Quick Reference Instructions for Xpert® Xpress CoV-2/Flu/RSV plus and GeneXpert® Xpress System (Tablet Configuration)

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

The user should be trained in the procedure. Wear the appropriate protective attire for your safety when handling patient samples. Clean testing surfaces according to your institution’s policy. This test is only for nasal and nasopharyngeal swab specimens.

Refer to Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing.

I Storage and Handling and Warnings

<table>
<thead>
<tr>
<th>Storage and Handling</th>
<th>Warnings</th>
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<tbody>
<tr>
<td>- Wear gloves. Change gloves between processing each sample. - Store the Xpert Xpress CoV-2/Flu/RSV plus cartridges at 2-28°C.</td>
<td>- DO NOT use a cartridge that is wet or has leaked. - DO NOT use a cartridge that has been dropped. - DO NOT open a cartridge lid until you are ready to perform testing. - DO NOT shake or tilt the cartridge after adding the sample. - DO NOT reuse disposable pipettes or cartridges. - DO NOT turn off or unplug the instrument while a test is in progress as this will stop the test. - DO NOT use a cartridge that has a missing or damaged reaction tube. - DO NOT use a cartridge beyond its expiration date.</td>
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II How to Start the Software

1. Start Software.
   a. Put on a pair of clean gloves.
   - Windows 7: The Windows 7 account screen appears. Touch the Cepheid-Admin icon to continue.
   - Windows 10: The Windows lock screen appears. Swipe up to continue.

2. Enter Password.
   a. Touch Password to display the keyboard.
   b. Enter your password.
   c. Touch the arrow button at the right of the password entry area.

3. Touch Begin Button.
   a. Press the TOUCH HERE TO BEGIN button.
   b. If applicable, enter your user name and password.

4. HOME Screen Displayed.
   - The Home screen will be displayed.
   - Touch the SKIP VIDEO and CONTINUE button to exit video.
   - Touch the SKIP VIDEO and CONTINUE button to exit video.

III How to Test a Patient Specimen

Before You Begin:
- Refer to the package insert for more information.
- Read through this entire Quick Reference Instructions before beginning a test. Instructions on how to prepare the specimen and the cartridge (presented below) are also shown in a video within the software.

1. Start a Test.
   a. Touch RUN NEW TEST on the Home screen (GeneXpert Xpress IV screen shown below).
   b. Check that the specimen tube cap is closed.

2. Enter & Confirm Patient/Sample ID.
   a. If there is a Patient/Sample ID barcode, touch the YES button then scan the Patient/Sample ID with the scanner.
   b. If there is no Patient/Sample ID barcode, touch the NO button then manually enter the Patient/Sample ID and touch the OK button.
   c. Touch the YES button to confirm that the Patient/Sample ID is correct.

3. Scan and Confirm Cartridge.
   a. Remove a cartridge and a transfer pipette from the cartridge kit box.
   b. Scan the barcode on the cartridge with the scanner.
   c. Select the test to run:
      - Xpress SARS-CoV-2_Flu_RSV plus (SARS-CoV-2, Flu A, Flu B and RSV)
      - Xpress SARS-CoV-2_Flu plus (SARS-CoV-2, Flu A, Flu B)
      - Xpress SARS-CoV-2 plus (SARS-CoV-2)
   d. If applicable, enter your user name and password.

5. Fill Pipette with Sample.
   - Remove the pipette from the wrapper.
   - Squeeze the top bulb of the pipette completely until the top bulb is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube.
   - 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.
   - Check that the pipette does not contain air bubbles.

7. Load Cartridge.
   a. Open the instrument door with the blinking green light.
   b. Load the cartridge with barcode facing the operator on the cartridge bay platform.
   c. Close the door until it clicks.

   a. Put on a new pair of gloves if performing a new test.
   b. Touch the HOME button to go to the Home Screen.
   c. Start a new test following the steps in this section starting with Step 1, Start a Test, or for starting a test while a test is running or a new test with another user, see Step 10.

10. Starting Another Test While a Test is Running.
    a. Put on a new pair of gloves if performing a new test.
    b. Touch the HOME button to go to the Home Screen.
    c. Touch the SIGN OUT button to log out previous user.
    d. Start a new test following the steps in this section starting with Step 1, Start a Test.

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VHow to View Status of Tests in Progress and Completed Tests

1 Touch HOME Button. Touch the HOME button to view the status of tests in progress or completed tests.

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

3 View Completed Tests. When a test is complete, touch the Test complete, touch to continue* button to view the result of the test.

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

VII Warnings

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