GeneXpert® System with Touchscreen

Reference Guide

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Good Laboratory Practice

Real Time Polymerase Chain Reaction (RT-PCR) is a standard laboratory testing method that is used to select a specific sequence of DNA or RNA. This segment is amplified exponentially which creates billions of detectable copies. This technique has become an important tool in clinical laboratories for the detection of infectious pathogens at extremely low levels. This highly sensitive technique makes RT-PCR highly susceptible to cross-contamination, particularly from sample to sample transfer, if proper clean molecular technique is not used. Implementation of safeguards and strict adherence to robust protocols is often sufficient to ensure that cross-contamination in the molecular laboratory is a rare event.

Follow general CMS guidance for good laboratory practice

CMS.gov Centers for Medicare & Medicaid Services

Preventing Cross Contamination

Use of Personal Protective Equipment (PPE)

Gloves: Change gloves after touching a sample. The outside of the sample harbors much of the sample DNA/RNA that transfers to the surface of gloves.

Lab coats: Wear a lab coat while processing samples. Wearing lab coats will prevent the transfer of sample DNA/RNA to other areas of the room.

Eye/face protection: Wear surgical masks, face shields, or other physical barriers, like a splash shield for procedures with a high likelihood of generating droplets or aerosols.

Cleaning

Bleach: Use a final concentration of 1:10 dilution of 5% household chlorine bleach (used within 1 day of preparation). Final active chlorine concentration should be 0.5%.

70% ethanol: Use only 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

- Disposable lint-free wipes
- Disposable paper towels

Reagent Storage

Store reagents according to their expected storage conditions in the Information for Use. In addition, cartridges should be kept in their original boxes with the lid shut.

Sample Setup

Dirty area (work area): Area where samples and controls are processed.

Clean area (loading area): Area where the prepared cartridge is loaded onto the instrument.

Cartridge Disposal

Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). **Do not open or attempt to alter any part of the cartridge for disposal**.

Each state has different regulations for classifying regulated medical waste (RMW). The first step to safe biohazard waste disposal is to check with your state's Department of Health to learn the specific regulations you'll need to follow.

Maintenance

Instrument maintenance is required to be performed according to the user guide or operator manual. Some of the maintenance is described in this reference guide, however not all requirements are covered.

Starting up the system

NOTE: The instructions here are a summary from the GeneXpert System with Touchscreen Operator Manual and are for reference only. For complete and detailed instructions, refer to the operator manual.

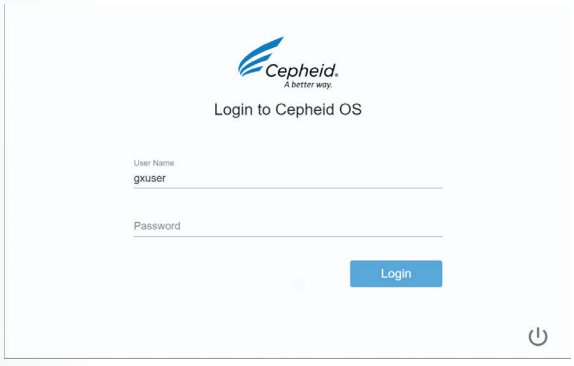
NOTE: These steps must be done in the order below for database synchronization

1. Press the switch on the back of the instrument to the **ON** position. The blue light on the front panel will light up.

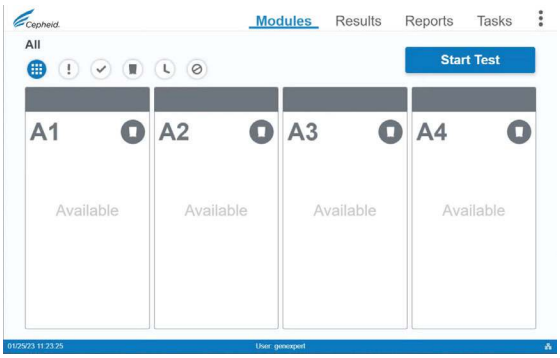
2. Press the switch on the back of the touchscreen unit to the **ON** position.

