GeneXpert® Xpress

Reference Guide

Cepheid®
A better way.

IVD *In Vitro* Diagnostic Medical Device

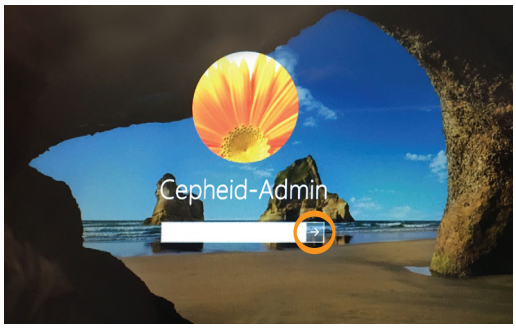
© 2020 Cepheid

Starting up the system

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 hub to the **ON** position.

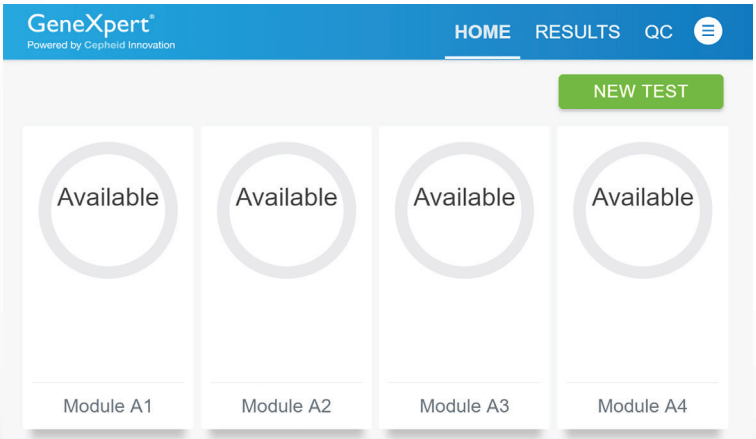
3. Swipe up on the screen, then enter the login information.
   User-Account: **Cepheid-Admin**
   Password: **cphd**



The GeneXpert® Xpress software starts automatically.

4. Enter user name and password, if applicable.

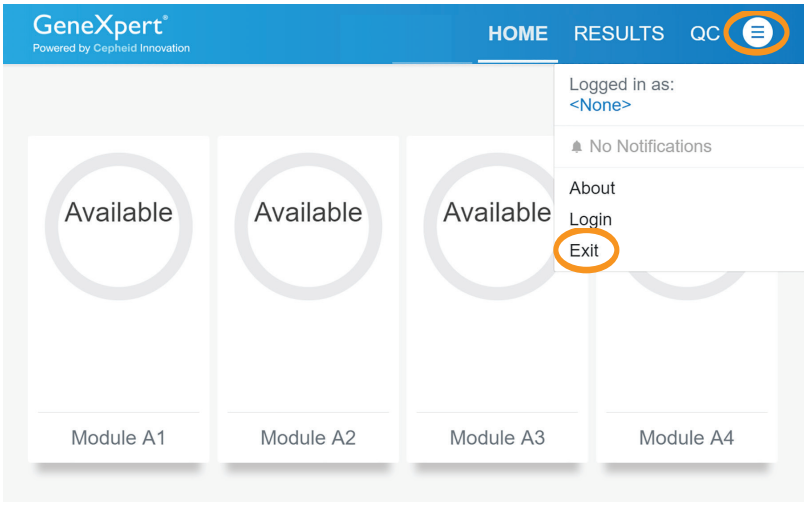
5. In the **Home** screen, verify that all the modules are available.



Shutting down the system

Note: Restart the system once per week.
When performing this task, make sure no tests are running.

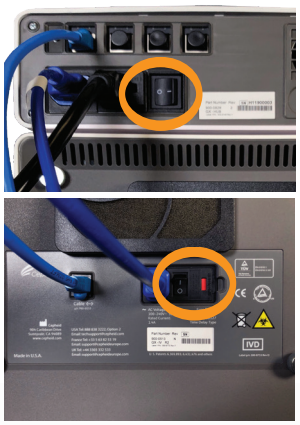
1. Exit the GeneXpert® Xpress software.



