Notes:

Quick Reference Guide

Xpert® Xpress Flu/RSV Assay

This test is only for nasal swab and nasopharyngeal swab specimens.

- Read the complete Package Insert before performing a test.
- Refer to the GeneXpert Xpress User's Guide for detailed information.
- For assistance, contact Cepheid Technical Support

301-7259 Rev. 2   Investigational Use Only

Table of Contents

Storage, Handling and Warnings

-Store the Xpert Xpress Flu/RSV Assay cartridges at 2-28°C.
-Do not open a cartridge lid until you are ready to perform testing.
-Do not use cartridges that have passed the expiration date.
-Do not reuse spent cartridges.
-Do not reuse spent disposable pipettes.
-Do not use a cartridge that has leaked.
-Do not use a cartridge that has been dropped.
-Do not shake the cartridge.
-Do not turn off or unplug the instrument while a test is in progress. Turning off or unplugging the GeneXpert Xpress instrument or computer will stop the test.
-Wear gloves. Change gloves between processing each sample.

Starting the Software and Instrument

1. Turn on the GeneXpert Xpress Instrument (GeneXpert Xpress II or GeneXpert Xpress IV)
2. Put on a clean pair of gloves.
3. Turn on the tablet computer. The Windows® screen will display.
4. Touch the Cepheid shortcut icon to continue.
5. The Windows Startup screen will display. Touch **Password** to display the keyboard. Enter your password.

6. Touch the blue arrow button at the right of the password entry area.

Specimen Collection

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 negative result; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality for accurate test results.
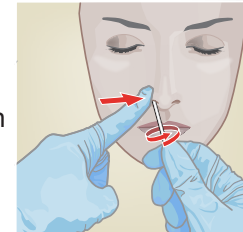
1. Use the recommended specimen collection device. Remove the swab from both the outer and inner envelopes.

2a. Nasal swab Specimen
   -Insert dry swab 1-1.5 cm into a nostril.
   -Rotate swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.
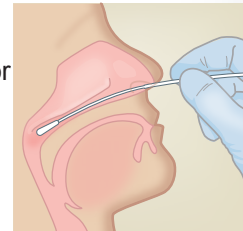
   -Repeat step 2a on the other nostril with the same swab, using external pressure on the outside of the nostril.
   To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.

2b. Nasopharyngeal Swab Specimen
   -Insert swab into either nostril, into the posterior pharynx as shown.
   -Rotate swab by firmly brushing against the nasopharynx several times.
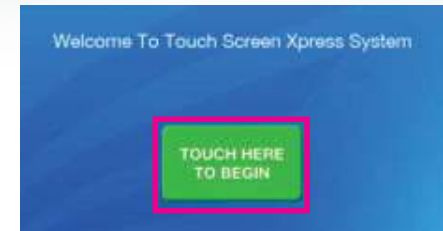
3. Uncap tube containing the transport medium. Place swab into the tube.
4. For the Nasopharyngeal swab, break swab at the indicated break line.
5. Cap tube.
NOTE: Specimens placed in transport medium following collection can be stored for up to 24 hours at 15-30 °C and for up to seven days at 2-8 °C prior to testing with the Xpert Xpress Flu/RSV Assay.

Possible Results

Result	Interpretation
Flu A POSITIVE Flu B POSITIVE RSV POSITIVE	All targets (Flu A, Flu B, and RSV) are positive.
Flu A NEGATIVE Flu B NEGATIVE RSV NEGATIVE	All targets (Flu A, Flu B, and RSV) are negative.
Flu A POSITIVE Flu B NEGATIVE RSV POSITIVE	The Flu A and RSV targets are positive and the Flu B target is negative.
Flu A NEGATIVE Flu B POSITIVE RSV NEGATIVE	The Flu A and RSV targets are negative and the Flu B target is positive.
Flu A NEGATIVE Flu B NEGATIVE RSV POSITIVE	The Flu A and Flu B targets are negative and the RSV target is positive.
Flu A NEGATIVE Flu B POSITIVE RSV POSITIVE	The Flu A target is negative and the Flu B and RSV targets are positive.
Flu A POSITIVE Flu B POSITIVE RSV NEGATIVE	The Flu A and Flu B targets are positive and RSV target is negative.
Flu A POSITIVE Flu B NEGATIVE RSV NEGATIVE	The Flu A target is positive and the Flu B and RSV targets are negative.
INSTRUMENT ERROR	If result is "INSTRUMENT ERROR", touch CLEAR ERROR and follow the on-screen instructions. When the Home screen appears, repeat the test using a new cartridge.
NO RESULT-REPEAT TEST	If result is "NO RESULT - REPEAT TEST", retest with a new cartridge. If retest is "NO RESULT - REPEAT TEST", call for assistance at 888-838-3222.