3. Wait for the system to boot. The software will start in kiosk mode.

4. Enter your User Name and Password. Touch **Login**.



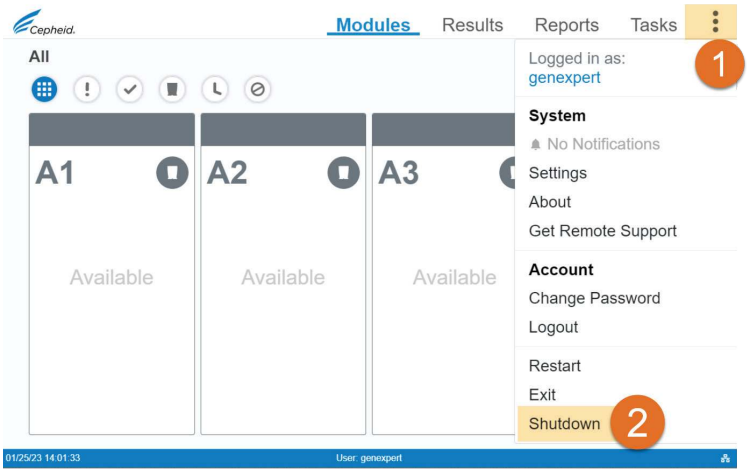
5. In the **Modules** screen, verify that all the modules are available.



Shutting down the system

NOTE: Shut down the system once per week. When performing this task, make sure no tests are running.

1. Touch ⋮ > **Shutdown**



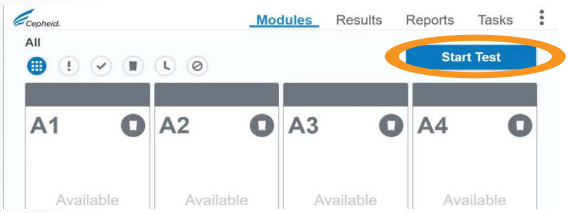
2. After screen turns black, press the switch on the back of the touchscreen unit to the **OFF** position.

3. Press the switch on the back of the instrument to the **OFF** position.
   The blue light on the front panel will turn off.

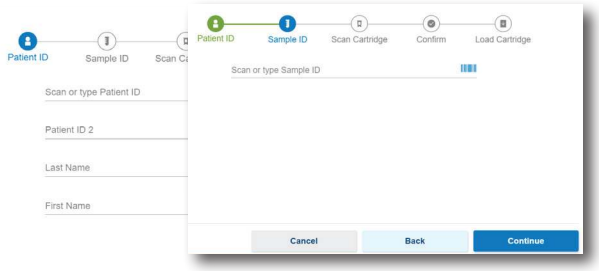
NOTE: Wait 2 minutes before restarting the system.

Starting a Test

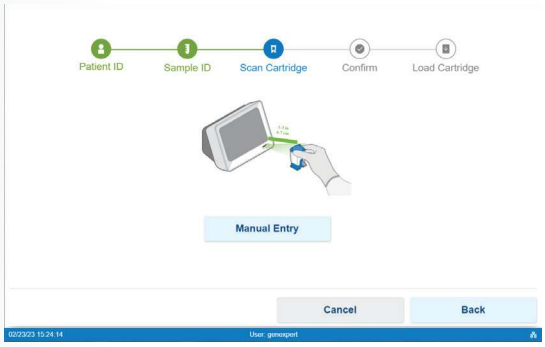
1. Touch **Start Test** on the Modules screen.



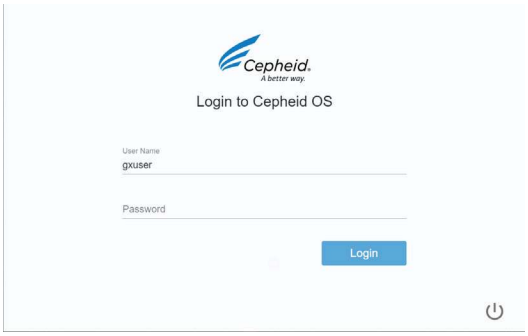
2. Enter the Patient ID (if applicable), and Sample ID.



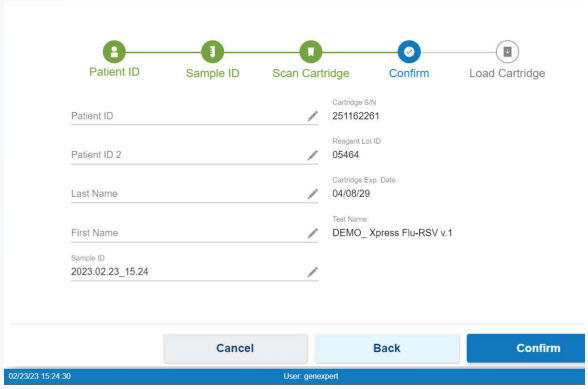
3. Scan the barcode on the cartridge then touch **Continue**.