2.Press the blue power switch on the right front of the GeneXpert hub.
Note: Wait 10 seconds before proceeding to Step 3.

3. Press the switch on the back of the hub to the **OFF** position.

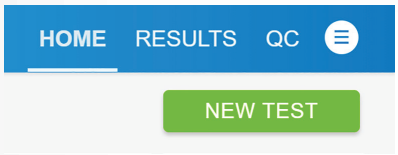
4.Press the switch on the back of the instrument to the **OFF** position.
The blue light on the front panel will turn off.



Note: Wait 2 minutes before restarting the sytsem.

Creating A Test

1. Touch **NEW TEST** from the home screen of the GeneXpert® Xpress.

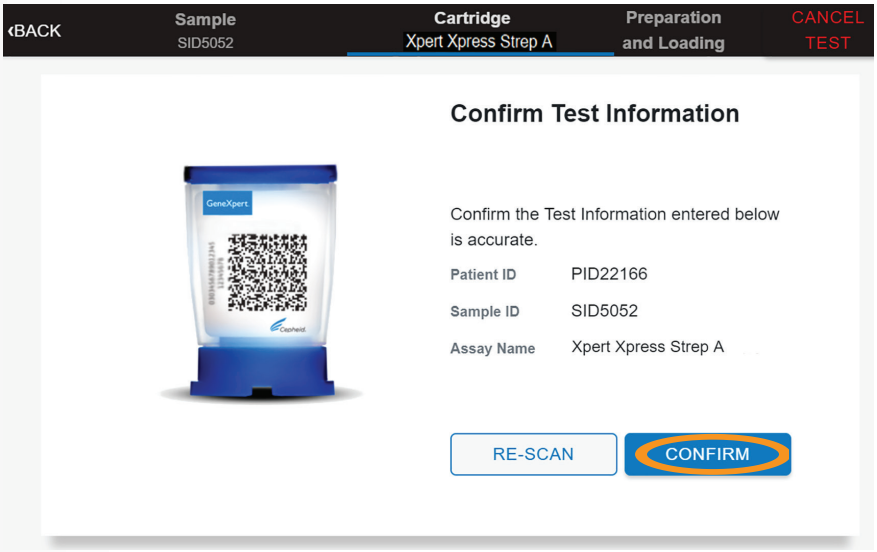


2. Enter or scan the Patient ID (if applicable). Select **CONTINUE**.

   Note: The scanner is located just behind the right side of the monitor.

3. Verifiy the information is correct and touch **CONFIRM**.
   If the Patient ID number is not correct, touch **RE-ENTER**.
4. Enter or scan the Sample ID. Select **CONTINUE**.
5. Verifiy the information is correct and touch **CONFIRM**.
   If the Sample ID number is not correct, touch **RE-ENTER.**
6. Scan the barcode on the cartridge. Select the correct assay and touch **CONFIRM**.

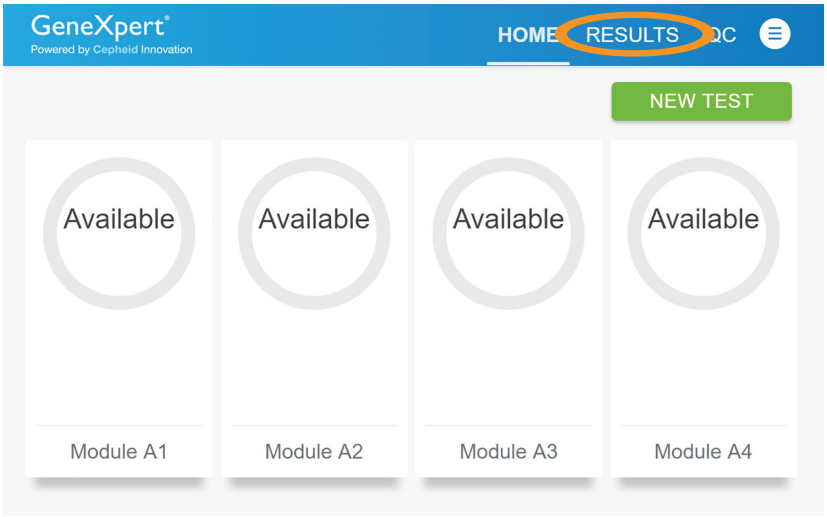
7. Verifiy the information is correct and touch **CONFIRM.**
   If the assay or cartridge number is not correct, touch **RE-SCAN.**



