Transport Medium (VTM), saline, or eNAT.
   2. Label the VTM/saline/eNAT tube with at least two patient identifiers, neither to be the room number.
      a. NOTE: The use of an Epic-generated Patient Label is preferable. In the absence of a patient label, the patient specimen must be labeled with handwritten patient identifiers; the patient’s first and last name, as well as CSN, are recommended at minimum.
   3. Insert the NP swab into one nostril, passing into the posterior nasopharynx (see Figure 1).
   4. Firmly brush the swab against the nasopharynx several times to rotate.
   5. Remove and place the swab into the properly labeled VTM/saline/eNAT tube.
   6. Break the swab at the indicated break line.
   7. Cap the specimen collection tube tightly.
   8. Discard the remainder of the swab in a Biohazard Sharps container.
   9. Place the properly labeled, prepared specimen in a double layer biohazard bag for transport to the testing location.
      a. NOTE: Care must be taken by both collection and testing personnel to ensure collected specimens are routed to the proper testing location, or delays in result availability will occur. Only POCT orders should be delivered to and processed in the POCT setting.

Nasopharyngeal (NP) swab specimens submitted in VTM, saline, or eNAT can be stored at room temperature (15-30°C) for up to 2 hours prior to testing. If unable to test within 2 hours of collection, patient testing will require the laboratory test order, placement of a laboratory label on top of the Epic-generated Patient Label with the name visible on both, and delivery of the prepared patient sample to the Microbiology Laboratory.

Figure 1.
VIII. PERFORMING QUALITY CONTROL (QC) TESTS

A. Internal Process Controls:
   1. Each Xpert Xpress Cartridge contains two internal process controls, which are interpreted with all tests performed, QC and patient, and must be acceptable in order for results to be reported.
   2. Sample Processing Control (SPC):
      a. Ensures the sample was processed correctly and adequately.
      b. Detects sample-associated inhibition of the RT-PCR assay.
      c. Ensures the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction.
      d. Confirms the PCR reagents are functional.
   3. Probe Check Control (PCC):
      a. The GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability.
   4. If either of these internal process controls fails to react as expected, the test is reported as Invalid and testing must be repeated, or the specimen collection preparation sent to the Microbiology Laboratory for analysis. See Corrective Action for additional information.

B. Two levels of External Quality Control - Positive and Negative - will be performed:
   1. At least once per week on each kit and analyzer in use, rotating across the available instrument ports as dictated by the instrument.
   2. When opening a new lot number and/or shipment of Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, or SARS-CoV-2 cartridges.
   3. When patient results are questionable, or any other issues are suspected or identified.
   4. All new operators must complete both levels of controls as part of initial hands-on training prior to testing patient specimens.
   5. Both levels of controls must be tested at least once a year by each trained operator.
      a. NOTE: Laboratory-prepared control materials may be substituted in select situations approved by the Point-of-Care Testing Medical Director.

C. Procedure:
   1. Prepare materials for testing:
      a. Don all required PPE - two layers of gloves, gown, N95 mask and face shield, or PAPR Hood with HEPA Filter.
      b. Verify that the Xpert Xpress SARS-CoV-2/Flu/RSV, or CoV-2/Flu/RSV plus, or SARS-CoV-2 test kits are dated and within the manufacturer's expiration date.
      c. Turn on the GeneXpert Xpress Instrument, followed by the Hub computer, if not already done.
         i. NOTE: If startup does not occur following this sequence, the Xpress software will not recognize the instrument being connected and an error message will appear.
         ii. NOTE: Following instrument startup, initial Login must occur via the Cepheid user account (Cepheid-Admin) in order to operate the system.
      d. Login to the GeneXpert Xpress System by scanning your JHED ID, using the barcode scanner located to the right of the Hub computer.
         i. NOTE: If the barcode scanner is not working for any reason, select Login Manually and enter your JHED ID for both Username and Password.
      e. Gather two Xpert Xpress cartridges, one Positive Control swab, one Negative Control swab, and two (3.0 mL) VTM/saline/eNAT transport tubes.
         i. NOTE: Do not open the control swab foil pouch(es) until ready to use.
f. Label the VTM/saline/eNAT transport tubes with the level of QC that is being assayed (Pos/Positive or Neg/Negative), or a barcode label with the lot number and level of QC.