4. If prompted, enter your user name and password and touch **Login**.



5. Verify the information is correct and touch **Confirm**. Touch (Edit) if not.

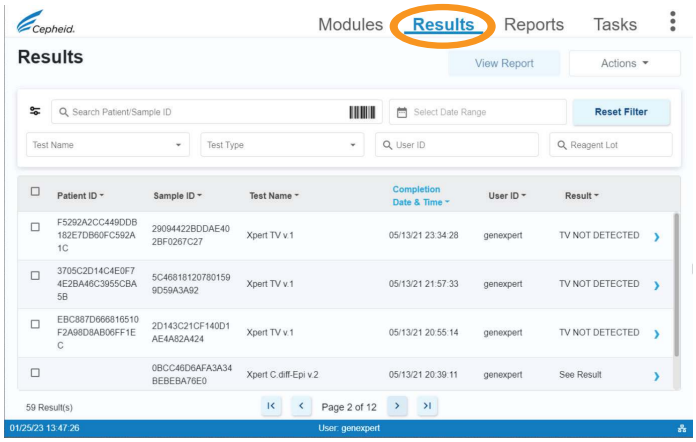


6. Load the cartridge in the module with the blinking green light.

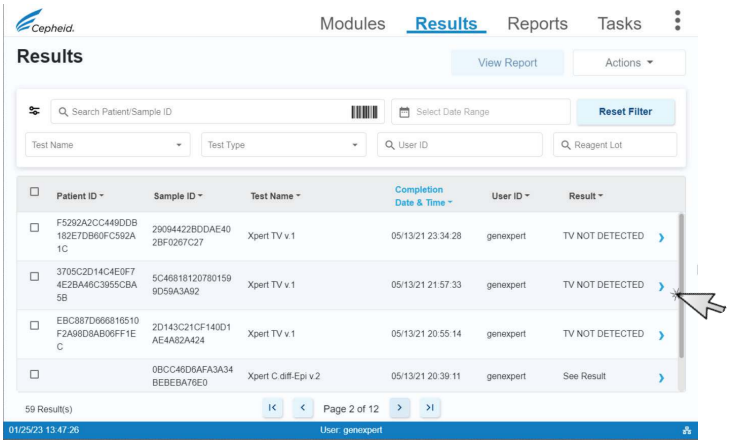
7. Close the module door and wait until the green light stops blinking.

Viewing Results and/or Printing a Report

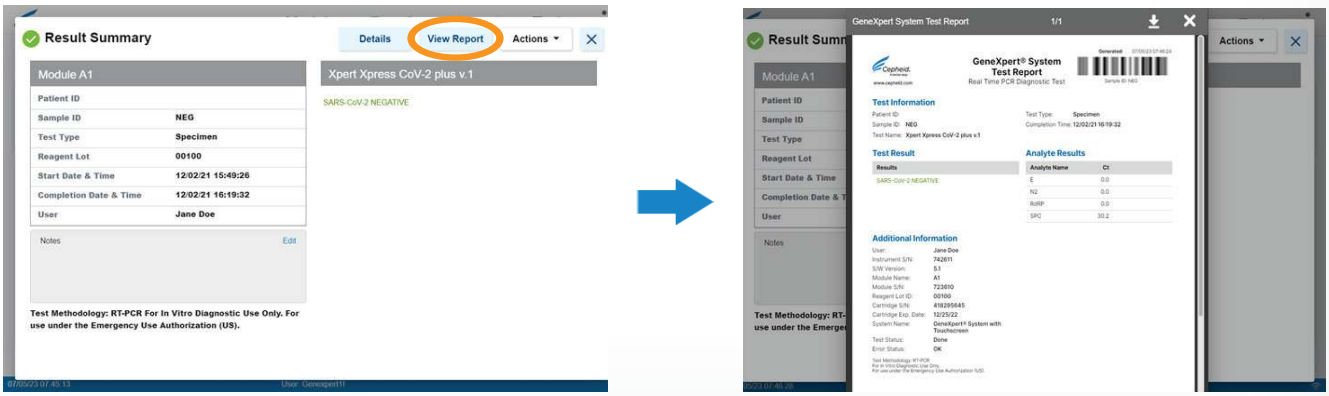
1. Touch the **Results** tab.