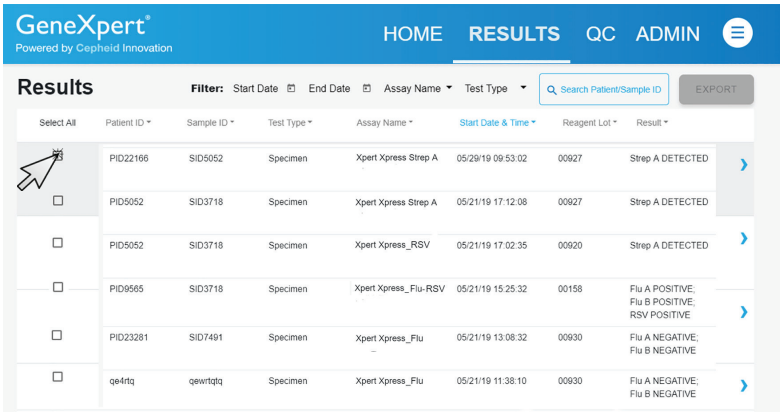
8. Prepare the cartridge per the steps in the video clip that appears on the next screen.
9. Load the cartridge in the module with the blinking green light.
10. Close the module door until the green light stops blinking.

View Results and Generate/Print a Report

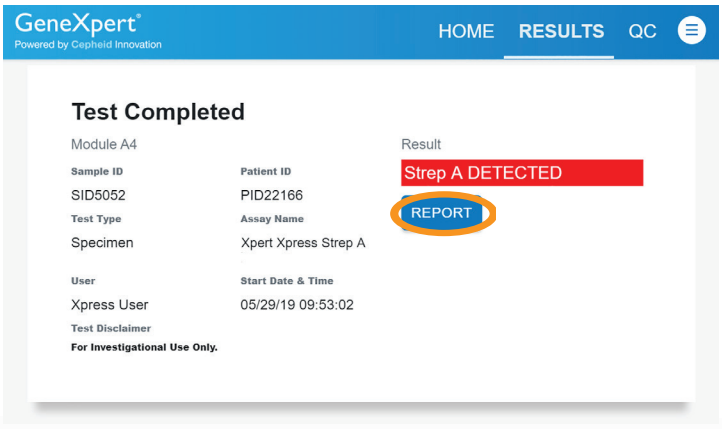
1. Touch the **RESULTS** tab.

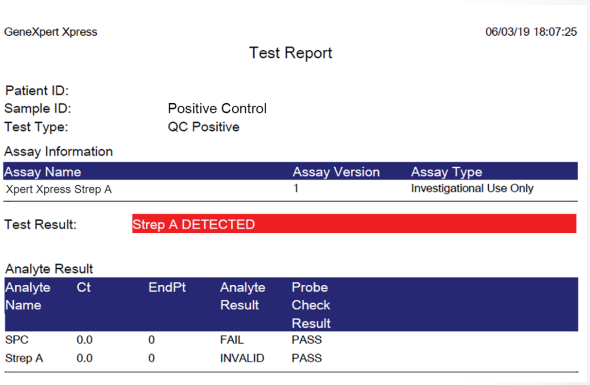


2. Check the box(es) of the test(s) to be viewed.



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




GeneXpert Xpress 06/03/19 18:07:25

Test Report

Patient ID:
Sample ID: Positive Control
Test Type: QC Positive

Assay Information

Assay Name	Assay Version	Assay Type
Xpert Xpress Strep A	1	Investigational Use Only