7. The Welcome Screen appears after the software initializes. Touch the **TOUCH HERE TO BEGIN** button.
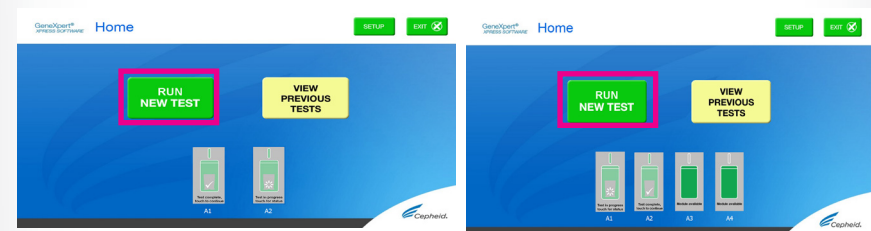

8. The **VIEW PREVIOUS TESTS** button will display. the **RUN NEW TEST** button will appear on the home screen within 3 minutes.

Starting a Test with a Patient Specimen

Before you begin
- Read the package insert provided with the cartridges for more information.
- Read through this entire guide before beginning a test.
- Instructions on how to prepare the specimen and the cartridge are also shown in a video within the software.
- Start the test within 15 minutes of adding the specimen to the cartridge.
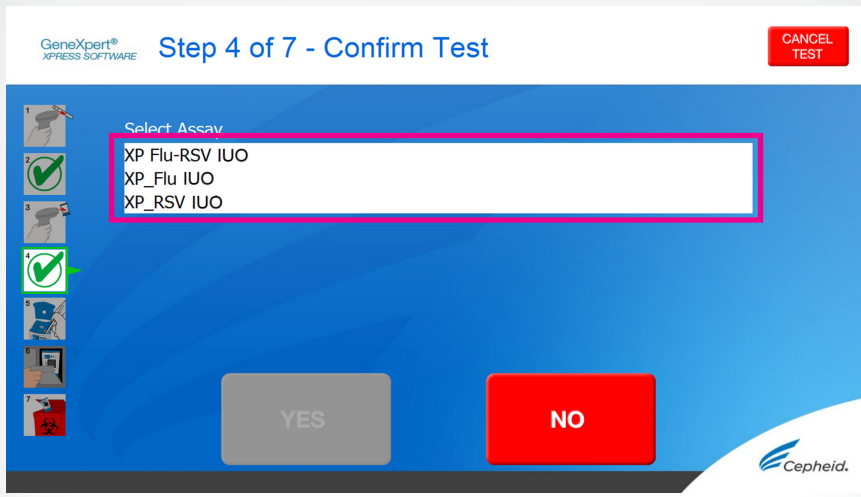1. Touch RUN NEW TEST on the Home screen (GeneXpert Xpress II or GeneXpert Xpress IV instrument).

2. Remove a cartridge and a transfer pipette from the cartridge kit box.
3. Check that the specimen tube cap is closed. Scan the Sample/Patient ID with the scanner or manually enter the Sample/Patient ID.
4. Touch YES if the displayed information is correct.
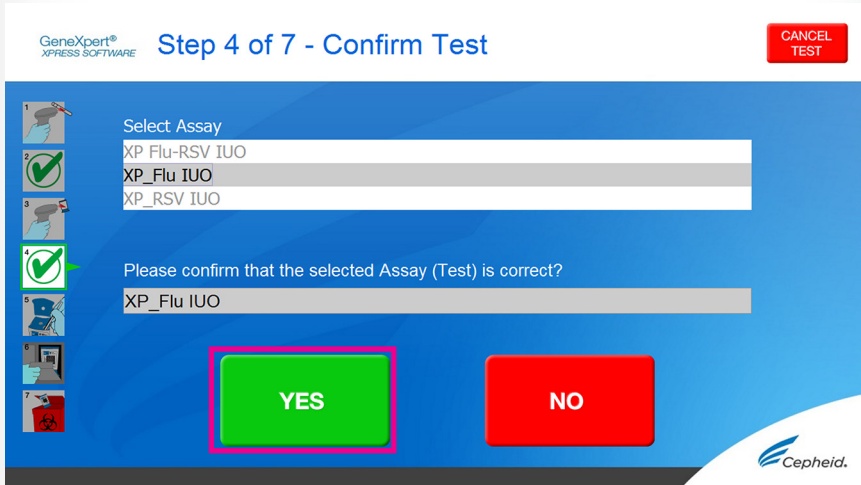5. Scan the barcode on the cartridge.

NOTE: If the barcode on the Xpert Xpress Flu/RSV Assay cartridge does not scan or scanning the barcode results in an error message stating the cartridge is expired, then repeat the test with a new cartridge.