2. Select the test to be viewed.

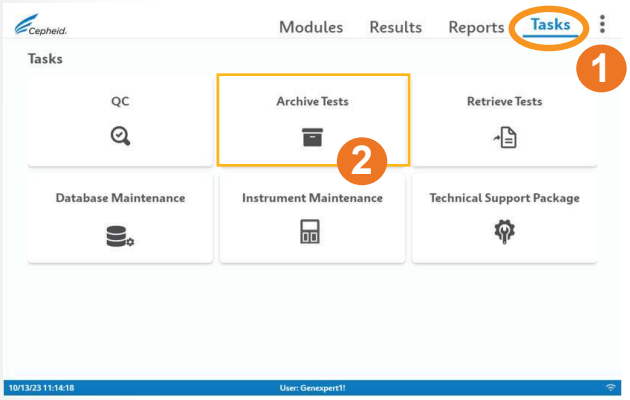


3. Touch **View Report**. The report opens as a printable PDF.

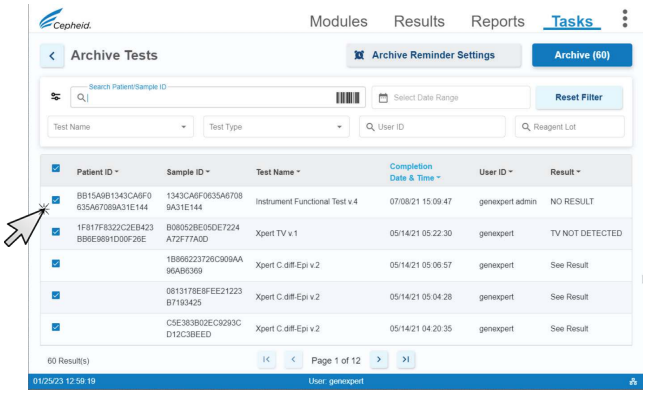


Archiving and Purging

1. Touch the **Tasks** tab on the Home screen, then touch **Archive Tests**.



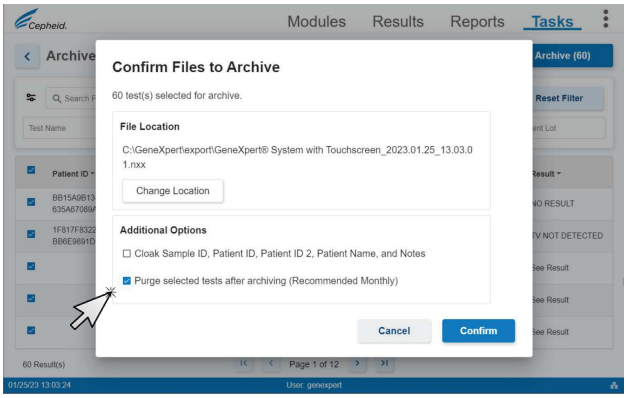
2. Tests are selected by default. Exclude any from the archive by unchecking its left box.



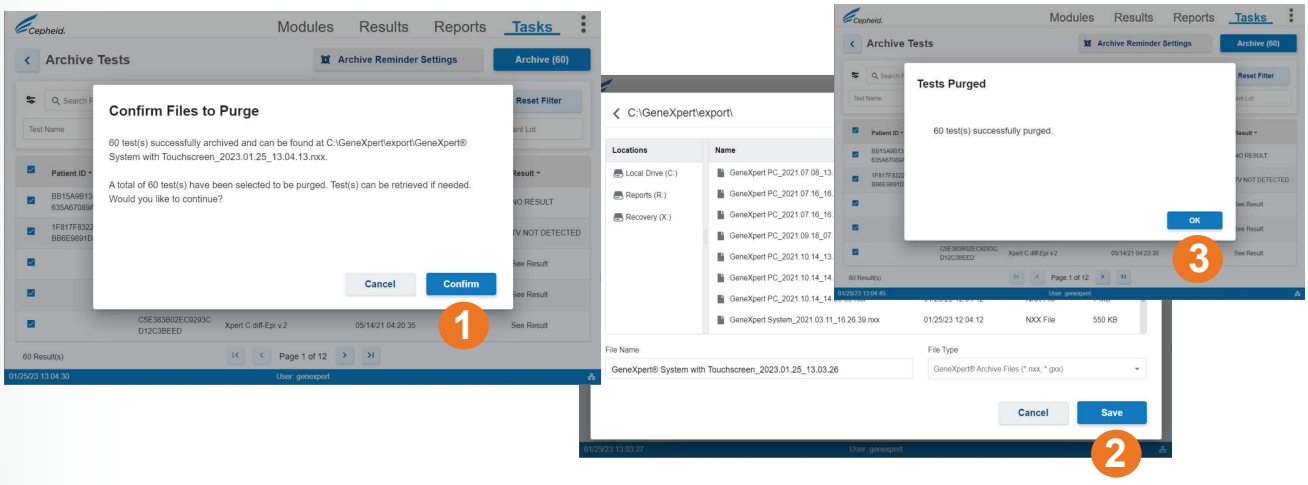
3. Touch **Archive**.