g. Remove the cap and set aside.

h. Tear open the pouch at the notch, then remove the swab and place it into the appropriately labeled VTM/saline/eNAT transport tube.

i. Lift the swab slightly from the bottom of the tube, then break the swab by pushing against the rim.
   i. NOTE: Each swab is intended as a single use test.

j. Recap the prepared UTM/VTM transport tube.

k. Discard the remainder of the control swab in a JHMI-approved Biohazard container.

l. Remove the outer layer of gloves, discard in a Biohazard Bin, sanitize gloves, then place a new second layer of gloves on.

2. Perform the test:
   a. For non-interfaced testing only: Record the last 4 digits of the cartridge serial number (10-digit vertical number closest to the barcode on the cartridge) on the appropriate QC Log.
      i. NOTE: See Appendix B for the Xpert Xpress SARS-CoV-2 QC Log.
   b. Touch the QC button on the Hub, then select RUN POSITIVE CONTROL or RUN NEGATIVE CONTROL.
   c. On the Sample ID screen, enter the 8 character (including the dash) lot number from the foil pouch (xxxx-xxx) or scan the barcode label on the prepared QC tube.
   d. Touch CONTINUE after confirming the displayed information is correct.
   e. Verify the Sample ID matches the lot number on the foil pouch, then touch CONFIRM.
   f. Scan the barcode on the cartridge using the scanner located on the right side of the Hub.
      i. NOTE: Cartridges must remain upright while scanning and at all times when handling.
   g. Select CONFIRM after reviewing the Sample ID and assay type and if all expected information is correct.
      i. NOTE: The Sample ID must always be the CSN for Point-of-Care Testing. If an ID other than a 10-digit CSN is noted, Cancel the test and investigate the cause.
   h. When prompted, scan your JHED ID using the scanner located on the right side of the Hub.
   i. On the Hub computer, videos will play demonstrating the following steps. Touch the CONTINUE button to advance as necessary.
      i. Mix the prepared control solution by rapidly inverting the VTM/saline/eNAT transport tube 5 times, then open the cap and set aside.
      ii. Open the cartridge lid.
      iii. Remove the pipette from the wrapper.
      iv. Squeeze the top bulb of the pipette completely until the top bulb is flat, then place the tip into the prepared solution in the VTM/saline/eNAT transport tube.
      v. 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 it from the transport tube.
         • NOTE: It is acceptable for sample to flow into the overflow reservoir.
         • NOTE: Confirm the pipette stem does not contain air bubbles prior to proceeding with testing. If there are air bubbles present, retry collection of specimen in the pipette or a Quantity Not Sufficient error may occur, requiring reprogramming and retesting with a new cartridge.
      vi. Squeeze the top bulb completely to empty the contents of the pipette into the large chamber opening (see Figure 2).
         • NOTE: It is acceptable for liquid to remain in the overflow reservoir.
Subject
Xpert Xpress SARS-CoV-2 Tests on the GeneXpert Xpress System

vii. Close the cartridge lid.
   • NOTE: The test must be started within 30 minutes of adding the sample to the cartridge.

viii. Dispose of the used pipette in a JHMI-approved Biohazard container.

ix. Open the instrument door with the blinking green light.

x. Load the cartridge with the barcode facing the operator on the cartridge bay platform.

xi. Close the door until it clicks.
   • NOTE: If necessary, touch the STOP TEST button to cancel a test while it is loading. No result will be available for the canceled test.

j. Remove the outer layer of gloves, discard them in a Biohazard Bin, sanitize gloves, then put on a new second layer of gloves.

k. Use a Caviwipe or other HEIC-approved preparation to sanitize the testing surface before proceeding with any additional testing.

l. Tests in Progress will be shown on the HOME screen, with the Sample ID below the circular graphic indicating the remaining testing time for all modules.

m. When the test is completed, the screen text changes to COMPLETE and the door unlocks.

n. Immediately dispose of the cartridge in a Biohazard bin.

o. Repeat steps 1f through 2n for the second control swab. Up to 4 tests can be run simultaneously per instrument.

p. Remove the outer layer of gloves, discard them in a Biohazard bin, sanitize gloves, then place a new second layer of gloves on.

q. Record all required information in each of the boxes on the appropriate QC Log (Appendix B or Appendix C), for non-interfaced testing only.
   i. NOTE: For interfaced testing, completion of the QC Log is not mandatory.