NOTE: If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will appear indicating the assay definition file is not loaded on the system. If this screen appears, refer to the GeneXpert Xpress User Guide, Administrative Tasks section for more information.

6. Select desired assay by touching the assay name.

7. Touch YES to confirm that the selected assay is correct.

8. Confirm the name on the cartridge is "Xpert Xpress Flu-RSV".
9. Mix the sample by inverting the specimen tube five times.

NOTE: If you encounter an instrument error, touch **CLEAR ERROR** and follow the on-screen instruction. When the HOME screen appears, test a new quality control sample using a new cartridge.

NOTE: If an unexpected result occurs, test a new quality control sample using a new cartridge. If an unexpected result occurs upon retest, contact Cepehid Technical Support.

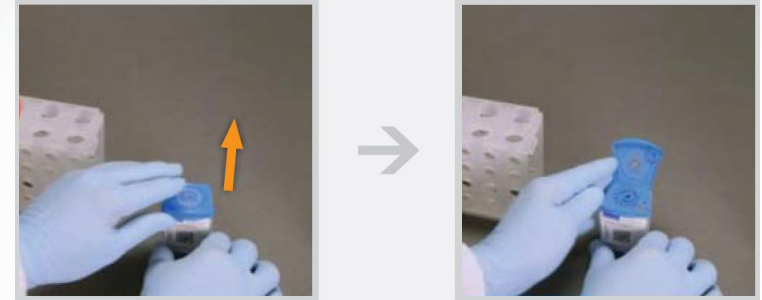**NOTE:** It is recommended that external controls be tested at the frequency noted below:
   -Prior to testing of the patient sample when the test is run for the first time during a shift.
   -Each time a new lot of Xpert Xpress Flu/RSV Assay reagents is received.
   -Each time a new shipment of Xpert Xpress Flu/RSV Assay reagents is received even if it is the same lot previously received.
   -Each time a new operator is performing the test (i.e., operator who has not performed the test before).
   -When problems (storage, operator, instrument, or other) are suspected or identified.
   -If otherwise required by your laboratory's standard QC procedures.

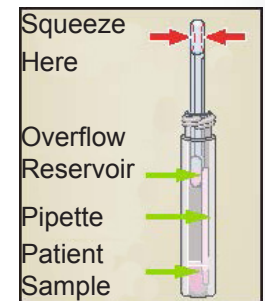# Notes:

Running Quality Control Samples

1. Put on a clean pair of gloves. Have a new Xpert Xpress Flu/RSV Assay cartridge, a quality control sample, and a transfer pipette ready.
2. Touch **RUN NEW TEST** on the HOME screen. Touch **NO** for the sample barcode on the Sample ID screen.
3. Touch the **Sample ID** field to display the keyboard. Type **negative control** for the Negative Control or **positive control** for the Positive Control. Touch **OK**.
4. Scan the bardcode on the cartridge.
5. Make the appropriate selection by touching the required assay from the Select Assay menu (see Starting a Test with a Patient Specimen, step 6).
6. Mix the sample by inverting the quality control sample 5 times.
7. Open the cartridge lid by lifting the front of the cartridge lid.
8. Remove the pipette from the wrapper by opening the end next to the top bulb.

Squeeze the top bulb of the pipette completely and place the pipette tip in the control tube containing the control sample.

Release the top bulb of the pipette to fill the pipette with the control sample. Check that the pipette does not contain bubbles. If the pipette contains bubbles or if the pipette section is not completely filled with sample, squeeze out the liquid and try again.

9. Transfer the control sample to the cartridge and squeeze the top bulb of the pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber). Overflow liquid left in the overflow reservoir of the pipette is OK.
10. Close the cartridge lid.
11. Dispose of the pipette and remaining quality control material in an appropriate waste container, according to your institution's standard practices.
12. Open the module door with the blinking green light.
13. Load the cartridge with the barcode facing the operator.
14. Close the door firmly until it engages. The green light will stop blinking and the test will start.
15. To run another quality control, touch the **HOME** button.
16. Repeat steps 1-15 with the other quality control sample.
17. When the Remove Cartridge screen is displayed, follow the on-screen instructions to remove the cartridge.
18. Dispose of the used cartridge(s) and gloves in an appropriate waste container according to your institution's standard practices.
19. Touch **CONTINUE** to view the result of the test.