   Check Purge Selected Tests after archiving.

   Note: The file name is generated automatically and can be found in the folder C:\GeneXpert\export.



4. **Confirm** files to be archived and **Save** files. Then touch **OK** to close the window.



5. Copy archived data file to an external location, if needed.

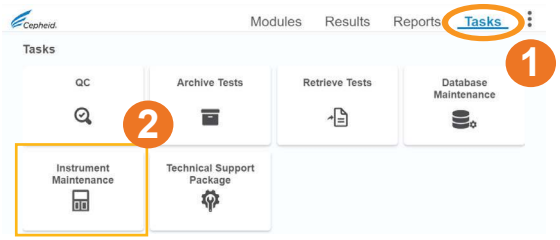
Cleaning Plunger Rod and Cartridge Bay

CAUTION: Do not spray directly inside the instrument.

Materials Required:

- 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol)
- 1:10 dilution of household bleach (0.5% final chlorine concentration)
- Lint-free wipes
- Institution mandated Personal Protective Equipment (PPE)

1. Touch **Tasks** on the Home screen then touch **Instrument Maintenance**.



2. On the Instrument screen, touch **Plunger Rod Maintenance**.

3. On the next screen, touch the check box of the module to be cleaned then touch **Clean**.
4. A new screen appears with instructions to open the selected module door and remove any cartridges from the modules.
5. After removing any cartridges, touch **Continue**. A new screen appears with instructions to clean the plunger rods and module bays, touch **Continue**.

6. Moisten a lint-free wipe with a 1:10 dilution of household chlorine bleach. Wipe plunger rod and entire cartridge bay interior with diluted bleach 3 times, allowing the bleach to remain for 2 minutes each time.
7. Moisten a lint-free wipe with 70% ethanol or denatured ethanol.
8. Wipe plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.
9. After cleaning, return to the Plunger Rod Cleaning Instructions screen. Manually close module doors and touch **Continue**.
10. Touch **OK** to acknowledge cleaning is completed.
11. On the Plunger Rod Maintenance screen, touch **Cancel** and then select **Modules** to return to the Modules screen.

Loading Assay Definition File (ADF)

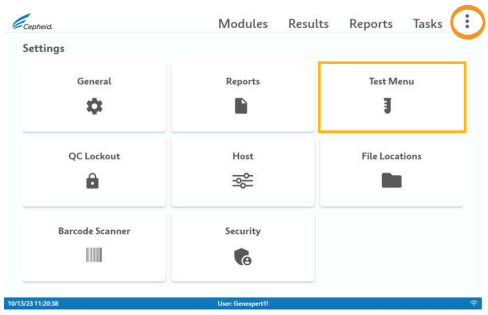
NOTE: Importing of the Assay Definition File (ADF) is required only when adding a new assay for the first time or when an assay has been updated.

(*ADFs are available on CD*)

1. If using a CD, plug the external DVD drive into the touchscreen unit.

   Insert the assay definition file CD into the external DVD drive.

2. On the touchscreen, touch ⋮ > **Settings** > **Test Menu**.

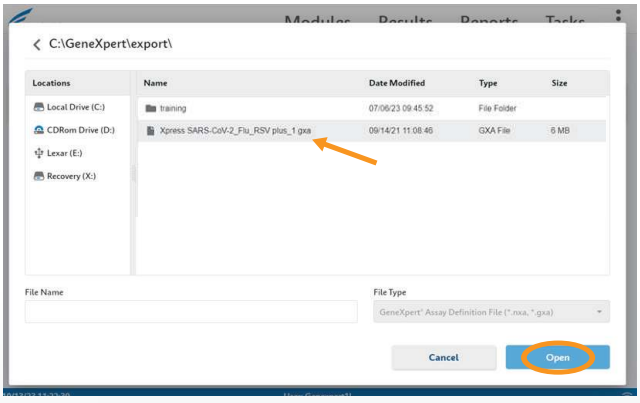


3. On the Test Menu screen, touch **Import Test**.

4. Navigate to the DVD and to the folder containing the ADF files. Locate and touch the ADF (.gxa/.nxa) file for your instrument. The test name appears in the filename field.
   If ADF was downloaded directly from website, navigate to folder where the ADF file was saved.

5. Touch **Open** to import the file into the system.

   The new test name and version number appear in the Test list.



Notes

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