D. Corrective Action:

1. If any QC test fails to give the expected results:
   a. Verify Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, or SARS-CoV-2 Test Kits and Microbiologics Control Swabs are within their expiration dates, and that they have been properly stored.
      i. Confirm the appropriate Control Swab is being used to match the cartridge type in use.
   b. Ensure proper testing technique is used to repeat testing with a new Test Cartridge and the same control swab preparation.
   c. If QC fails again, repeat testing using a new Test Cartridge and a new VTM/saline/eNAT and control swab preparation.
   d. If QC fails again, DO NOT PERFORM ANY PATIENT TESTING. Contact the POCT Office (5-2645) or by sending an EPIC Secure Chat message to "POCT Consult".
      i. NOTE: During this time, patient testing will require the laboratory test order, placement of a laboratory label on the prepared patient sample(s), and delivery of specimens to the Microbiology Laboratory.

2. Note any QC failures and corrective actions on the QC log, as applicable.

Figure 2.

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IX. PATIENT TEST PROCEDURE

A. Specimen Collection and Extraction:
   1. Collect and prepare the NP swab as indicated in Section VII: Specimen Collection and Handling.

B. Prepare Materials for Testing:
   1. Don all required PPE - two layers of gloves, gown, N95 mask and face shield, or PAPR hood with HEPA filter.
   2. Verify that the Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and/or SARS-CoV-2 Test Kits are dated, within the manufacturer's expiration date, and that QC has been performed successfully and documented within the last week on the analyzer to be used.
   3. Turn on the GeneXpert Xpress Instrument, followed by the Hub computer, if not already done.
      a. NOTE: If startup does not occur following this sequence, the Xpress software may not recognize the instrument being connected and an error message will appear.
      b. NOTE: Following instrument startup, initial Login must occur via the Cepheid user account (Cepheid-Admin) in order to operate the system.
   4. Login to the GeneXpert Xpress System by scanning your JHED ID, using the barcode scanner located to the right of the Hub computer.
      a. NOTE: If the barcode scanner is not working for any reason, troubleshoot first by exiting, then restarting the software. The alternate option is to select Login Manually and enter your JHED ID for both Username and Password.