Test Result: Strep A DETECTED

Analyte Result

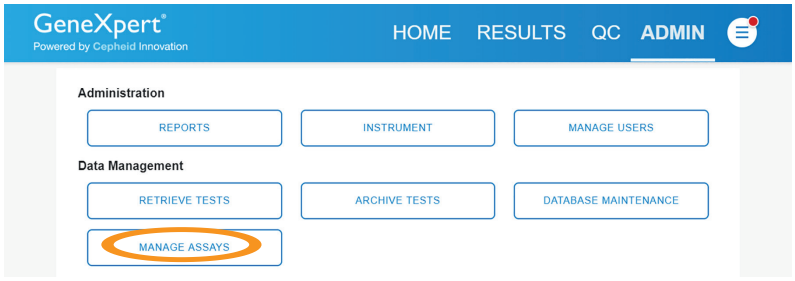
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	0.0	0	FAIL	PASS
Strep A	0.0	0	INVALID	PASS

Loading Assay Definition File (ADF)

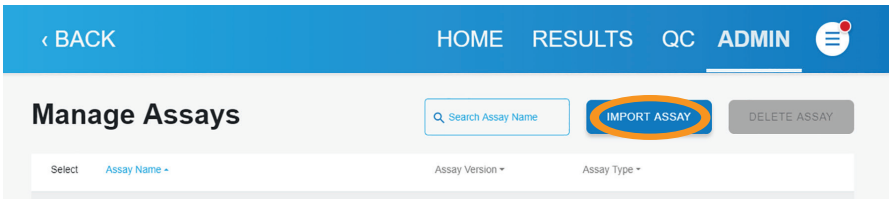
Note: Importing of the Assay Definition File (ADF), located in the kit, is required only when adding a new assay for the first time or when an assay has been updated.

1. Plug the external DVD drive into the hub. Insert the assay definition CD, located in the kit, into the external DVD drive.

2. Touch the **ADMIN** tab, then touch **MANAGE ASSAYS**.

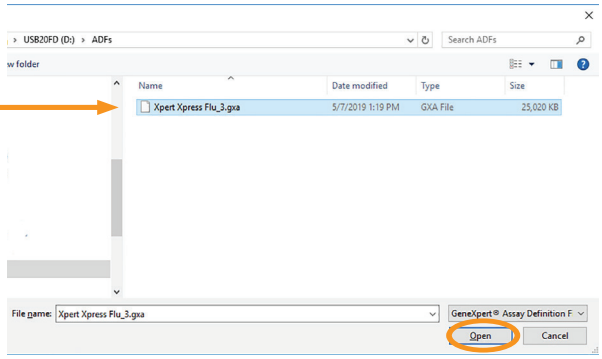


3. Touch **IMPORT ASSAY**.



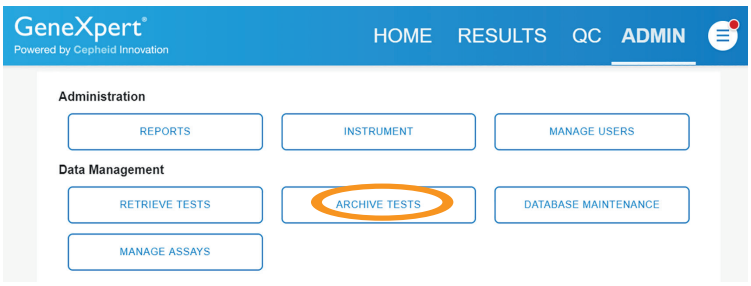
4. Navigate to the DVD and to the folder containing ADF files.