10. Unscrew the top of the patient specimen tube.
11. Open the cartridge lid by lifting the front of the cartridge lid.

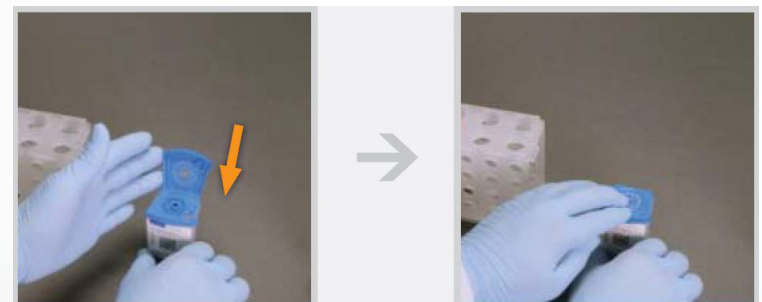12. Remove the pipette from the wrapper by opening the end next to the top bulb.
13. Squeeze the bulb of the pipette completely and place the pipette tip in the patient specimen tube.
    Release the top bulb of the pipette to fill the pipette with the patient sample. Check that the pipette does not contain bubbles. If the pipette contains bubbles or if the pipette is not completely filled with the sample, squeeze out the liquid and try again.

Squeeze Here
Overflow Reservoir
Pipette
Patient Sample

14. Transfer the sample to the cartridge and squeeze the top bulb of the pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) shown. Overflow liquid left in the overflow reservoir of the pipette is OK.

15. Close the Cartridge lid.

16. Dispose of the pipette in an appropriate waste container according to your institution's standard practices.
17. Open the module door with the blinking green light.
18. Load the cartridge by gently setting it onto the black loading platform with the bardcode facing the operator.

19. Close the door firmly until it engages. The green light will stop blinking and the test will start.

NOTE: To start another test before this test is complete, see Starting a Test With a Test in Progress.

20. When the Test is complete, the green light will go out and the door will unlock.

NOTE: If you encounter an instrument error, touch **CLEAR ERROR** and follow the on-screen instructions to remove the cartridge.

21. When the Remove Cartridge screen is displayed, follow the on-screen instructions to remove the cartridge.

NOTE: To access the Remove Cartridge screen from the HOME screen after a test is complete, touch the T**est complete, touch to continue** button.

22. Dispose of the used cartridge and gloves in an appropriate waste container according to your institution's standard practices.
23. Touch **CONTINUE** to view the result of the test.
24. Touch **HOME** to go back to the Home screen.

NOTE: Refer to the Package Insert and GeneXpert User's Guide for information on reviewing past results or printing results.
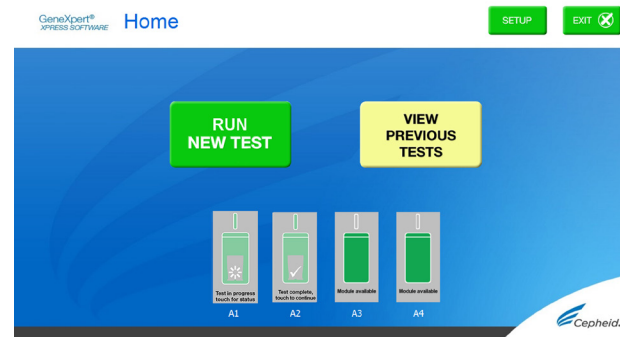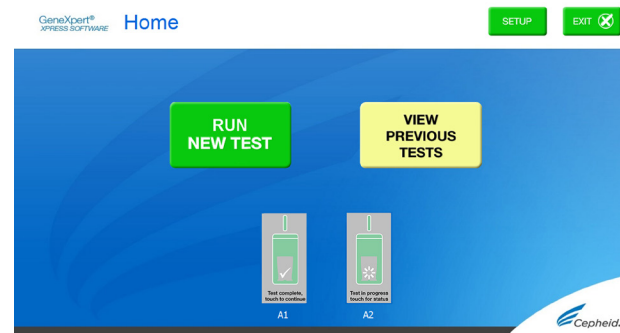
Starting a Test With a Test in Progress

An additional test may be started while a test is running.

1. Touch the **HOME** button. HOME 🏠

2. The HOME screen will display the module in use as slightly gray and the icon will read "Test in progress, touch for status".
3. Touch **RUN NEW TEST** and proceed with the new test following the steps in "Starting a test with a Patient Specimen".
4. After the second test is in progress, touch the **HOME** button to view the status of both tests.

NOTE: To view additional details of a test in progress, touch the icon of the module in question from the HOME screen.

5. When a test is complete, the icon text will change to "Test complete, touch to continue" and will show a check mark on the icon. Touch the **Test complete, touch to continue** button to continue on to the Remove Cartridge screen as show below.

NOTE: If you encounter an instrument error,touch **CLEAR ERROR** and follow the on-screen instructions.

6. Follow the instructions on the screen to remove the cartridge.
7. Touch **CONTINUE** to view the result of the test.