C. Perform the Test:
   1. Gather one properly labeled prepared patient specimen and one Xpert Xpress cartridge corresponding to the order on the specimen label.
      a. For non-interfaced tests only, gather one extra patient label and place it on the appropriate Patient Result Log.
         i. NOTE: For the Xpert Xpress SARS-CoV-2 Patient Result Log, see Appendix D.
         ii. NOTE: For the Xpert Xpress SARS-CoV-2/Flu/RSV and CoV-2/Flu/RSV plus Patient Result Log, see Appendix E.
      b. Record the last 4 digits of the cartridge serial number (10-digit vertical number closest to the barcode on the cartridge) in the appropriate box prior to continuing with testing.
   2. Prepare the Assay:
      a. Touch the NEW TEST button on the Home Screen.
      b. Scan the patient's barcode label using the integrated barcode scanner on the right-hand side of the Hub, or manually enter the patient's 10-digit CSN.
      c. Verify the CSN on the barcode matches the information on the Hub screen.
         i. If there is not a match, touch the CLEAR button and rescans the barcode label, or manually enter the patient's CSN.
            • NOTE: Care must be taken both by collection and testing personnel to ensure only POCT orders are delivered and processed in the POCT Lab. The identifier required for all POCT is the CSN, a 10-digit number unique to each specific patient's movement within the health system.
            • NOTE: A Microbiology order generates a different order number and, if tested in the POCT Lab, will cause delays in result availability on the patient's chart.
         ii. If there is a match, touch the CONTINUE button and the Confirm Patient Information screen will appear.
      d. Verify Sample ID and touch CONFIRM.
      e. Scan the barcode on the cartridge using the scanner located on the right side of the Hub.
         i. NOTE: The cartridge must remain upright while scanning and otherwise handling it.
3. Prepare the Cartridge:
   a. On the Hub screen, videos will play demonstrating the following steps. Touch the CONTINUE button to advance as necessary.
   b. Confirm the prepared patient sample is tightly capped, then rapidly invert 5 times.
   c. Open the cartridge and specimen lids.
   d. Remove the pipette from the wrapper.
   e. Squeeze the top bulb of the pipette completely until the bulb is flat, then place the tip below the surface of the prepared patient specimen transport tube.
   f. 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 it from the tube.
      i. NOTE: It is acceptable for sample to flow into the overflow reservoir.
      ii. NOTE: Confirm the pipette stem does not contain air bubbles.
   g. Squeeze the top bulb completely to empty the contents of the pipette into the large chamber opening.
      i. NOTE: It is acceptable for liquid to remain in the overflow reservoir.
   h. Close the cartridge lid.
      i. NOTE: The test must be started within 30 minutes of adding the sample to the cartridge.
   i. Dispose of the used pipette in a JHMI-approved Biohazard container.
   j. Open the instrument door with the blinking green light.
   k. Load the cartridge with the barcode facing the operator on the cartridge bay platform (see Figure 3).
   l. Close the door until it clicks.
      i. NOTE: If necessary, touch the STOP TEST button to cancel a test while it is loading. No result will be obtained from a canceled test.

4. Remove the outer layer of gloves, discard them in a Biohazard bin, sanitize the base layer of gloves, then place a new second layer of gloves on.

5. Sanitize the testing surface with Caviwipes or another HEIC-approved preparation before proceeding with any additional testing.

6. The Tests in Progress will be shown on the HOME screen with the Sample ID below the circular graphic for each module indicating the remaining testing time.

D. Remove Cartridge, Record Results:
1. When the test is completed, the HOME screen text will change to COMPLETE, the module door unlocks, and the light above the module shuts off.
2. For non-interfaced tests: Record all applicable information on the appropriate patient result log. Each box must be filled out completely.
3. For interfaced tests: Confirm that results have posted on the appropriate patient's chart.
   a. NOTE: If an ID other than the CSN is used, the results will be held as an exception. The POCT Office requires direct feedback from unit liaisons or testing personnel in order to resolve all exceptions, which are handled only during business hours.
4. Immediately dispose of the used Xpert Xpress cartridge in a Biohazard Bin.
5. Store the properly labeled prepared patient samples in a rack in the refrigerator for pickup.
6. Remove gloves, discard them in a Biohazard Bin, sanitize the base layer of gloves, then place a new second layer of gloves on before proceeding with entering results on the patient's chart in Epic (for non-interfaced tests only) or additional testing.

![Image of a test device with a flashing green light](image)

Figure 3.

**X. REFERENCE RANGE**

The expected result using the Xpert® Xpress SARS-CoV-2/Flu/RSV Test and Xpert® Xpress CoV-2/Flu/RSV plus Test is RNA NOT Detected (Negative) for SARS-CoV-2, Flu-A, Flu-B, and RSV.

The expected result using the Xpert® Xpress SARS-CoV-2 Test is RNA NOT Detected (Negative) for SARS-CoV-2.

**XI. RESULT INTERPRETATION**

The GeneXpert Xpress System interprets results automatically. Test results are available in the View Results window.

For non-interfaced tests, all results must be recorded on the appropriate Xpert Xpress Patient Result Log and in Epic using Enter/Edit.