5. Select the .gxa/.nxa file, then touch **Open**.
The new assay name and version number appear in the Assay list.

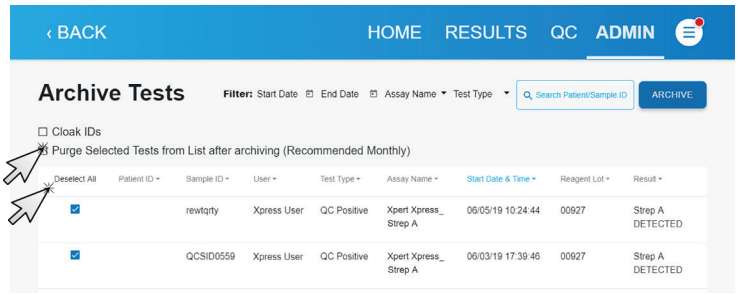


Archiving and Purging

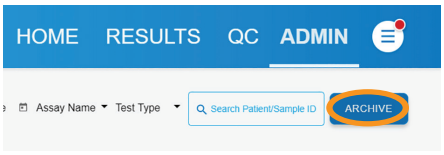
1. Touch the **ADMIN** button on the Home screen. Touch **ARCHIVE TESTS**.

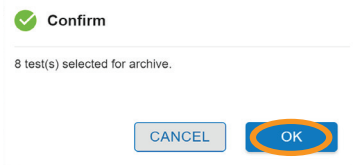


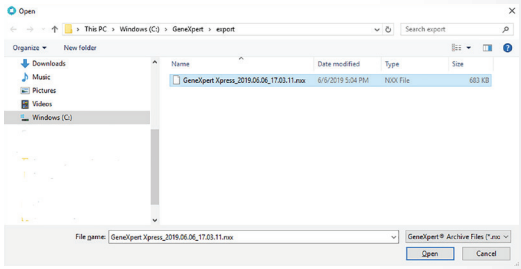
2. Touch **Select All** or select individual tests to be archived or removed.
   To remove selected files, check **Purge Selected Tests from List after archiving**.



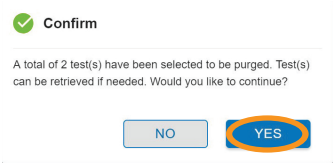
3. Touch **ARCHIVE**. Confirm files to be archived and save files.
   Note: The file name is generated automatically and can be found in the folder C:\GeneXpert\export.

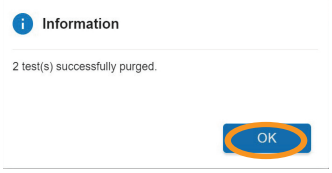






4. If **Purge Selected Tests** was checked, confirm the selection by touching **Yes**.
   Then touch **OK**.





5. Copy archived data file to an external location.

Maintenance

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

Quarterly:

Clean Plunger Rod and Cartridge Bay

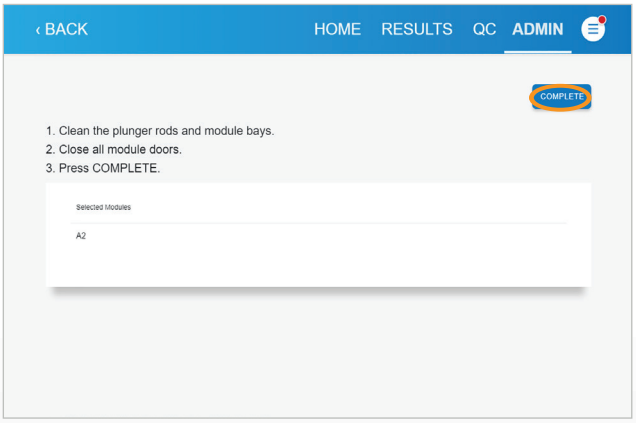
CAUTION: Do not spray directly inside the instrument.

Materials Required:

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

Procedure:

1. Touch the **ADMIN** button on the Home screen.
2. Touch the Instrument button.
3. Touch **PLUNGER ROD MAINTENANCE**.
4. Select the modules that require maintenance, then touch **CLEAN**.
5. 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.
6. Moisten lint free wipe with 70% ethanol or denatured ethanol.
7. Wipe plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.
8. Touch **COMPLETE** when finished.



Notes:

mpower

The molecular revolution is here.

Cepheid®

A better way.

302-3173, Rev. A.1 May 2020