For interfaced tests, results will automatically flow from the instrument to the patient's chart, given the correct patient CSN is used to identify the specimen during test setup.
<table>
<thead>
<tr>
<th>Result (GeneXpert Xpress)</th>
<th>Interpretation (Patient Result Log and Epic)</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Positive</td>
<td>RNA Detected</td>
<td>None</td>
</tr>
<tr>
<td>Flu A Positive</td>
<td>RNA Detected</td>
<td>None</td>
</tr>
<tr>
<td>Flu B Positive</td>
<td>RNA Detected</td>
<td>None</td>
</tr>
<tr>
<td>RSV Positive</td>
<td>RNA Detected</td>
<td>None</td>
</tr>
<tr>
<td>SARS-CoV-2, Flu A, Flu B, and/or RSV Negative</td>
<td>RNA Not Detected</td>
<td>None</td>
</tr>
<tr>
<td>SARS-CoV-2 Presumptive Positive</td>
<td>SARS-CoV-2 Nucleic Acids may be present</td>
<td>Repeat test with new cartridge. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted if necessary.</td>
</tr>
<tr>
<td>No Result - Repeat Test</td>
<td>Presence or absence of SARS-CoV-2, Flu A, Flu B, and/or RSV target nucleic acids cannot be determined. Indicates that insufficient data was collected.</td>
<td>Repeat test with new cartridge. If the same result is obtained on retest, collect a new specimen and repeat the test.</td>
</tr>
<tr>
<td>Error</td>
<td>Presence or absence of SARS-CoV-2, Flu A, Flu B, and/or RSV target nucleic acids cannot be determined. May result due to a number of issues.</td>
<td>Touch CLEAR ERROR and follow the on-screen instructions to resolve the instrument error. When the Home screen appears, repeat test using a new cartridge.</td>
</tr>
</tbody>
</table>

NOTE: With the CoV-2/Flu/RSV cartridges, if the SPC is negative and the results for any of the targets are positive, the results for all targets are considered valid.

### XII. REPORTING RESULTS

For non-interfaced tests: All patient test results must be manually documented on the appropriate Xpert Xpress Patient Result Log (see Appendices D and E). The completed log must then be used to ensure results are properly documented in Epic using Manual Result Entry. Result documentation on the Patient Result Log and in Epic will be regularly audited by the POCT Office.

1. Each of the fields is mandatory when completing the Patient Result Log.
   a. Attach a patient label from Epic, or manually record the patient's name and CSN legibly in the appropriate field.
2. Non-interfaced Cepheid SARS-CoV-2/Flu/RSV viral RNA testing is orderable in Epic using test code POC101214 "POCT SARS-CoV2/FLU A+B/RSV NP SWAB, SYMPTOMATIC".
   a. Results will be manually entered in Epic using the Enter/Edit function as "RNA Detected" for Positive results, and "RNA Not Detected" for Negative results.
3. Non-interfaced Cepheid SARS-CoV-2 viral RNA testing is orderable in Epic using test code POC101218 "POCT SARS-CoV2 NP SWAB, SYMPTOMATIC".
   1. Results will be manually entered in Epic using the Enter/Edit function as "RNA Detected" for Positive results, and "RNA Not Detected" for Negative results.
   2. If a Presumptive Positive result is obtained, the test must first be repeated before resulting on the patient's chart.
4. Once patient results are entered, they will display under the "Labs" tab in Epic, among other locations.

For interfaced tests: All patient test results will post automatically to the patient's charts in Epic, provided the correct patient's CSN is used when programming the test on the instrument. If a Presumptive Positive result is obtained, the test must be repeated and both results will be posted to the patient's chart.

NOTE: In the event an ID other than the valid CSN is used for interfaced tests, the results will be held as an exception, and the POCT Office will need to be contacted or will reach out requesting patient information, to include the CSN for the ED admission. Exceptions are resolved only during regular business hours.

XIII. LIMITATIONS

A. Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV plus, and SARS-CoV-2 tests have only been established in NP swab specimens. Use of these tests with other specimen types has not been assessed and performance characteristics are unknown.

B. The clinical performance has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation. 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.

C. The performance of this device has not been assessed in a population vaccinated against COVID-19.

D. Inadequate specimen collection and improper specimen handling may produce a false result.
   1. Careful compliance with this procedure is necessary to avoid erroneous results.
   2. Specimen transport media containing GTC may interfere with the test, and cause false negative results.

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

F. False negative results may occur if any of the viruses are present at levels below the analytical limit of detection.

G. 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.
   1. Results from this test should be correlated with the clinical history, epidemiological data, and other available data.

H. This test is a qualitative test and does not provide the quantitative value of the detected organism(s) present.

I. Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.

J. Detection of analyte target(s) does not imply the corresponding virus(es) are infectious or the causative agents of clinical symptoms.

K. Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.

L. The presence of other coronaviruses, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.

M. 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.

N. This test has not been evaluated for patients without signs and symptoms of respiratory tract infection.

O. This test has not been evaluated for monitoring treatment of infection.
P. This test is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use of *in vitro* diagnostic test 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.

XIV. PROCEDURAL NOTES

A. Proper PPE must be worn at all times while handling specimens (QC and patient), setting up tests, and while tests are running on the Cepheid instruments.

B. When shutting down and turning on the system, the sequence matters. If either routine is done in the incorrect order, a communication break in the system may occur and an error message will appear.
   1. When shutting down the system, Exit the software on the hub touchscreen, then press the blue power button behind the hub touchscreen, then the hub power switch on the back, and finally the instrument switch on the lower piece of the back.
   2. When turning on the system, the instrument must be powered on first. This switch can be found on the back of the instrument - the lower half of the Cepheid. Once the blue light near the modules is on, the hub power switch can be turned on. The touch screen should turn on by itself.
      a. NOTE: If the touch screen does not automatically turn on, check the blue power button behind the touch screen, and the white power button underneath the touch screen.

C. When starting up the system, the initial Windows log in must occur using the Cepheid-admin account.
   1. NOTE: If login is attempted using a different username and profile, login will fail.
   2. NOTE: Do not change the Cepheid user profile. Changing the profile can cause loss of data during a test.

D. Do not use an Xpert Xpress SARS-CoV-2/Flu/RSV, CoV-2/Flu/RSV, or SARS-CoV-2 cartridge that is wet or has leaked.

E. Do not use a cartridge that has a missing or damaged reaction tube.

F. Do not open the cartridge lid until ready for testing.

G. If a cartridge is dropped during handling, discard the cartridge and use a new one.

H. If a pipette is dropped during handling, discard it and use a new sterile pipette.

I. After adding sample to the cartridge, do not shake or tilt the cartridge.

J. Do not reuse disposable pipettes or cartridges; immediately dispose in a biohazard bin following use.

K. Do not turn off or unplug the instrument, or exit the software while a test is in progress, as this will stop the test.
   1. NOTE: Tests will continue to run in the background if the Log-Off function is used in the middle of a test run.

L. Keep the doors to the modules closed at all times when not in use.

M. If a Presumptive Positive result is obtained with the Xpert Xpress SARS-CoV-2 cartridge, the test must be repeated.
   1. NOTE: If manual entry of results is being used, only report the repeated test result on the patient's chart.
   2. NOTE: If the interface is active, both the original Presumptive Positive and the repeated test result will be reported to the patient's chart. The POCT Office will manually credit the repeated testing on the back end.

N. Results from the Xpert Xpress SARS-CoV-2 tests should be correlated with clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

XV. MAINTENANCE

Document completion of all required maintenance, as indicated below, on the Maintenance Log (see Appendix F).

**Daily and As Needed following all Spills, Splashes, or Visible Contamination:** Decontaminate the testing surface.

A. Using Sani-Cloth Bleach Germicidal Wipes, a 10% bleach solution, or an appropriate commercial surface decontamination preparation that has been approved by the HEIC Department:
1. Leave the testing surface wet for a minimum of 2 minutes.
   a. NOTE: A CaviWipe may be used after 2 minutes to remove any lingering bleach residue.
B. In the event of a spill, a bleach solution must be used.
   1. Using Sani-Cloth Bleach Germicidal Wipes, clean the affected surface(s) with bleach three separate times.
      a. Change wipes frequently while decontaminating.
   2. Leave the bleach on the testing surface(s) for at least 2 minutes each time, but no longer than 8 minutes.
   3. Repeat steps 1-2 two more times, for a total of three times.
   4. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution or a CaviWipe and wipe all surfaces to remove the bleach residue.

**Weekly:** Power down the system to clear out unwanted temporary files, while also guarding against system malfunction.

A. Confirm there are no active tests running, then touch the Home button if not already on the screen.
B. From the Home screen, touch the User Menu icon in the upper right-hand corner to display a drop-down menu.
C. Touch Exit, then select Yes to exit the software and return to the Windows desktop.
D. Press the blue power button on the right front of the Xpress Hub to turn off the hub computer.
E. Wait 10 seconds for Windows to shut down, then power down the Xpress Hub by pressing the power switch located on the back of the hub to the OFF position.
F. Turn off the Xpert Xpress Instrument by pressing the power switch located on the back of the instrument to the OFF position.
G. Wait 10 minutes, then power up and log onto the system.
   1. Turn on the Xpert Xpress Instrument by pressing the power switch located on the back of the instrument to the ON position.
      a. NOTE: The instrument must be powered up first, before the Xpert Xpress Hub, or the software will not recognize the instrument being connected.
   2. Turn on the Xpress Hub by pressing the power switch located on the back of the hub to the ON position.
   3. The hub touch screen should automatically power on. If this does not occur, there are two power buttons that must be checked.
      a. The first is the blue power button on the right front of the Xpress Hub.
      b. The second is a white power button on the bottom right-hand side of the hub computer screen.
   4. Once the system boots, the Windows screen will appear. Swipe up anywhere on the screen to display the login field.
      a. Initial login must occur via the Cepheid user account (Cepheid-admin) in order to operate the system.
      b. Touch the login field to activate the virtual keyboard.
         i. NOTE: Do not change the Cepheid user account profile. Changing the profile can cause loss of data during a test.
   5. The GeneXpert Xpress software starts automatically on system startup.
   6. Scan your JHED ID to gain access to the testing platform.

**Quarterly and As Needed following all Spills, Splashes, or Visible Contamination:** Clean GeneXpert Xpress Instrument and Hub surfaces.

A. Clean GeneXpert Hub and Instrument Surfaces with ethanol.
   1. Power down the system, as indicated above under Weekly Maintenance requirements.
   2. If performing cleaning only, use an ethanol solution to wipe off all outside surfaces of the instrument housing, including the top, sides, and outside doors of the modules.
Subject

Xpert Xpress SARS-CoV-2 Tests on the GeneXpert Xpress System

B. In the event of a spill, a bleach solution must be used.
   1. Thoroughly moisten a lint-free wipe or paper towel with an approved 1:10 bleach solution.
   2. Wipe down the affected surface(s) with bleach three separate times.
      a. Change wipes or paper towels frequently while wiping.
   3. Leave the bleach on the instrument surfaces for at least 2 minutes each time, but no longer than 8 minutes.
   4. Repeat steps 1-3 two more times, for a total of three times.
   5. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
   6. Wipe all surfaces with ethanol to remove the bleach residue.

C. If a spill is suspected to have affected the interior of the instrument, immediately perform shut down and notify the POCT Office.

Monthly: Additional maintenance will be completed by the Point-of-Care Testing Office.

Quarterly: Additional maintenance will be completed by the Point-of-Care Testing Office.

Annually and As Needed: Calibration checks will be performed annually or following module failure by the Cepheid Field Service Engineer or Point-of-Care Testing Office.

As Directed: Swipe Testing will be performed by the Point-of-Care Testing Office to assess compliance with cleanliness guidelines required for accurate Molecular Point-of-Care Testing results (see Appendix A for the QA Plan for Molecular POCT).

A. The exterior of each of the analyzers, as well as the testing surface, will be swabbed and tested separately for the presence of SARS-CoV-2 viral RNA (see Appendix G) or SARS-CoV-2/Flu/RSV viral RNA (see Appendix H).
   1. NOTE: If a Swipe Test results as RNA Detected for any of the analytes, the POCT Office will notify the testing unit to cease testing immediately, pending additional investigation.
   2. NOTE: Additional Swipe Testing locations may be assessed as needed.
### XVI. TROUBLESHOOTING

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>System will not start.</td>
<td>Instrument is not connected to the power outlet.</td>
<td>Check the instrument power connections.</td>
</tr>
<tr>
<td>Screen does not automatically light up after system power on.</td>
<td>Touchscreen is powered off.</td>
<td>Press the power button on the right side of the hub behind the touchscreen and/or the white power button on the bottom of the touchscreen.</td>
</tr>
<tr>
<td>Barcode scanner light not on.</td>
<td>System may require restart, or barcode scanner reprogramming</td>
<td>Manually enter all required information as needed. Exit out of software when no tests are running, then double tap the icon on the home screen to restart. Contact POCT Office.</td>
</tr>
<tr>
<td>Cartridge stuck inside instrument module.</td>
<td>Module mechanical failure.</td>
<td>Contact POCT Office.</td>
</tr>
<tr>
<td>Module red light is flashing.</td>
<td>Module mechanical failure.</td>
<td>Confirm no cartridge is in the module. Contact POCT Office.</td>
</tr>
<tr>
<td>No Result - Repeat Test</td>
<td>Multiple potential causes.</td>
<td>Repeat test with a new cartridge. If repeat fails, collect new specimen and repeat test.</td>
</tr>
<tr>
<td>Module Communication Error</td>
<td>Multiple potential causes.</td>
<td>Allow all onboard tests to finish, then Exit out of the software. Shut the system down, wait approximately 5 minutes, then restart. If the issue repeats, Contact the POCT Office.</td>
</tr>
<tr>
<td>Instrument Error</td>
<td>Multiple potential causes.</td>
<td>Touch CLEAR ERROR and follow the on-screen instructions.</td>
</tr>
</tbody>
</table>

On a monthly basis, the POCT Office will perform an Archive and Purge of all tests. When tests have been archived, they have not been permanently deleted from the computer. They have been removed from the main system database and saved to an archive file when the Purge Selected Tests from List after Archiving (Recommended Monthly) option has been selected. Tests may be retrieved from the archive file if needed for later use.
At least 6-8 inches of clearance on each side of the GeneXpert Xpress system must be maintained at all times. Lack of proper ventilation may cause the instrument and/or GeneXpert hub to malfunction.

XVII. OPERATOR TRAINING AND COMPETENCY

Testing may only be performed by currently certified staff members who have been trained by a Point-of-Care Coordinator, or a Nurse Educator or designated unit trainer who has undergone appropriate training and observation for training others in Molecular Point-of-Care Tests. Training records must be kept in the employee's personnel file, and a copy sent to the Point-of-Care Testing Office.

Initial training will include the following:

1. Review the policy online.
2. Completion of the MyLearning module and obtaining a passing score on the associated quiz.
3. Completion of the Initial Training and Competency Checklist (see Appendix I).
4. Successful performance of both levels of external quality control, based on the cartridge type in use at time of orientation.

In order to maintain competency, operators must successfully complete both levels of external controls and/or approved laboratory-prepared control modules and obtain a passing score on the MyLearning module quiz once a year.

XVIII. PROFICIENCY TESTING

Alternate Proficiency Testing will be performed twice a year, in the form of blinded specimens. Any trained operator may be asked to perform the PT specimens, and is expected to treat them the same as a patient test. The Xpert Xpress SARS-CoV-2 Tests Alternate Proficiency Testing assessment form must be completed by the individual testing the specimens (see Appendix J).

XIX. REFERENCES


XX. SIGNATURES

Revision: Appendix F updated to include only Daily and Weekly Maintenance on 5/30/2024

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Clarke</td>
<td>02/28/2024</td>
</tr>
<tr>
<td>Medical Director Point of Care Testing</td>
<td></td>
</tr>
<tr>
<td>Aaron Tobian</td>
<td>03/08/2024</td>
</tr>
<tr>
<td>CLIA Laboratory Director, Johns Hopkins Hospital</td>
<td></td>
</tr>
<tr>
<td>Subject</td>
<td>Xpert Xpress SARS-CoV-2 Tests on the GeneXpert Xpress System</td>
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<td>Page</td>
<td>19 of 19</td>
</tr>
<tr>
<td>Supersedes Date</td>
<td>11/09/2023</td>
</tr>
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